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The Controlled Substances Act (CSA): A Legal Overview for the 116th Congress

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SUMMARY

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The Controlled Substances Act (CSA): A Legal Overview for the 116th Congress

The Controlled Substances Act (CSA) imposes a unified legal framework to regulate certain drugs—whether medical or recreational, legally or illicitly distributed—that are deemed to pose a risk of abuse and dependence. The CSA 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 statute also applies to controlled substance analogues that are intended to mimic the effects of controlled substances and 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 present 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. Most substances subject to 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 under the United States' international treaty obligations. In the alternative, Congress may place a substance under control by statute.

The CSA simultaneously aims to protect public health from the dangers of controlled substances diverted into the illicit market while also seeking to ensure that patients have access to pharmaceutical controlled substances for legitimate medical purposes. 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 implement various measures 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 registration provisions and works with the Criminal Division of the Department of Justice to enforce the trafficking provisions of the CSA. 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 that would amend the CSA in various ways. For example, after Congress passed several bills in recent years in response to the opioid crisis, additional proposals aimed at addressing the crisis are pending before the 116th Congress, including the John S. McCain Opioid Addiction Prevention Act (H.R. 1614, S. 724), which would limit practitioners' ability to prescribe opioids; the LABEL Opioids Act (H.R. 2732, S. 1449), which would require prescription opioids to bear certain warning labels; and the Ending the Fentanyl Crisis Act of 2019 (S. 1724), which would increase criminal liability for illicit trafficking in the powerful opioid fentanyl. The 116th Congress has also considered measures specifically seeking to address the proliferation of synthetic drugs that mimic the effects of fentanyl, including the Stopping Overdoses of Fentanyl Analogues Act (H.R. 2935, S. 1622) and the Modernizing Drug Enforcement Act of 2019 (H.R. 2580). In addition, multiple recent proposals would seek to address the divergence between federal and state marijuana laws. For example, the Secure And Fair Enforcement Banking Act of 2019 (SAFE Banking Act) (H.R. 1595, S. 1200) would seek to protect depository institutions that provide financial services to cannabis-related businesses from regulatory sanctions, and the Strengthening the Tenth Amendment Through Entrusting States Act (STATES Act) (H.R. 2093, S. 1028) would amend the CSA so that most provisions concerning marijuana do not apply to marijuana-related activities that comply with state law. Other proposals, such as the Legitimate Use of Medicinal Marihuana Act (H.R. 171) and the Marijuana Justice Act of 2019 (H.R. 1456, S. 597) could address the gap between federal and state law in the area of marijuana regulation by moving marijuana from Schedule I to a less restrictive schedule or remove marijuana from the CSA's schedules. Finally, recent legislative proposals would aim to facilitate clinical research involving controlled substances, particularly marijuana. These various proposals raise a number of legal questions as Congress contemplates whether to change the laws governing controlled substances.

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Prescription drugs play a vital role in American public health. The Centers for Disease Control and Prevention (CDC) estimates that between 2011 and 2014 just under half of all Americans had used one or more prescription drugs in the last 30 days.[1] On the other hand, unfettered access to drugs may pose serious public health risks. The CDC reports that in 2017 over 70,000 Americans died of overdoses on prescription and nonprescription drugs.[2] The Controlled Substances Act[3] (CSA or the Act) seeks to balance those competing interests.[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, and 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 116th 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 categories—known as *schedules*—into which controlled substances subject to the Act are divided and discusses how substances are added to the schedules.[10] The report next summarizes the CSA's registration requirements, which apply to entities that register with the government to legally handle pharmaceutical controlled substances,[11] before summarizing the CSA's criminal trafficking provisions, which apply to activities involving controlled substances that are not sanctioned 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, and the legal limits on clinical research involving certain controlled substances.[13]

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 narcotic drugs including opium and coca leaves and their derivatives.[14] With the passage of the

[1] *See* CDC, HEALTH, UNITED STATES, 2017: WITH SPECIAL FEATURE ON MORTALITY, Table 79 (2018).

[2] *See* Holly Hedegaard, et al., *Drug Overdose Deaths in the United States, 1999–2017*, NCHS DATA BRIEF No. 369 (Nov. 2018).

[3] 21 U.S.C. §§ 801-904.

[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 116th Congress."

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

Harrison Narcotics Tax Act of 1914, Congress began in earnest to regulate the domestic trade in narcotic drugs.[15] The Harrison Act provided for 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]

Congress revamped federal drug regulation by enacting the Comprehensive Drug Abuse Prevention and Control Act of 1970.[18] The Comprehensive Drug Abuse Prevention and Control 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 considered to pose a risk of abuse and dependence.[22] In enacting the CSA, Congress recognized two competing interests related to drug regulation: on the 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 that patients have access to pharmaceutical controlled substances for legitimate medical purposes.

To accomplish those two goals, the statute creates two overlapping legal schemes. *Registration provisions* require 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]

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

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

[16] S*ee* 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." 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.

[27] *Id.* § 811.

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 contemplated by the Act. Those drugs 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 prescription 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 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, 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] In addition, misbranding may include

[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, 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.

[36] 21 U.S.C. §§ 301-399i.

[37] *Id.* § 331(a).

[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).

misrepresenting that a substance offered for sale is a brand-name drug (even if the seller believes the substance for sale is chemically identical to the brand-name drug).[41] 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.[42]

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.[43] The FD&C Act, by contrast, is a consumer protection statute that seeks to prevent harm to consumers who obtain drugs (and other public health products) through commercial channels.[44] 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 Act are also subject to state drug laws.[45] State substance control laws often mirror federal law and are relatively uniform across jurisdictions because almost all states have adopted a version of the Uniform Controlled Substances Act (UCSA).[46] However, states are free to modify the UCSA, and have done so to varying extents.[47] Moreover, the model statute does not specify sentences for violations, so penalties for state controlled substance offenses vary widely.[48]

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.[49] For example, some states have controlled the fentanyl analogues benzylfentayl and thenylfentanyl, but those substances are not currently subject to federal control.[50] Second, states may wish to adopt federal scheduling decisions at the state level but lag behind federal regulators

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[41] *See, e.g.*, United States v. Xin He, 405 Fed. App'x 220, 221 (9th Cir. 2010).

[42] 21 U.S.C. § 351.

[43] *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.").

[44] *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.

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

[46] 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").

[47] 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).

[48] Braun, *Uniform Controlled Substances Act of 1990*, 13 CAMPBELL L. REV. at 371; *see also* Kreit, *supra* note 45 at 628.

[49] Kreit, *supra* note 45 at 628.

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

due to the need for a separate state scheduling process.[51] 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.[52] Crucially, however, the states cannot alter federal law, and when state and federal law conflict, the federal law controls.[53] 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.[54] Any federal controls remain in effect and potentially enforceable in those states.[55]

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.[56] Drugs become subject to the CSA by being placed in one of five lists, referred to as "schedules."[57] 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.[58] As discussed below, scheduling decisions by Congress and DEA follow different procedures.[59]

Overview of Schedules

The CSA establishes five categories of controlled substances, referred to as Schedules I through V.[60] The schedule on which a controlled substance is placed determines the level of restriction on its production, distribution, and possession, as well as the penalties applicable to any improper handling of the substance.[61] As **Figure 1** describes, each controlled substance is assigned to a schedule based on its medical utility and its potential for abuse and dependence.

[51] Kreit, *supra* note 45 at 629.

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

[53] 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").

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

[55] For further discussion of the relationship between state legalization of controlled substances and the CSA, see the "Marijuana Policy Gap" section.

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

[57] 21 U.S.C. § 812.

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

[59] *See id.*

[60] 21 U.S.C. § 812.

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

Figure 1. CSA Scheduling Criteria

	ABUSE POTENTAL	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]

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.[62] 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.[63]

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."[64] A substance that meets those criteria *and* is intended for human consumption is treated as a controlled substance in Schedule I.[65]

Listed chemicals subject to the CSA are precursor chemicals for controlled substances. They may be placed on one of two lists:

- **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, and

[62] *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.").

[63] *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 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) Products*, by Agata Dabrowska and Renée Johnson.

[64] *Id.* § 802(32).

[65] *Id.* § 813(a). 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.

[66] 21 C.F.R. § 1300.02(b18).

[67] *Id.* § 1300.02(b19).

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 of the same controls as 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. A key difference between controlled substance analogues and listed chemicals is that a substance does not qualify for control as an analogue unless it is intended for human consumption as a substitute for a controlled substance, while listed chemicals generally are not intended for human consumption standing alone but are used as ingredients in the manufacture of controlled substances.[72] In addition, listed chemicals include only specific substances identified for control under the CSA by statute or rulemaking.[73] By contrast, controlled substance analogues need not be individually scheduled; they need only satisfy the statutory criteria.[74]

Scheduling Procedures

Substances may be added to or removed from a schedule or moved to a different schedule through agency action or by legislation.[75]

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 a drug it views as posing an urgent concern. For example, the Synthetic Drug Abuse Prevention Act of 2012 permanently added two synthetic cathinones

[68] *Id.* § 1310.02(a).

[69] *Id.* § 1310.02(b).

[70] *See, e.g.*, 21 U.S.C. § 823(h).

[71] *Id.* § 830.

[72] *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).

[73] 21 U.S.C. §§ 802(34), (35).

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

[75] *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).

(central nervous system stimulants) and certain cannabimimetic substances (commonly referred to as synthetic marijuana) to Schedule I.[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 Secretary has delegated the authority to prepare the scientific and medical evaluation to FDA.[82] In preparing the evaluation, FDA considers 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] And if FDA recommends against controlling the substance, DEA may not schedule it.[86]

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

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[76] *See* Pub. L. No. 112-144, 126 Stat. 1130 (2012). The first congressional proposal to control any 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 first 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).

[77] The CSA grants the Attorney General the authority to administer its provisions. S*ee, e.g.*, 21 U.S.C. § 811. The Attorney General has delegated that authority to the DEA Administrator. S*ee* 28 C.F.R. § 0.100(b). Accordingly, this report refers to enforcement by DEA or the DEA Administrator rather than the Attorney General.

[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.*

[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.

abuse and dependence.[88] DEA scheduling decisions are subject to notice-and-comment rulemaking, meaning that interested parties must have the opportunity to submit comments on the DEA Administrator's decision before it becomes final.[89]

The DEA Administrator's decision whether to schedule, reschedule, or deschedule a substance through the ordinary administrative process is subject to judicial review.[90] Such review is generally deferential: courts accept DEA's interpretation of the CSA as long as the interpretation of ambiguous statutory text is reasonable,[91] 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.[92]

Emergency Scheduling

Ordinary DEA scheduling decisions are made through notice-and-comment rulemaking and can take years to consider and finalize.[93] Recognizing that in some cases faster scheduling may be appropriate, Congress amended the CSA through the Comprehensive Crime Control Act of 1984[94] to allow the DEA Administrator to place a substance in Schedule I temporarily when "necessary to avoid an imminent hazard to the public safety."[95] Further amendments enacted in the Synthetic Drug Abuse Prevention Act of 2012 extended the maximum length of the temporary scheduling period.[96] 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.[97] 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.[98] The DEA Administrator must also consider any comments from the Secretary of HHS.[99]

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.[100] A temporary scheduling order is vacated once permanent scheduling proceedings are completed with respect to the substance at issue.[101] The CSA provides that emergency scheduling orders are not subject to judicial review.[102]

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[88] *Id.* § 812(b).

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

[90] *See id.* § 877.

[91] *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)).

[92] 21 U.S.C. § 877.

[93] *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.").

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

[95] 21 U.S.C. § 811(h)(1).

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

[97] 21 U.S.C. § 811(h)(1).

[98] *Id.* § 811(h)(3).

[99] *Id.* § 811(h)(4).

[100] *Id.* § 811(h)(2).

[101] *Id.* § 811(h)(5).

[102] *Id.* § 811(h)(6).

DEA has recently used its emergency scheduling power to temporarily control certain analogues to the opioid fentanyl[103] and several synthetic cannabinoids.[104]

International Treaty Obligations

The United States is a party to the Single Convention on Narcotic Drugs of 1961, which was designed to establish effective control over international and domestic traffic in narcotics, coca leaf, cocaine, and marijuana.[105] That treaty 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 Convention.[106]

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.[107] 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.[108]

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."[109] 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.[110]

Registration Requirements

Once a substance is brought within the scope of the CSA, almost any person or organization that handles that substance, except for the end user, becomes subject to a comprehensive system of regulatory requirements.[111] The goal of the regulatory scheme is to create a "closed system" of distribution in which only authorized handlers may distribute controlled substances.[112] 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,

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

[104] *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).

[105] *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").

[106] *Id.* art. 36.

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

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

[109] 21 U.S.C. § 811(d)(1).

[110] *Id.*

[111] *See id.* § 822.

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

distributors, practitioners, and pharmacists,[113] are referred to as *registrants*.[114] 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.[115]

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.[116] 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.[117]

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.[118] 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 users."[119] 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."[120]

Manufacturers and distributors of controlled substances, such as pharmaceutical companies, must register with DEA annually.[121] 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.[122] Registrations specify the extent to which registrants may manufacture, possess, distribute, or dispense controlled substances, and each

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[113] 21 U.S.C. § 822(a).

[114] 21 C.F.R. § 1300.02(b)(24).

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

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

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

[118] 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).

[119] 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"). The Act also exempts from registration any "agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical" or "common or contract carrier or warehouseman, or an employee thereof," acting in the usual course of business. 21 U.S.C. §§ 822(c)(1), (2). DEA has created certain additional exemptions by regulation. *See* 21 C.F.R. §§ 1301.22-24.

[120] DEA, Definition and Registration of Reverse Distributors, 68 Fed. Reg. 41,222, 41,226 (proposed July 11, 2003).

[121] 21 U.S.C. § 822(a)(2).

[122] *Id.* § 822(a)(1).

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.[123] And certain activities can give rise to additional registration requirements. For instance, a special registration is required to operate an opioid treatment program such as a methadone clinic.[124]

The CSA directs the DEA Administrator to grant registration if it would be consistent with the public interest, outlining the criteria the DEA Administrator must consider when evaluating the public interest.[125] 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.[126]

The registration of an individual or organization expires at the end of the registration period unless it is renewed.[127] Registration also ends when the registrant dies, ceases legal existence, or discontinues business or professional practice.[128] A registration cannot be transferred to someone else without the express, written consent of the DEA Administrator.[129]

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.[130] In addition, controlled substances in Schedules I and II may only be distributed pursuant to a written order.[131] Copies of each order form must be transmitted to DEA.[132] Records of orders must be preserved for two years and made available for government review upon request.[133]

Registrants are also required to "design and operate a system to identify suspicious orders" and to notify DEA of any suspicious orders they detect.[134] DEA regulations provide that "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and

[123] *Id.* § 822(e)(1).

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

[125] *Id.* § 823(a)-(f).

[126] *Id.*

[127] 21 C.F.R. §§1301.13(c), (d).

[128] *Id.* § 1301.52.

[129] *Id.* § 1301.52(b).

[130] 21 U.S.C. § 827; 21 C.F.R. Part 1304.

[131] 21 U.S.C. § 828; 21 C.F.R. Part 1305.

[132] 21 U.S.C. § 828(c)(2).

[133] *Id.* § 828(c)(1).

[134] *Id.* § 832.

orders of unusual frequency."[135] That list is not exhaustive, however—orders may also be deemed 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.[136]

Inspections

The CSA permits the DEA Administrator to inspect the establishment of any registrant or applicant for registration.[137] DEA regulations express the intent of the agency "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."[138] Absent the consent of the registrant or special circumstances such as an imminent danger to health or safety, a warrant is required for inspection.[139] "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."[140] Issuance of a warrant requires probable cause.[141] 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.[142]

Security

The CSA's implementing regulations require all registrants to "provide effective controls and procedures to guard against theft and diversion of controlled substances."[143] The regulations establish specific physical security requirements, which vary depending on the type of registrant and the classification of the controlled substance at issue.[144] For example, nonpractitioners must store controlled substances in Schedules I and II in a safe, steel cabinet, or vault that meets certain specifications.[145] Nonpractitioners must further ensure that controlled substance storage areas are "accessible only to an absolute minimum number of specifically authorized employees."[146] Practitioners must store controlled substances "in a securely locked, substantially constructed cabinet."[147] In addition to those physical security requirements, practitioners subject to CSA registration 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

[135] 21 C.F.R. § 1304.74(b).

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

[137] 21 U.S.C. § 822(f).

[138] 21 C.F.R. §1316.13.

[139] 21 U.S.C. § 880(c).

[140] *Id.* § 880(d)(1).

[141] *Id.*

[142] *Id.* The CSA's definition of probable cause is conceptually distinct from what is required under the Fourth Amendment. *See* United States v. Schiffman, 572 F.2d 1137, 1139-40 (5th Cir. 1978).

[143] 21 C.F.R. § 1301.71.

[144] *Id.* §§ 1301.72-76.

[145] *Id.* § 1301.72(a).

[146] *Id.* § 1301.72(d).

[147] *Id.* §§ 1301.75(a), (b).

application for CSA registration denied, had a CSA registration revoked, or surrendered a CSA registration for cause.[148]

Quotas

To prevent the production of excess amounts of controlled substances, which may be prone to diversion, the CSA directs DEA to set production quotas for controlled substances in Schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine.[149] 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.[150] 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.[151]

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."[152]

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.[153] The Act does not mandate that Schedule V substances be distributed by prescription, but such substances may be dispensed only "for a medical purpose."[154] 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.[155]

Enforcement and Penalties

DEA is the federal agency primarily responsible for enforcing the CSA's registration requirements.[156] If a registrant contravenes the Act's registration requirements, DEA may take formal or informal administrative action including issuing warning letters, suspending or revoking an entity's registration, and imposing fines.[157]

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[148] *Id.* § 1301.76(a).

[149] 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.

[150] *Id.* §§ 826(b), (c).

[151] *Id.* § 826(i).

[152] *Id.* § 952. The Controlled Substances Import and Export Act also imposes controls on the exportation of controlled substances, but does not establish specific export quotas. *See id.* § 953.

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

[154] *Id.* § 829(c).

[155] *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).

[156] *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).

[157] *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,

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."[158] 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.[159] 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"[160] Those conditions are satisfied, for example, when a practitioner prescribes controlled substances outside the usual course of professional practice without a legitimate medical purpose in violation of state and federal controlled substances laws.[161]

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.[162] However, in the event of a knowing violation DEA, through 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.[163] 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, it may be punished by a fine of up to $500,000.[164]

Trafficking Provisions

In addition to the registration requirements outlined above, the CSA also contains provisions that define multiple offenses involving the production, distribution, and possession of controlled substances outside the legitimate confines of the registration system, that is, the Act's *trafficking*

1429-30 (11th Cir. 1984); *see also infra* "Trafficking Provisions."

[158] *Id.* § 824(a).

[159] *Id.* §§ 824(c), (d).

[160] *Id.* § 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 Bernstein, *The Drug Industry's Triumph over the DEA*, WASH. POST, Oct. 15, 2017.

[161] *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.

[162] 21 U.S.C. § 842(c)(1).

[163] *Id.* § 842(c)(2)(A).

[164] *Id.* § 842(c)(2)(D).

provisions.[165] 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.[166]

Prohibitions

The CSA's trafficking provisions make it illegal to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance," except as authorized under the Act.[167] They also make it unlawful "knowingly or intentionally to possess a controlled substance," unless the substance was obtained in a manner authorized by the CSA.[168] Penalties vary based on the type and amount of the controlled substance in question.[169] Other sections of the CSA define more specific offenses, such as distributing controlled substances at truck stops or rest areas,[170] at schools,[171] or to people under age 21;[172] endangering human life while manufacturing a controlled substance;[173] selling drug paraphernalia;[174] and engaging in a "continuing criminal enterprise"—that is, an ongoing, large-scale drug dealing operation.[175] An attempt or conspiracy to commit any offense defined under the Act also constitutes a crime.[176]

Enforcement and Penalties

DOJ enforces the CSA's trafficking provisions by bringing criminal charges against alleged violators.[177] 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.[178] 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."[179]

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

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[165] *See id.* §§ 841-865.

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

[167] *Id.* § 841(a)(1).

[168] *Id.* § 844(a).

[169] *See, e.g.*, *id.* §§ 841(b).

[170] *Id.* § 849.

[171] *Id.* § 860.

[172] *Id.* § 859.

[173] *Id.* § 858.

[174] *Id.* § 863.

[175] *Id.* § 848.

[176] *Id.* § 846.

[177] 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.

[178] 423 U.S. 122, 133 (1975).

[179] *Id.* at 124.

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 effect, he acted as a large-scale 'pusher' not as a physician."[180] Appellate courts have relied on *Moore* to uphold convictions of a pharmacist who signed thousands of prescriptions for sale through an online pharmacy,[181] 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," including prescribing one patient more than 20,000 pills in a single year.[182] 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 intent must be established with respect to the nature of the defendant's failure to abide by professional norms.[183]

For decades, DOJ has brought criminal trafficking charges against doctors and pharmacists who dispensed pharmaceutical controlled substances outside the usual course of professional practice.[184] 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.[185] Similarly, in July 2019, a federal grand jury indicted defendants including two former executives at the pharmaceutical distributor Miami-Luken, Inc. for conspiracy to violate the CSA's trafficking provisions.[186]

Violations of the CSA's trafficking provisions are criminal offenses that may give rise to large fines and significant jail 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

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

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

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

[183] 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").

[184] *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.

[185] *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.

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

prison.[187] Distribution of large quantities of certain drugs—including Schedule I controlled substances such as heroin and LSD and Schedule II controlled substances such as cocaine and methamphetamine—carries a prison sentence of 10 years to life and a fine of up to $10 million for an individual or a fine of up to $50 million for an organization.[188] Penalties increase for second or subsequent offenses, or if death or serious bodily injury results from the use of the controlled substance.[189] Compared with the CSA's registration provisions, prosecution under the Act's trafficking provisions generally entails greater potential liability—particularly for individual defendants—but also entails a more exacting burden of proof.[190]

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.[191] Companies and criminal organizations may be subject to federal charges under the Racketeer Influenced and Corrupt Organizations Act.[192] 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.[193]

Legal Considerations for the 116th 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; and the ability of researchers to conduct clinical research involving Schedule I controlled substances.

Opioid Crisis

One of the most salient current issues 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 drugs.[194] Some opioids have legitimate medical purposes, primarily related to pain

[187] 21 U.S.C. § 844(a).

[188] *Id.* § 841(b)(1)(A).

[189] *Id.* § 841(b).

[190] 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.

[191] 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.

[192] *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.

[193] See, e.g., National Prescription Opiate Litigation, No. 17-MD-2804 (N.D. Ohio Dec. 12, 2017); see also CRS Legal Sidebar LSB10226, *State and Local Governments Pursue Judicial Solutions to the Opioid Epidemic*, by Jennifer A. Staman.

[194] See CRS Report R44987, *The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions*, by Lisa N. Sacco and Erin Bagalman.

management, while others have no recognized medical use.[195] 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.[196] The CDC reports that overdoses on prescription and nonprescription opioids claimed a record 47,600 lives in 2017.[197] The CDC further estimates that the misuse of prescription opioids alone costs the United States $78.5 billion per year.[198]

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)[199] and the 21st Century Cures Act (Cures Act).[200] 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.[201] 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.[202] Key amendments to the CSA under the SUPPORT Act included provisions expanding access to medication-assisted treatment for opioid addiction,[203] specifying the factors for determining whether a controlled substance analogue is intended for human consumption,[204] revising the factors DEA considers when establishing opioid production quotas,[205] and codifying the definition of "suspicious order" and outlining the CSA's suspicious order reporting requirements.[206]

Notwithstanding the flurry of recent legal changes, many recent legislative proposals seek to further address the opioid crisis by amending the CSA.[207] For example, the DEA Enforcement

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[195] *Id.*

[196] *Id.*

[197] *See* Lawrence Scholl, et al., *Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017*, MORBIDITY AND MORTALITY WEEKLY REPORT (Jan. 4, 2019), https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm675152e1-H.pdf.

[198] *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).

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

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

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

[202] 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 Dabrowska.

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

[204] *Id.* § 3241.

[205] *Id.* § 3282.

[206] *Id.* §§ 3291-92.

[207] 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.*,

Authority Act of 2019[208] would revise the standard for "imminent danger" required to support an immediate suspension of DEA registration. Specifically, the bill would lower the threshold for what constitutes imminent danger, requiring "*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 that "*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."[209] In addition, the John S. McCain Opioid Addiction Prevention Act[210] would, as part of the CSA's registration regime, require 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.[211] The LABEL Opioids Act[212] would amend the CSA to require that opioids in Schedules I through V bear labels warning that they can cause dependence, addiction, and overdose. Failure to comply with the labeling requirements would violate the CSA's registration requirements.[213]

Some proposals target specific opioids, especially fentanyl. For instance, the Ending the Fentanyl Crisis Act of 2019[214] would amend the CSA to reduce the amounts of fentanyl required to constitute a trafficking offense. The Comprehensive Fentanyl Control Act,[215] introduced in the 115th Congress, would likewise have reduced the amount of fentanyl triggering criminal liability. That bill would have also increased penalties applicable to offenses involving fentanyl and provided separate procedures for emergency scheduling of synthetic opioids.[216] The Screening All Fentanyl-Enhanced Mail Act of 2019[217] seeks 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[218] would aim to gather information about the illicit production of illicit fentanyl in foreign countries and to withhold bilateral assistance from countries that fail to enforce certain controlled substance regulations.

Opioid Treatment Surge Act, S. 1662, 116th Cong. (2019); Budgeting for Opioid Addiction Treatment Act, S. 425, 116th Cong. (2019).

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

[209] *Compare id. with* 21 U.S.C. § 824(d)(2).

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

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

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

[213] *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).

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

[215] H.R. 1781, 115th Cong. (2017).

[216] 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." *Id.* For discussion of the current requirements for emergency scheduling, see *supra* "Emergency Scheduling."

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

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

Analogue Fentanyl

A related issue currently before Congress is the proliferation of synthetic drugs, especially synthetic opioids. Synthetic drugs are drugs that are chemically produced in a laboratory; they may have a chemical structure identical to or different from that of a natural drug.[219] Synthetic drugs are often intended to mimic or enhance the effects of natural drugs, but have chemical structures that have been slightly modified to circumvent existing drug laws.[220]

One particular concern in this area relates to synthetic opioids, including fentanyl analogues and other fentanyl-like substances. Fentanyl is a powerful opioid that has legitimate medical uses including pain management for cancer patients.[221] But, due to its potency, it also poses a particularly high risk of abuse, dependency, and overdose.[222] Prescription fentanyl is a Schedule II controlled substance; multiple nonpharmaceutical substances related to fentanyl are controlled in Schedule I.[223] However, experts have noted that it is relatively easy to manipulate the chemical structure of fentanyl in order to produce new substances that may have similar effects to fentanyl or pose other dangers if consumed but that are not included in the CSA's schedules.[224]

Since March 2011, DEA has used its emergency scheduling authority 23 times to impose temporary controls on 68 synthetic drugs, including 17 fentanyl-like substances.[225] Most recently, in February 2018, DEA issued an emergency scheduling order that applies broadly to all "fentanyl-related substances" that meet certain criteria related to their chemical structure.[226] Absent further action by DEA or Congress, the temporary scheduling order will expire in February 2020.[227]

Even if not individually scheduled on a temporary or permanent basis, fentanyl-related substances may still be subject to DEA control as controlled substance analogues.[228] However, to secure a conviction for an offense involving an analogue controlled substance, DOJ must, among other elements, prove beyond a reasonable doubt 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.[229] Thus, DOJ has stated that analogue controlled substance prosecutions can be burdensome because they raise "complex chemical and scientific

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

[220] *See id.*

[221] *See id.*

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

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

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

[225] *See* DOJ Testimony, *supra* note 35 at 2.

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

[227] *Id.* at 5188.

[228] *See supra* "Analogues and Listed Chemicals." On the other hand, 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. *See* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea.

[229] 21 U.S.C. §§ 802(32), 813; *see also* DOJ Testimony, *supra* note 35 at 5.

issues," and has argued that permanent scheduling of fentanyl analogues will reduce uncertainty and aid enforcement.[230]

Several proposals in the 116th Congress would seek to permanently schedule fentanyl analogues. For instance, the Stopping Overdoses of Fentanyl Analogues Act[231] would permanently add 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[232] would amend the CSA to add to Schedule I all "mu opioid receptor agonists" not otherwise scheduled, subject to certain exceptions.[233] One of the sponsors of the Modernizing Drug Enforcement Act has stated that the bill's aim is "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.[234]

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.[235] 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.[236] 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.[237] Alternatively, defining covered opioids based on their effects rather than their chemical structure could impose a heavy burden on prosecutors, similar to the burden they currently face when bringing analogue controlled substance charges.[238]

Marijuana Policy Gap

Another area raising 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.[239] As of June 2019, 11 states and the District of Columbia have passed laws removing

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

[231] H.R. 2935, 116th Cong. (2019); S. 1622, 116th Cong. (2019).

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

[233] 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).

[234] 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.

[235] 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).

[236] *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.

[237] *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).

[238] *See supra* note 229.

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

state prohibitions on medical and recreational marijuana use by adults age 21 or older.[240] An additional 35 states have passed laws permitting medical use of marijuana or CBD.[241] However, marijuana remains a Schedule I controlled substance under federal law, and state legislation decriminalizing marijuana has no effect on that status.[242]

Because of resource limitations, DOJ typically has 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."[243] Moreover, in each budget cycle since FY2014 Congress has passed an appropriations rider preventing 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."[244] The current appropriations rider is in effect through November 21, 2019.[245] 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.[246] However, activities that fall outside the scope of state medical marijuana laws remain subject to prosecution. For example, in *United States v. Evans*, the Ninth Circuit upheld the prosecution of medical marijuana growers who smoked some of the marijuana they grew because the defendants failed to show they were "qualifying patients" who acted in strict compliance with state medical marijuana law.[247]

Notwithstanding the appropriations rider, marijuana-related activity may still give rise to serious legal consequences under federal law. 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."[248] Furthermore, regardless

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[240] *See* NAT'L CONFERENCE OF STATE LEGISLATURES, STATE MEDICAL MARIJUANA LAWS (July 2, 2019), http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx.

[241] *Id.*

[242] *See, e.g.*, Gonzales v. Raich, 545 U.S. 1, 29 (2004). Notably, however, not all CBD is subject to the CSA. CBD may be derived either from marijuana or from hemp, and the 2018 Farm Bill exempted hemp from control under the CSA. *See* 21 U.S.C. § 802(16)(B)(i). Accordingly, CBD derived from hemp 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); s*ee 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) Products*, by Agata Dabrowska and Renée Johnson.

[243] 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).

[244] Pub. L. No. 116-6, div. C, sec. 537, 133 Stat. 138 (2019). 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.

[245] *See* Pub. L. No. 116-59, sec. 101(2) (continuing funding "under the authority and conditions" provided in Pub. L. No. 116-6, div. C); *id.*, sec. 106 (providing that the appropriations in Pub. L. No. 116-59 shall apply until November 21, 2019, or until the enactment of "the applicable appropriations Act for fiscal year 2020").

[246] *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).

[247] 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).

[248] Memorandum from Jefferson B. Sessions, Attorney Gen., U.S. Dep't of Justice, on Marijuana Enforcement to all

whether they are subject to criminal prosecution, participants in the cannabis industry may face numerous collateral consequences arising from the federal prohibition of marijuana because other federal laws impose noncriminal consequences based on criminal activity, including violations for the CSA. For example, cannabis businesses that are legal under state law may be unable to access banking services due to federal anti-money laundering laws,[249] and those businesses may be ineligible for certain federal tax deductions.[250] The involvement of income from a cannabis-related business may also prevent a bankruptcy court from approving a bankruptcy plan.[251] And participation in the cannabis industry, even if legal under state law, may have adverse immigration consequences.[252]

Numerous proposals currently before Congress aim to address issues related to the marijuana policy gap. Some proposals target 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)[253] would seek 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[254] would make certain loan programs of the Small Business Administration (SBA) available to cannabis-related businesses.[255]

Other proposals would seek to address the marijuana policy gap more broadly by attempting to mitigate any conflict between federal and state law. For example, the Strengthening the Tenth Amendment Through Entrusting States Act (STATES Act)[256] would amend the CSA to provide

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United States Attorneys (Jan. 4, 2018), https://www.justice.gov/opa/press-release/file/1022196/download.

[249] 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.

[250] *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.").

[251] 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).

[252] *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").

[253] H.R. 1595, 116th Cong. (2019); S. 1200, 116th Cong. (2019). The SAFE Banking Act passed the House on September 25, 2019.

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

[255] *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).

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

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 remove the risk of federal prosecution under the CSA for individuals and entities whose marijuana-related activities comply with state law, but the bill does 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[257] would both remove marijuana-related activities that comply with state law from the scope of the CSA and seek to address specific collateral consequences of such activity, including access to banking services, bankruptcy proceedings, and certain tax deductions. By contrast, the State Cannabis Commerce Act[258] would take an approach similar to the current DOJ appropriations rider with respect to all federal agencies: while it would not alter the scope of the CSA's restrictions on marijuana, the State Cannabis Commerce Act would prevent any 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.

Additional proposed legislation could address the marijuana policy gap by altering the status of marijuana under the CSA across the board. Some proposals would move marijuana from Schedule I to a less restrictive schedule.[259] Others would remove marijuana from the CSA's schedules completely.[260]

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.[261] As a 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.[262] In addition, Congress would not be precluded from regulating marijuana in other ways if it were to remove the drug from the ambit of the CSA. For instance, legislation has been introduced that would impose new federal regulations on marijuana akin to those applicable to alcohol and cigarettes.[263]

In addition, descheduling marijuana would not, standing alone, alter the status of the substance under the FD&C Act and, thus, would not bring the existing cannabis industry into compliance with federal law.[264] FDA has explained that it "treat[s] products containing cannabis or cannabis-

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

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

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

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

[261] *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 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).

[262] *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).

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

[264] *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; s*ee also* CRS In Focus IF11250, *FDA Regulation of*

derived compounds as [it does] any other FDA-regulated products," and 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."[265] FDA is currently engaged in "consideration of a framework for the lawful marketing of appropriate cannabis and cannabis-derived products under our existing authorities."[266] Congress could also pass legislation to alter FDA regulation of cannabis-based products. For example, the Legitimate Use of Medicinal Marihuana Act would provide 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.[267]

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, 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.[268] 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.[269] The two treaties are not self-executing,[270] meaning that they do not have the same status as judicially enforceable domestic law.[271] However, failure to abide by its treaty obligations could expose the United States to international legal consequences.[272]

Cannabidiol (CBD) Products, by Agata Dabrowska and Renée Johnson.

[265] *Id.*

[266] 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.

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

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

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

[270] 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.

[271] *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.

[272] *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

Research Access

Another significant legal issue before the 116th Congress is the effect of the CSA on researchers' ability to conduct clinical research involving Schedule I controlled substances, including marijuana. 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.[273] In addition, federal law generally prevents the use of federal funding for such research: a rider to the appropriations bill for FY2019 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."[274] 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.[275] With respect to clinical research involving marijuana specifically, currently there is one farm that legally produces marijuana for research purposes,[276] and researchers have complained that such marijuana is deficient in both quality and quantity.[277]

In 2015, Congress passed the Improving Regulatory Transparency for New Medical Therapies Act, which imposes deadlines on DEA to issue notice of each application to manufacture Schedule I substances for research and then act on the application.[278] In 2016, DEA stated that it planned to grant additional licenses to grow marijuana for research purposes; however, as of June 2019 no new licenses had been granted.[279] One applicant for a license petitioned the U.S. Court of Appeals for the D.C. Circuit (D.C. Circuit) for a writ of mandamus compelling DEA to issue notice of its application.[280] In July 2019, the D.C. Circuit ordered DEA to respond to the petition.[281] On August 27, 2019, DEA published a notice in the *Federal Register* (1) providing

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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].").

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

[274] Pub. L. No. 115-245 div. B, sec. 509, 132 Stat. 2981 (2018).

[275] *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.

[276] *See* Pet. for Writ of Mandamus at 13, *In re* Scottsdale Research Inst., No. 19-1120 (D.C. Cir. June 6, 2019) ("For almost 50 years, the only legal source of cannabis for research in the United States has been a single farm at the University of Mississippi.").

[277] *See, e.g.*, *id.* at 13-15; *see also* CRS Report R44782, *The Marijuana Policy Gap and the Path Forward*, coordinated by Lisa N. Sacco.

[278] 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].

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

[280] *See id.* at 4.

[281] Order, *In re* Scottsdale Research Inst., No. 19-1120 (D.C. Cir. July 29, 2019). The court's decision to order a response to a mandamus petition does not mean that the petitioner will necessarily prevail, but does indicate that the court does not consider the petition to be patently without merit. *See* D.C. CIRCUIT HANDBOOK OF PRACTICE AND INTERNAL PROCEDURES 18 (2018) ("If the panel finds [a mandamus] petition to be without merit, it may deny the petition without calling for an answer. Otherwise, the panel issues an order fixing a time within which an answer must

notice of the 33 applications it has received to manufacture Schedule I controlled substances for research purposes and (2) announcing the agency's intent to promulgate regulations governing the manufacture of marijuana for research purposes.[282] The next day, DEA filed a response to the mandamus petition in the D.C. Circuit, asserting that the petition was moot because DEA had issued the requested notice of application.[283] The petitioner disputes that the matter is moot and asks the court to retain jurisdiction "to ensure the agency acts with dispatch and processes [petitioner's] application promptly."[284] The court has yet to rule on the petition.

DEA's *Federal Register* notice stated that the agency intends to 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."[285] The notice further explained that DEA is engaged in an ongoing "policy review process to ensure that the [marijuana] growers program is consistent with applicable laws and treaties."[286] It remains to be seen how many applications DEA will grant and what new regulations will apply to the successful applicants.

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,[287] which was introduced before the recent developments in the D.C. Circuit and remains pending before Congress, would aim to increase the number of licenses to produce cannabis for research purposes, 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.[288] 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.[289]

be filed.").

[282] *See generally* DEA Notice.

[283] *See* Resp. to Pet. for Writ of Mandamus at 1, *In re* Scottsdale Research Inst., No. 19-1120 (D.C. Cir. Aug. 28, 2019).

[284] Reply at 2, *In re* Scottsdale Research Inst., No. 19-1120 (D.C. Cir. Sept. 11, 2019).

[285] DEA Notice at 44,921.

[286] *Id.*

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

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

[289] *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.").

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