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

Matthew C. Zorn (argued), Yetter Coleman LLP, Houston, Texas; Kathryn L. Tucker, Emerge Law Group, Portland, Oregon; James F. Williams and Thomas J. Tobin, Perkins Coie LLP, Seattle, Washington; Andrew J. Kline, Perkins Coie LLP, Denver, Colorado; Holly Martinez, Perkins Coie

LLP, Portland, Oregon; Shane Pennington, Vicente Sederberg LLP, New York, New York; for Petitioner.

Thomas Pulham (argued), and Mark B. Stern, Appellate Staff; Brian M. Boynton, Acting Assistant Attorney General; United States Department of Justice, Civil Division, Washington, D.C.; for Respondents.

Peter B. Gonick (argued) and Brendan Selby, Assistant Attorneys General; Robert W. Ferguson, Attorney General; Office of the Attorney General, Olympia, Washington; Mark Brnovich, Attorney General, Phoenix, Arizona; Kathleen Jennings, Attorney General, Wilmington, Delaware; Kwame Raoul, Attorney General, Chicago, Illinois; Dana Nessel, Attorney General, Lansing, Michigan; Keith Ellison, Attorney General, St. Paul, Minnesota; David Yost, Attorney General, Columbus, Ohio; Ellen F. Rosenblum, Attorney General, Salem, Oregon; Karl A. Racine, Attorney General, Washington, D.C.; for Amici Curiae States of Washington, Arizona, Delaware, Illinois, Michigan, Minnesota, Ohio, and Oregon, and District of Columbia.

Christina Sandefur and Timothy Sandefur, Scharf-Norton Center for Constitutional Litigation at the Goldwater Institute, Phoenix, Arizona; Ilya Shapiro and Trevor Burrus, Cato Institute, Washington, D.C.; for Amici Curiae Goldwater Institute and Cato Institute.

David M. Poell, Bradley C. Graveline, and Elizabeth M. Rowe, Sheppard Mullin Richter & Hampton LLP, Chicago, Illinois; Nicholas W. van Aelstyn, Sheppard Mullin Richter & Hampton LLP, San Francisco, California; for Amici Curiae Kathy L. Cerminara, Sylvia Law, Thaddeus Pope, and Rob Schwartz.

Eleanor Hamburger, Sirianni Youtz Spoonemore Hamburger PLLC, Seattle, Washington; Hank Balson, Budge & Heipt PLLC, Seattle, Washington; for Amici Curiae End of Life Washington, EvergreenHealth, The Washington State Psychological Association, A Sacred Passing, and Participating End of Life Care Clinicians and Researchers.

John Wolfe, Orrick Herrington & Sutcliffe LLP, Seattle, Washington; Nicholas Peterson, Orrick Herrington & Sutcliffe LLP, Washington, D.C.; Nancy Talner, American Civil Liberties Union of Washington, Seattle, Washington; for Amicus Curiae American Civil Liberties Union of Washington.

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.

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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.

Expanded Access and Right to Try: Access to Investigational Drugs

Updated March 16, 2021

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

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SUMMARY

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Agata Bodie
Analyst in Health Policy

Expanded Access and Right to Try: Access to Investigational Drugs

The Food and Drug Administration (FDA) regulates the safety and effectiveness of drugs and biological products under its authorities in the Federal Food, Drug and Cosmetic Act (FFDCA) and Public Health Service Act (PHSA). In general, a manufacturer may not sell a drug or biologic in the United States until FDA has reviewed and approved its marketing application (i.e., a new drug application [NDA] or biologics license application [BLA]).

The primary route for an individual to obtain an investigational (i.e., unapproved) drug is to enroll in a clinical trial testing that new drug. However, an individual may be excluded from the clinical trial because its enrollment is limited to patients with particular characteristics (e.g., in a particular stage of a disease, with or without certain other conditions, or in a specified age range), or because the trial has reached its target enrollment number. In certain circumstances, FDA may allow an individual to obtain an investigational drug outside of a clinical trial through its expanded access procedures. Another option, the pathway created by the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 ("Right to Try Act," P.L. 115-176), does not require FDA permission.

Right to Try Act

The Right to Try Act became federal law on May 30, 2018. Prior to its passage, 40 states had enacted related legislation. The goal of these legislative efforts was to allow individuals with imminently life-threatening diseases or conditions to seek access to investigational drugs directly from the manufacturer without the step of procuring permission from FDA. Another goal—cited by the Goldwater Institute, which led the initiative toward state bills, and some of the legislative proponents—was focused more on the process: to eliminate government's role in an individual's choice.

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

The Right to Try Act offers eligible individuals and their physicians a pathway other than FDA's expanded access procedures to obtain investigational drugs. It defines an *eligible patient* as one who (1) has been diagnosed with a life-threatening disease or condition, (2) has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug (as certified by a physician who meets specified criteria), and (3) has given written informed consent regarding the drug to the treating physician.

It defines an *eligible investigational drug* as an investigational drug (1) for which a Phase 1 clinical trial has been completed, (2) that FDA has not approved or licensed for sale in the United States for any use, (3) that is the subject of an NDA or BLA pending FDA decision or is the subject of an active investigational new drug application and is being studied in a clinical trial that is intended to support the drug's effectiveness, and (4) for which the manufacturer has not discontinued active development or production and for which the FDA has not placed on clinical hold.

The Right to Try Act also has provisions that limit how the Secretary of Health and Human Services (through the FDA) can use data regarding clinical outcomes of patients who get these drugs through this pathway; require a drug's sponsor or manufacturer to report annually to FDA on use of the pathway; and require FDA to post certain annual summaries. Finally, the Right to Try Act states that the sponsor or manufacturer has "no liability" for actions under these provisions. The no-liability provision applies also to a prescriber, dispenser, or "other individual entity" unless there is "reckless or willful misconduct, gross negligence, or an intentional tort."

Before the Right to Try Act was enacted, observers discussed several obstacles to access to investigational drugs through FDA's expanded access procedures. These included some that were FDA-related: the reportedly difficult process to request FDA permission, concern about FDA use of adverse event data, and the role of FDA as gatekeeper. Some related to why a manufacturer might decline to provide an investigational drug: limited available supply, liability, limited staff and facility resources, and concerns about use of outcomes data. The Right to Try Act directly eliminates some of these concerns, addresses some others, and leaves others unaddressed.

Opponents of the law have expressed concern about the erosion of protections for patients who may be exposed to drugs that are unsafe or ineffective. For example, in taking FDA out of the equation, the Right to Try Act limits the agency's ability to make suggestions to the protocols under which investigational drugs are provided, potentially compromising patient safety.

Congressional Considerations

While the Right to Try Act aimed to remove certain perceived obstacles to obtaining investigational drugs, unknowns remain regarding its impact on patients, drug manufacturers, and FDA. These unknowns include (1) whether more patients have received investigational drugs than prior to the law's enactment, (2) whether manufacturers are granting more requests for investigational drugs under the Right to Try Act pathway than previously under expanded access, and (3) FDA's role in implementing certain Right to Try Act requirements when the purpose of the law was to remove FDA from the situation. Congress may consider whether the law has had the effect its sponsors intended or whether legislative changes are necessary.

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

Contents

Figures

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

Tables

Contacts

Introduction

The Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 ("Right to Try Act," P.L. 115-176) became federal law on May 30, 2018. Prior to its passage, 40 states had enacted related legislation. The law's goal was to allow individuals with imminently life-threatening diseases or conditions to seek access to investigational drugs without the step of procuring permission from the Food and Drug Administration (FDA). Another goal—held by the Goldwater Institute, which led the initiative toward state bills, and some of the legislative proponents—was focused more on the process: to eliminate government's role in an individual's choice.[1]

The effort to publicize the issue and press for a federal solution involved highlighting the poignant situations of individuals who sought access. For example, in March 2014, millions of Americans heard about the plight of a seven-year-old boy with cancer. He was battling an infection following a bone marrow transplant that no antibiotic had been able to treat.[2] His physicians thought an experimental antiviral drug might help. Because FDA had not yet approved that experimental drug, it was not available in pharmacies. FDA did have the authority to permit the use of an unapproved drug in certain circumstances—a process referred to as *expanded access*. For FDA to grant that permission, however, the manufacturer must have agreed to provide the drug. The manufacturer, which was still testing the drug, declined. Other stories often pointed toward FDA as an obstacle.

During this time, certain groups—for example, the Goldwater Institute—encouraged Congress to act on right-to-try legislation (i.e., legislation that would allow patients to access investigational drugs without FDA permission). The institute framed the issue as one of individual freedom and circulated model legislation.[3] After 33 states[4] enacted legislation reflecting the Goldwater Institute-provided model bill, in January 2017, some Members of Congress introduced a bill to try to address the issue. The Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017—named for several individuals facing amyotrophic lateral sclerosis (ALS, Lou Gehrig's disease) or Duchenne muscular dystrophy—sought to remove what proponents saw as FDA obstacles to patient access. On May 30, 2018, President Trump signed the bill into law (P.L. 115-176).

No. 21-70544 archived on January 25, 2022
Cited in AIMS v. US DEA

This report discusses

[1] Goldwater Institute, "President Trump Signs Right to Try Act into Law," May 30, 2018, https://goldwaterinstitute.org/article/president-trump-signs-right-to-try-act-into-law/. The Goldwater Institute's website describes itself as "a leading free-market public policy research and litigation organization that is dedicated to empowering all Americans to live freer, happier lives … the Institute focuses on advancing the principles of limited government, economic freedom, and individual liberty" (Goldwater Institute, https://goldwaterinstitute.org/about/).

[2] Steve Usdin, "Josh Hardy chronicles: How Chimerix, FDA grappled with providing compassionate access to Josh Hardy," *BioCentury*, March 31, 2014, https://www.biocentury.com/biocentury/regulation/2014-03-31/how-chimerix-fda-grappled-providing-compassionate-access-josh-hardy; Kim Painter, "Drug company changes course, gives drug to sick boy," *USA Today*, March 12, 2014, http://www.usatoday.com/story/news/nation/2014/03/11/chimerix-josh-hardy-drug/6308891/; and David Kroll, "Josh Hardy Going Home After Getting Chimerix Anti-Viral Drug," *Forbes*, July 17, 2014, http://www.forbes.com/sites/davidkroll/2014/07/17/josh-hardy-going-home-after-getting-chimerix-anti-viral-drug/.

[3] Goldwater Institute, "Right to Try Model Legislation," https://goldwaterinstitute.org/wp-content/uploads/cms_page_media/2016/1/5/GoldwaterInstituteRighttoTryModel.pdf.

[4] Starlee Coleman, "Ohio becomes 33rd state to adopt right to try law for terminally ill," Goldwater Institute, January 5, 2017, https://goldwaterinstitute.org/article/ohio-33rd-state-to-adopt-right-to-try-law-terminally-ill/.

- how FDA regulates investigational drugs;
- FDA's expanded access procedures and the perceived obstacles to individuals accessing experimental drugs through this mechanism;
- a summary of the provisions in the Right to Try Act and how they are meant to address those obstacles; and
- selected provisions in the Right to Try Act and what questions remain unresolved.

FDA Regulation of Investigational Drugs

The FDA regulates the safety and effectiveness of drugs and biological products ("biologics") under its authorities in the Federal Food, Drug and Cosmetic Act (FFDCA) and Public Health Service Act (PHSA).[5] In general, a manufacturer may not sell a drug or biologic in the United States until FDA has reviewed and approved its marketing application (i.e., a new drug application [NDA] or biologics license application [BLA]). That application for a new drug or biologic must include data from clinical trials as evidence of the product's safety and effectiveness for its stated purpose(s).[6]

After laboratory and animal studies have identified a potential drug or biologic, the sponsor of the clinical trial, usually its manufacturer, may submit an investigational new drug (IND) application to FDA for permission to begin testing the drug in humans.[7] An IND must include information about the proposed study design, chemistry and manufacturing of the drug, and the investigator's qualifications, among other information.[8] The investigator also must provide assurance that an Institutional Review Board (IRB) will provide initial and continuous review and approval of each of the studies in the clinical investigation to ensure that participants are aware of the drug's investigative status and that any risk of harm will be necessary, explained, and minimized.[9] Sponsors of clinical trials also must comply with FDA regulations governing protection of human subjects (e.g., informed consent),[10] adverse event reporting,[11] and charging for investigational new drugs,[12] among other requirements.

No. 21-70544 archived on January 25, 2022
cited in Alli S. v. US DEA

FDA has 30 days to review an IND, after which a sponsor may begin clinical testing if the agency has not objected and imposed a clinical hold.[13] In reviewing an IND, FDA's primary objective is to assure the safety and rights of human subjects, and with respect to Phase 2 and 3 trials

[5] Whereas the FFDCA (§505) authorizes FDA to approve and regulate drugs, the Public Health Service Act (PHSA §351) authorizes FDA to license biological products (e.g., monoclonal antibodies, vaccines). Most FDA procedures regarding drugs also apply to the agency's regulation of biological products.

[6] FFDCA §505(b) [21 U.S.C. §355(b)], PHSA §351(a) [42 U.S.C. §262(a)], 21 C.F.R. §314.50, §601.2. For an overview of the general process of drug approval in the United States, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*. See, also, FDA, "How Drugs are Developed and Approved," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm.

[7] FFDCA §505(i) [21 U.S.C. §355(i)], PHSA §351(a)(3) [42 U.S.C. §262(a)(3)], 21 C.F.R. Part 312.

[8] 21 C.F.R. §312.23.

[9] 21 C.F.R. §312.23(a)(1)(iv) and 21 C.F.R. Part 56.

[10] 21 C.F.R. Part 50.

[11] 21 C.F.R. §312.32.

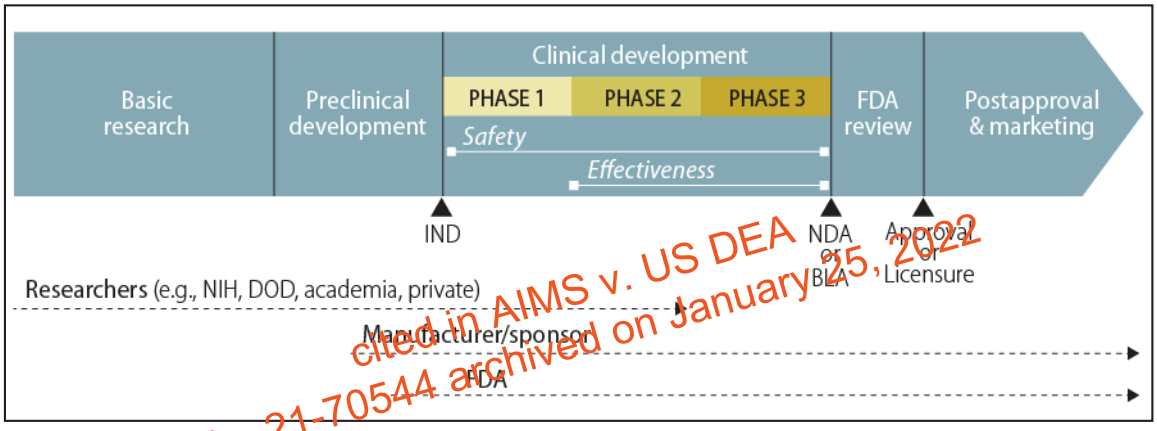
[12] 21 C.F.R. §312.8.

[13] 21 C.F.R. §312.20(c).

specifically, to ensure that the quality of the scientific investigations and evaluations is adequate to permit an evaluation of the drug's safety and effectiveness.[14]

Once the IND application is approved, the sponsor may then start the first of three major phases of clinical—human—trials. (**Figure 1** illustrates the general path of a pharmaceutical product.) Researchers first test in a small number of human volunteers the *safety* they had previously demonstrated in animals. These trials, called Phase 1 clinical trials, attempt "to determine dosing, document how a drug is metabolized and excreted, and identify acute side effects."[15] If a sponsor considers the product still worthy of investment based on the results of a Phase 1 trial, it continues with Phase 2 and Phase 3 trials. Those trials look for evidence of the product's *effectiveness*—how well it works for individuals with the particular characteristic, condition, or disease of interest.[16] Phase 2 is a first attempt at assessing effectiveness and its experience helps to plan the subsequent Phase 3 clinical trial, which the sponsor designs to be large enough to statistically test for meaningful differences attributable to the drug.

Figure 1. Standard Drug Development Path



No. 21-70544 archived on January 25, 2022 cited in AIMS v. US DEA

Source: Created by CRS.

Notes: The figure does not show the elements of the path to scale.
BLA = biologics license application. DOD = Department of Defense. FDA = Food and Drug Administration. IND = investigational new drug application. NDA = new drug application. NIH = National Institutes of Health.

The primary route for an individual to obtain an investigational drug is to enroll in a clinical trial testing that new drug. However, an individual may be excluded from the clinical trial because its enrollment is limited to patients with particular characteristics (e.g., in a particular stage of a disease, with or without certain other conditions, or in a specified age range), or because the trial has reached its target enrollment number. In certain circumstances, FDA may allow an individual to obtain an investigational drug outside of a clinical trial through its expanded access procedures. Another option, the pathway created by the Right to Try Act, does not require permission from FDA. **Table 1** summarizes selected differences in criteria for access to investigational drugs through participation in clinical trials, expanded access, and right to try.[17]

[14] 21 C.F.R. §312.22(a).

[15] FDA, "Inside Clinical Trials: Testing Medical Products in People," http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143531.htm.

[16] 21 C.F.R. §312.21(b) & (c).

[17] Under certain emergency circumstances, FDA may issue an emergency use authorization (EUA) to allow the use of an unapproved medical product or the unapproved use of an approved product. The EUA mechanism is beyond the

Table 1. Access to Investigational Drugs

Clinical Trials, Expanded Access, and Right to Try

	Clinical Trials	Expanded Access	Right to Try
Who is eligible?	Individual who meets the trial's requirements for inclusion and exclusion	Individual must have a serious or *immediately* life-threatening disease or condition, be unable to participate in a clinical trial, and have no comparable therapeutic options	Individual must have a serious or life-threatening disease or condition, be unable to participate in a clinical trial, and have exhausted approved treatment options
When can patients gain access?	May enroll in Phase 1, 2, or 3 trials	During or after Phase 1, 2, or 3 trials	After Phase 1 trials have been completed
Who must provide permission?	FDA, IRB, and drug manufacturer	FDA, IRB, and drug manufacturer	Drug manufacturer
Is informed consent from the individual required?	Yes, in accord with 21 C.F.R. Part 50 "Protection of Human Subjects"	Yes, in accord with 21 C.F.R. Part 50	Yes, but not defined and exempt from 21 C.F.R. Part 50

Source: FFDCA §§561 & 561B, 21 C.F.R. §312.305, FDA, "Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers," Guidance for Industry, June 2016, updated October 2017, https://www.fda.gov/media/85675/download.

Expanded Access and Obstacles

No. 21-70544 archived on January 25, 2022 cited in AIMS v. US DEA

FDA Requirements

The primary purpose of expanded access is to provide investigational drugs as treatment for patients who lack therapeutic alternatives. This is in contrast to clinical trials, which are designed primarily to generate evidence of safety and effectiveness to support approval of an NDA or BLA.[18]

Through FDA's expanded access procedure, a person, acting through a licensed physician, may request access to an investigational drug—through either a new IND or a revised protocol to an existing IND—if[19]

- a *licensed physician* determines (1) the patient has "no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat" the serious disease or condition; and (2) "the probable risk to the person from the investigational drug

scope of this report but is discussed in other CRS products. See, for example, CRS In Focus IF10745, *Emergency Use Authorization and FDA's Related Authorities*.

[18] FDA, "Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers," Guidance for Industry, June 2016, updated October 2017, pp. 2-3, https://www.fda.gov/media/85675/download.

[19] FFDCA §561(b) [21 U.S.C. §360bbb(b)]. See, also, FDA, "Expanded Access: Information for Patients," https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm20041768.htm. In addition to the individual IND or protocol, regulations describe other categories of expanded use of investigational drugs: intermediate-size patient populations, with one IND or protocol that consolidates several individual access requests, and treatment IND or treatment protocol for "widespread treatment use" when a drug is farther along the clinical trial and marketing application process. See FFDCA §561(c) [21 U.S.C. §360bbb(c)]; and 21 C.F.R. §§312.305, 312.310, 312.315, and 312.320.

or investigational device is not greater than the probable risk from the disease or condition";

- the *Secretary* (FDA, by delegation of authority) determines (1) "that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug" for this person; and (2) "that provision of the investigational drug ... will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval"; and
- the *sponsor* of the investigational drug, or clinical investigator, submits to FDA a clinical protocol consistent with the requirements of FFDCA Section 505(i) and related regulations.

FDA makes most expanded access IND and protocol decisions on an individual-case basis. Consistent with the IND process under which the expanded access mechanism falls, it considers the requesting physician as the investigator. The investigator must comply with informed consent and IRB review of the expanded use.[20] The sponsor of the IND must make required safety reports to FDA.[21] FDA may permit a sponsor to charge a patient for the investigational drug, but "only [for] the direct costs of making its investigational drug available"[22] (i.e., not for development costs or profit).

Expanded access could apply outside of the clinical trial arena in these situations:

> (1) use in situations when a drug has been withdrawn for safety reasons, but there exists a patient population for whom the benefits of the withdrawn drug continue to outweigh the risks; (2) use of a similar, but unapproved drug (e.g., foreign-approved drug product) to provide treatment during a drug shortage of the approved drug; (3) use of an approved drug where availability is limited by a risk evaluation and mitigation strategy (REMS) for diagnostic, monitoring, or treatment purposes, by patients who cannot obtain the drug under the REMS; or (4) use for other reasons.[23]

No. 21-70544 archived on January 25, 2022 cited in AIMS v. US DEA

Obstacles to Access

The widespread use of expanded access is limited by an important factor: whether the manufacturer agrees to provide the drug, which—because it is not FDA-approved—cannot be obtained otherwise. FDA does not have the authority to compel a manufacturer to participate. In addition, some manufacturers have expressed concern regarding how FDA would use adverse event data from expanded access when reviewing drug applications. Many highly publicized accounts of specific individuals' struggles with life-threatening conditions and efforts by activists influenced public debate over access. Examples of public attitudes included news accounts of specific individuals' struggles with life-threatening conditions. Some found the process of asking FDA for a treatment IND too cumbersome. Others questioned FDA's right to act as a gatekeeper

[20] 21 C.F.R. §312.305(c)(4).

[21] 21 C.F.R. §312.305(c)(5).

[22] 21 C.F.R. §312.8 and FDA, "Guidance for Industry: Charging for Investigational Drugs Under an IND—Questions and Answers," Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, June 2016, https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351264.pdf.

[23] FDA, "Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers," Guidance for Industry, June 2016, updated October 2017, p. 3, https://www.fda.gov/media/85675/download.

at all.[24] Some pointed to manufacturers' refusal to provide their experimental drugs.[25] Most critics, therefore, see solutions as within the control of FDA or pharmaceutical companies. This section lays out key perceived obstacles and issues—both FDA- and manufacturer-related—with respect to expanded access prior to the enactment of the Right to Try Act.

FDA-Related Issues

Difficult Process to Request FDA Permission

In February 2015, FDA issued draft guidance (finalized in June 2016 and updated in October 2017) on individual patient expanded access applications, acknowledging difficulties with requesting permission for access to investigational drugs from the agency.[26] FDA developed a new form that a physician could use when requesting expanded access for an individual patient. It reduced the amount of information required from the physician by allowing reference (with the sponsor's permission) to the information the sponsor had already submitted to FDA in its IND.[27]

In October 2017, FDA modified its expanded access IRB review policy to allow one IRB member to concur with the treatment use rather than the full IRB.[28] This policy change was made pursuant to a statutory directive that FDA streamline IRB review of individual patient expanded access requests.[29] A September 2019 report published by the Government Accountability Office (GAO) found that the IRB update was helpful for physicians and patients, for example, by reducing the amount of time for patients to obtain access to investigational drugs.[30]

In instances where a patient needs emergency treatment with the investigational product before a physician can submit a written request, FDA can authorize expanded access for an individual patient by phone or email, and the physician or sponsor must agree to submit an IND or protocol

cited in AIMS V. US DEA
No. 21-70544 archived on January 25, 2022

[24] The Abigail Alliance, formed by the father of a young woman with cancer who had unsuccessfully attempted to get an investigational drug, subsequently went to court, claimed "as a fundamental aspect of constitutional due process, the right to choose to take medication of unknown benefit and risk that might potentially be lifesaving" (Linda Greenhouse, "Justices Won't Hear Appeal on Drugs for Terminally Ill," *New York Times*, January 15, 2008, http://www.nytimes.com/2008/01/15/washington/15appeal.html?_r=0). The U.S. Court of Appeals for the District of Columbia Circuit 2007 opinion found "that there is no Constitutional right to access to experimental drugs for terminally ill patients"; in 2008, the Supreme Court declined to consider an appeal (FDA, "Court Decisions, Fiscal Year 2008," http://www.fda.gov/downloads/iceci/enforcementactions/enforcementstory/ucm129820.pdf).

[25] Jonathan J. Darrow, Ameet Sarpatwari, Jerry Avorn, M.D., and Aaron S. Kesselheim, "Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs," *New England Journal of Medicine*, January 2015, vol. 372, pp. 279-286.

[26] FDA, "Individual Patient Expanded Access Applications: Form FDA 3926," Guidance for Industry, June 2016, Updated October 2017, p. 4, https://www.fda.gov/media/91160/download.

[27] FDA estimated that it would take a physician about 45 minutes to complete the proposed new form rather than the 8 hours estimated for the original form (or 16 hours when the request was for emergency access) (80 FR 7318). FDA, "Guidance for Industry: Individual Patient Expanded Access Applications: Form FDA 3926."

[28] FDA, "Statement from FDA Commissioner Scott Gottlieb, M.D., on new efforts to strengthen FDA's expanded access program," November 8, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-efforts-strengthen-fdas-expanded-access-program. FDA, "Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers," Guidance for Industry, p. 6.

[29] P.L. 115-52, §610(b).

[30] GAO, "Investigational Drugs: FDA and Drug Manufacturers Have Ongoing Efforts to Facilitate Access for Some Patients," GAO-19-630, September 2019, pp. 18-19, https://www.gao.gov/assets/710/701243.pdf.

within 15 working days.[31] In such emergency circumstances, treatment with the investigational drug may begin prior to IRB approval, but the IRB must be notified within five working days.[32]

Coincident with discussions preceding passage of the Right to Try Act, FDA had commissioned an independent report on its expanded access program. Citing that report,[33] in November 2018, then-FDA Commissioner Gottlieb announced several actions to improve its program.[34] These included an enhanced webpage to help applicants navigate the application process and establishing an agency-wide Expanded Access Coordinating Committee. In July 2019, FDA launched the Oncology Center of Excellence Project Facilitate, which provides a single point of contact through which FDA oncology staff help physicians through the process of submitting an expanded access request for an individual patient with cancer.[35] According to a 2019 GAO report, officials from one drug manufacturer indicated that Project Facilitate may help reduce the burden on oncologists seeking expanded access to investigational drugs for their patients. However, other officials from the same manufacturer "raised concerns about the potential for FDA to intentionally or unintentionally pressure companies to make their investigational drugs available to patients, should FDA have increased involvement with drug manufacturers as part of the pilot program."[36]

Use of Adverse Event Data from Expanded Access

In October 2017, FDA updated its guidance to address how the agency reviews adverse event data in the expanded access context. In the guidance, FDA explains that reviewers are aware of the context in which adverse event data are generated—for example, that patients who receive a drug through expanded access may have a more advanced stage of the disease than those enrolled in a clinical trial—and evaluate adverse events in that context. The guidance further states that "FDA is not aware of instances in which adverse event information from expanded access has prevented FDA from approving a drug."[37] However, FDA officials have indicated to GAO that "efficacy and safety data from the expanded access program have been used to support drug approvals in several instances."[38] Further, expanded access use may allow for the detection of rare adverse events or may contribute to information about use of the drug in certain populations that are not exposed to the drug in clinical trials.[39] While some drug manufacturers have indicated that they

No. 21-70544 Archived on January 25, 2022 cited in AIMS v. US DEA

[31] 21 C.F.R. §312.310(d). FDA "For Physicians: How to Request Single Patient Expanded Access ("Compassionate Use")," https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use.

[32] FDA, "Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers," Guidance for Industry, p. 5.

[33] FDA, "Expanded Access Program Report," May 2018, https://www.fda.gov/media/119971/download.

[34] FDA, "Statement from FDA Commissioner Scott Gottlieb, M.D., on new efforts to strengthen FDA's expanded access program," November 8, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-efforts-strengthen-fdas-expanded-access-program.

[35] FDA, "Project Facilitate," https://www.fda.gov/about-fda/oncology-center-excellence/project-facilitate. GAO, "Investigational Drugs: FDA and Drug Manufacturers Have Ongoing Efforts to Facilitate Access for Some Patients," pp. 18-19.

[36] GAO, "Investigational Drugs: FDA and Drug Manufacturers Have Ongoing Efforts to Facilitate Access for Some Patients," p. 19.

[37] FDA, "Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers," Guidance for Industry, p. 18.

[38] GAO, "Investigational Drugs: FDA and Drug Manufacturers Have Ongoing Efforts to Facilitate Access for Some Patients," p. 22.

[39] FDA, "Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers," Guidance for

view FDA's updated guidance as an improvement, others maintained that they still had significant concerns about adverse event data from expanded access use negatively affecting development of their investigational new drugs.[40]

FDA as Gatekeeper

FDA action is not the final obstacle to access, as the manufacturer still needs to agree to provide their product. Between FY2010 through FY2020, FDA received 16,380 expanded access requests and granted 16,258 (99.3%) of them.[41]

Leading up to passage of the Right to Try Act, in August 2014, a *USA Today* editorial had called the FDA procedures that patients must follow for compassionate use access "bureaucratic absurdity," "daunting," and "fatally flawed." Echoing much of the criticism that FDA had received regarding the issue, it called for one measure that would "cut out the FDA, which now has final say."[42] The solution the editorial proposed involved what proponents term "right to try" laws. By spring 2018, 40 states had passed right to try laws in the absence of federal legislation.[43] The laws varied on the detail required in informed consent and liability issues of the manufacturer and the patient's estate.[44] However, several experts had suggested that this state law approach is unlikely to directly increase patient access.[45] Before passage of the federal Right to Try Act, analysts raised questions about how federal law (the FFDCA), which required FDA approval of such arrangements, might preempt this type of state law.[46] After the enactment of the federal Right to Try Act, some legal analysts had predicted that the issue of federal preemption of state laws would "likely be determined on a case-by-case basis."[47]

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

Industry, p. 18.

[40] GAO, "Investigational Drugs: FDA and Drug Manufacturers Have Ongoing Efforts to Facilitate Access for Some Patients," pp. 21-22.

[41] Reports for 2010 through 2020 are at FDA, "Expanded Access INDs and Protocols," https://www.fda.gov/drugs/ind-activity/expanded-access-inds-and-protocols.

[42] The Editorial Board, "FDA vs. right to try: Our view," *USA Today*, August 17, 2014, http://www.usatoday.com/story/opinion/2014/08/17/ebola-drugs-terminally-ill-right-to-try-editorials-debates/14206039/.

[43] National Conference of State Legislatures, "'Right to Try' Experimental Prescription Medicines State Laws and Legislation for 2014-2017," March 7, 2018, http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx#Right_to_Try.

[44] For example: House Bill 14-1281, State of Colorado, Sixty-ninth General Assembly, http://www.leg.state.co.us/clics/clics2014a/csl.nsf/fsbillcont/CE8AAA4FAF92567487257C6F005C8D97?Open&file=1281_enr.pdf; House Bill No. 891, Enrolled, Louisiana, https://www.legis.la.gov/Legis/ViewDocument.aspx?d=902583; Conference Committee Substitute No. 2 for Senate Substitute for House Committee Substitute for House Bill No. 1685, Truly Agreed To and Finally Passed, Missouri, 97th General Assembly, 2014, http://www.house.mo.gov/billtracking/bills141/billpdf/truly/HB1685T.PDF; Public Act Numbers 345 and 346 of 2014, State of Michigan, 97th Legislature, http://www.legislature.mi.gov/(S(gb2onn55vxkuylrvqmn3axrp))/mileg.aspx?page=PublicActs.

[45] Arthur Caplan, "Bioethicist: 'Right to Try' Law More Cruel Than Compassionate," NBC NEWS, May 18, 2014, http://www.nbcnews.com/health/health-news/bioethicist-right-try-law-more-cruel-compassionate-n108686; and David Kroll, "The False Hope Of Colorado's 'Right To Try' Investigational Drug Law," *Forbes*, May 19, 2014, http://www.forbes.com/sites/davidkroll/2014/05/19/the-false-hope-of-colorados-right-to-try-act/.

[46] See, generally, Elizabeth Richardson, "Health Policy Brief: Right-to-Try Laws," *Health Affairs*, March 5, 2015, http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=135.

[47] Phoebe Mounts, Kathleen Sanzo, and Jacqueline Berman, "A Closer Look At New Federal 'Right To Try' Law," Law 360, June 1, 2018, https://www.law360.com/articles/1048871/a-closer-look-at-new-federal-right-to-try-law.

Manufacturer-Related Issues

The manufacturer faces a complex decision in determining whether or not to give its experimental drug to a patient who requests it. In making a decision in each case, the manufacturer considers available supply of the drug, liability, safety, and whether adverse event or outcome data will affect FDA's consideration of a new drug application in the future.

Available Supply

If a manufacturer has only a tiny amount of an experimental drug, that paucity may limit distribution, no matter what the manufacturer would like to do.[48] Sponsors of early clinical research make small amounts of experimental products for use in small Phase 1 safety trials, and progressively more for Phase 2 and 3 trials. Although one or two additional patients may not cause supply problems, a manufacturer does not know how many expanded access requests it will receive. Investment in building up to large-scale production usually comes only after reasonable assurance that the product will get FDA approval. For a company to redirect its current manufacturing capacity involves financial, logistic, and public relations decisions.

Liability

In discussing expanded access, some manufacturers have raised liability concerns if patients report injury from the investigational products.[49] Whether these concerns become illustrated by court cases and how any issues may be resolved in future laws are beyond the scope of this discussion.[50]

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

Limited Staff and Facility Resources

Any energy put into setting up and maintaining an expanded access program could take away from a company's focus on completing clinical trials, preparing an NDA, and launching a product into the market. While this delay would have bottom-line implications, one CEO, in denying expanded access, portrayed the decision as an equity issue, saying, "We held firm to the ethical standard that, were the drug to be made available, it had to be on an equitable basis, and we couldn't do anything to slow down approval that will help the hundreds or thousands of [individuals]." Pointing to ways granting expanded access might divert them from research tasks and postpone approval, he said, "Who are we to make this decision?"[51]

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[48] GAO, "Investigational Drugs: FDA and Drug Manufacturers Have Ongoing Efforts to Facilitate Access for Some Patients," p. 25.

[49] For example, see Sam Adriance, "Fighting for the 'Right To Try' Unapproved Drugs: Law as Persuasion," *Yale Law Journal Forum*, vol. 124, December 4, 2014, http://www.yalelawjournal.org/forum/right-to-try-unapproved-drugs; Darshak Sanghavi, Meaghan George, and Sara Bencic, "Individual Patient Expanded Access: Developing Principles For A Structural And Regulatory Framework," *Health Affairs Blog*, July 31, 2014, http://healthaffairs.org/blog/2014/07/31/individual-patient-expanded-access-developing-principles-for-a-structural-and-regulatory-framework/; and Elizabeth Richardson, "Health Policy Brief: Right-to-Try Laws," *Health Affairs*, March 5, 2015, http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=135.

[50] CRS Legal Sidebar LSB10115, *Federal "Right-to-Try" Legislation: Legal Considerations*.

[51] Steve Usdin, "Josh Hardy chronicles: How Chimerix, FDA grappled with providing compassionate access to Josh Hardy," BioCentury, March 31, 2014, https://www.biocentury.com/biocentury/regulation/2014-03-31/how-chimerix-fda-grappled-providing-compassionate-access-josh-hardy.

Data for Assessing Safety and Effectiveness

By distributing the drug outside a carefully designed clinical trial, it may be difficult, if not impossible, to collect the data that would validly assess safety and effectiveness. Clinical trials are structured to assess the safety of a drug as well as its effectiveness. The trial design may exclude subjects who are so ill from either the disease or condition for which the drug is being tested or another disease or condition. This allows, among other reasons, the analysis of adverse events in the context of the drug and disease of interest. The patients who would seek a drug under a right to try pathway are likely to be very ill and likely to experience serious health events. Those events could be a result of the drug or those events could be unrelated. They would present difficulties both scientific and public relations-wise to the manufacturer. A manufacturer may avoid those risks by choosing to not provide a drug outside a clinical trial.

As mentioned, FDA has indicated that it is not aware of any instances in which safety and effectiveness data obtained from expanded access have prevented approval of a drug, but there are instances in which such data have been used to support approval (see the section "Use of Adverse Event Data from Expanded Access").

Disclosure

It is unclear how many people request and are denied expanded access to experimental drugs by manufacturers. This lack of information makes devising solutions to manufacturer-based obstacles difficult. Although FDA reports the number of requests it receives, manufacturers do not (nor does FDA require them to do so). The number of individuals who approach manufacturers is unknown.

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

In December 2016, the 21st Century Cures Act amended the FFDCA to require a manufacturer or distributor of an investigational drug intended for a serious disease or condition to make its policies on evaluating and responding to compassionate use requests publicly available.[52] However, the law does not require manufacturers to disclose how many requests they receive, grant, or deny.

A 2019 GAO study surveyed 29 drug manufacturers regarding their policies for individual patient access to investigational drugs.[53] Of those surveyed, 23 reported using their websites to communicate whether they considered individual requests for access to investigational drugs outside of clinical trials; the remaining 6 were in the process of developing this content for their websites. Of those 23 manufacturers, 19 stated they were willing to consider requests, while 4 stated they were not. Of the 19 drug manufacturers willing to consider requests, 13 indicated that they require the relevant regulatory authority to review requests, of which 6 specified that they require FDA to review requests for access in the United States.

The Right to Try Act

On January 24, 2017, Senator Johnson introduced S. 204, the Trickett Wendler Right to Try Act of 2017, and the bill had 43 cosponsors at that time. On August 3, 2017, the Senate Committee on Health, Education, Labor, and Pensions discharged the bill by unanimous consent. The same day,

[52] FFDCA §561A [21 U.S.C. §360bbb-0], as added by P.L. 114-255, §3032.

[53] GAO, "Investigational Drugs: FDA and Drug Manufacturers Have Ongoing Efforts to Facilitate Access for Some Patients," pp. 24-26.

the Senate passed S. 204, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act (P.L. 115-176) with a substantial amendment also by unanimous consent.

On March 13, 2018, Representative Fitzpatrick introduced a related bill, H.R. 5247, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018, and the bill had 40 cosponsors at that time. On March 21, the House passed the bill (voting 267-149). The House accepted the Senate bill on May 22, 2018 (voting 250-169), and President Trump signed it into law on May 30, 2018.

This section of the report first summarizes the provisions in the Right to Try Act. It then discusses how those provisions address some of the obstacles described in the previous section.

Provisions in the Right to Try Act

The Right to Try Act added FFDCA Section 561B, Investigational Drugs for Use by Eligible Patients. It has a separate paragraph that is not linked to an FFDCA section to limit the liability to all entities involved in providing an eligible drug to an eligible patient. It concludes with a "Sense of the Senate" section.

FFDCA Section 561B has several provisions that mirror many steps in FDA's expanded access program. A major difference is that the new section is designed to exist wholly outside the jurisdiction and participation of FDA. These provisions

- define an *eligible patient* as one who (1) has been diagnosed with a life-threatening disease or condition, (2) has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug (as certified by a physician who meets specified criteria), and (3) has given written informed consent regarding the drug to the treating physician;[54]
- define an *eligible investigational drug* as an investigational drug (1) for which a Phase 1 clinical trial has been completed, (2) that FDA has not approved or licensed for sale in the United States for any use, (3) that is the subject of an NDA or BLA pending FDA decision or is the subject of an active IND and is being studied in a clinical trial that is intended to form the primary basis of the drug's effectiveness, and (4) for which the manufacturer has not discontinued active development or production and which the FDA has not placed on clinical hold;[55] and
- exempt use under this section from parts of the FFDCA and FDA regulations regarding misbranding, certain labeling and directions for use, drug approval, investigational new drug regulations, protection of human subjects, and IRBs.[56]

FFDCA Section 561B includes provisions that address use of clinical outcomes and reporting of certain information to FDA. These provisions

- prohibit the Secretary (FDA) from using clinical outcome data related to use under this section "to delay or adversely affect the review or approval of such drug" unless the FDA determines its use is "critical to determining [its] safety," at which time the FDA must provide written notice to the sponsor to include a

No. 21-70544 archived on January 25, 2022 cited in AIMS v. U.S. DEA

[54] FFDCA §561B(a)(1) [21 U.S.C. §360bbb-0a(a)(1)].

[55] FFDCA §561B(a)(2) [21 U.S.C. §360bbb-0a(a)(2)].

[56] FFDCA §561B(b) [21 U.S.C. §360bbb-0a(b)].

public health justification, or unless the sponsor requests use of such clinical outcome data;[57]

- require the sponsor to submit an annual summary to FDA to include "the number of doses supplied, the number of patients treated, the uses for which the drug was made available, and any known serious adverse events";[58] and
- require FDA to post an annual summary on its website to include the number of drugs for which (1) FDA determined the need to use clinical outcomes in the review or approval of an investigational drug, (2) the sponsor requested that clinical outcomes be used, and (3) the clinical outcomes were not used.[59]

The act has an uncodified section titled "No Liability," which does not correspond to the FDA's expanded access program. The provision states that, related to use of a drug under the new FFDCA Section 561B,

- "no liability in a cause of action shall lie against … a sponsor or manufacturer; or … a prescriber, dispenser, or other individual entity … unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law"; and
- no liability, also, for a "determination not to provide access to an eligible investigational drug."[60]

Discussion of Selected Provisions in the Right to Try Act

Eligible Patients

Cited in AIMS v. US DEA No. 21-70544 archived on January 25, 2022

The Right to Try Act defines eligibility, in part, as a person diagnosed with a "life threatening disease or condition." That definition differs from many of the state-passed laws, as well as from what FDA preferred: that the definition make clear patients were eligible only if they faced a "terminal illness."[61] FDA Commissioner Gottlieb noted that "[many] chronic conditions are life-threatening, but medical and behavioral interventions make them manageable."[62] Examples of such diseases or conditions are diabetes and heart disease.

Speaking in support of right to try bills, supporters told of people facing death who, with no alternatives remaining, would be willing to risk an experimental drug that might even hasten their death.[63] By not limiting eligibility to those at the end of options, the Right to Try Act could allow people with chronic conditions to take extreme risks rather than live a normal lifespan with treatments now available. Because of the broad eligibility, manufacturers could see a significant

[57] FFDCA §561B(c) [21 U.S.C. §360bbb-0a(c)].

[58] FFDCA §561B(d)(1) [21 U.S.C. §360bbb-0a(d)(1)].

[59] FFDCA §561B(d)(2) [21 U.S.C. §360bbb-0a(d)(2)].

[60] P.L. 115-176, §2(b).

[61] Statement of Scott Gottlieb, M.D., Commissioner of Food and Drugs, before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, October 3, 2017, https://www.fda.gov/NewsEvents/Testimony/ucm578634.htm.

[62] Statement of Scott Gottlieb, M.D., Commissioner of Food and Drugs, before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, October 3, 2017, https://www.fda.gov/NewsEvents/Testimony/ucm578634.htm.

[63] For example, Rep. Barton during House floor debate on S. 204, Congressional Record, May 22, 2018, p. H4359, https://www.congress.gov/crec/2018/05/22/CREC-2018-05-22-pt1-PgH4355.pdf.

increase in requests. If Congress revisits the Right to Try Act, Members might consider the definition and clarify what they want for patients and manufacturers.

Informed Consent

The Right to Try Act makes it mandatory that before eligible patients receive an investigational drug, they give the treating doctor their informed consent in writing—but it does not define "informed consent."[64] Other right to try bills, including the House-passed H.R. 5247 (115th Congress), included more specific direction for consent, such as criteria already laid out in 21 CFR Part 50.[65] The Right to Try Act neither provides nor requires the development of such criteria. It thus may weaken patient protections that FDA's expanded access program provides. The Right to Try Act also eliminates the requirement that an IRB review the investigational use of a drug.[66]

If Congress decides to revisit the Right to Try Act, it may seek to create a more explicit informed consent requirement and some outside oversight to reduce the risk to patients either by well-meaning but less knowledgeable physicians or by unscrupulous actors some opponents of the law anticipate.[67]

Data to FDA

Clinical Outcomes

It sometimes takes thousands of patients to establish an accurate evaluation of a drug's safety and effectiveness. Researchers exclude from the clinical trial patients who—for reasons other than the drug's effectiveness—may not show evident benefit from the drug. Those are the patients who would get access through the Right to Try Act pathway.

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

The Right to Try Act prohibits FDA from using clinical outcome data related to use under this section "to delay or adversely affect the review or approval of such drug."[68] This might make a sponsor more likely to approve the use of its investigational drug under this pathway. The Right to Try Act, however, includes two exceptions. It allows FDA to use those data if the agency determines their use is "critical to determining [the drug's] safety" or if the sponsor requests use of such outcomes.[69] If drug sponsors find that this remains an obstacle to their permitting access to investigational drugs, Congress could work with them, FDA, and patient advocacy groups to devise another approach.

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[64] FFDCA §561B(a)(1)(C) [21 U.S.C. §360bbb-0a(a)(1)(C)].

[65] 21 C.F.R. 312.305(c)(4); Rep. Walden, during House debate on S. 204, May 22, 2018, pp. H4357-4358, https://www.congress.gov/crec/2018/05/22/CREC-2018-05-22-pt1-PgH4355.pdf; and Letter to Speaker Ryan and Minority Leader Pelosi, dated May 21, 2018, from 104 advocacy groups, including the American Cancer Society Cancer Action Network, the American Lung Association, the Cystic Fibrosis Foundation, and the Leukemia & Lymphoma Society, as entered into the record by Rep. Castor during House debate on S. 204, May 22, 2018, p. H4358, https://www.congress.gov/crec/2018/05/22/CREC-2018-05-22-pt1-PgH4355.pdf.

[66] FFDCA §561B(b) [21 U.S.C. §360bbb-0a(b)].

[67] Rep. Pallone, during House floor debate on S. 204, Congressional Record, May 22, 2018, p. H4360, https://www.congress.gov/crec/2018/05/22/CREC-2018-05-22-pt1-PgH4355.pdf.

[68] FFDCA §561B(c)(1) [21 U.S.C. §360bbb-0a(c)(1)].

[69] FFDCA §561B(c)(1)(A) & (B) [21 U.S.C. §360bbb-0a(c)(1)(A)&(B)].

Adverse Events

The Right to Try Act requires the manufacturer to report once a year to FDA, including an account of all serious adverse events that occurred in the preceding 12 months.[70] It does not require immediate reporting of adverse events.[71] This is less than what FDA requires of sponsors of approved drugs and investigational drugs provided in clinical trials or under expanded access. All must periodically inform FDA of such events—and immediately if the event is "serious and unexpected."[72] An adverse event may not be clearly attributable to a drug. A clustering of such reports, though, could signal FDA that this might be something worth exploring.

If Congress were to reconsider the Right to Try Act, it could explore with stakeholders—FDA, drug sponsors, and physicians and patients who use this pathway—ways to make data available to advance the goal of developing safe and effective drugs while protecting the legitimate business interests of manufacturers and the access of seriously ill individuals to try risky drugs.

Disclosure

The Right to Try Act requires the manufacturer or sponsor to submit an annual summary to FDA to include "the number of doses supplied, the number of patients treated, the uses for which the drug was made available, and any known serious adverse events."[73] FDA has issued a proposed rule to implement this annual reporting requirement, which will not become effective until FDA promulgates a final rule and establishes a deadline for such reports.[74] The Right to Try Act also requires FDA to post an annual summary on its website to include the number of drugs for which (1) the agency has determined the need to use clinical outcomes in the review or approval of an investigational drug, (2) the sponsor requested that clinical outcomes be used, and (3) the clinical outcomes were not used.[75]

Cited in AIMS V. US DEA
No. 21-70544 archived on January 25, 2022

Congress may choose to revisit these reporting requirements, to require the manufacturer or sponsor to provide more information to FDA, to require FDA to make public additional information, or both.

Financial Cost to Patient

FDA's expanded use process permits a sponsor to charge a patient for the investigational drug, but only to recover the direct costs of making the drug available, as defined under 21 C.F.R. 312.8(d).[76] This includes costs to manufacture the drug in the quantity needed or costs to acquire the drug from another source (e.g., shipping, handling, storage).[77] The sponsor cannot charge for development costs or to make a profit. The Right to Try Act extends this requirement to drugs that

[70] FFDCA §561B(d)(1) [21 U.S.C. §360bbb-0a(d)(1)].

[71] Letter to Speaker Ryan and Minority Leader Pelosi, dated May 21, 2018, from 104 advocacy groups, including the American Cancer Society Cancer Action Network, the American Lung Association, the Cystic Fibrosis Foundation, and the Leukemia & Lymphoma Society, as entered into the record by Rep. Castor during House debate on S. 204, May 22, 2018, p. H4358, https://www.congress.gov/crec/2018/05/22/CREC-2018-05-22-pt1-PgH4355.pdf.

[72] 21 C.F.R. §314.80(c)(1)(i), 21 C.F.R. §312.32(c)(1).

[73] FFDCA §561B(d)(1) [21 U.S.C. §360bbb-0a(d)(1)].

[74] FDA, "Annual Summary Reporting Requirements Under the Right to Try Act," 85 *Federal Register* 44803, July 24, 2020.

[75] FFDCA §561B(d)(2) [21 U.S.C. §360bbb-0a(d)(2)].

[76] 21 C.F.R. §312.8(d)(1).

[77] FDA, "Guidance for Industry: Charging for Investigational Drugs Under an IND—Questions and Answers," p. 6.

sponsors may provide under this pathway.[78] However, it does not require insurers to pay for the drug—or pay for doctor office visits or hospital stays associated with its use or potential adverse outcomes—and these costs may therefore fall on the patient. Congress may consider examining the effect of the Right to Try Act on costs incurred by patients.

Liability Protections

Manufacturers may see liability costs as an obstacle to providing an investigational drug to patients. The no-liability provision in the Right to Try Act seems to remove that obstacle, although it may leave the patient with limited legal recourse. In the past, Congress has sometimes tried to protect both recipients and the manufacturer from harm (e.g., the National Childhood Vaccine Injury Act of 1986 and the Smallpox Emergency Personnel Protection Act of 2003). In those cases, where Congress felt the public health benefit to the larger group outweighed the smaller risk to some, the federal government accepted responsibility for compensating injured patients and indemnifying manufacturers from lawsuits.[79] That has not been the motivating force behind the Right to Try Act. Discussions of earlier versions of liability protections raised concerns that they might not fully protect the manufacturer.[80] As patients use drugs under the Right to Try Act pathway, it is possible that they will test such protections in the courts. This is yet another issue that Congress might pursue.

Concluding Comments

Several questions remain regarding the impact of the Right to Try Act on patients, drug manufacturers, and FDA.

- **First: Will more patients get investigational drugs?** The Right to Try Act requires manufacturers or sponsors to report each year on the number of doses supplied and patients treated as a result of the law, as well as what the drugs were used for and any known serious adverse events.[81] Over time—and perhaps with requesting other data—Congress could determine whether the law has had the effect its sponsors intended.
- **Second: Has the law removed the obstacles to access to investigational drugs?** While the Right to Try Act achieves proponents' objective of removing the FDA application step in a patient's quest for an investigational drug, it does not address other obstacles—such as a limited drug supply or limits on staff and facility resources—that could lead a manufacturer to refuse access to its drugs. Further, it is not clear whether it sufficiently deals with the obstacles it does address—use of clinical outcomes data and liability protection. While the reporting required by the Right to Try Act was not designed to answer those questions, Congress could ask GAO to evaluate the law's impact on manufacturers' willingness to provide investigational drugs under this pathway.

No. 21-70544 archived on January 25, 2022
cited in AIMS v. US DEA

[78] FFDCA §561B(b) [21 U.S.C. §360bbb-0a(b)].

[79] The National Childhood Vaccine Injury Act of 1986 (P.L. 99-660) established the National Vaccine Injury Compensation Program. The Smallpox Emergency Personnel Protection Act of 2003 (P.L. 108-20) established the Smallpox Vaccine Injury Compensation Program.

[80] Bexis, "Federal Right to Try Legislation—Is It Any Better?" Drug & Device Law, September 5, 2017, https://www.druganddevicelawblog.com/2017/09/federal-right-to-try-legislation.

[81] FFDCA §561B(d)(1) [21 U.S.C. §360bbb-0a(d)(1)].

- **Third: How will this affect FDA?** One news article referred to the Right to Try Act's "bizarre twist," as FDA must determine its role in implementing a law whose function is to remove FDA from the situation.[82] Writing in opposition to the bill, four former FDA commissioners warned that it would "create a dangerous precedent that would erode protections for vulnerable patients."[83] That is something Congress may choose to address.

The Right to Try Act concludes with a "Sense of the Senate" section that appears to acknowledge that this legislation offers minimal opportunity to patients. It is explicit in asserting that the new law "will not, and cannot, create a cure or effective therapy where none exists." The legislation, it says, "only expands the scope of individual liberty and agency among patients." The drafters realistically end that phrase with "in limited circumstances."

Author Information

Agata Bodie
Analyst in Health Policy

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cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

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[82] For almost a decade, the Goldwater Institute has been working toward the goal it achieved with the signing of the Right to Try Act. It says that "people have a fundamental right to try to save their own lives without applying to the federal government for permission." (Goldwater Institute quoted in Erin Mershon, "Drug makers have to post policies for patients seeking experimental medicines. Not all do." Stat+, April 5, 2018, https://www.statnews.com/2018/04/05/drug-makers-compassionate-use-policies/.)

[83] Laurie McGinley, "Former FDA commissioners say right-to-try bills could endanger 'vulnerable patients,'" *Washington Post*, March 18, 2018, https://www.washingtonpost.com/news/to-your-health/wp/2018/03/18/former-fda-commissioners-say-right-to-try-bills-could-endanger-vulnerable-patients/?utm_term=.3fe265fa04eb.

The Controlled Substances Act (CSA): A Legal Overview for the 117th Congress

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SUMMARY

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February 5, 2021

Joanna R. Lampe
Legislative Attorney

The Controlled Substances Act (CSA): A Legal Overview for the 117th Congress

The Controlled Substances Act (CSA) establishes a unified legal framework to regulate certain drugs that are deemed to pose a risk of abuse and dependence. The CSA may apply to drugs that are medical or recreational, legally or illicitly distributed, but the statute does not apply to all drugs. Rather, it applies to specific substances and categories of substances that have been designated for control by Congress or through administrative proceedings. The CSA also applies to *controlled substance analogues* that are intended to mimic the effects of controlled substances and to certain *precursor chemicals* commonly used in the manufacturing of controlled substances.

Controlled substances subject to the CSA are divided into categories known as Schedules I through V based on their medical utility and their potential for abuse and dependence. Substances considered to pose the greatest risk to the public health and safety are subject to the most stringent controls and sanctions. A lower schedule number corresponds to greater restrictions, so substances in Schedule I are subject to the strictest controls, while substances in Schedule V are subject to the least strict. Many substances regulated under the CSA are also subject to other federal or state regulations, including the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The Drug Enforcement Administration (DEA) is the federal agency primarily responsible for implementing and enforcing the CSA. DEA may designate a substance for control through notice-and-comment rulemaking if the substance satisfies the applicable statutory criteria. The agency may also place a substance under temporary control on an emergency basis if the substance poses an imminent hazard to public safety. In addition, DEA may designate a substance for control if required by the United States' international treaty obligations. In the alternative, Congress may place a substance under control by statute.

The CSA simultaneously aims to ensure that patients have access to pharmaceutical controlled substances for legitimate medical purposes while also seeking to protect public health from the dangers of controlled substances diverted into or produced for the illicit market. To accomplish those two goals, the statute creates two overlapping legal schemes. *Registration provisions* require entities working with controlled substances to register with DEA and take various steps to prevent diversion and misuse of controlled substances. *Trafficking provisions* establish penalties for the production, distribution, and possession of controlled substances outside the legitimate scope of the registration system. DEA is primarily responsible for enforcing the CSA's registration provisions and works with the Criminal Division of the Department of Justice to enforce the Act's trafficking provisions. Violations of the registration provisions generally are not criminal offenses, but certain serious violations may result in criminal prosecutions, fines, and even short prison sentences. Violations of the trafficking provisions are criminal offenses that may result in large fines and lengthy prison sentences.

Drug regulation has received significant attention from Congress in recent years, with a number of bills introduced in the 116th Congress to amend the CSA in various ways. For example, the 116th Congress considered multiple proposals aimed at addressing the opioid crisis, including the John S. McCain Opioid Addiction Prevention Act (H.R. 1614, S. 724), which would have limited practitioners' ability to prescribe opioids; the LABEL Opioids Act (H.R. 2732, S. 1449), which would have required prescription opioids to bear certain warning labels; and the Ending the Fentanyl Crisis Act of 2019 (S. 1724), which would have increased criminal liability for illicit trafficking in the powerful opioid fentanyl. The 116th Congress also enacted the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (P.L. 116-114), which placed a broad class of fentanyl analogues in Schedule I on a temporary basis, and considered other measures specifically seeking to address the proliferation of synthetic drugs that mimic the effects of fentanyl. In addition, multiple recent proposals sought to address the divergence between federal and state marijuana laws. The MORE Act of 2019 (H.R. 3884, S. 2227), which passed the House in December 2020, would have removed marijuana from the schedules of controlled substances. Other recent legislative proposals sought to facilitate clinical research involving marijuana and other Schedule I controlled substances. In addition, the emergence of the Coronavirus Disease 2019 (COVID-19) pandemic in 2020 raised legal issues under the CSA, including questions around the availability of controlled substances used in treating COVID-19 and medical practitioners' ability to prescribe controlled substances via telemedicine. The various proposals introduced in the 116th Congress raise a number of legal questions that Congress may contemplate when deciding whether to change the laws governing controlled substances.

No. 21-70544 archived on January 25, 2022
Cited in AIMS V. US DEA

Contents

Figures

Contacts

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

Prescription drugs play a vital role in American public health. The Centers for Disease Control and Prevention (CDC) estimates that during 2015 and 2016 over 45% of Americans had used one or more prescription drugs in the last 30 days.[1] But unfettered access to drugs may pose serious public health risks. The CDC reports that in 2018 over 67,000 Americans died of overdoses of prescription and nonprescription drugs.[2] The Controlled Substances Act[3] (CSA or the Act) seeks to balance those competing considerations.[4] The CSA regulates *controlled substances*—prescription and nonprescription drugs and other substances that are deemed to pose a risk of abuse and dependence.[5] By establishing rules for the proper handling of controlled substances[6] and imposing penalties for any illicit production, distribution, or possession of such substances,[7] the Act seeks to protect the public health from the dangers of controlled substances while also ensuring that patients have access to pharmaceutical controlled substances for legitimate medical purposes.[8]

This report provides an overview of the CSA and select legal issues that have arisen under the Act, with a focus on legal issues of concern for the 117th Congress. The report first summarizes the history of the CSA and explains how the regulation of drugs under the CSA overlaps with other federal and state regulatory regimes.[9] It then outlines the five main categories of substances subject to the Act—known as *schedules*—and discusses how substances are added to the schedules.[10] The report next outlines the CSA's *registration requirements*, which govern the activities of individuals and entities that register with the government to receive authorization to handle pharmaceutical controlled substances,[11] before summarizing the CSA's criminal *trafficking provisions*, which apply to controlled-substance-related activities that are not authorized under the Act.[12] Finally, the report outlines select legal issues for Congress related to the CSA, including issues related to the response to the opioid crisis, the control of analogues to the potent opioid fentanyl, the growing divergence between the treatment of marijuana under federal and state law, the legal limits on medical use of certain controlled substances, and the effects of the COVID-19 pandemic on controlled substance regulation.[13]

No. 21-70544 archived on January 25, 2022
Cited in AIMS v. US DEA

Background and Scope of the CSA

Congress has regulated drugs in some capacity since the 19th century. Federal drug regulation began with tariffs, import and export controls, and purity and labeling requirements applicable to

[1] *See* Crescent B. Martin, et al., *Prescription Drug Use in the United States, 2015–2016*, NCHS DATA BRIEF No. 334 (May 2019).

[2] *See* Holly Hedegaard, et al., *Drug Overdose Deaths in the United States, 1999–2018*, NCHS DATA BRIEF No. 356 (Jan. 2020).

[3] 21 U.S.C. §§ 801-904. Unless otherwise indicated, this report uses *United States Code* citations for statutory material.

[4] *See id.* §§ 801(1), (2).

[5] *See id.* §§ 802(6), 811.

[6] *See id.* §§ 821-832.

[7] *See id.* §§ 841-865.

[8] *See id.* §§ 801(1), (2).

[9] *See infra* "Background and Scope of the CSA" and "Other Regulatory Schemes."

[10] *See infra* "Classification of Controlled Substances."

[11] *See infra* "Registration Requirements."

[12] *See infra* "Trafficking Provisions."

[13] *See infra* "Legal Considerations for the 117th Congress."

narcotic drugs such as opium and coca leaves and their derivatives.[14] With the passage of the Harrison Narcotics Tax Act of 1914, Congress began in earnest to regulate the domestic trade in narcotic drugs.[15] The Harrison Act imposed federal oversight of the legal trade in narcotic drugs and imposed criminal penalties for illicit trafficking in narcotics.[16] Over the course of the 20th century, the list of drugs subject to federal control expanded beyond narcotic drugs to include marijuana, depressants, stimulants, and hallucinogens.[17]

In 1970, Congress revamped federal drug regulation by enacting the Comprehensive Drug Abuse Prevention and Control Act.[18] That act repealed nearly all existing federal substance control laws and, for the first time, imposed a unified framework of federal controlled substance regulation.[19] Title II of the Comprehensive Drug Abuse Prevention and Control Act is known as the Controlled Substances Act.[20]

The CSA regulates certain drugs[21]—whether medical or recreational, legally or illicitly distributed—that are found to pose a risk of abuse and dependence.[22] In enacting the CSA, Congress recognized two competing interests related to drug regulation. On one hand, many drugs "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people."[23] On the other hand, "illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people."[24] Accordingly, the Act simultaneously aims to protect public health from the dangers of controlled substances while also ensuring access to controlled substances for legitimate purposes.

To accomplish those two goals, the statute creates two overlapping legal schemes. *Registration provisions* require individuals and entities working with controlled substances to register with the government, take steps to prevent diversion and misuse of controlled substances, and report certain information to regulators.[25] *Trafficking provisions* establish penalties for the production, distribution, and possession of controlled substances outside the legitimate scope of the registration system.[26]

No. 21-70544 archived on January 25, 2022
cited in AIMS v. US DEA

[14] Thomas M. Quinn & Gerald T. McLaughlin, *The Evolution of Federal Drug Control Legislation*, 22 CATH. U.L. REV. 586, 589-93 (1973).

[15] Pub. L. No. 63-223, 38 Stat. 785 (1915).

[16] *See* Quinn & McLaughlin, *supra* note 14 at 593.

[17] *Id.* at 600-03.

[18] Pub. L. No. 91-513, 84 Stat. 1236 (1970). Congress has the authority to regulate controlled substances under the Commerce Clause. *See* Gonzales v. Raich, 545 U.S. 1, 15 (2004).

[19] Quinn & McLaughlin, *supra* note 14 at 605.

[20] Title III of the Comprehensive Drug Abuse Prevention and Control Act is the closely related Controlled Substances Import and Export Act. *See* 21 U.S.C. §§ 951-971.

[21] The CSA does not apply exclusively to "drugs," providing more broadly for the control of any "drug or other substance" included in the CSA's schedules. 21 U.S.C. § 802(6). Substances subject to the CSA may include plants, such as marijuana or peyote, or chemicals not generally recognized as drugs. However, for the sake of simplicity, this report refers to "drugs" subject to the Act.

[22] *See* 21 U.S.C. §§ 811, 812.

[23] *Id.* § 801(1).

[24] *Id.* § 801(2).

[25] *See id.* §§ 821-832.

[26] *Id.* §§ 841-865.

The CSA does not apply to all drugs. As discussed below, substances must be specifically identified for control (either individually or as a class) to fall within the scope of the Act.[27] For medical drugs, the CSA primarily applies to prescription drugs, not drugs available over the counter.[28] Moreover, the statute does not apply to all prescription drugs, but rather to a subset of those drugs deemed to warrant additional controls.[29] As for nonpharmaceutical drugs, well-known recreational drugs such as marijuana, cocaine,[30] heroin, and lysergic acid diethylamide (LSD) are all controlled substances, as are numerous lesser-known substances, some of which are identified only by their chemical formulas.[31] Some recreational drugs are not classified as federally controlled substances.[32] Alcohol and tobacco, which might otherwise qualify as drugs potentially warranting control under the CSA, are explicitly excluded from the scope of the Act,[33] as is hemp that meets certain statutory requirements.[34] Finally, it is possible for legitimate researchers and illicit drug manufacturers to formulate new drugs not listed in any of the Act's schedules. Even if those drugs are similar to existing controlled substances, they may fall outside the scope of the CSA unless they are classified as controlled substances.[35]

Other Regulatory Schemes

Many drugs classified as controlled substances subject to the CSA are also subject to other legal regimes. For example, all pharmaceutical drugs, including those subject to the Act, are subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act).[36] The U.S. Food and Drug Administration (FDA) is the agency primarily responsible for enforcing the FD&C Act which, among other things, prohibits the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded."[37] The FD&C Act defines misbranding broadly: a drug is considered misbranded if, among other things, its labeling,

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[27] *Id.* § 811.

[28] *Id.* § 829; *see also infra* "Prescriptions."

[29] The Drug Enforcement Administration (DEA) has estimated that 10%-11% of all drug prescriptions written in the United States are for controlled substances. *See* DEA, Dispensing of Controlled Substances to Residents at Long Term Care Facilities, 75 Fed. Reg. 37,463, 37,464 (June 29, 2010).

[30] Although cocaine is commonly considered a nonpharmaceutical drug, it has been placed in Schedule II, reflecting a finding that it has an accepted medical use. *See* 21 C.F.R. § 1308.12(b)(4); *see also infra* "Overview of Schedules."

[31] The full schedules are promulgated at 21 C.F.R. §§ 1308.11-1308.15.

[32] For example, Salvia divinorum (an herb with hallucinogenic effects) and kratom (a tropical tree whose leaves may have either stimulant or sedative effects depending on dosage) are not subject to the CSA at this writing, although DEA has identified them as "drugs of concern." DEA, DRUGS OF ABUSE: A DEA RESOURCE GUIDE, 84-85 (2017).

[33] *See* 21 U.S.C. § 802(6).

[34] *Id.* § 802(16)(B)(i). Hemp and marijuana are both varieties of the cannabis plant. Hemp is defined as "the plant Cannabis sativa L. and any part of that plant . . . with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." 7 U.S.C. § 1639(o). The cannabis plant and most products produced from that plant remain controlled substances subject to the CSA, unless they meet the statutory definition of hemp. *See* 21 C.F.R. § 1308.11(d)(23).

[35] *See* The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order: Hearing Before the Sen. Comm. on the Judiciary, 116th Cong. 1, 4 (2019) (statement of the U.S. Dep't of Justice) [hereinafter, DOJ Testimony]; see also CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea. In some cases, substances not specifically listed in the CSA's schedules may qualify as controlled substance analogues. *See infra* "Analogues and Listed Chemicals."

[36] 21 U.S.C. §§ 301-399i.

[37] *Id.* § 331(a).

advertising, or promotion "is false or misleading in any particular."[38] Unlabeled drugs are considered misbranded,[39] as are prescription drugs that FDA has not approved, including imported drugs.[40] The FD&C Act provides that a drug is deemed to be adulterated if, among other things, it "consists in whole or in part of any filthy, putrid, or decomposed substance," "it has been prepared, packed, or held under insanitary conditions," its container is made of "any poisonous or deleterious substance," or its strength, quality, or purity is not as represented.[41]

The key aims of the FD&C Act are related to but distinct from those of the CSA. The CSA establishes distribution controls to prevent the misuse of substances deemed to pose a potential danger to the public welfare.[42] The FD&C Act, by contrast, is a consumer protection statute that seeks to protect consumers from obtaining unsafe or ineffective drugs (and other public health products) through commercial channels.[43] Any person or organization that produces, distributes, or otherwise works with prescription drugs that are also controlled substances must comply with the requirements of both the CSA and the FD&C Act.

With respect to both pharmaceutical and nonpharmaceutical drugs, many drugs subject to the CSA are also subject to state controlled substance laws.[44] State substance control laws often mirror federal law and are relatively uniform across jurisdictions because almost all states have adopted a version of a model statute called the Uniform Controlled Substances Act (UCSA).[45] However, states are free to modify the UCSA, and have done so to varying extents.[46] Moreover, the model statute does not specify sentences for violations, so penalties for state controlled substance offenses vary widely.[47]

There is not a complete overlap between drugs subject to federal and state control for several reasons. First, states may elect to impose controls on substances that are not subject to the CSA.[48] For example, some states have controlled the fentanyl analogues benzylfentanyl and thenylfentanyl, but those substances are not currently scheduled under the CSA.[49] Second, states

No. 21-70544 archived on January 25, 2022
cited in AIMS v. US DEA

[38] *Id.* § 352.

[39] *See* United States v. Wood, 8 F.3d 33, 1993 WL 425948 (Table) at *3 (9th Cir. 1993).

[40] *See, e.g.*, *In re* Canadian Import Antitrust Litigation, 470 F.3d 785, 788-90 (8th Cir. 2006); United States v. Patwardhan, 422 Fed. App'x. 614, 616-17 (9th Cir. 2011). Misbranding also includes misrepresenting that a substance offered for sale is a brand-name drug. *See, e.g.*, United States v. Xin He, 405 Fed. App'x 220, 221 (9th Cir. 2010).

[41] 21 U.S.C. § 351.

[42] *See id.* § 801(1) ("The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.").

[43] *See, e.g.*, United States v. Kordel, 397 U.S. 1, 11 (1970) (invoking the "public interest in protecting consumers throughout the Nation from misbranded drugs"); *see also* CRS Report R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues*, by Jennifer A. Staman.

[44] ALEX KREIT, CONTROLLED SUBSTANCES: CRIME, REGULATION, AND POLICY 628 (2013).

[45] Richard L. Braun, *Uniform Controlled Substances Act of 1990*, 13 CAMPBELL L. REV. 365, 365 (1991) (The UCSA "has been the basic law pertaining to control of narcotic drugs in forty-six (46) states.").

[46] For example, Arkansas has adopted the UCSA but added a sixth schedule for "substances that are determined to be inappropriately classified by placing them in Schedules I through V." Ark. Code Ann. § 5-64-213. In addition, the UCSA classifies marijuana as a Schedule I controlled substance subject to stringent controls; however, many states have passed laws decriminalizing some or all marijuana use. *See infra* "Marijuana Policy Gap"; *see also* Kimberly A. Houser, *What Inconsistent Federal Policy Means for Marijuana Business Owners: Washington's I-502 and the Federal Controlled Substances Act*, 50 GONZ. L. REV. 305, 308-09 (2015).

[47] Braun, *Uniform Controlled Substances Act of 1990*, 13 CAMPBELL L. REV. at 371; *see also* Kreit, *supra* note 44 at 628.

[48] Kreit, *supra* note 44 at 628.

[49] *See, e.g.*, United States v. Guerrero, 910 F.3d 72, 75 (2d Cir. 2018) (discussing difference in scheduling between

may wish to adopt federal scheduling decisions at the state level but lag behind federal regulators due to the need for a separate state scheduling process.[50] Third, states may decide not to impose state controls on substances subject to the CSA, or they may choose to impose modified versions of federal controls at the state level.[51]

Crucially, however, the states cannot alter federal law, and when state and federal law conflict, the federal law controls.[52] Thus, when states "legalize" or "decriminalize" a federally controlled substance (as many have done recently with respect to marijuana), the sole result is that the substance is no longer controlled *under state law*.[53] Any federal controls remain in effect and potentially enforceable in those states.[54]

Classification of Controlled Substances

The heart of the CSA is its system for classifying controlled substances, as nearly all the obligations and penalties that the Act establishes flow from the classification system.[55] Drugs become subject to the CSA by being placed in one of five lists, referred to as "schedules."[56] Both the Administrator of the Drug Enforcement Administration (DEA)—an arm of the Department of Justice (DOJ)—and Congress can place a substance in a schedule, move a controlled substance to a different schedule, or remove a controlled substance from a schedule.[57] As discussed below, scheduling decisions by Congress and DEA follow different procedures.[58]

Overview of Schedules

The CSA establishes five categories of controlled substances, referred to as Schedules I through V.[59] The schedule on which a controlled substance is placed determines the level of restriction imposed on its production, distribution, and possession, as well as the penalties applicable to any improper handling of the substance.[60] As **Figure 1** describes, when DEA places substances under

cited in Alms v. US DEA
No. 21-70544 archived on January 25, 2022

federal law and Arizona law); McCoy v. United States, 707 F.3d 184 (2d Cir. 2013) (same with respect to Connecticut law). Benzylfentanyl and thenylfentanyl were temporarily placed under federal control in 1985, but the temporary scheduling expired in 1986, and DEA has determined that the substances are "essentially inactive, with no evidence of abuse potential." DEA, Correction of Code of Federal Regulations: Removal of Temporary Listing of Benzylfentanyl and Thenylfentanyl as Controlled Substances, 75 Fed. Reg. 37,300, 37,300 (June 29, 2010).

[50] Kreit, *supra* note 44 at 629.

[51] *Id.* at 628 (citing Ruiz-Vidal v. Gonzales, 473 F.3d 1072, 1078 (9th Cir. 2007)).

[52] U.S. CONST. art. VI, cl. 2 ("the laws of the United States . . . shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding").

[53] *See* Gonzales v. Raich, 545 U.S. 1, 29 (2005).

[54] DEA and DOJ sometimes do not enforce federal controlled substances law with respect to state-legal activities that violate the CSA. Reasons for this include the exercise prosecutorial discretion and the existence of appropriations riders limiting enforcement of the CSA in some circumstances. For further discussion of the relationship between state legalization of controlled substances and the CSA, see the "Marijuana Policy Gap" section.

[55] For further discussion of the obligations and penalties that the Act imposes, see the "Registration Requirements" and "Trafficking Provisions" sections.

[56] 21 U.S.C. § 812.

[57] *See infra* "Scheduling Procedures."

[58] *See id.*

[59] 21 U.S.C. § 812.

[60] *See, e.g.*, 21 U.S.C. § 823 (registration requirements); *id.* § 829 (prescription requirements); *id.* §§ 841-842 (prohibitions and penalties).

control by regulation, the agency assigns each controlled substance to a schedule based on its medical utility and its potential for abuse and dependence.

Figure 1. CSA Scheduling Criteria

	ABUSE POTENTIAL	MEDICAL USE	SAFETY/DEPENDENCE	EXAMPLES
SCHEDULE I	High	⊗ Not currently accepted	Lack of accepted safety for use of the substance under medical supervision[1]	Marijuana,[2] heroin, lysergic acid diethylamide (LSD), 3,4 methylenedioxymethampheta-mine (MDMA), peyote[3]
SCHEDULE II	High	✓ Currently accepted	Abuse may lead to severe psychological or physical dependence[4]	Cocaine, methamphetamine, oxycodone, fentanyl,[5] Adderall[6]
SCHEDULE III	**Less than** the substances in Schedules I and II	✓ Currently accepted	Abuse may lead to moderate or low physical dependence or high psychological dependence[7]	Ketamine, anabolic steroids, testosterone, Tylenol with codeine[8]
SCHEDULE IV	**Low potential** for abuse relative to the substances in Schedule III	✓ Currently accepted	Abuse may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III[9]	Xanax, Valium, Ambien[10]
SCHEDULE V	**Low potential** for abuse relative to the substances in Schedule IV	✓ Currently accepted	Abuse may lead to limited physical dependence or psychological dependence relative to the substances in Schedule IV[11]	Cough medicines with codeine, certain antidiarrheal medicines, FDA-approved drugs containing the marijuana extract cannabidiol (CBD)[12]

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

Notes:

[1] 21 U.S.C. § 812(b)(1).

[2] The CSA generally uses the word "marihuana" to refer to the cannabis plant and its derivatives. This report uses the more widely accepted spelling, "marijuana," unless quoting other sources.

[3] For the full list of substances in Schedule I, see 21 C.F.R. § 1308.11.

[4] 21 U.S.C. § 812(b)(2).

[5] The CSA distinguishes between prescription fentanyl and illicit fentanyl. Prescription fentanyl and several related medications are in Schedule II. Numerous nonprescription fentanyl analogues are in Schedule I.

[6] For the full list of substances in Schedule II, see 21 C.F.R. § 1308.12.

[7] 21 U.S.C. § 812(b)(3).

[8] For the full list of substances in Schedule III, see 21 C.F.R. § 1308.13.

[9] 21 U.S.C. § 812(b)(4).

[10] For the full list of substances in Schedule IV, see 21 C.F.R. § 1308.14

[11] 21 U.S.C. § 812(b)(5).

[12] For the full list of substances in Schedule V, see 21 C.F.R. § 1308.15.

A lower schedule number corresponds to greater restrictions, so controlled substances in Schedule I are subject to the most stringent controls, while substances in Schedule V are subject to the least stringent.[61] Notably, because substances in Schedule I have no accepted medical use, it is only legal to produce, dispense, and possess those substances in the context of federally approved scientific studies.[62]

Analogues and Listed Chemicals

In addition to the controlled substances listed in Schedules I through V, the CSA also regulates (1) *controlled substance analogues* and (2) *listed chemicals*.

Under the CSA, a controlled substance analogue is a substance that FDA has not approved and that is not specifically scheduled under the Act, but that has (1) a chemical structure substantially similar to that of a controlled substance in Schedule I or II, or (2) an actual or intended effect that is "substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II."[63] A substance that meets those criteria *and* is intended for human consumption is treated as a controlled substance in Schedule I.[64] It may seem counterintuitive that an analogue to a Schedule II controlled substance is treated as if it were a Schedule I controlled substance and thus is subject to more stringent controls than the substance it mimics. However, substances in Schedules I and II may have a similarly high potential for abuse. The key difference between those schedules is that Schedule II controlled substances have an accepted medical use, which controlled substance analogues do not have.

Listed chemicals subject to the CSA are precursor chemicals that are generally not intended for human consumption but can be used to produce controlled substances.[65] They may be placed on one of two lists:

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[61] *See* John Doe, Inc. v. DEA, 484 F.3d 561, 563 (D.C. Cir. 2007) ("Schedule I is the most stringently controlled, and schedule V the least.").

[62] *See* 21 U.S.C. § 823(f); *see also* Gonzales v. Raich, 545 U.S. 1, 14 (2004). Perhaps counterintuitively, marijuana and marijuana extract are in Schedule I, *see* 21 C.F.R. §§ 1308.11(23), 1308.11(58), but FDA-approved drugs containing the marijuana extract cannabidiol (CBD) are in Schedule V, *see id.* § 1308.15(f). As of July 2019, FDA has approved one drug containing CBD, a seizure medication called Epidiolex. *See* Press Release, FDA, FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy (June 26, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms; *see also* CRS In Focus IF11250, *FDA Regulation of Cannabidiol (CBD) Consumer Products*, by Agata Bodie and Renée Johnson.

[63] *Id.* § 802(32).

[64] *Id.* § 813(a).

[65] *See* United States v. Hofstatter, 8 F.3d 316, 321-22 (6th Cir. 1993) (in upholding convictions for possession of listed chemicals with intent to manufacture controlled substance analogues, considering evidence that "the defendants were attempting to manufacture substances designed for human consumption and designed to produce amphetamine-like effects when ingested"). It is, however, possible for a substance to be both a listed chemical and a controlled substance analogue. *See* 21 U.S.C. § 802(32)(B) ("The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue."); *see also* United States v. Fisher, 289 F.3d 1329, 1335-36 (11th Cir. 2002) (finding that a listed chemical could be treated as a controlled substance analogue if intended for human consumption).

- **List I Chemicals**—designated chemicals that, in addition to legitimate uses, are used in manufacturing a controlled substance in violation of the CSA *and* are important to the manufacture of a controlled substance.[66]
- **List II Chemicals**—designated chemicals that, in addition to legitimate uses, are used in manufacturing a controlled substance in violation of the CSA.[67]

List I chemicals include substances such as ephedrine, white phosphorous, and iodine, which are used to produce methamphetamine, as well as chemicals used to manufacture LSD, MDMA (also known as "ecstasy" or "molly"), and other drugs.[68] List II chemicals include, among others, solvents such as acetone, hydrochloric acid, and sulfuric acid.[69]

Listed chemicals are subject to some controls similar to those that apply to controlled substances.[70] In addition, entities that sell listed chemicals must record the transactions, report them to regulators, and comply with statutory limits on sales to a single purchaser.[71]

There are a number of differences between how controlled substance analogues and listed chemicals are regulated. In addition, listed chemicals include only specific substances identified for control under the CSA by statute or rulemaking.[72] By contrast, controlled substance analogues need not be individually scheduled; they need only satisfy the statutory criteria.[73]

Scheduling Procedures

Substances may be added to or removed from a schedule or moved to a different schedule through agency action or by legislation.[74] As described below, the procedures for modifying a substance's scheduling differ depending on whether Congress or DEA makes the change.

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

Legislative Scheduling

Perhaps the most straightforward way to change a substance's legal status under the CSA is for Congress to pass legislation to place a substance under control, alter its classification, or remove it from control. The procedural requirements for administrative scheduling discussed in the following section do not apply to legislative scheduling. Thus, Congress may use its legislative scheduling power to respond quickly to regulate a drug that poses an urgent concern. For example, the Synthetic Drug Abuse Prevention Act of 2012 permanently added two synthetic cathinones (central nervous system stimulants) and certain cannabimimetic substances

[66] 21 C.F.R. § 1300.02(b18).

[67] *Id.* § 1300.02(b19).

[68] *Id.* § 1310.02(a).

[69] *Id.* § 1310.02(b).

[70] *See, e.g.*, 21 U.S.C. § 823(h) (requiring DEA registration to distribute List I chemicals); *id.* § 841(c) (imposing criminal penalties for, among other things, "possess[ing] or distribut[ing] a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance except as authorized by" the CSA); *id.* § 842(a) (imposing civil and criminal penalties for certain unauthorized retail sales of listed chemicals).

[71] *Id.* § 830.

[72] 21 U.S.C. §§ 802(34), (35).

[73] *See, e.g.*, *Hofstatter*, 8 F.3d at 321-22 (upholding against Fifth Amendment vagueness challenge the statutory criteria for controlled substance analogues).

[74] *See* 21 U.S.C. § 811; United States v. Ways, 832 F.3d 887, 893 (8th Cir. 2016) (summarizing the addition of certain substances to Schedule I by legislation).

(commonly referred to as synthetic marijuana) to Schedule I.[75] More recently, in February 2020, Congress enacted the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which placed a broad class of fentanyl analogues in Schedule I on a temporary basis.[76]

Administrative Scheduling

DEA makes scheduling decisions through a complex process requiring participation by other agencies and the public.[77] DEA may undertake administrative scheduling on its own initiative, at the request of the U.S. Department of Health and Human Services (HHS), or "on the petition of any interested party."[78] With regard to the last route for initiating administrative scheduling, the DEA Administrator may deny a petition to begin scheduling proceedings based on a finding that "the grounds upon which the petitioner relies are not sufficient to justify the initiation of proceedings."[79] Denial of a petition to initiate scheduling proceedings is subject to judicial review, but courts will overturn a denial only if it is arbitrary and capricious.[80]

Before initiating rulemaking proceedings, DEA must request a scientific and medical evaluation of the substance at issue from the Secretary of HHS.[81] The HHS Secretary has delegated the authority to prepare the scientific and medical evaluation to FDA.[82] In preparing the evaluation, FDA considers a number of factors, including the substance's potential for abuse and dependence, scientific evidence of its pharmacological effect, the state of current scientific knowledge regarding the substance, any risk the substance poses to the public health, and whether the substance is an immediate precursor of an existing controlled substance.[83] Based on those factors, FDA makes a recommendation on whether the substance should be controlled and, if so, in which schedule it should be placed.[84] FDA's scientific and medical findings are binding on DEA.[85] Furthermore, if FDA recommends against controlling the substance, DEA may not schedule it.[86]

cited in AMS v. US DEA
No. 21-70544 archived on January 25, 2022

[75] *See* Pub. L. No. 112-144, 126 Stat. 1130 (2012). An early congressional proposal to control some of those substances was introduced in March 2011, *see* S. 605, 112th Cong. (2011), to respond to "new and very dangerous substances packaged as innocent products," 157 Cong. Rec. S1830 (2011) (statement of Sen. Grassley). The Synthetic Drug Abuse Prevention Act was introduced on May 16, 2012, *see* S. 3190, 112th Cong. (2012), and became law as part of the Food and Drug Safety and Innovation Act on July 9, 2012, Pub. L. No. 112-144, 126 Stat. 1130 (2012).

[76] Pub. L. 116-114, 134 Stat. 103 (2020). Absent further legislative or administrative action, the substances subject to this legislation will remain in Schedule I until May 6, 2021. For further discussion of the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, see CRS Legal Sidebar LSB10404, *Scheduling of Fentanyl Analogues: The New Legal Landscape*, by Joanna R. Lampe.

[77] The CSA grants the Attorney General the authority to administer its provisions. *See, e.g.*, 21 U.S.C. § 811. The Attorney General has delegated that authority to the DEA Administrator. *See* 28 C.F.R. § 0.100(b).

[78] 21 U.S.C. § 811(a).

[79] 21 C.F.R. § 1308.43.

[80] *See* Ams. for Safe Access v. DEA, 706 F.3d 438, 440 (D.C. Cir. 2013).

[81] 21 U.S.C. § 811(b).

[82] *See, e.g.*, DEA, Schedules of Controlled Substances: Placement of Solriamfetol in Schedule IV, 84 Fed. Reg. 27,943, 27,944 (June 17, 2019).

[83] *See* 21 U.S.C. §§ 811(c)(1)-(8) (full list of factors FDA and DEA must consider in making scheduling decisions).

[84] *Id.* § 811(b).

[85] *Id.*

[86] *Id.*

Upon receipt of FDA's report, the DEA Administrator evaluates all of the relevant data and determines whether the substance should be scheduled, rescheduled, or removed from control.[87] Before placing a substance on a schedule, the DEA Administrator must make specific findings that the substance meets the applicable criteria related to accepted medical use and potential for abuse and dependence.[88] DEA scheduling decisions are subject to notice-and-comment rulemaking under the Administrative Procedure Act,[89] meaning that interested parties must have the opportunity to submit comments on the DEA Administrator's decision before it becomes final.[90]

The DEA Administrator's decision whether to schedule, reschedule, or deschedule a substance through the ordinary administrative process is subject to judicial review.[91] Such review is generally deferential: courts accept DEA's interpretation of the CSA as long as the interpretation of ambiguous statutory text is reasonable,[92] and the CSA provides that the DEA Administrator's findings of fact are "conclusive" on judicial review if the findings are supported by substantial evidence.[93] Overall, courts will set aside DEA action "only if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'"[94]

Emergency Scheduling

Ordinary DEA scheduling decisions are made through notice-and-comment rulemaking and can take years to consider and finalize.[95] Recognizing that in some cases faster scheduling may be appropriate, Congress amended the CSA through the Comprehensive Crime Control Act of 1984[96] to allow the DEA Administrator to place a substance in Schedule I temporarily when "necessary to avoid an imminent hazard to the public safety."[97] Before issuing a temporary scheduling order, the DEA Administrator must provide 30 days' notice to the public and the Secretary of HHS stating the basis for temporary scheduling.[98] In issuing a temporary scheduling order, the DEA Administrator must consider only a subset of the factors relevant to permanent scheduling: the history and current pattern of abuse of the substance at issue; the scope, duration, and significance of abuse; and the risk to the public health.[99] The DEA Administrator must also consider any comments from the Secretary of HHS.[100]

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[87] *Id.* Like FDA, the DEA Administrator is required to consider all the factors in 21 U.S.C. §§ 811(c)(1)-(8) in making this determination.

[88] *Id.* § 812(b).

[89] 5 U.S.C. § 500, et seq.

[90] 21 U.S.C. § 811(a); *see also* Touby v. United States, 500 U.S. 160, 162-63 (1991).

[91] *See id.* § 877.

[92] *See* All. for Cannabis Therapeutics v. DEA, 930 F.2d 936, 939 (D.C. Cir. 1991) (citing Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843-45 (1984)).

[93] 21 U.S.C. § 877.

[94] *See, e.g.*, Ams. for Safe Access v. DEA, 706 F.3d 438, 449 (D.C. Cir. 2013) (quoting 5 U.S.C. § 706(2)(A)).

[95] *See, e.g.*, Washington v. Barr, 925 F.3d 109, 120 (2d Cir. 2019) ("Plaintiffs document that the average delay in deciding petitions to reclassify drugs under the CSA is approximately nine years.").

[96] Pub. L. No. 98-473, 98 Stat. 1976 (1984).

[97] 21 U.S.C. § 811(h)(1).

[98] 21 U.S.C. § 811(h)(1).

[99] *Id.* § 811(h)(3).

[100] *Id.* § 811(h)(4).

Pursuant to amendments in the Synthetic Drug Abuse Prevention Act of 2012,[101] a substance may be temporarily scheduled for up to two years; if permanent scheduling proceedings are pending, the DEA Administrator may extend the temporary scheduling period for up to one additional year.[102] A temporary scheduling order is vacated once permanent scheduling proceedings are completed with respect to the substance at issue.[103] The CSA provides that emergency scheduling orders are not subject to judicial review.[104]

DEA has recently used its emergency scheduling power to temporarily control certain analogues to the opioid fentanyl[105] and several synthetic cannabinoids.[106]

International Treaty Obligations

The United States is a party to the Single Convention on Narcotic Drugs of 1961, which was designed to establish controls on the international and domestic traffic in narcotics, coca leaf, cocaine, and marijuana.[107] The treaty requires signatories, among other things, to criminalize any "cultivation, production, manufacture, extraction, preparation, possession, offering, offering for sale, distribution, purchase, sale, . . . importation and exportation of drugs" that are subject to the Convention, except to the extent the Convention authorizes such activities.[108]

The United States is also party to the Convention on Psychotropic Substances of 1971, which was designed to establish similar control over stimulants, depressants, and hallucinogens.[109] The Convention on Psychotropic Substances requires parties to adopt various controls applicable to controlled substances, including mandating licenses for manufacture and distribution, requiring prescriptions for dispensing such substances, and adopting measures "for the repression of acts contrary to laws or regulations" adopted pursuant to treaty obligations.[110]

If existing controls of a drug are less stringent than those required by the United States' treaty obligations, the CSA directs the DEA Administrator to "issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations."[111] Scheduling pursuant to international treaty obligations does not require the factual findings that are necessary for other administrative scheduling actions, and may be implemented without regard to the procedures outlined for regular administrative scheduling.[112]

No. 21-70544 archived on January 25, 2022
cited in AMS v. US DEA

[101] Pub. L. No. 112-144, 126 Stat. 993 (2012).

[102] *Id.* § 811(h)(2).

[103] *Id.* § 811(h)(5).

[104] *Id.* § 811(h)(6).

[105] *See* DEA, Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188 (Feb. 6, 2018); *see also* CRS Legal Sidebar LSB10404, *Scheduling of Fentanyl Analogues: The New Legal Landscape*, by Joanna R. Lampe.

[106] *See* DEA, Schedules of Controlled Substances: Temporary Placement of 5F-EDMBPINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 into Schedule I, 84 Fed. Reg. 15,505 (Apr. 16, 2019).

[107] *See* United Nations Single Convention on Narcotic Drugs, 1961, Mar. 30, 1961, 18 U.S.T. 1407, preamble (stating the parties' desire "to conclude a generally acceptable international convention replacing existing treaties on narcotic drugs, limiting such drugs to medical and scientific use").

[108] *Id.* art. 36.

[109] United Nations Convention on Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543.

[110] *Id.* art. 2(1)(7).

[111] 21 U.S.C. § 811(d)(1).

[112] *Id.*

Registration Requirements

Once a substance is brought within the scope of the CSA through one of the scheduling processes discussed above, almost any person or organization that handles that substance, except for the end user, becomes subject to a comprehensive system of regulatory requirements.[113] The goal of the regulatory scheme is to create a "closed system" of distribution in which only authorized handlers may distribute controlled substances.[114] Central to the closed system of distribution is the requirement that individuals or entities that work with controlled substances register with DEA. Those covered entities, which include manufacturers, distributors, practitioners, and pharmacists,[115] are referred to as *registrants*.[116] As DEA has described the movement of a pharmaceutical controlled substance from the manufacturer to the patient,

> [A] controlled substance, after being manufactured by a DEA-registered manufacturer, may be transferred to a DEA-registered distributor for subsequent distribution to a DEA-registered retail pharmacy. After a DEA-registered practitioner, such as a physician or a dentist, issues a prescription for a controlled substance to a patient . . . , that patient can fill that prescription at a retail pharmacy to obtain that controlled substance. In this system, the manufacturer, the distributor, the practitioner, and the retail pharmacy are all required to be DEA registrants, or to be exempted from the requirement of registration, to participate in the process.[117]

As discussed further below, registrants must maintain records of transactions involving controlled substances, establish security measures to prevent theft of such substances, and monitor for suspicious orders to prevent misuse and diversion.[118] Thus, the registration system aims to ensure that any controlled substance is always accounted for and under the control of a DEA-registered person until it reaches a patient or is destroyed.[119]

No. 21-70544 archived on January 25, 2022 cited in AIMS v. US DEA

Entities Required to Register

Under the CSA, every person who produces, distributes, or dispenses any controlled substance, or who proposes to engage in any of those activities, must register with DEA, unless an exemption applies.[120] Significantly, the CSA exempts from registration individual consumers of controlled substances, such as patients and their family members, whom the Act refers to as "ultimate

[113] *See id.* § 822.

[114] DEA, Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,235, 16,237 (Mar. 31, 2010).

[115] 21 U.S.C. § 822(a).

[116] 21 C.F.R. § 1300.02(b)(24).

[117] DEA, Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration, 74 Fed. Reg. 3480, 3481 (Jan. 21, 2009).

[118] *See infra* "Obligations of Registrants."

[119] *See* DEA, Definition and Registration of Reverse Distributors, 70 Fed. Reg. 22,591, 22,591 (May 2, 2005).

[120] 21 U.S.C. § 822; 21 C.F.R. Part 1301. *See also* 21 U.S.C. § 957 (section of the Controlled Substances Import and Export Act imposing registration requirements for importers and exporters of controlled substances).

users."[121] Ultimate users and other entities exempt from the CSA's registration provisions can still violate the Act's criminal trafficking provisions if they engage in unauthorized activities.[122]

Manufacturers and distributors of controlled substances, such as pharmaceutical companies, must register with DEA annually.[123] By contrast, entities that dispense controlled substances, such as hospitals, pharmacies, and individual medical practitioners and pharmacists, may obtain registrations lasting between one and three years.[124] Registrations specify the extent to which registrants may manufacture, possess, distribute, or dispense controlled substances, and each registrant may engage only in the specific activities covered by its registration. In some instances, applicants must obtain more than one registration to comply with the CSA. For example, separate registrations are required for each principal place of business where controlled substances are manufactured, distributed, imported, exported, or dispensed.[125] Special registration is required for certain activities, including operating an opioid treatment program such as a methadone clinic.[126]

The CSA directs the DEA Administrator to issue a registration if it would be consistent with the public interest, and the Act outlines the criteria the DEA Administrator must consider when evaluating the public interest.[127] The criteria vary depending on (1) whether the applicant is a manufacturer, distributor, researcher, or practitioner, and (2) the classification of the controlled substances that are the focus of the application. However, the requirements generally serve to help DEA determine whether the applicant has demonstrated the capacity to maintain effective controls against diversion and comply with applicable laws.[128]

The registration of an individual or organization expires at the end of the registration period unless it is renewed.[129] Registration also ends when the registrant dies, ceases legal existence, or discontinues business or professional practice.[130] A registration cannot be transferred to someone else without the express, written consent of the DEA Administrator.[131]

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[121] 21 U.S.C. § 822(c)(3). *See also id.* § 802(25) (defining "ultimate user" as a "person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household"). DEA has explained that ultimate users need not register because the controlled substances in their possession "are no longer part of the closed system of distribution and are no longer subject to DEA's system of corresponding accountability." DEA, Definition and Registration of Reverse Distributors, 68 Fed. Reg. 41,222, 41,226 (proposed July 11, 2003). Some other exemptions are specified by statute, *see* 21 U.S.C. §§ 822(c)(1), (2); or by regulation, *see* 21 C.F.R. §§ 1301.22-24.

[122] *Cf.* United States v. Mancuso, 718 F.3d 780, 798 (9th Cir. 2013) (rejecting an argument that defendant was "merely 'an ultimate user'" of cocaine because he shared the drug with others, and sharing drugs constitutes "distribution" for purposes of the CSA's trafficking provisions, "even if there is no commercial scheme involved").

[123] 21 U.S.C. § 822(a)(2).

[124] *Id.* § 822(a)(1).

[125] *Id.* § 822(e)(1).

[126] *Id.* § 823(g); *see also* CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*, by Johnathan H. Duff.

[127] *Id.* § 823(a)-(f).

[128] *Id.*

[129] 21 C.F.R. §§ 1301.13(c), (d).

[130] *Id.* § 1301.52.

[131] *Id.* § 1301.52(b).

Obligations of Registrants

Recordkeeping and Reporting

The CSA and its implementing regulations impose multiple recordkeeping and reporting requirements on registrants. Registrants must undertake a biennial inventory of all stocks of controlled substances they have on hand, and maintain records of each controlled substance they manufacture, receive, sell, deliver, or otherwise dispose of.[132] In addition, controlled substances in Schedules I and II may only be distributed pursuant to a written order.[133] Copies of each order form must be transmitted to DEA.[134] Records of orders must be preserved for two years and made available for government review upon request.[135]

Registrants are also required to "design and operate a system to identify suspicious orders" and to notify DEA of any suspicious orders they detect.[136] DEA regulations provide that "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[137] That list is not exhaustive, however—courts have suggested that orders may be suspicious if, for example, a pharmacy mostly sells controlled substances rather than a more typical mix of controlled and noncontrolled medications, if many customers pay for controlled substances with cash, or if pharmacies purchase drugs at a price higher than insurance would reimburse.[138]

Inspections

The CSA permits the DEA Administrator to inspect the establishment of any registrant or applicant for registration.[139] DEA regulations express the agency's intent "to inspect all manufacturers of controlled substances listed in Schedules I and II and distributors of controlled substances listed in Schedule I once each year," and other manufacturers and distributors of controlled substances "as circumstances may require."[140] Absent the consent of the registrant or special circumstances such as an imminent danger to health or safety, a warrant is required for inspection.[141] "Any judge of the United States or of a State court of record, or any United States magistrate judge" may issue such a warrant "within his territorial jurisdiction."[142] Issuance of a warrant requires probable cause.[143] The CSA defines probable cause as "a valid public interest in the effective enforcement of this subchapter or regulations thereunder sufficient to justify" the inspection at issue.[144]

No. 21-70544 archived on January 25, 2022 cited in AIMS v. US DEA

[132] 21 U.S.C. § 827; 21 C.F.R. Part 1304.

[133] 21 U.S.C. § 828; 21 C.F.R. Part 1305.

[134] 21 U.S.C. § 828(c)(2).

[135] *Id.* § 828(c)(1).

[136] *Id.* § 832.

[137] 21 C.F.R. § 1304.74(b).

[138] *See* Masters Pharmas. Inc. v. DEA, 861 F.3d 206, 220 (D.C. Cir. 2017).

[139] 21 U.S.C. § 822(f).

[140] 21 C.F.R. §1316.13.

[141] 21 U.S.C. § 880(c).

[142] *Id.* § 880(d)(1).

[143] *Id.*

[144] *Id.* The CSA's definition of probable cause is conceptually distinct from what is required under the Fourth

Security

The CSA's implementing regulations require all registrants to "provide effective controls and procedures to guard against theft and diversion of controlled substances."[145] The regulations establish specific physical security requirements, which vary depending on the type of registrant and the classification of the controlled substance at issue.[146] For example, practitioners[147] subject to CSA registration must store controlled substances "in a securely locked, substantially constructed cabinet."[148] In addition to those physical security requirements, practitioners may not "employ, as an agent or employee who has access to controlled substances" any person who has been convicted of a felony related to controlled substances, had an application for CSA registration denied, had a CSA registration revoked, or surrendered a CSA registration for cause.[149] Registered non-practitioners must store controlled substances in Schedules I and II in a safe, steel cabinet, or vault that meets certain specifications.[150] Non-practitioners must further ensure that controlled substance storage areas are "accessible only to an absolute minimum number of specifically authorized employees."[151]

Quotas

To prevent the production of excess amounts of controlled substances, which may increase the likelihood of diversion, the CSA directs DEA to set aggregate production quotas for controlled substances in Schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine.[152] The DEA Administrator is also required to set individual quotas for each registered manufacturer seeking to produce such substances and to limit or reduce individual quotas as necessary to prevent oversupply.[153] With respect to certain opioid medications, the Act further directs the DEA Administrator to estimate the amount of diversion of each opioid and reduce quotas to account for such diversion.[154]

Relatedly, the Controlled Substances Import and Export Act allows the importation of certain controlled substances and listed chemicals only in amounts the DEA Administrator determines to be "necessary to provide for the medical, scientific, or other legitimate needs of the United States."[155]

No. 21-70544 cited in AIMS v. US DEA archived on January 25, 2022

Amendment. *See* United States v. Schiffman, 572 F.2d 1137, 1139-40 (5th Cir. 1978).

[145] 21 C.F.R. § 1301.71.

[146] *Id.* §§ 1301.72-76.

[147] The CSA defines "practitioner" to include any "physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." 21 U.S.C. § 802(21). The Act and its implementing regulations do not define the term "non-practitioner," but it appears to include registrants not engaged in the practice of medicine, such as manufacturers and distributors.

[148] 21 C.F.R. §§ 1301.75(a), (b).

[149] *Id.* § 1301.76(a).

[150] 21 C.F.R. § 1301.72(a).

[151] *Id.* § 1301.72(d).

[152] 21 U.S.C. § 826(a); *see also* 21 C.F.R. § 1303.11. Ephedrine, pseudoephedrine, and phenylpropanolamine are List I chemicals that may be used in the manufacture of methamphetamine.

[153] *Id.* §§ 826(b), (c).

[154] *Id.* § 826(i).

[155] *Id.* § 952. The Controlled Substances Import and Export Act also imposes controls on the exportation of controlled

Prescriptions

Under the CSA, controlled substances in Schedules II through IV must be provided directly to an ultimate user by a medical practitioner or dispensed pursuant to a prescription.[156] The Act does not mandate that Schedule V substances be distributed by prescription, but such substances may be dispensed only "for a medical purpose."[157] As a practical matter, Schedule V substances are almost always dispensed pursuant to a prescription due to separate requirements under the FD&C Act or state law.[158]

Enforcement and Penalties

DEA is the federal agency primarily responsible for enforcing the CSA's registration requirements.[159] DEA may take formal or informal administrative action to enforce the registration requirements, including issuing warning letters, suspending or revoking an entity's registration, and imposing fines.[160]

The DEA Administrator may suspend or revoke a registration (or deny an application for registration) on several bases, including findings that a registrant or applicant has falsified application materials, been convicted of certain felonies, or "committed such acts as would render his registration . . . inconsistent with the public interest."[161] Unless the DEA Administrator finds that there is an imminent danger to the public health or safety, the DEA Administrator must provide the applicant or registrant with notice, the opportunity for a hearing, and the opportunity to submit a corrective plan before denying, suspending, or revoking a registration.[162] Imminent danger exists when, due to the failure of the registrant to comply with the registration requirements, "there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration."[163] To illustrate, those conditions may be satisfied when a practitioner prescribes

No. 21-70544 archived on January 25, 2022
cited in AMS v. US DEA

substances, but does not establish specific export quotas. *See id.* § 953.

[156] *Id.* §§ 829(a), (b). Substances in Schedule I may not be dispensed by prescription because they have no accepted medical use.

[157] *Id.* § 829(c).

[158] *Cf., e.g.*, Ga. Code Ann. § 16-13-29.2 (permitting the State Board of Pharmacy to allow the sale of Schedule V controlled substances without a prescription); Fla. Stat. Ann. § 893.08 (permitting the sale of Schedule V controlled substances over-the-counter by a registered pharmacist, if a prescription is not required under the FD&C Act).

[159] *See* 28 C.F.R. § 0.100(b) (delegating to the Administrator of DEA functions that relate to, arise from, or supplement investigations of matters concerning drugs under the Comprehensive Drug Abuse Prevention and Control Act of 1970).

[160] *See* 21 U.S.C. §§ 822(f), 824(a), 842(c), 842(d). A person who must register under the CSA but fails to do so is subject to prosecution under the Act's general trafficking provisions. *See* United States v. Blanton, 730 F.2d 1425, 1429-30 (11th Cir. 1984); *see also infra* "Trafficking Provisions."

[161] 21 U.S.C. § 824(a).

[162] *Id.* §§ 824(c), (d). Enforcement actions based on imminent danger are subject to review by DEA, and a registrant may seek judicial review of the agency's final decision under the Administrative Procedure Act. *See, e.g.*, Volkman v. DEA, 567 F. 3d 215, 219 (6th Cir. 2006).

[163] 21 U.S.C. § 824(d)(2). Congress added the opportunity to submit a corrective plan and the standard for determining whether an imminent danger to the public health or safety exists through the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, 130 Stat. 354 (2016). Those amendments made it more difficult for DEA to issue immediate suspensions: previously, the Act simply provided that "[t]he Attorney General [through the DEA Administrator] may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety." 21 U.S.C. § 824(d) (2000). As amended, the Act limits DEA's discretion by requiring a specific finding of "imminent threat [of] death, serious bodily harm, or abuse of a controlled substance." 21 U.S.C. § 824(d)(2); *see also* Scott Higham & Lenny

controlled substances outside the usual course of professional practice without a legitimate medical purpose in violation of state and federal controlled substances laws.[164]

A violation of the CSA's registration requirements—including failure to maintain records or detect and report suspicious orders, noncompliance with security requirements, or dispensing controlled substances without the necessary prescriptions—generally does not constitute a criminal offense unless the violation is committed knowingly.[165] However, in the event of a knowing violation, DOJ may bring criminal charges against both individual and corporate registrants. Potential penalties vary depending on the offense. For example, a first criminal violation of the registration requirements by an individual is punishable by a fine or up to a year in prison.[166] If "a registered manufacturer or distributor of opioids" commits knowing violations such as failing to report suspicious orders for opioids or maintain effective controls against diversion of opioids, the registrant may be punished by a fine of up to $500,000 for each registration violation.[167]

Trafficking Provisions

In addition to the registration requirements outlined above, the CSA contains provisions that define offenses involving the production, distribution, and possession of controlled substances outside the legitimate confines of the registration system—what this report refers to as the Act's *trafficking provisions*.[168] Although the word "trafficking" may primarily call to mind the illegal distribution of recreational drugs, the CSA's trafficking provisions in fact apply to a wide range of illicit activities involving either pharmaceutical or nonpharmaceutical controlled substances.[169]

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

Prohibitions

Key sections of the CSA's trafficking provisions make the following activities illegal, unless otherwise authorized under the Act:

- **Manufacture** of a controlled substance,[170] which includes the synthesis of a controlled substance that is a chemical, the cultivation of a controlled substance that is a plant, or the processing or packaging of a controlled substance;[171]

Bernstein, *The Drug Industry's Triumph over the DEA*, WASH. POST, Oct. 15, 2017.

[164] *See* Akhtar-Zaidi v. DEA, 841 F.3d 707, 710 (6th Cir. 2016). The court in *Akhtar-Zaidi* found that a physician violated federal and state law "by (1) prescribing medication without patients' addresses, (2) overstating the nature and extent of examinations conducted and pain levels reported by patients, and (3) failing to comply with state requirements relating to the treatment of chronic pain," and thus "created a substantial likelihood that abuse of controlled substances would occur in the absence of an immediate suspension." *Id.* at 710, 713.

[165] 21 U.S.C. § 842(c)(1).

[166] *Id.* § 842(c)(2)(A).

[167] *Id.* § 842(c)(2)(D).

[168] *See id.* §§ 841-865.

[169] *See, e.g.*, *id.* §§ 841, 844 (criminalizing the manufacture, distribution, and possession of "a controlled substance," except as authorized by the CSA).

[170] *Id.* § 841(a)(1).

[171] *Id.* §§ 802(15) ("'manufacture' means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container"); 802(22) ("'production' includes the

- **Distribution** or **dispensing** of a controlled substance;[172]
- **Possession** of a controlled substance with or without intent to distribute.[173]

Penalties for the foregoing offenses vary based on the type and amount of the controlled substance in question.[174] Other sections of the CSA define more specific offenses, such as distributing controlled substances at truck stops or rest areas,[175] at schools,[176] or to people under age 21;[177] endangering human life while manufacturing a controlled substance;[178] selling drug paraphernalia;[179] and engaging in a "continuing criminal enterprise"—that is, an ongoing drug dealing operation that involves at least five other people and provides the defendant with substantial income or resources.[180] An attempt or conspiracy to commit any offense defined under the Act also constitutes a crime.[181]

Enforcement and Penalties

DOJ enforces the CSA's trafficking provisions by bringing criminal charges against alleged violators.[182] Notably, the CSA's registration system and its trafficking regime are not mutually exclusive, and participation in the registration system does not insulate registrants from the statute's trafficking penalties. In *United States v. Moore*, the Supreme Court rejected a claim that the CSA "must be interpreted in light of a congressional intent to set up two separate and distinct penalty systems," one for registrants and one for persons not registered under the Act.[183] The Court in *Moore* held that physicians registered under the CSA can be prosecuted under the Act's general drug trafficking provisions "when their activities fall outside the usual course of professional practice."[184]

Numerous judicial opinions provide guidance on what sorts of conduct fall outside the usual course of professional practice. The defendant in *Moore* was a registered doctor who distributed large amounts of methadone with inadequate patient exams and no precautions against misuse or diversion. The Court held that "[t]he evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of 'professional practice'" because, "[i]n practical

No. 21-70544 archived on January 25, 2022 cited in AIMS v. US DEA

manufacture, planting, cultivation, growing, or harvesting of a controlled substance").

[172] *Id.* § 841(a)(1). "Dispensing" refers to delivery of a controlled substance by a registered practitioner, including prescribing or administering a pharmaceutical controlled substance, while "distribution" refers to other delivery of a controlled substance. *Id.* §§ 802(10), 802(11).

[173] *Id.* §§ 841(a)(1) (criminalizing possess with intent to manufacture, distribute, or dispense, a controlled substance, except as authorized under the Act); *id.* § 844(a) (making it unlawful "knowingly or intentionally to possess a controlled substance," unless the substance was obtained in a manner authorized by the CSA).

[174] *See, e.g.*, *id.* §§ 841(b).

[175] *Id.* § 849.

[176] *Id.* § 860.

[177] *Id.* § 859.

[178] *Id.* § 858.

[179] *Id.* § 863.

[180] *Id.* § 848.

[181] *Id.* § 846.

[182] Trafficking that involves smuggling may also implicate the Controlled Substances Import and Export Act, 21 U.S.C. §§ 951-971, and/or the Maritime Drug Law Enforcement Act, 46 U.S.C. §§ 70501-70508.

[183] 423 U.S. 122, 133 (1975).

[184] *Id.* at 124.

effect, he acted as a large-scale 'pusher'—not as a physician."[185] Appellate courts have relied on *Moore* to uphold convictions of a pharmacist who signed thousands of prescriptions for sale through an online pharmacy[186] and a practitioner who "freely distributed prescriptions for large amounts of controlled substances that are highly addictive, difficult to obtain, and sought after for nonmedical purposes."[187] But several courts have cautioned that a conviction under *Moore* requires more than a showing of mere professional malpractice. For instance, the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) has held that the prosecution must prove that the defendant "acted with intent to distribute the drugs *and with intent to distribute them outside the course of professional practice*," suggesting that specific intent must be established with respect to the defendant's failure to abide by professional norms.[188]

For decades, DOJ has brought criminal trafficking charges against doctors and pharmacists who dispensed pharmaceutical controlled substances outside the usual course of professional practice.[189] In April 2019, DOJ for the first time brought criminal trafficking charges against a pharmaceutical company—Rochester Drug Cooperative—and two of its executives based on the company's sale of the opioids oxycodone and fentanyl to pharmacies that illegally distributed the drugs.[190] Similarly, in July 2019, a federal grand jury indicted two former executives at the pharmaceutical distributor Miami-Luken, Inc, among others, for conspiracy to violate the CSA's trafficking provisions.[191]

Violations of the CSA's trafficking provisions are criminal offenses that may give rise to large fines and significant prison time. Penalties vary according to the offense and may further vary based on the type and amount of the controlled substance at issue. Unauthorized simple possession of a controlled substance may prompt a minimum fine of $1,000 and a term of up to a year in prison.[192] Distribution of large quantities of certain drugs—including specific Schedule I controlled substances such as heroin and LSD and specific Schedule II controlled substances such as cocaine and methamphetamine—carries a prison sentence of 10 years to life and a fine of up to

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[185] *Id.* at 142-43.

[186] *See* United States v. Nelson, 383 F.3d 1227, 1230 (10th Cir. 2004).

[187] United States v. McIver, 470 F.3d 550, 564 (4th Cir. 2006).

[188] United States v. Feingold, 454 F.3d 1001, 1008 (9th Cir. 2006) (emphasis in original); *see also* United States v. Armstrong, 550 F.3d 382, 401 (5th Cir. 2008) (explaining that "the *mens rea* of a § 841 offense is encompassed in the second and third element of the crime—whether the practitioner intentionally dispensed controlled substances without a legitimate medical purpose or outside the scope of professional practice," and distinguishing "a § 841 prosecution from a mere civil malpractice suit where a plaintiff may prevail regardless of a defendant doctor's good faith intent to act within the scope of medical practice"); United States v. Schneider, 704 F.3d 1287, 1295 (10th Cir. 2013) (approving jury instructions "nearly identical" to those upheld in *Feingold* and holding that "the jury, on the instructions given, found that [the defendant] knowingly acted not for a legitimate medical purpose or not within the usual course of professional practice").

[189] *See, e.g.*, *Moore*, 423 U.S. 122; Press Release, DEA, Multiple Cases Lead to Arrests of Five Doctors, One Pharmacist, One Nurse Practitioner and Three Others (Oct. 11, 2018), https://www.dea.gov/press-releases/2018/10/11/multiple-cases-lead-arrests-five-doctors-one-pharmacist-one-nurse; Press Release, DEA, DEA Large-scale Operation Targets 26 Pharmacies In Three States In Attack Against Illicit Opioid Abuse And Trafficking (Dec. 5, 2017), https://www.dea.gov/press-releases/2017/12/05/dea-large-scale-operation-targets-26-pharmacies-three-states-attack.

[190] *See* Press Release, DOJ, Manhattan U.S. Attorney And DEA Announce Charges Against Rochester Drug Co-Operative And Two Executives For Unlawfully Distributing Controlled Substances (Apr. 23, 2019), https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-and-dea-announce-charges-against-rochester-drug-co-operative-and; *see also* CRS Legal Sidebar LSB10307, *Corporate Drug Trafficking Liability—a New Legal Front in the Opioid Crisis*, by Joanna R. Lampe.

[191] *See* Indictment, United States v. Rattini, No. 19-cr-00081 (S.D. Ohio July 17, 2019).

[192] 21 U.S.C. § 844(a).

$10 million for an individual or a fine of up to $50 million for an organization.[193] Penalties increase for second or subsequent offenses, or if death or serious bodily injury results from the use of the controlled substance.[194] Compared with the CSA's registration provisions, the Act's trafficking provisions generally entail greater potential liability—particularly for individual defendants—but also require prosecutors to show that a violation was intentional.[195]

The CSA is not the only means to target misconduct related to the distribution of pharmaceutical and nonpharmaceutical controlled substances. Rather, such conduct can give rise to liability under numerous other provisions of federal and state law. For example, drug companies may face administrative sanctions or criminal charges under the FD&C Act.[196] Companies and individuals may also be subject to federal criminal charges under the Racketeer Influenced and Corrupt Organizations Act[197] or the Federal Anti-Kickback Statute.[198] Those statutes notably formed part of the basis for the significant settlement between DOJ and opioid manufacturer Purdue Pharma in 2020.[199] And manufacturers and distributors of opioids currently face numerous civil suits under federal and state law based on the companies' marketing and distribution of prescription opioids.[200]

Legal Considerations for the 117th Congress

Drug regulation has received significant attention from Congress in recent years, prompting a range of proposals concerning the opioid epidemic; the proliferation of synthetic drugs, in particular analogues to the opioid fentanyl; the divergence between the status of marijuana under state and federal law; the ability of researchers to conduct clinical research involving Schedule I controlled substances; and the response to the COVID-19 pandemic.

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

Opioid Crisis

One salient current issue in the realm of controlled substance regulation is the opioid epidemic. Opioids are drugs derived from the opium poppy or emulating the effects of opium-derived

[193] *Id.* § 841(b)(1)(A).

[194] *Id.* § 841(b).

[195] A violation of the CSA's recordkeeping and reporting requirements requires only a showing of negligence. *See* 21 U.S.C. § 842. By contrast, a violation of the CSA's trafficking provisions must be committed "knowingly or intentionally," with corporations subject to liability "based on the 'knowledge and intent' of their employees." United States v. Philip Morris USA Inc., 566 F.3d 1095, 1118 (D.C. Cir. 2009); *see also* 21 U.S.C. § 841.

[196] *See, e.g.*, *id.* § 333; see also CRS Report R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues*, by Jennifer A. Staman.

[197] *See, e.g.*, Press Release, DOJ, Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering (Oct. 26, 2017); Gabrielle Emmanuel and Katie Thomas, *Opioid Company Executives Convicted of Racketeering*, N.Y. TIMES, May 3, 2019, at B1.

[198] *See, e.g.*, Press Release, DOJ, Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family (Oct. 21, 2020).

[199] Purdue Pharma LP plead guilty to violating the Federal Anti-Kickback Statute and conspiracy to defraud the United States; the company and its shareholders also settled civil claims brought by the United States. *See id.*

[200] *See, e.g.*, National Prescription Opiate Litigation, No. 17-MD-2804 (N.D. Ohio Dec. 12, 2017); *see also* CRS Legal Sidebar LSB10365, *Overview of the Opioid Litigation and Related Settlements and Settlement Proposals*, by Wen W. Shen; CRS Legal Sidebar LSB10226, *State and Local Governments Pursue Judicial Solutions to the Opioid Epidemic*, by Jennifer A. Staman.

drugs.[201] Some opioids have legitimate medical purposes, primarily related to pain management, while others have no recognized medical use.[202] Both pharmaceutical opioids (such as oxycodone, codeine, and morphine) and nonpharmaceutical opioids (such as heroin) may pose a risk of abuse and dependence and may be dangerous or even deadly in excessive doses.[203] The CDC reports that overdoses of prescription and nonprescription opioids claimed over 50,000 lives in 2019.[204] CDC researchers further estimate that the misuse of prescription opioids alone cost the United States $78.5 billion in 2013.[205]

In recent years, the opioid crisis has prompted various legislative proposals aiming to prevent the illicit distribution of opioids; curb the effects of the crisis on individuals, families, and communities; and cover the costs of law enforcement efforts and treatment programs. In 2016, Congress enacted the Comprehensive Addiction and Recovery Act of 2016 (CARA)[206] and the 21st Century Cures Act (Cures Act).[207] CARA authorized grants to address the opioid crisis in areas including abuse prevention and education, law enforcement, and treatment, while the Cures Act, among other things, provided additional funding to states combating opioid addiction.[208] In 2018, Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), which sought to address the opioid crisis through far-ranging amendments to the CSA, the FD&C Act, and other statutes.[209] Key amendments to the CSA under the SUPPORT Act included provisions expanding access to medication-assisted treatment for opioid addiction,[210] specifying the factors for determining whether a controlled substance analogue is intended for human consumption,[211] revising the factors DEA considers when establishing opioid production quotas,[212] and codifying the definition of "suspicious order" and outlining the CSA's suspicious order reporting requirements.[213]

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[201] *See* CRS Report R44987, *The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions*, by Lisa N. Sacco and Erin Bagalman. Technically, the term "opiates" refers to natural compounds found in the opium poppy, while the term "opioids" refers to synthetic compounds that emulate the effects of opiates, but commentators often use the term "opioids" to refer to both categories of substances, and this report adopts that usage. *See id.*

[202] *Id.*

[203] *Id.*

[204] *See* American Hospital Association, *CDC: Drug overdose deaths up 4.6% in 2019* (July 16, 2020), https://www.aha.org/news/headline/2020-07-16-cdc-drug-overdose-deaths-46-2019.

[205] *See* Curtis S. Florence, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, 54 MEDICAL CARE 901 (2016).

[206] Pub. L. No. 114-198, 130 Stat. 695 (2016).

[207] Pub. L. No. 114-255, 130 Stat. 1033 (2016).

[208] *See* CRS Report R45449, *The SUPPORT for Patients and Communities Act (P.L.115-271): Medicare Provisions*, coordinated by Suzanne M. Kirchhoff.

[209] Pub. L. No. 115-271, 132 Stat. 3894 (2018); *see also* CRS Report R45449, *The SUPPORT for Patients and Communities Act (P.L.115-271): Medicare Provisions*, coordinated by Suzanne M. Kirchhoff; CRS Report R45423, *Public Health and Other Related Provisions in P.L 115-271, the SUPPORT for Patients and Communities Act*, coordinated by Elayne J. Heisler and Johnathan H. Duff; CRS Report R45405, *The SUPPORT for Patients and Communities Act (P.L. 115-271): Food and Drug Administration and Controlled Substance Provisions*, coordinated by Agata Bodie.

[210] Pub. L. No. 115-271, §§ 3201-04.

[211] *Id.* § 3241.

[212] *Id.* § 3282.

[213] *Id.* §§ 3291-92.

Notwithstanding the flurry of recent legal changes, numerous legislative proposals in the 116th Congress sought to address the opioid crisis by further amending the CSA.[214] For example, the DEA Enforcement Authority Act of 2019[215] would have made it easier for DEA to suspend a registration. Specifically, the bill would have lowered the threshold for what constitutes imminent danger, allowing suspension upon a finding of "*probable cause* that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration," rather than the current statutory requirement of "*a substantial likelihood of an immediate threat* that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration."[216] In addition, the John S. McCain Opioid Addiction Prevention Act[217] would have required medical practitioners applying for new or renewed CSA registration to certify that they will not prescribe more than a seven-day supply of opioids for the treatment of acute pain.[218] The LABEL Opioids Act[219] would have amended the CSA to require that opioids in Schedules II through V bear labels warning that they can cause dependence, addiction, and overdose. Failure to comply with the labeling requirements would have violated the CSA's registration requirements.[220] Other proposals sought to improve treatment of opioid use disorder.[221]

Some proposals targeted specific opioids, especially fentanyl.[222] Fentanyl is a powerful opioid that has legitimate medical uses such as pain management for cancer patients and patients on ventilators.[223] But, due to its potency, it also poses a particularly high risk of abuse, dependency,

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[214] Numerous additional proposals to address the opioid epidemic fall outside the scope of this report. For instance, some proposals would amend the FD&C Act to increase liability for pharmaceutical companies or executives that violate the FD&C Act. *See, e.g.*, Opioid Crisis Accountability Act, S. 1584, 116th Cong. (2019). Others would provide additional funding for local law enforcement efforts, opioid dependence treatment, or other related initiatives. *See, e.g.*, Opioid Treatment Surge Act, S. 1662, 116th Cong. (2019); Budgeting for Opioid Addiction Treatment Act, S. 425, 116th Cong. (2019).

[215] S. 424, 116th Cong. (2019).

[216] *Compare id. with* 21 U.S.C. § 824(d)(2). For brief discussion of several additional bills from the 116th Congress that would have altered the CSA's registration requirements in an effort to combat the opioid crisis, see Emily Field, *House Passes Bipartisan Bills To Fight Opioid Crisis*, Law360, Nov. 17, 2020.

[217] H.R. 1614, 116th Cong. (2019); S. 724, 116th Cong. (2019).

[218] The bill includes exceptions for other types of treatment including management of chronic pain, end-of-life care, and treatment of addiction.

[219] H.R. 2732, 116th Cong. (2019); S. 1449, 116th Cong. (2019).

[220] *See* 21 U.S.C. § 842(a)(4) (providing that it is unlawful "to remove, alter, or obliterate a symbol or label required by" the CSA).

[221] *See* Strengthening Medicaid Coverage of MAT Act, S. 4674, 116th Cong. (2020) (clarifying that drugs and biologicals used for medication-assisted treatment under Medicaid are subject to the requirements of the Medicaid Drug Rebate Program); MATE Act of 2020, S. 4640, 116th Cong. (2020) (requiring physicians and other prescribers of controlled substances to complete training on treating and managing patients with opioid and other substance use disorders); Easy MAT for Opioid Addiction Act, H.R. 2281, 116th Cong. (2019) (directing the Attorney General to amend certain regulations so that practitioners may administer not more than 3 days' medication to a person at one time when administering narcotic drugs for the purpose of relieving acute withdrawal symptoms). The Easy MAT for Opioid Addiction Act passed the House on November 17, 2020. "MAT" stands for "medication-assisted treatment" and refers to the combined use of medication and other services to treat addiction. *See* CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*, by Johnathan H. Duff.

[222] For additional discussion of fentanyl regulation, see *infra* "Analogue Fentanyl."

[223] *See id.*; CRS Insight IN11321, *COVID-19: The Drug Enforcement Administration's Regulatory Role*, by Lisa N. Sacco.

and overdose.[224] The Ending the Fentanyl Crisis Act of 2019[225] would have amended the CSA to reduce the amounts of fentanyl required to constitute a trafficking offense.[226] That bill would have also increased penalties applicable to offenses involving fentanyl and provided separate procedures for emergency scheduling of synthetic opioids.[227] The Screening All Fentanyl-Enhanced Mail Act of 2019[228] sought to require screening of all inbound international mail and express cargo from high-risk countries to detect and prevent the importation of illicit fentanyl and other synthetic opioids. Finally, the Blocking Deadly Fentanyl Imports Act[229] aimed to gather information about the production of illicit fentanyl in foreign countries and to withhold bilateral assistance from countries that fail to enforce certain controlled substance regulations.

Analogue Fentanyl

A related issue that garnered significant attention in the 116th Congress is the proliferation of synthetic drugs, especially synthetic opioids. In contrast to drugs derived from natural materials such as plants, synthetic drugs are drugs that are chemically produced in a laboratory; they may have the same chemical structure as an existing natural drug or mimic the effects of an existing drug using a different chemical structure.[230] Many legal pharmaceutical drugs are synthetically produced.[231] On the other hand, clandestine actors seeking to circumvent existing drug laws often design synthetic drugs to mimic the effects of other drugs—or even produce similar but stronger effects—but have chemical structures that have been slightly modified to circumvent existing drug laws.[232]

One particular concern in this area relates to synthetic opioids, including fentanyl analogues and other fentanyl-like substances. Prescription fentanyl is a Schedule II controlled substance; multiple nonpharmaceutical substances related to fentanyl are controlled in Schedule I.[233] However, experts have noted that it is relatively easy to manipulate the chemical structure of fentanyl in order to produce new substances that are not included in the CSA's schedules but may have similar effects to fentanyl or pose other dangers if consumed.[234] Since March 2011, DEA has

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[224] *See* DEA, Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188, 5188-90 (Feb. 6, 2018).

[225] S. 1724, 116th Cong. (2019).

[226] The Comprehensive Fentanyl Control Act, introduced in the 115th Congress, would likewise have reduced the amount of fentanyl triggering criminal liability. *See* H.R. 1781, 115th Cong. (2017).

[227] The Comprehensive Fentanyl Control Act would have allowed for temporary scheduling of a substance if the DEA Administrator found that "the drug or other substance satisfies the criteria for being considered a synthetic opioid" and "adding such drug or other substance to the definition of synthetic opioids will assist in preventing abuse or misuse of the drug or other substance." S. 1724, 116th Cong. (2019). For discussion of the current requirements for emergency scheduling, see *supra* "Emergency Scheduling."

[228] H.R. 4102, 116th Cong. (2019); S. 2323, 116th Cong. (2019).

[229] H.R. 1098, 116th Cong. (2019); S. 400, 116th Cong. (2019).

[230] *See* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea.

[231] *See, e.g.*, Kevin R. Campos, et al., *The Importance of Synthetic Chemistry in the Pharmaceutical Industry*, SCIENCE, Jan. 18, 2019.

[232] Synthetic drugs that slightly modify the molecular structures of controlled substances to circumvent existing drug laws may also be called "designer drugs." *See* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea.

[233] *See* 21 C.F.R. §§ 1308.11, 1308.12.

[234] *See* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea.

used its emergency scheduling authority[235] to impose temporary controls on 74 synthetic drugs, including 17 fentanyl-like substances.[236]

Even if not individually scheduled under the CSA, fentanyl-like substances may be subject to DEA control as controlled substance analogues.[237] However, analogue controlled substance prosecutions can be burdensome because they raise "complex chemical and scientific issues."[238] That is because liability for trafficking in controlled substance analogues requires proof that the substance at issue (1) is intended for human consumption and (2) has either a chemical structure substantially similar to the chemical structure of a Schedule I or II controlled substance or an actual or intended effect similar to or greater than that of a Schedule I or II controlled substance.[239] If fentanyl analogues were explicitly scheduled, proof of those additional elements would not be necessary. Moreover, some synthetic drugs do not meet the applicable criteria to be deemed controlled substance analogues—for example, because their effects are unpredictable or because they replicate the effects of more than one class of drugs.[240] DOJ has therefore argued that permanent scheduling of fentanyl analogues can reduce uncertainty and aid enforcement.[241]

A key challenge in permanently scheduling fentanyl analogues is how to define the substances subject to regulation. Not all analogues of fentanyl have effects similar to fentanyl itself, and due to the large number of potential analogues there are many whose effects are unknown.[242] On one hand, defining covered substances based on chemical structure may be overinclusive because the definition may include inactive substances, potentially allowing for prosecution of individuals who possess substances that pose no threat to public health and safety.[243] On the other hand, such a definition may also be underinclusive because it excludes opioids that are not chemically related to fentanyl or that are made using different modifications to fentanyl's chemical structure.[244] Alternatively, defining covered opioids based on their effects rather than their chemical structure would do little to reduce the burden that prosecutors currently face when bringing analogue controlled substance charges.[245]

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

The 116th Congress did not permanently schedule fentanyl analogues, but it did take action to facilitate DEA's regulation of those substances. In February 2018, DEA issued an emergency scheduling order that applied broadly to "fentanyl-related substances" that meet certain criteria related to their chemical structure.[246] The temporary scheduling order was set to expire in

[235] *See supra* "Emergency Scheduling."

[236] *See* Fentanyl Analogues: Perspectives on Classwide Scheduling: Hearing Before the House Comm. on the Judiciary, 116th Cong. 2 (2019) (statement of the U.S. Dep't of Justice).

[237] *See supra* "Analogues and Listed Chemicals."

[238] DOJ Testimony, *supra* note 35 at 5.

[239] 21 U.S.C. §§ 802(32), 813; *see also* DOJ Testimony, *supra* note 35 at 5.

[240] *See* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea.

[241] DOJ Testimony, *supra* note 35 at 5.

[242] DEA previously temporarily scheduled two fentanyl analogues before determining that the substances were "essentially inactive." *See* DEA, Correction of Code of Federal Regulations: Removal of Temporary Listing of Benzylfentanyl and Thenylfentanyl as Controlled Substances, 75 Fed. Reg. 37,300, 37,300 (June 29, 2010).

[243] *See* Letter from A New PATH, et al. to Sens. Graham and Feinstein (July 1, 2019), https://www.hrw.org/news/2019/07/03/coalition-opposes-s1622-stopping-overdoses-fentanyl-analogues-act-sofa.

[244] *The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order: Hearing Before the Sen. Comm. on the Judiciary*, 116th Cong. 2-3 (2019) (statement of Kemp L. Chester).

[245] *See supra* note 239.

[246] DEA, Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188 (Feb. 6, 2018). The emergency scheduling order applies to "any substance not otherwise [subject to the

February 2020.[247] However, on February 6, 2020, Congress enacted the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which extended the temporary scheduling of fentanyl-related substances until May 6, 2021.[248] Absent further legislative or administrative action, substances subject to the legislation will remain in Schedule I until that date and will be subject to all restrictions and penalties applicable to Schedule I substances. After the expiration date, the substances at issue will no longer be scheduled under the CSA but may still be subject to control as controlled substance analogues. Notably, fentanyl itself and certain other related chemicals are permanently controlled in Schedules I and II.[249] The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act does not affect those classifications.

Several proposals in the 116th Congress sought to permanently schedule fentanyl analogues. For instance, the Stopping Overdoses of Fentanyl Analogues Act[250] would have permanently added to Schedule I certain specific synthetic opioids, as well as the whole category of "fentanyl-related substances," as defined in the February 2018 emergency scheduling order. The Modernizing Drug Enforcement Act of 2019[251] would have amended the CSA to add to Schedule I all "mu opioid receptor agonists" not otherwise scheduled, subject to certain exceptions.[252] One of the sponsors of the Modernizing Drug Enforcement Act stated that the bill's aim was "to automatically classify drugs or other substances that act as opioids, such as synthetic fentanyl, as a schedule I narcotic based on their chemical structure and functions," avoiding the need for such substances to be individually scheduled.[253]

Marijuana Policy Gap

Another area that raised a number of legal considerations for the 116th Congress is the marijuana policy gap—the increasing divergence between federal and state law in the area of marijuana regulation.[254] As of December 2020, 15 states and the District of Columbia have passed laws removing state prohibitions on medical and recreational marijuana use by adults age 21 or older.[255] An additional 33 states have passed laws permitting medical use of marijuana or the

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

CSA] that is structurally related to fentanyl by one or more [specified] modifications." *Id.* at 5191-92.

[247] *Id.* at 5188.

[248] Pub. L. 116-114, 134 Stat. 103 (2020). For further discussion of the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, see CRS Legal Sidebar LSB10404, *Scheduling of Fentanyl Analogues: The New Legal Landscape*, by Joanna R. Lampe.

[249] *See* 21 C.F.R. §§ 1308.11, 1308.12.

[250] H.R. 2935, 116th Cong. (2019); S. 1622, 116th Cong. (2019). *See also* Zero Tolerance for Deceptive Fentanyl Trafficking Act, S. 3342, 116th Cong. (2020) (permanently adding "fentanyl-related substances" to Schedule I and imposing criminal penalties for knowingly misrepresenting or knowingly marketing as another substance a mixture or substance containing fentanyl, a fentanyl analogue, or a fentanyl-related substance).

[251] H.R. 2580, 116th Cong. (2019).

[252] Mu opioid receptor agonists are a class are opioids including morphine, defined by the specific molecular reactions that produce their pharmacological effects. *See* Teresa Kasere, et al., *μ Opioid Receptor: Novel Antagonists and Structural Modeling*, SCIENTIFIC REPORTS (Feb. 18, 2016).

[253] Press Release, Rep. Phil Roe, Roe, Suozzi Reintroduce the Modernizing Drug Enforcement Act (May 8, 2019), https://roe.house.gov/news/documentsingle.aspx?DocumentID=400515.

[254] *See generally* CRS Report R44782, *The Marijuana Policy Gap and the Path Forward*, coordinated by Lisa N. Sacco.

[255] *See* NAT'L CONFERENCE OF STATE LEGISLATURES, STATE MEDICAL MARIJUANA LAWS (Nov. 4, 2020), http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx.

marijuana-derived compound cannabidiol (CBD).[256] However, marijuana remains a Schedule I controlled substance under federal law, and state legislation decriminalizing marijuana has no effect on that status.[257]

In each budget cycle since FY2014 Congress has passed an appropriations rider prohibiting DOJ from using taxpayer funds to prevent the states from "implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana."[258] The current appropriations rider is in effect through September 30, 2021.[259] Several courts have interpreted the appropriations rider to bar DOJ from expending any appropriated funds to prosecute activities involving marijuana that are conducted in "strict compliance" with state law.[260] For example, in *United States v. Evans*, the Ninth Circuit upheld the prosecution of two individuals involved in the production of medical marijuana who smoked marijuana as they processed plants for sale.[261] Although state law permitted medical marijuana use by "qualifying patients," the court concluded that the defendants failed to show they were "qualifying patients," and thus they could be prosecuted because their personal marijuana use did not strictly comply with state medical marijuana law.[262]

Notwithstanding the appropriations rider, activities that fall outside the scope of state medical marijuana laws remain subject to prosecution. DOJ has typically not prosecuted individuals who possess marijuana for personal use on private property but instead has "left such lower-level or localized marijuana activity to state and local authorities through enforcement of their own drug laws."[263] However, DOJ issued guidance in 2018 reaffirming the authority of federal prosecutors to exercise prosecutorial discretion to target federal marijuana offenses "in accordance with all applicable laws, regulations, and appropriations."[264] Under that policy, DOJ has pursued

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[256] *Id.*

[257] *See, e.g.*, Gonzales v. Raich, 545 U.S. 1, 29 (2004). *See also* CRS Legal Sidebar LSB10482, *State Marijuana "Legalization" and Federal Drug Law: A Brief Overview for Congress*, by Joanna R. Lampe. Notably, however, not all CBD is subject to the CSA. The 2018 Farm Bill exempted "hemp"—cannabis and cannabis derivatives containing very low levels of tetrahydrocannabinol (THC)—from control under the CSA. *See* 21 U.S.C. § 802(16)(B)(i). Accordingly, CBD that meets those requirements is no longer a federally controlled substance. CBD remains subject to federal regulation under the FD&C Act, and FDA has taken the position that CBD is a drug that may not lawfully added to foods or marketed as a dietary supplement. *See* Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Signing of the Agriculture Improvement Act and the Agency's Regulation of Products Containing Cannabis and Cannabis-Derived Compounds (Dec. 20, 2018); *see also* Sean M. O'Connor & Erika Lietzan, *The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling*, 68 AM. U. L. REV. 823 (2019); CRS In Focus IF11250, *FDA Regulation of Cannabidiol (CBD) Consumer Products*, by Agata Bodie and Renée Johnson.

[258] Pub. L. No. 116-260, Div. B, § 531 (2020). The appropriations rider enumerates the specific states and territories to which it applies. The list excludes the four states that have not decriminalized medical marijuana use.

[259] *See id.* § 5.

[260] *See* United Sates v. McIntosh, 833 F.3d 1163, 1178 (9th Cir. 2016); Duval v. United States, 372 F. Supp. 3d 544, 555-56 (E.D. Mich. 2019); Sandusky v. Goetz, 2018 WL 6505803 at *4-5 (D. Colo. Dec. 11, 2018); United States v. Jackson, 2019 WL 3239844 at *6-8 (E.D. Pa. June 5, 2019).

[261] 929 F.3d 1073, 1076-79 (9th Cir. 2019). *See also* United States v. Kleinman, 880 F.3d 1020, 1027-30 (9th Cir. 2017) (prosecution was proper because sales of marijuana to out-of-state customers violated state law); United Sates v. Bloomquist, 361 F. Supp. 3d 744, 749-51 (W.D. Mich. 2019) (same where defendant violated state law by possessing excessive amounts of marijuana and selling marijuana to someone who was not allowed to use medical marijuana).

[262] *Evans*, 929 F.3d at 1078-79 (9th Cir. 2019).

[263] U.S. Government Accountability Office, *State Marijuana Legalization: DOJ Should Document Its Approach to Monitoring the Effects of Legalization*, GAO-16-1, 9 (Dec. 2015).

[264] Memorandum from Jefferson B. Sessions, Attorney Gen., U.S. Dep't of Justice, on Marijuana Enforcement to all United States Attorneys (Jan. 4, 2018), https://www.justice.gov/opa/press-release/file/1022196/download.

marijuana prosecutions in the context of large-scale trafficking operations or gang-related activity.[265]

Furthermore, regardless of whether they are subject to criminal prosecution, participants in the cannabis industry may face numerous collateral consequences arising from the federal prohibition of marijuana. Other federal laws impose legal consequences based on criminal activity, including violations of the CSA. For example, even if authorized under state law, cannabis businesses may be unable to access banking services due to federal anti-money laundering laws,[266] and those businesses may be ineligible for certain federal tax deductions.[267] The involvement of income from a cannabis-related business may also prevent a bankruptcy court from approving a bankruptcy plan.[268] For individuals, participation in the cannabis industry may have adverse immigration consequences.[269] Drug use or convictions may limit individuals' eligibility for federal student financial aid and other benefits.[270] Federal law also prohibits the possession of firearms or ammunition by any person who is "an unlawful user of or addicted to any controlled substance."[271] Furthermore, people who use marijuana, even for medical purposes, generally enjoy little or no legal protection from adverse employment consequences.[272]

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[265] *See, e.g.*, Press Release, DOJ, DEA Investigation in Chapel Hill Area Uncovers Large-Scale Drug Ring (Dec. 17, 2020), https://www.justice.gov/usao-mdnc/pr/dea-investigation-chapel-hill-area-uncovers-large-scale-drug-ring; Press Release, DOJ, Pittsburgh-area Man Sentenced for Supplying SCO Gang with Drugs (Jan. 21, 2021), https://www.justice.gov/usao-wdpa/pr/pittsburgh-area-man-sentenced-supplying-sco-gang-drugs; Press Release, DOJ, Indictment Charges Bridgeport Gang Members with Drug Trafficking, Committing 4 Murders (Jan. 22, 2021), https://www.justice.gov/usao-ct/pr/indictment-charges-bridgeport-gang-members-drug-trafficking-committing-4-murders.

[266] Anti-money laundering laws prohibit, *inter alia*, "conduct[ing] or attempt[ing] to conduct . . . a financial transaction which in fact involves the proceeds of specified unlawful activity . . . with the intent to promote the carrying on of specified unlawful activity" 18 U.S.C. §§ 1956(a). For a full list of predicate offenses, see the "Specified Unlawful Activities" section of CRS Report RL33315, *Money Laundering: An Overview of 18 U.S.C. § 1956 and Related Federal Criminal Law*, by Charles Doyle. For further discussion of banking law issues related to the marijuana policy gap, see the "Banking and the Marijuana Industry" section of CRS Report R45726, *Federal Preemption in the Dual Banking System: An Overview and Issues for the 116th Congress*, by Jay B. Sykes.

No. 21-70544 archived on January 25, 2022
Cited in AWMS v. US DEA

[267] *See* 26 U.S.C. § 280E ("No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act) which is prohibited by Federal law or the law of any State in which such trade or business is conducted.").

[268] A court may not confirm a bankruptcy plan "proposed . . . by any means forbidden by law." 11 U.S.C. § 1129(a). Courts have split on how that provision applies to cannabis-related businesses. *Compare* Garvin v. Cook Investments NW, SPNWY, LLC, 922 F.3d 1031, 1033 (9th Cir. 2019) (concluding that bankruptcy plan involving leased property used to grow marijuana was not proposed "by any means forbidden by law"), *with In re* Rent-Rite Super Kegs W. Ltd., 484 B.R. 799, 809 (Bankr. D. Colo. 2012) (dismissing bankruptcy case where the debtor derived roughly 25% of its revenues from leasing warehouse space to tenants who grew marijuana because "a significant portion of the Debtor's income is derived from an illegal activity") (footnote omitted).

[269] *See* 8 U.S.C. § 1427(a) (providing that no person shall be naturalized unless that person, among other things, "has been and still is a person of good moral character"); 8 C.F.R. § 316.10(b)(2) ("An applicant shall be found to lack good moral character if during the statutory period the applicant . . . [v]iolated any law of the United States, any State, or any foreign country relating to a controlled substance, provided that the violation was not a single offense for simple possession of 30 grams or less of marijuana").

[270] *See* CRS Legal Sidebar LSB10556, *The MORE Act: House Plans Historic Vote on Federal Marijuana Legalization*, by Joanna R. Lampe; CRS Report R42394, *Drug Testing and Crime-Related Restrictions in TANF, SNAP, and Housing Assistance*, by Maggie McCarty et al.

[271] 18 U.S.C. § 922.

[272] *See* Kathryn Evans, *What Legal Protections Exist for Employees who Use Medical Marijuana?*, NAT'L LAW REV., Oct. 21, 2020, https://www.natlawreview.com/article/what-legal-protections-exist-employees-who-use-medical-

Numerous proposals in the 116th Congress aimed to address issues related to the marijuana policy gap. Some proposals targeted specific issues that arise from the divergence between federal and state law. For instance, the Secure And Fair Enforcement Banking Act of 2019 (SAFE Banking Act)[273] sought to protect depository institutions that provide financial services to cannabis-related businesses from regulatory sanctions. The Ensuring Safe Capital Access for All Small Businesses Act of 2019[274] would have made certain loan programs of the Small Business Administration (SBA) available to cannabis-related businesses.[275]

Other proposals sought to address the marijuana policy gap more broadly by attempting to mitigate any conflict between federal and state law. For example, the State Cannabis Commerce Act[276] would have taken an approach similar to the current DOJ appropriations rider with respect to all federal agencies. While that bill would not have altered the scope of the CSA's restrictions on marijuana, it would have prevented any federal agency from using appropriated funds "to prevent any State from implementing any law of the State that . . . authorizes the use, distribution, possession, or cultivation of marijuana" within the state. The Strengthening the Tenth Amendment Through Entrusting States Act (STATES Act)[277] would have amended the CSA to provide that most provisions related to marijuana "shall not apply to any person acting in compliance with State law relating to the manufacture, production, possession, distribution, dispensation, administration, or delivery" of marijuana. The STATES Act would have removed the risk of federal criminal prosecution under the CSA for individuals and entities whose marijuana-related activities comply with state law, but the bill did not specifically address the potential consequences of such activity under other areas of federal law. The Responsibly Addressing the Marijuana Policy Gap Act of 2019[278] would have removed marijuana-related activities that comply with state law from the scope of the CSA and also sought to address specific collateral consequences of such activities, including access to banking services, bankruptcy proceedings, and certain tax deductions.

No. 21-70544 cited in AMMS v. US DEA archived on January 25, 2022

Additional proposed legislation would have changed federal policy with respect to marijuana by altering its status under the CSA, thus also addressing the policy gap between federal and state law. Some proposals would have moved marijuana from Schedule I to a less restrictive schedule.[279] Others would have removed marijuana from the CSA's schedules completely.[280]

Removing marijuana from the coverage of the CSA could, however, raise new legal issues. For instance, by default, the repeal of federal criminal prohibitions rarely applies retroactively.[281] As a

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marijuana.

[273] H.R. 1595, 116th Cong. (2019); S. 1200, 116th Cong. (2019). The SAFE Banking Act passed the House on September 25, 2019. The 116th Congress adjourned without taking final legislative action on either bill.

[274] H.R. 3540, 116th Cong. (2109).

[275] *See also* Ensuring Access to Counseling and Training for All Small Businesses Act of 2019, H.R. 3543, 116th Cong. (2019) (ensuring access to SBA entrepreneurial development services).

[276] H.R. 3546, 116th Cong. (2019); S. 2030, 116th Cong. (2019).

[277] H.R. 2093, 116th Cong. (2019); S. 1028, 116th Cong. (2019).

[278] H.R. 1119, 116th Cong. (2019); S. 421, 116th Cong. (2019).

[279] *See, e.g.*, Legitimate Use of Medicinal Marihuana Act, H.R. 171, 116th Cong. (2019); Compassionate Access Act, H.R. 715, 115th Cong. (2017).

[280] *See, e.g.*, MORE Act of 2019, H.R. 3884 (116th Cong. 2019); S. 2227 (116th Cong. 2019); Marijuana Justice Act of 2019, H.R. 1456, 116th Cong. (2019); S. 597, 116th Cong. (2019).

[281] *See* 1 U.S.C. § 109 (federal savings statute providing that "[t]he repeal of any statute shall not have the effect to release or extinguish any penalty, forfeiture, or liability incurred under such statute, unless the repealing Act shall so expressly provide, and such statute shall be treated as still remaining in force for the purpose of sustaining any proper

result, if Congress were to remove marijuana from the CSA, it might want to consider how to address past criminal convictions related to marijuana and whether to take any action to mitigate the effects of past convictions.[282]

One high-profile proposal in the 116th Congress, the Marijuana Opportunity Reinvestment and Expungement Act of 2019 (MORE Act)[283] is noteworthy as the first time either chamber of Congress voted on a proposal to decriminalize marijuana.[284] That bill aimed to "decriminalize and deschedule cannabis, to provide for reinvestment in certain persons adversely impacted by the War on Drugs, [and] to provide for expungement of certain cannabis offenses." Key provisions of the MORE Act would have (1) removed marijuana from Schedule I, (2) required expungement of past federal cannabis offenses, (3) prohibited the denial of any "Federal public benefit" or "any benefit or protection under the immigration laws" based on cannabis use or a past cannabis conviction, (4) imposed a 5 percent tax on cannabis to fund community reinvestment grants supporting substance abuse treatment programs and other services, and (5) provided funding for loans to assist small cannabis businesses that are owned and controlled by socially and economically disadvantaged individuals.[285]

If Congress were to remove marijuana from the ambit of the CSA, that would not affect other existing statutes and regulations that apply to the drug and thus would not bring aspects of the existing cannabis industry into compliance with federal law.[286] For instance, marijuana and substances derived from the plant are currently regulated under the FD&C Act. FDA has explained that it "treat[s] products containing cannabis or cannabis-derived compounds as [it does] any other FDA-regulated products."[287] FDA has approved drugs made from CBD and tetrahydrocannabinol (THC); therefore the agency deems those compounds to be drugs and takes the position that it is "unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived."[288] FDA is currently engaged in "consideration of a framework for the lawful marketing of appropriate cannabis and cannabis-

No. 21-70544 archived on January 25, 2022
cited in AIMS V. US DEA

action or prosecution for the enforcement of such penalty, forfeiture, or liability"); Hurwitz v. United States, 53 F.2d 552, 552 (D.C. Cir. 1931) (applying then-applicable federal savings statute to prevent retroactive application of the repeal of a criminal law to a prosecution undertaken before the repeal); *see also* S. David Mitchell, *In With the Old, Out With the New: Expanding the Scope of Retroactive Amelioration*, 37 AM. J. CRIM. L. 1, 28-38 (2009).

[282] *See, e.g.*, *Marijuana Laws in America: Racial Justice and the Need for Reform : Hearing Before the House Comm. on the Judiciary*, 116th Cong. 12-13 (2019) (statement of Marilyn J. Mosby).

[283] H.R. 3884 (116th Cong. 2019); S. 2227 (116th Cong. 2019). The MORE Act passed the House on December 4, 2020.

[284] *See* Nicholas Wu, House Will Vote on Federal Marijuana Legalization for the First Time, Bill's Future in Senate Uncertain, USA TODAY, Sept. 4, 2020.

[285] For additional information on the MORE Act, see CRS Legal Sidebar LSB10556, *The MORE Act: House Plans Historic Vote on Federal Marijuana Legalization*, by Joanna R. Lampe.

[286] *See* Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Signing of the Agriculture Improvement Act and the Agency's Regulation of Products Containing Cannabis and Cannabis-Derived Compounds (Dec. 20, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys; *see also* CRS In Focus IF11250, *FDA Regulation of Cannabidiol (CBD) Consumer Products*, by Agata Bodie and Renée Johnson.

[287] Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Signing of the Agriculture Improvement Act and the Agency's Regulation of Products Containing Cannabis and Cannabis-Derived Compounds (Dec. 20, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys.

[288] *Id.*

derived products under our existing authorities."[289] Congress could also enact legislation to alter FDA regulation of cannabis-based products. For example, the Legitimate Use of Medicinal Marihuana Act would have provided that neither the CSA nor the FD&C Act "shall prohibit or otherwise restrict" certain activities related to medical marijuana that are legal under state law.[290]

In addition, Congress might enact new legislation affecting marijuana in conjunction with any legislation removing it from the scope of the CSA. For instance, legislation introduced during the 116th Congress would have imposed new federal regulations on marijuana akin to those applicable to alcohol and tobacco.[291]

Reducing or removing federal restrictions on marijuana might also create tension with certain treaty obligations of the United States. The United States is a party to the Single Convention on Narcotic Drugs of 1961 (1961 Convention), which requires signatories, among other things, to criminalize "cultivation, production, manufacture, extraction, preparation, possession, offering, offering for sale, distribution, purchase, sale, . . . importation and exportation of drugs" contrary to the provisions of the Convention.[292] The United States is also party to the Convention on Psychotropic Substances of 1971, which requires parties to impose various restrictions on controlled substances, including measures "for the repression of acts contrary to laws or regulations" adopted pursuant to treaty obligations.[293] Both conventions require parties to impose certain controls on cannabis; however, in December 2020, the United Nations Commission on Narcotic Drugs voted to remove some of the restrictions on cannabis under the 1961 Convention.[294] While some commentators view that vote as part of a significant shift in international cannabis policy,[295] cannabis and its derivatives remain subject to restrictions under the international drug control treaties that may be inconsistent with legalization of marijuana, particularly for recreational purposes.[296] The treaties are not self-executing,[297] meaning that they

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[289] Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Advance Agency's Continued Evaluation of Potential Regulatory Pathways for Cannabis-Containing and Cannabis-Derived Products (Apr. 2, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation.

[290] H.R. 171, 116th Cong. (2019).

[291] *See, e.g.*, Regulate Marijuana Like Alcohol Act, H.R. 420, 116th Cong. (2019).

[292] United Nations Single Convention on Narcotic Drugs, 1961, art. 36, Mar. 30, 1961, 18 U.S.T. 1407.

[293] United Nations Convention on Psychotropic Substances, art. 2(1)(7), Feb. 21, 1971, 32 U.S.T. 543.

[294] Like the CSA, the international drug control treaties categorize controlled substances into schedules subject to different requirements. Cannabis and cannabis resin were previously included in both Schedule I and Schedule IV of the 1961 Convention, but in December 2020, the United Nations Commission on Narcotic Drugs voted to remove cannabis and cannabis resin from Schedule IV. *See* Press Release, *United Nations Commission on Narcotic Drugs, CND Votes on Recommendations for Cannabis and Cannabis-related Substances* (Dec. 2, 2020).

[295] *See, e.g.*, Bill Chappell, *U.N. Commission Removes Cannabis from Its Most Strict Drug Control List*, NPR, Dec. 2, 2020; Jariel Arvin, *The UN Now Says Medical Weed is a Less Dangerous Drug*, VOX, Dec. 3, 2020.

[296] Cannabis and cannabis resin remain in Schedule I of the 1961 Convention. United Nations Single Convention on Narcotic Drugs, 1961, List of Drugs Included in Schedule I, Mar. 30, 1961, 18 U.S.T. 1407. The 1961 Convention also contains provisions imposing specific requirements on the cultivation of cannabis. *Id.* art. 28. In addition, THC remains subject to control under the Convention on Psychotropic Substances of 1971. United Nations Convention on Psychotropic Substances, List of Substances in Schedule I, Feb. 21, 1971, 32 U.S.T. 543.

[297] The Supreme Court has held, "Only '[i]f the treaty contains stipulations which are self-executing, that is, require no legislation to make them operative, [will] they have the force and effect of a legislative enactment.'" Medellin v. Texas, 552 U.S. 491, 505-06 (2008). Congress has made explicit findings that the Convention on Psychotropic Substances "is not self-executing, and the obligations of the United States thereunder may only be performed pursuant to appropriate legislation." 21 U.S.C. § 801a(2). Because the enforcement provisions of the two treaties are similar, with neither stating that it is self-executing, it appears the Single Convention on Narcotic Drugs also is not self-executing.

do not have the same status as judicially enforceable domestic law; for example, an individual would not be subject to prosecution on the basis of the treaties without some implementing statute such as the CSA.[298] However, failure to abide by its treaty obligations could expose the United States to diplomatic consequences.[299]

Clinical Research and Use of Schedule I Substances

Another issue that received significant attention during the 116th Congress was the possibility that certain Schedule I controlled substances, especially marijuana and psilocybin, may have medical benefits. As a legal matter, Schedule I status limits researchers' ability to conduct clinical research involving these substances and patients' ability to access such substances for medical purposes.

Because substances in Schedule I have no accepted medical use under the CSA, it is only legal to produce, dispense, and possess those substances in the context of federally approved scientific studies.[300] In addition, federal law limits the use of federal funding for such research: a rider to the appropriations bill for FY2021 provides that no appropriated funds may be used "for any activity that promotes the legalization of any drug or other substance included in schedule I" of the CSA, except "when there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or . . . federally sponsored clinical trials are being conducted to determine therapeutic advantage."[301]

Schedule I status under the CSA raises two key legal issues related to medical use and clinical research. First, some commentators have expressed concerns that the CSA places too many restrictions on research involving controlled substances, particularly Schedule I controlled substances that might have a legitimate medical use.[302] With respect to clinical research involving marijuana specifically, currently there is one farm that legally produces marijuana for research

No. 21-70544 archived on January 25, 2022
cited in AIMS v. US DEA

[298] *See Medellin*, 552 U.S. at 527 ("A non-self-executing treaty, by definition, is one that was ratified with the understanding that it is not to have domestic effect of its own force."). For additional background on the legal effect of self-executing and non-self-executing treaties, see CRS Report RL32528, *International Law and Agreements: Their Effect upon U.S. Law*, by Stephen P. Mulligan, at 15.

[299] *See* United Nations Single Convention on Narcotic Drugs, 1961, art. 14, Mar. 30, 1961, 18 U.S.T. 1407 (authorizing the Narcotics Control Board to recommend to treaty signatories that they stop the export or import of drugs to a signatory country that violates the treaty, or to publish a report on any matter related to enforcement of the treaty); United Nations Convention on Psychotropic Substances, art. 19, Feb. 21, 1971, 32 U.S.T. 543 (same). Some commentators have suggested that it is possible state laws decriminalizing marijuana already conflict with the United States' obligations under the treaties. *See* Brian M. Blumenfeld, Pacta Sunt Servanda *State Legislation of Marijuana and Subnational Violations of International Treaties: A Historical Perspective*, 46 PEPP. L. REV. 69, 94-101 (2018) (while acknowledging that the "operative articles of the drug treaties do, in fact, leave room for debate," concluding that "the constitutional authority of the federal government to enforce marijuana prohibition in all fifty states is well-settled American law," and, because the "United States' administrative-discretionary measures have thus far failed to deter numerous subnational actors from engaging in commercialized recreational marijuana activity, and instead have created a sphere of tolerance for its growth, the United States will remain vulnerable to censure from members of the international community"); Jonathan Remy Nash, *Doubly Uncooperative Federalism and the Challenge of U.S. Treaty Compliance*, 55 COLUM. J. TRANSNAT'L L. 3, 21-23 (2016) ("Limits on federal government power notwithstanding, strict application of the doctrine of state responsibility would seem to mean that U.S. state actions have put the United States in breach [of its treaty obligations].").

[300] *See* 21 U.S.C. § 823(f); *see also* Gonzales v. Raich, 545 U.S. 1, 14 (2004).

[301] Pub. L. No. 116-260, Div. H, § 509 (2020).

[302] *See, e.g.*, Michael H. Andreae, et al., *An Ethical Exploration of Barriers to Research on Controlled Drugs*, AM. J. BIOETH., Apr. 2016, at 5-6, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4849133/pdf/nihms-778176.pdf.

purposes, and researchers have complained that marijuana from that source is deficient in both quality and quantity.[303]

Second, there is a growing gulf between federal and state law with respect to Schedule I controlled substances with potential medical benefits. The gap between federal and state regulation of medical—and recreational—marijuana is discussed in greater detail above.[304] But, following the 2020 election, it appears that a gap may also be developing with respect to certain other Schedule I substances. On November 3, 2020, voters in Oregon approved a ballot measure authorizing the use of psilocybin for medical purposes under state law.[305] The same day, District of Columbia voters passed a ballot measure deprioritizing the enforcement of criminal prohibitions on certain psychedelic plants and fungi.[306] The District of Columbia measure is not limited to medicinal use but was motivated in part by the possibility that psychedelic substances may provide medical benefits.[307] As with marijuana, these changes in D.C. and state law do not alter the status of the affected Schedule I controlled substances under the federal CSA but potentially raise similar legal issues.[308]

Congress has previously acted to facilitate research involving marijuana while also retaining strict controls over the Schedule I controlled substance, but regulatory delays have reduced the potential impact of that action. In 2015, Congress passed the Improving Regulatory Transparency for New Medical Therapies Act, which imposed deadlines on DEA to issue notice of each application to manufacture Schedule I substances for research and then act on the application.[309] Although DEA stated in 2016 that it planned to grant additional licenses to grow marijuana for research purposes, it has not yet done so.[310] Perhaps prompted by litigation related to the delay, DEA published a notice in the *Federal Register* in August 2019 announcing an ongoing "policy review process to ensure that the [marijuana] growers program is consistent with applicable laws

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[303] *See* CRS Report R44782, *The Marijuana Policy Gap and the Path Forward*, coordinated by Lisa N. Sacco; Pet. for Writ of Mandamus at 13-15, *In re* Scottsdale Research Inst., No. 19-1120 (D.C. Cir. June 6, 2019).

[304] *See supra* "Marijuana Policy Gap."

[305] *See* Lizzy Acker, *Oregon Becomes First State to Legalize Psychedelic Mushrooms*, OREGOINAN, Nov. 3, 2020. Through a separate ballot measure, Oregonians voted to decriminalize possession of small amounts of certain Schedule I and II controlled substances, including cocaine, heroin, oxycodone and methamphetamines. *See* Cleve R. Wootson Jr. and Jaclyn Peiser, *Oregon Decriminalizes Possession of Hard Drugs, as Four Other States Legalize Recreational Marijuana*, WASH. POST, Nov. 4, 2020.

[306] *See* Justin Wm. Moyer, *D.C. Voters Approve Ballot Question to Decriminalize Psychedelic Mushrooms*, WASH. POST, Nov. 3, 2020. The D.C. ballot measure does not repeal criminal laws related to psychedelic plants and fungi but rather provides that prosecution for the use and sale of such substances shall be "among the Metropolitan Police Department's lowest law enforcement priorities." *Id.* The ballot measure appears to have been tailored to comply with a federal appropriations rider that prohibits the District of Columbia from expending any federal funds "to enact or carry out any law, rule, or regulation to legalize or otherwise reduce penalties associated with the possession, use, or distribution of any schedule I substance under the Controlled Substances Act[.]" Pub. L. No. 116-93 Div. C, § 909, 133 Stat. 2317 (2019).

[307] *See* Justin Wm. Moyer, *D.C. Voters to Weigh in on 'Magic Mushroom' Decriminalization After Months-long Campaign*, WASH. POST, Oct. 8, 2020. ("In February, the D.C. Board of Elections approved the initiative after hearing testimony from supporters who argued ibogaine, mescaline and the hallucinogen psilocybin, among other chemicals, help people recover from post-traumatic stress syndrome and addiction.").

[308] *See* CRS Legal Sidebar LSB10482, *State Marijuana "Legalization" and Federal Drug Law: A Brief Overview for Congress*, by Joanna R. Lampe.

[309] Pub. L. No. 114-89, 129 Stat.703 (2015); 21 U.S.C. § 823(i)(2). "Manufacturing" of controlled substances includes growing marijuana. *See, e.g.*, DEA, Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana, 84 Fed. Reg. 44,920 (Aug. 27, 2019) [hereinafter, DEA Notice].

[310] *See* Pet. for Writ of Mandamus at 16, *In re* Scottsdale Research Inst., No. 19-1120 (D.C. Cir. June 6, 2019).

and treaties."[311] That notice announced the agency's intent to promulgate regulations governing the manufacture of marijuana for research purposes. It also provided notice of the 33 applications DEA had received to manufacture Schedule I controlled substances for research purposes, and stated that DEA would review all pending applications and grant "the number that the agency determines is necessary to ensure an adequate and uninterrupted supply of the controlled substances at issue under adequately competitive conditions."[312]

In December 2020, DEA issued a final rule (based on its August 2019 proposal) governing registration for bulk marijuana manufacturers.[313] The final rule provides that the DEA Administrator "may grant an application for a registration to manufacture marihuana . . . only if he determines that such registration is consistent with the public interest and with United States obligations under the Single Convention."[314] The rule further provides that "[a]ll registered manufacturers who cultivate cannabis shall deliver their total crops of cannabis" to DEA, and the agency "shall purchase and take physical possession of such crops as soon as possible" and "have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks [of cannabis] other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations."[315] The rule also allows DEA to delegate some of its responsibilities, such as storage and trading of cannabis, to "appropriately registered persons."[316] The effective date of the final rule is January 19, 2021.[317] As of January 2021, DEA had not registered any additional marijuana manufacturers.

As it did with the Improving Regulatory Transparency for New Medical Therapies Act, Congress could pass further legislation to guide DEA's consideration of applications to manufacture marijuana for research purposes. For instance, the Medical Cannabis Research Act of 2019[318] would have aimed to increase the number of licenses to produce cannabis for research purposes by requiring DEA to approve at least three additional manufacturers within a year of passage. Congress could also legislate more broadly to facilitate research involving controlled substances. For example, a proposed amendment to the appropriations bill for FY2020 would have eliminated the appropriations rider restricting the use of federal funding for research involving Schedule I substances.[319] That amendment, which would have applied to research involving all Schedule I controlled substances, was intended to facilitate research involving not only marijuana but also psilocybin, MDMA, and other Schedule I drugs that might have legitimate medical uses.[320]

No. 21-70544 cited in AIMS v. US DEA archived on January 25, 2022

[311] *Id.*

[312] DEA Notice at 44,921.

[313] *See* DEA, *Controls To Enhance the Cultivation of Marihuana for Research in the United States*, 85 Fed. Reg. 82,333 (Dec. 18, 2020).

[314] *Id.* at 82,353.

[315] *Id.*

[316] *Id.*

[317] *Id.*

[318] H.R. 601, 116th Cong. (2019).

[319] H.Amdt. 321, 116th Cong. (2019). The amendment was not adopted.

[320] *See* 165 Cong. Rec. H4612 (2019) (statement of Rep. Ocasio-Cortez) ("I rise today to offer this critical bipartisan amendment that will allow United States researchers to study and examine the extraordinary promise shown by several schedule I drugs that have been shown in treating critical diseases, such as MDMA's success in veteran PTSD, psilocybin's promise in treatment-resistant depression, or ibogaine's effectiveness in opioid and other drug addiction. Additionally, this will allow research into marijuana's impact in cancer relief, seizure treatment, and more.").

COVID-19 Pandemic

The spread of COVID-19 in the United States beginning in early 2020 altered the daily lives of millions of Americans and raised a wide range of legal issues.[321] Issues relating to the CSA include the supply of controlled substances used for treatment of COVID-19 and the prescription of controlled substances via telemedicine.[322]

Supply of Controlled Substances

The COVID-19 pandemic has increased the demand for certain controlled substances for legitimate medical purposes.[323] In particular, Schedule II controlled substances such as fentanyl and hydromorphone are used to relieve pain relief associated with intubation for patients on ventilators.[324] The CSA requires DEA to set aggregate production quotas for controlled substances in Schedules I and II and for certain listed chemicals.[325] DEA set the quotas for 2020 in December 2019.[326] As COVID-19 spread in the United States in the spring of 2020, health care providers became worried that existing supplies would be inadequate for the unprecedented number of patients needing artificial ventilation and asked DEA to increase production quotas.[327] In April 2020, DEA published a final order adjusting the 2020 production quotas for certain Schedule II controlled substances, including fentanyl and hydromorphone, and the List I chemicals ephedrine and pseudoephedrine.[328]

Increased production of controlled substances may raise concerns about increased potential for diversion and abuse. The SUPPORT Act requires DEA to account for diversion when setting quotas for certain controlled substances, and DEA did so in revising the 2020 production quotas.[329] More generally, some worry that the pandemic will lead to an increase in the misuse of controlled substances as people across the country face illness, anxiety, depression, and social isolation due to the pandemic and related life changes.[330] One July 2020 report described "alarming spikes in drug overdoses" during the first months of the pandemic potentially driven by "continued isolation, economic devastation and disruptions to the drug trade."[331]

cited in AMS v. US DEA
No. 21-70544 archived on January 25, 2022

[321] *See* CRS Legal Sidebar LSB10433, *Legal Issues Related to the COVID-19 Outbreak: An Overview*, coordinated by Caitlain Devereaux Lewis.

[322] For discussion of DEA's role in responding to the COVID-19 pandemic, including DEA actions outside these two areas, see CRS Insight IN11321, *COVID-19: The Drug Enforcement Administration's Regulatory Role*, by Lisa N. Sacco.

[323] *See, e.g.*, Dan Levine, *Exclusive: Opioid Supply Crunch for U.S. Coronavirus Patients Prompts Appeal to Relax Limits*, REUTERS, Apr. 2, 2020.

[324] *See* CRS Insight IN11321, *COVID-19: The Drug Enforcement Administration's Regulatory Role*, by Lisa N. Sacco.

[325] 21 U.S.C. § 826(a); *see also* 21 C.F.R. § 1303.11.

[326] *See* DEA, *Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020*, 84 Fed. Reg. 66,014, (Dec. 2, 2019).

[327] *See, e.g.*, Dan Levine, *Exclusive: Opioid Supply Crunch for U.S. Coronavirus Patients Prompts Appeal to Relax Limits*, REUTERS, Apr. 2, 2020.

[328] DEA, *Adjustments to Aggregate Production Quotas for Certain Schedule II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine and Pseudoephedrine for 2020, in Response to the Coronavirus Disease 2019 Public Health Emergency*, 85 Fed. Reg. 20,302 (Apr. 10, 2020).

[329] *See id.* at 20,304-05.

[330] *See, e.g.*, CDC, *Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020*, MORBIDITY AND MORTALITY WEEKLY REPORT, Aug. 14, 2020.

[331] William Wan & Heather Long, *"Cries for Help": Drug Overdoses Are Soaring During the Coronavirus Pandemic*,

These developments implicate both of the CSA's core considerations: seeking to protect the public health from the dangers of controlled substances while also ensuring that patients have access to pharmaceutical controlled substances for legitimate medical purposes.[332] Congress has several means at its disposal to balance those interests. If Congress determined that the supply of controlled substances was inadequate to address the COVID-19 pandemic or that the previous increase in quotas had resulted in a surplus of controlled substances, it could legislatively alter manufacturing quotas or enact legislation directing DEA to consider additional factors in setting or revising quotas. Congress could also take steps to prevent misuse of controlled substances without changing the national supply of such substances. For instance, the Emergency Support for Substance Use Disorders Act would have authorized federal grants to support "overdose prevention, syringe services programs, and other harm reduction services that address the harms of drug misuse during the COVID-19 pandemic."[333]

Telehealth Services

Another area where the COVID-19 pandemic has affected the CSA's regulatory framework is telemedicine.[334] As the COVID-19 pandemic has limited individuals' ability or desire to seek medical care in person, the demand for telehealth services has increased.[335] However, the CSA limits the circumstances in which health care providers may prescribe controlled substances via telemedicine. The CSA provides that most pharmaceutical controlled substances may be dispensed only pursuant to a valid prescription,[336] and a valid prescription must generally be predicated on an in-person medical evaluation.[337] A practitioner who has previously evaluated a patient in person may prescribe the patient a controlled substance via telemedicine.[338] However, a practitioner who has not evaluated a patient in person may prescribe controlled substances via telemedicine only in more limited circumstances, including at the request of a practitioner who has conducted an in-person evaluation when that practitioner is unavailable, when a patient is being treated in a CSA-registered facility, when the practitioner has obtained a special telemedicine registration from DEA, during a medical emergency situation, or during a public health emergency.[339]

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

With respect to the last option, the CSA authorizes the practice of telemedicine during a public health emergency declared by the HHS Secretary under Section 319 of the Public Health Service

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WASH. POST, July 1, 2020. *See also* Joseph Friedman *et al.*, *Overdose-Related Cardiac Arrests Observed by Emergency Medical Services During the US COVID-19 Epidemic*, JAMA PSYCHIATRY, Dec. 3, 2020.

[332] *See id.* §§ 801(1), (2).

[333] S. 4058, 116th Cong. (2020).

[334] Telemedicine is also subject to regulation under legal authorities other than the CSA. *See* CRS Report R46239, *Telehealth and Telemedicine: Frequently Asked Questions*, by Victoria L. Elliott.

[335] Lisa M. Koonin, *et al.*, *Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic — United States, January–March 2020*, MORBIDITY AND MORTALITY WEEKLY REPORT, Oct. 30, 2020.

[336] 21 U.S.C. § 829. The CSA does not mandate that Schedule V controlled substances be distributed by prescription, but such substances may be dispensed only "for a medical purpose." *Id.* § 829(c). As a practical matter, Schedule V substances are almost always dispensed pursuant to a prescription due to separate requirements under the FD&C Act or state law. *Cf. e.g.*, Ga. Code Ann. § 16-13-29.2 (permitting the State Board of Pharmacy to allow the sale of Schedule V controlled substances without a prescription); Fl. Stat. Ann. § 893.08 (permitting the sale of Schedule V controlled substances over-the-counter by a registered pharmacist, if a prescription is not required under the FD&C Act).

[337] 21 U.S.C. § 829(e).

[338] 21 U.S.C. § 829(e)(2); *see also* DEA, COVID-19 Information Page, https://www.deadiversion.usdoj.gov/coronavirus.html (accessed Dec. 2, 2020).

[339] 21 U.S.C. §§ 829(e)(2), 802(54).

Act[340] when the practice "involves patients located in such areas, and such controlled substances, as the [HHS] Secretary, with the concurrence of the Attorney General, designates."[341] On January 31, 2020, the HHS Secretary issued a determination that a public health emergency exists under the Public Health Service Act "[a]s a result of confirmed cases of 2019 Novel Coronavirus."[342] Subsequently, citing the CSA's exception for telehealth services during a declared public health emergency, DEA issued guidance on its website authorizing the use of telemedicine.[343] DEA stated that on March 16, 2020, the HHS Secretary (with the concurrence of the acting DEA Administrator) applied the public health emergency exception to "all schedule II-V controlled substances in all areas of the United States." Thus, subject to applicable federal and state laws and other conditions,[344] from March 16, 2020, until the expiration of the public health emergency related to COVID-19, DEA-registered practitioners anywhere in the United States may prescribe any pharmaceutical controlled substance via telemedicine without conducting an in-person medical evaluation.[345]

Numerous proposals before the 116th Congress sought to increase access to telehealth care during the COVID-19 pandemic or maintain advances in telemedicine after the pandemic ends. The Telehealth Act, among other things, would have allowed practitioners to prescribe controlled substances in Schedule III or Schedule IV based on a telehealth visit.[346] A number of other legislative proposals addressed regulation of telemedicine outside the scope of the CSA.[347] If similar proposals are introduced in the 117th Congress, legislators may consider whether they would affect the prescribing of controlled substances via telemedicine and whether they should include specific provisions related to the CSA.

cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

[340] 42 U.S.C. § 247d.

[341] 21 U.S.C. § 802(54)(D). The statute provides that "such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of title 5," *i.e.*, the Administrative Procedure Act. *Id.* § 802(54)(D)(ii).

[342] Alex M. Azar II, Determination that a Public Health Emergency Exists (Jan. 31, 2020) https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx. The determination has been renewed several times, most recently in October 2020. Alex M. Azar II, Determination that a Public Health Emergency Exists (Oct. 2, 2020) https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx.

[343] DEA, COVID-19 Information Page, https://www.deadiversion.usdoj.gov/coronavirus.html (accessed Dec. 2, 2020).

[344] The applicable conditions for the use of telemedicine to prescribe controlled substances during the current public health emergency are: (1) the prescription is "issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice," (2) the "telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system," and (3) the prescribing practitioner is acting in accordance with applicable federal and State laws.

[345] DEA specifically noted: "If the prescribing practitioner has previously conducted an in-person medical evaluation of the patient, the practitioner may issue a prescription for a controlled substance after having communicated with the patient via telemedicine, or any other means, regardless of whether a public health emergency has been declared by the Secretary of Health and Human Services, so long as the prescription is issued for a legitimate medical purpose and the practitioner is acting in the usual course of his/her professional practice. In addition, for the prescription to be valid, the practitioner must comply with applicable Federal and State laws."

[346] H.R. 7992, 116th Cong. (2020). Legislative proposals to reform CSA regulation of telemedicine are not limited to addressing the COVID-19 pandemic. For instance, the METH Addiction Act, S. 2244, 116th Cong. (2019), would have amended the CSA to allow community addiction treatment facilities and community mental health facilities to register to dispense controlled substances through the practice of telemedicine. *See also* Improving Access to Remote Behavioral Health Treatment Act of 2019, H.R. 4131, 116th Cong. (2019).

[347] *See, e.g.*, Mental Health Telemedicine Expansion Act, H.R. 1301, 116th Cong. (2019); VA Mission Telehealth Clarification Act, S. 3643, 116th Cong. (2020); Telehealth Modernization Act, H.R. 8727, 116th Cong. (2020).

Author Information

Joanna R. Lampe
Legislative Attorney

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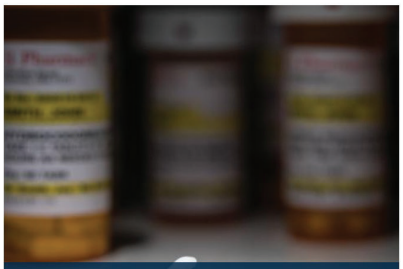
cited in AIMS v. US DEA
No. 21-70544 archived on January 25, 2022

An official website of the United States government Here's how you know

Diversion Control Division

Many problems associated with drug abuse are the result of legitimately made controlled substances being diverted from their lawful purpose into illicit drug traffic. The mission of DEA's Diversion Control Division 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.

Visit DEA's Diversion Control Web Site



Program Description

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No. 21-70544 archived on January 25, 2022

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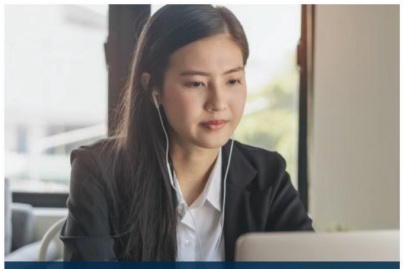

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Information Regarding Judgment and Post-Judgment Proceedings

Judgment

- This Court has filed and entered the attached judgment in your case. Fed. R. App. P. 36. Please note the filed date on the attached decision because all of the dates described below run from that date, not from the date you receive this notice.

Mandate (Fed. R. App. P. 41; 9th Cir. R. 41-1 & -2)

- The mandate will issue 7 days after the expiration of the time for filing a petition for rehearing or 7 days from the denial of a petition for rehearing, unless the Court directs otherwise. To file a motion to stay the mandate, file it electronically via the appellate ECF system or, if you are a pro se litigant or an attorney with an exemption from using appellate ECF, file one original motion on paper.

Petition for Panel Rehearing (Fed. R. App. P. 40; 9th Cir. R. 40-1)
Petition for Rehearing En Banc (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3)

(1) A. Purpose (Panel Rehearing):

- A party should seek panel rehearing only if one or more of the following grounds exist:
  - ► A material point of fact or law was overlooked in the decision;
  - ► A change in the law occurred after the case was submitted which appears to have been overlooked by the panel; or
  - ► An apparent conflict with another decision of the Court was not addressed in the opinion.
- Do not file a petition for panel rehearing merely to reargue the case.

B. Purpose (Rehearing En Banc)

- A party should seek en banc rehearing only if one or more of the following grounds exist:

- ► Consideration by the full Court is necessary to secure or maintain uniformity of the Court's decisions; or
- ► The proceeding involves a question of exceptional importance; or
- ► The opinion directly conflicts with an existing opinion by another court of appeals or the Supreme Court and substantially affects a rule of national application in which there is an overriding need for national uniformity.

(2) Deadlines for Filing:

- A petition for rehearing may be filed within 14 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the United States or an agency or officer thereof is a party in a civil case, the time for filing a petition for rehearing is 45 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the mandate has issued, the petition for rehearing should be accompanied by a motion to recall the mandate.
- *See* Advisory Note to 9th Cir. R. 40-1 (petitions must be received on the due date).
- An order to publish a previously unpublished memorandum disposition extends the time to file a petition for rehearing to 14 days after the date of the order of publication or, in all civil cases in which the United States or an agency or officer thereof is a party, 45 days after the date of the order of publication. 9th Cir. R. 40-2.

(3) Statement of Counsel

- A petition should contain an introduction stating that, in counsel's judgment, one or more of the situations described in the "purpose" section above exist. The points to be raised must be stated clearly.

(4) Form & Number of Copies (9th Cir. R. 40-1; Fed. R. App. P. 32(c)(2))

- The petition shall not exceed 15 pages unless it complies with the alternative length limitations of 4,200 words or 390 lines of text.
- The petition must be accompanied by a copy of the panel's decision being challenged.
- A response, when ordered by the Court, shall comply with the same length limitations as the petition.
- If a pro se litigant elects to file a form brief pursuant to Circuit Rule 28-1, a petition for panel rehearing or for rehearing en banc need not comply with Fed. R. App. P. 32.

- The petition or response must be accompanied by a Certificate of Compliance found at Form 11, available on our website at www.ca9.uscourts.gov under *Forms.*
- You may file a petition electronically via the appellate ECF system. No paper copies are required unless the Court orders otherwise. If you are a pro se litigant or an attorney exempted from using the appellate ECF system, file one original petition on paper. No additional paper copies are required unless the Court orders otherwise.

Bill of Costs (Fed. R. App. P. 39, 9th Cir. R. 39-1)

- The Bill of Costs must be filed within 14 days after entry of judgment.
- See Form 10 for additional information, available on our website at www.ca9.uscourts.gov under *Forms.*

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- Please refer to the Rules of the United States Supreme Court at www.supremecourt.gov

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UNITED STATES COURT OF APPEALS
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9th Cir. Case Number(s)

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