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The Controlled Substances Act (CSA): A Legal Overview for the 119th Congress

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SUMMARY

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Joanna R. Lampe
Legislative Attorney

The Controlled Substances Act (CSA): A Legal Overview for the 119th Congress

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

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

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 or may undertake such rulemaking to alter or remove existing controls on a controlled substance. The agency may also place a substance under temporary control on an emergency basis if the substance poses an imminent hazard to public safety. In addition, DEA may designate a substance for control if required by the United States' international treaty obligations. In the alternative, Congress may place a substance under control or modify or remove controls by statute.

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

During the 117th and 118th Congresses, significant legal developments related to controlled substances regulation occurred via executive branch actions, court decisions, and enacted federal and state legislation. Some Members of Congress also introduced a number of proposals to amend the CSA in various ways. Recent years saw developments in marijuana law and policy, including a growing divergence between federal and state marijuana laws, a 2022 presidential grant of clemency for federal and D.C. marijuana possession offenses, and 2024 DEA rulemaking proceedings proposing to reschedule marijuana under the CSA. Some Members of the 118th Congress reintroduced legislation such as the MORE Act (H.R. 5601) and the Cannabis Administration and Opportunity Act (S. 4226), both of which would have removed marijuana from control under the CSA. Some Members also introduced other bills that would have addressed specific aspects of the divergence between federal and state marijuana law, including proposals seeking to facilitate clinical research involving marijuana and other Schedule I controlled substances. In addition, the 118th Congress confronted ongoing issues related to the opioid epidemic, including the regulation of the powerful opioid fentanyl and its analogues. Some Members of Congress also considered whether to impose controls on xylazine, an unscheduled veterinary sedative that is sometimes used by humans alone or in combination with controlled substances.

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Pharmaceutical drugs play a vital role in American public health. Surveys by the Centers for Disease Control and Prevention (CDC) between 2017 and 2020 estimated that nearly 50% of Americans had used one or more prescription drugs in the last 30 days.[1] However, both pharmaceutical and non-pharmaceutical drugs may also pose serious public health risks. The CDC reports that 105,007 Americans died of drug overdoses in 2023.[2] The Controlled Substances Act[3] (CSA or the Act) seeks to balance those competing considerations.[4] The CSA regulates *controlled substances*—pharmaceutical and non-pharmaceutical drugs and other substances that are deemed to pose a risk of abuse and dependence.[5] By establishing rules for the proper handling of controlled substances[6] and imposing penalties for any illicit production, distribution, or possession of such substances,[7] the Act seeks to protect the public 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 that may be relevant to the 119th Congress. The report first summarizes the history of the CSA and explains how the regulation of controlled substances under the CSA overlaps with other federal and state regulatory regimes.[9] It then outlines the five main categories of substances subject to the Act—known as *schedules*—and discusses how substances are added to the schedules.[10] The report next outlines the CSA's *registration requirements*, which govern the activities of individuals and entities that register with the government to receive authorization to handle pharmaceutical controlled substances,[11] before summarizing the CSA's criminal *trafficking provisions*, which apply to controlled-substance-related activities that are not authorized under the Act.[12] Finally, the report outlines select legal considerations for Congress related to the CSA, including the growing divergence between the

[1] *See* National Center for Health Statistics, *Therapeutic Drug Use*, CDC (Oct. 7, 2024), https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm.

[2] *See* Matthew F. Garnett, M.P.H., and Arialdi M. Miniño, M.P.H., *Drug Overdose Deaths in the United States, 2003-2023*, NCHS DATA BRIEF No. 522 (Dec. 2024).

[3] Controlled Substances Act, Pub. L. 91-513, tit. II, 84 Stat. 1242 (1970) (codified as amended at 21 U.S.C. §§ 801–904).

[4] *See id.* §§ 801(1), (2).

[5] *See id.* §§ 802(6), 811. The CSA adopts the definition of "drug" used in the Federal Food, Drug and Cosmetic Act (FD&C Act) of 1938, ch. 675, 52 Stat 1040. *See* 21 U.S.C. §§ 802(12), 321(g)(1) ("The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)."). The CSA does not apply exclusively to "drugs," providing more broadly for the control of any "drug or other substance" included in the CSA's schedules. 21 U.S.C. § 802(6). Substances subject to the CSA may include plants, such as marijuana or peyote, or chemicals not generally recognized as drugs. However, for the sake of simplicity, this report at times refers to "drugs" subject to the Act.

[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."

status of marijuana under federal and state law, legal limits on clinical research and medical use of certain controlled substances, and issues related to the opioid epidemic.[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 such as opium and coca leaves and their derivatives.[14] With the passage of the Harrison Narcotics Tax Act of 1914, Congress began in earnest to regulate the domestic trade in narcotic drugs.[15] The Harrison Act imposed federal oversight of the legal trade in narcotic drugs and imposed criminal penalties for illicit trafficking in narcotics.[16] Over the course of the 20th century, the list of drugs subject to federal control expanded beyond narcotic drugs to include marijuana, depressants, stimulants, and hallucinogens.[17]

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

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

To accomplish those two goals, the statute imposes two overlapping legal schemes. *Registration provisions* require individuals and entities working with controlled substances to register with the government, take steps to prevent diversion and misuse of controlled substances,[24] and report

[13] *See infra* "Legal Considerations for the 119th Congress."

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

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

[16] *Id.* 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, U.S. CONST. art. I, § 8, cl. 3. *See* Gonzales v. Raich, 545 U.S. 1, 15 (2004).

[19] *Id.* S*ee* 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, Pub. L. 91-513, tit. III, 84 Stat. 1285 (1970) (codified as amended at 21 U.S.C. §§ 951–971).

[21] *See* 21 U.S.C. §§ 811, 812.

[22] *Id.* § 801(1).

[23] *Id.* § 801(2).

[24] *Diversion* refers to the movement of controlled substances produced for legal uses from legitimate sources to unauthorized channels or users. *See Program Description*, DRUG ENFORCEMENT ADMINISTRATION (DEA), https://www.deadiversion.usdoj.gov/about-us.html (last visited Jan. 17, 2025).

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 generally must be identified for control (either individually or as a class) to fall within the scope of the Act.[27] For medical drugs, the CSA primarily applies to prescription drugs, not drugs available over the counter.[28] Moreover, the statute does not apply to all prescription drugs but rather to a subset of those drugs deemed to warrant additional controls.[29] As for non-pharmaceutical drugs, well-known recreational drugs such as 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 controlled substances, such as marijuana and fentanyl, are used for both medical and recreational purposes.[32] Some recreational drugs are not classified as federally controlled substances.[33] Alcohol and tobacco, which might otherwise qualify as drugs potentially warranting control under the CSA, are explicitly excluded from the scope of the Act,[34] as is hemp that meets certain statutory requirements.[35] It is possible for legitimate researchers and illicit drug manufacturers to formulate new drugs not listed in any of the Act's schedules. Even if those drugs are similar to existing controlled substances, they may fall outside the scope of the CSA unless they are classified as controlled substances.[36] In some cases, however, substances not specifically listed in the CSA's schedules may nonetheless be subject to CSA regulation as *controlled substance analogues*.[37]

[25] 21 U.S.C. §§ 821–832.

[26] *Id.* §§ 841–865.

[27] *Id.* § 811.

[28] *Id.* § 829; *see also infra* "Prescriptions." The U.S. Food and Drug Administration also regulates pharmaceutical drugs, including pharmaceutical controlled substances, under the FD&C Act. *See infra* "Federal Food, Drug, and Cosmetic Act."

[29] DEA has estimated that 10% to 11% of all drug prescriptions written in the United States are for controlled substances. *See* Dispensing of Controlled Substances to Residents at Long Term Care Facilities, 75 Fed. Reg. 37463, 37464 (June 29, 2010).

[30] Although cocaine is commonly considered a non-pharmaceutical 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) (2024); *see also infra* "Overview of Schedules."

[31] The full schedules are promulgated at 21 C.F.R. §§ 1308.11–.15.

[32] *See infra* "Federal and State Marijuana Regulation," and "Opioid Epidemic."

[33] For example, Salvia divinorum (an herb with hallucinogenic effects) and kratom (a tropical tree whose leaves may have either stimulant or sedative effects depending on dosage) are not subject to the CSA at this writing, although DEA has identified them as "drugs of concern." DEA, DRUGS OF ABUSE: A DEA RESOURCE GUIDE, 106–07 (2024).

[34] *See* 21 U.S.C. § 802(6).

[35] *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) (2024).

[36] *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 Amanda Liskamm, Director of Opioid Enforcement and Preventions Efforts, Office of the Deputy Attorney General, and Greg Cherundolo, Acting Chief of Operations, Drug Enforcement Administration, U.S. Dep't of Justice); *see also* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea (2016).

[37] *See infra* "Analogues and Listed Chemicals."

Other Regulatory Schemes

Federal Food, Drug, and Cosmetic Act

Many drugs classified as controlled substances subject to the CSA are also subject to other legal regimes. For example, all pharmaceutical drugs, including those subject to the Act, are subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act).[38] The U.S. Food and Drug Administration (FDA) is the agency primarily responsible for enforcing the FD&C Act, which, among other things, prohibits the "introduction or delivery for introduction into interstate commerce of any … drug … that is adulterated or misbranded."[39] 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."[40] Unlabeled drugs are considered to be misbranded,[41] as are prescription drugs that FDA has not approved, including imported drugs.[42] 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.[43]

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.[44] The FD&C Act, by contrast, is a consumer protection statute that seeks to protect consumers from obtaining unsafe or ineffective drugs (and other public health products) through commercial channels.[45] 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.

State Laws Addressing Controlled Substances

In addition to the federal CSA, each state has its own controlled substances laws. With respect to both pharmaceutical and non-pharmaceutical drugs, many drugs subject to the CSA are also subject to those state controlled substances laws.[46] Such state laws often mirror federal law, and they are relatively uniform across jurisdictions because almost all states have adopted a version of

[38] FD&C Act, ch. 675, 52 Stat 1040 (codified as amended at 21 U.S.C. §§ 301–99i).

[39] *Id.* § 331(a).

[40] *Id.* § 352.

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

[42] *See, e.g.*, *In re* Canadian Import Antitrust Litigation, 470 F.3d 785, 788–90 (8th Cir. 2006); United States v. Patwardhan, 422 Fed. App'x. 614, 616–17 (9th Cir. 2011). Misbranding also includes misrepresenting that a substance offered for sale is a brand-name drug. *See, e.g.*, United States v. Xin He, 405 Fed. App'x 220, 221 (9th Cir. 2010). The FD&C Act also contains a separate provision stating, "No person shall introduce or deliver for introduction into interstate commerce any new drug," unless the drug is approved under the FD&C Act. 21 U.S.C. § 355(a).

[43] 21 U.S.C. § 351.

[44] *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.").

[45] *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 (2018).

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

a model statute called the Uniform Controlled Substances Act (UCSA).[47] However, states are free to modify the UCSA, and have done so to varying extents.[48] Moreover, the model statute does not specify sentences for violations, so penalties for state controlled substance offenses vary widely.[49]

There is not a complete overlap between drugs subject to federal and state controlled substance laws for several reasons. First, states may elect to impose controls on substances that are not subject to the CSA.[50] For example, some states have controlled the fentanyl analogues benzylfentanyl and thenylfentanyl, but those substances are not currently scheduled under the CSA.[51] Likewise, some states have taken steps to control the veterinary sedative xylazine.[52] Second, states may wish to adopt federal scheduling decisions at the state level but lag behind federal regulators due to the need for a separate state scheduling process.[53] 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.[54]

States cannot alter federal law. When state and federal law conflict, the federal law controls.[55] 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*.[56] Any federal controls remain in effect and potentially enforceable in those states.[57]

[47] 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.").

[48] 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 (2023). 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* "Federal and State Marijuana Regulation"; *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).

[49] Braun, *supra* note 47, at 371; *see also* Kreit, *supra* note 46, at 628.

[50] Kreit, *supra* note 46, at 628.

[51] *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." Correction of Code of Federal Regulations: Removal of Temporary Listing of Benzylfentanyl and Thenylfentanyl as Controlled Substances, 75 Fed. Reg. 37300, 37300 (June 29, 2010) (codified at 21 C.F.R. § 1308 (2024)).

[52] *See, e.g.*, FLA. STAT. § 893.03 (2024); W.V. CODE § 60A-2-210 (2023). The 118th Congress also considered proposals to schedule xylazine, but at the time of publication the substance is not scheduled at the federal level. *See infra* "Xylazine."

[53] Kreit, *supra* note 46, at 629.

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

[55] 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").

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

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

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.[58] Drugs become subject to the CSA by being placed in one of five lists, referred to as *schedules*.[59] Either the administrator of the Drug Enforcement Administration (DEA)[60]—an agency within the Department of Justice (DOJ)—or Congress can place a substance in a schedule, move a controlled substance to a different schedule, or remove a controlled substance from a schedule.[61] As discussed below, scheduling decisions by Congress and DEA follow different procedures.[62]

Overview of Schedules

The CSA establishes five categories of controlled substances, referred to as Schedules I through V.[63] The schedule on which a controlled substance is placed determines the level of restriction imposed on its production, distribution, and possession, as well as the penalties applicable to any improper handling of the substance.[64] As **Figure 1** describes, when DEA places substances under control by regulation, the agency assigns each controlled substance to a schedule based on its medical utility and its potential for abuse and dependence.

[58] For further discussion of the obligations and penalties that the CSA imposes, see *infra* "Registration Requirements," and "Trafficking Provisions."

[59] 21 U.S.C. § 812.

[60] 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) (2024).

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

[62] *See id.*

[63] 21 U.S.C. § 812.

[64] *See, e.g.*, 21 U.S.C. §§ 823 (registration requirements), 829 (prescription requirements),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 (2024).

[4] 21 U.S.C. § 812(b)(2).

[5] The CSA distinguishes between fentanyl and non-pharmaceutical fentanyl analogues. Fentanyl and several related medications are in Schedule II. Numerous nonprescription fentanyl-related compounds 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.[65] Notably, because substances in Schedule I have no accepted medical use in the United States, it is only legal to produce, dispense, and possess those substances in the context of federally approved scientific studies.[66]

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."[67] A substance that meets those criteria *and* is intended for human consumption is treated as a controlled substance in Schedule I.[68] 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 because they have not been approved by FDA.

Listed chemicals subject to the CSA are chemicals that are generally not intended for human consumption but can be used to produce controlled substances either as precursor chemicals or as part of the manufacturing process.[69] 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.[70]
- **List II Chemicals**—designated chemicals that, in addition to legitimate uses, are used in manufacturing a controlled substance in violation of the CSA.[71]

List I chemicals include substances such as ephedrine, white phosphorous, and iodine, which are used to produce methamphetamine, as well as chemicals used to manufacture LSD, MDMA (also

[65] *See* John Doe, Inc. v. DEA, 484 F.3d 561, 563 (D.C. Cir. 2007).

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

[67] 21 U.S.C. § 802(32).

[68] *Id.* § 813(a).

[69] *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).

[70] 21 C.F.R. § 1300.02(b).

[71] *Id.* § 1300.02(b).

known as "ecstasy" or "molly"), and other drugs.[72] List II chemicals include, among others, solvents such as acetone, hydrochloric acid, and sulfuric acid.[73]

Listed chemicals are generally less stringently regulated than controlled substances, though they are subject to some controls similar to those that apply to controlled substances.[74] 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.[75]

There are a number of differences between how controlled substance analogues and listed chemicals are regulated. In addition, listed chemicals include only specific substances identified for control under the CSA by statute or rulemaking.[76] By contrast, controlled substance analogues need not be individually scheduled; they need only satisfy the statutory criteria.[77]

Scheduling Procedures

Substances may be placed under control (often called scheduling), reclassified to a different schedule (rescheduling), or removed from control (descheduling) through agency action or by legislation.[78] As described below, the procedures for modifying a substance's scheduling differ depending on whether Congress or DEA makes the change.

Legislative Scheduling

Perhaps the most straightforward way to change a substance's legal status under the CSA is for Congress to pass legislation. The procedural requirements for administrative scheduling discussed in the next section do not apply to legislative scheduling. This means that scheduling legislation does not need to incorporate scientific and medical findings and is not subject to the Administrative Procedure Act (APA).[79]

Congress placed a number of substances in each schedule when it enacted the CSA in 1970.[80] Since the CSA's enactment, Congress has at times passed legislation to schedule new controlled substances or modify existing controls.[81] Congress has sometimes used its legislative scheduling power to respond quickly to regulate drugs that pose an urgent concern. For example, the Synthetic Drug Abuse Prevention Act of 2012 permanently added two synthetic cathinones (central nervous system stimulants) and certain cannabimimetic substances (commonly referred to as synthetic marijuana) to Schedule I.[82] In 2020, Congress enacted the Temporary

[72] *Id.* § 1310.02(a).

[73] *Id.* § 1310.02(b).

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

[75] *Id.* § 830.

[76] 21 U.S.C. §§ 802(34), (35).

[77] *See, e.g.*, United States v. Hofstatter, 8 F.3d 316, 321–22 (6th Cir. 1993) (upholding against Fifth Amendment vagueness challenge the statutory criteria for controlled substance analogues).

[78] *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).

[79] Ch. 324, 60 Stat. 237 (1946) (as amended).

[80] Comprehensive Drug Abuse Prevention and Control Act, Pub. L. No. 91-513, 84 Stat. 1236 (1970).

[81] *See generally* CRS In Focus IF12709, *Legislative Scheduling of Controlled Substances*, by Joanna R. Lampe (2024).

[82] *See* Pub. L. No. 112-144, 126 Stat. 1130 (2012).

Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which placed a broad class of fentanyl analogues in Schedule I on a temporary basis.[83]

Administrative Scheduling

DEA makes scheduling decisions through a complex administrative process requiring participation by other agencies and the public.[84] 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."[85] 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."[86] Denial of a petition to initiate scheduling proceedings is subject to judicial review, but a court may overturn a denial only if it determines the denial is arbitrary and capricious.[87]

Before initiating rulemaking proceedings, DEA must request a scientific and medical evaluation of the substance at issue from the Secretary of HHS.[88] The HHS Secretary has delegated the authority to prepare the scientific and medical evaluation to FDA.[89] In preparing the evaluation, FDA considers a number of factors, including the substance's potential for abuse and dependence, scientific evidence of its pharmacological effect, the state of current scientific knowledge regarding the substance, any risk the substance poses to the public health, and whether the substance is an immediate precursor of an existing controlled substance.[90] Based on those factors, FDA makes a recommendation as to whether the substance should be controlled and, if so, in which schedule it should be placed.[91] FDA's scientific and medical findings are binding on DEA.[92] Furthermore, if FDA recommends against controlling a substance, DEA may not schedule it.[93] DEA has stated that it has "the final authority to schedule, reschedule, or deschedule a drug under the [CSA], after considering the relevant statutory and regulatory criteria and HHS's scientific and medical evaluation."[94]

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[83] Pub. L. 116-114, 134 Stat. 103 (2020). For further discussion of the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act and related legislation, see *infra* "Fentanyl Analogues."

[84] 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, see 28 C.F.R. § 0.100(b), but also retains the authority to undertake scheduling proceedings, see Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44601 (proposed May 21, 2024) (to be codified at 21 C.F.R. § 1308).

[85] 21 U.S.C. § 811(a).

[86] 21 C.F.R. § 1308.43.

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

[88] 21 U.S.C. § 811(b). DEA may also request a scientific and medical evaluation and subsequently deny a rescheduling petition. *See, e.g.*, Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688, 53688 (proposed Aug. 12, 2016).

[89] *See, e.g.*, Schedules of Controlled Substances: Placement of Solriamfetol in Schedule IV, 84 Fed. Reg. 27943, 27944 (June 17, 2019).

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

[91] *Id.* § 811(b).

[92] *Id.*

[93] *Id.*

[94] *See* Letter from Michael D. Miller, Acting Chief, Office of Congressional Affairs, DEA to Earl Blumenauer, U.S. Representative (Dec. 19, 2023), https://www.documentcloud.org/documents/24253753-dea-letter-to-blumenauer/.

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.[95] Before placing a substance on a schedule, the DEA administrator must make specific findings that the substance meets the applicable criteria related to accepted medical use and potential for abuse and dependence.[96] DEA scheduling decisions are subject to the requirements for formal rulemaking under the APA,[97] meaning that interested parties may submit comments and DEA must provide an opportunity for a hearing on the decision before it becomes final.[98]

The DEA administrator's decision whether to schedule, reschedule, or deschedule a substance through the ordinary administrative process is subject to judicial review.[99] Historically, such review has generally been deferential: Courts have accepted DEA's interpretation of the CSA as long as the interpretation of ambiguous statutory text is reasonable,[100] 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.[101] Overall, courts set aside DEA action "only if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'"[102] It is possible that the Supreme Court's 2024 decision in *Loper Bright Enterprises v. Raimondo*,[103] which eliminated judicial deference to reasonable agency interpretations of ambiguous statutes, will mean that future DEA scheduling decisions that rely on statutory interpretations will receive less deference from reviewing courts. *Loper Bright* will not alter the effect of statutory provisions that specifically govern judicial review of rulemaking under the CSA, however.[104]

Emergency Scheduling

Ordinary DEA scheduling decisions made through notice-and-comment rulemaking can take years to consider and finalize.[105] Recognizing that in some cases faster scheduling may be appropriate, Congress amended the CSA through the Comprehensive Crime Control Act of 1984[106] to allow the DEA administrator to place a substance in Schedule I temporarily when "necessary to avoid an imminent hazard to the public safety."[107] Before issuing a temporary

[95] *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.

[96] *Id.* § 812(b).

[97] 5 U.S.C. § ch. 5.

[98] 21 U.S.C. § 811(a); *see also* Touby v. United States, 500 U.S. 160, 162–63 (1991).

[99] *See* 21 U.S.C. § 877.

[100] *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)).

[101] 21 U.S.C. § 877.

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

[103] 603 U.S. 369 (2024).

[104] *Id.* For discussion of the Supreme Court's decision in *Loper Bright*, see CRS Report R48320, *Loper Bright Enterprises v. Raimondo and the Future of Agency Interpretations of Law*, by Benjamin M. Barczewski (2024).

[105] *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."). As an example of rescheduling proceedings that have moved relatively quickly, in October 2022, President Biden directed the Attorney General to review the status of marijuana under federal law. DOJ and DEA published a notice of proposed rulemaking in the Federal Register proposing to reschedule marijuana in May 2024. *See* Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44601 (proposed May 21, 2024). As of the publication date of this report, the agencies have not issued a final rule rescheduling marijuana and a public hearing on the issue remains pending.

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

[107] 21 U.S.C. § 811(h)(1).

scheduling order, the DEA administrator must provide 30 days' notice to the public and the Secretary of HHS stating the basis for temporary scheduling.[108] 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.[109] The DEA administrator must also consider any comments from the Secretary of HHS.[110]

Pursuant to amendments in the Synthetic Drug Abuse Prevention Act of 2012,[111] 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.[112] If DEA completes the permanent scheduling process for a substance while a temporary scheduling order is in effect, the temporary scheduling order is vacated.[113] The CSA provides that emergency scheduling orders are not subject to judicial review.[114]

DEA has recently used its emergency scheduling power to temporarily control a large class of analogues to the opioid fentanyl,[115] other synthetic opioids,[116] and several synthetic cannabinoids.[117]

International Treaty Obligations

The CSA outlines procedures for scheduling controlled substances based on the United States' treaty obligations. The United States is a party to the Single Convention on Narcotic Drugs of 1961, which was designed to establish controls on the international and domestic traffic in narcotics, coca leaf, cocaine, and marijuana.[118] The treaty requires signatories, among other things, to criminalize any "cultivation, production, manufacture, extraction, preparation, possession, offering, offering for sale, distribution, purchase, sale… importation and exportation of drugs" that are subject to the Convention, except to the extent the Convention authorizes such activities.[119]

[108] *Id.*

[109] *Id.* § 811(h)(3).

[110] *Id.* § 811(h)(4).

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

[112] 21 U.S.C. § 811(h)(2). As originally enacted, the Comprehensive Crime Control Act of 1984, Pub. L. No. 98-473, tit. II, 98 Stat. 1976, 2072, authorized temporary scheduling for up to one year, with a possible extension for up to six months if permanent scheduling proceedings were pending.

[113] 21 U.S.C. § 811(h)(5).

[114] *Id.* § 811(h)(6).

[115] *See* Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188 (Feb. 6, 2018); *see also infra* "Fentanyl Analogues."

[116] *See* Schedules of Controlled Substances: Temporary Placement of Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene in Schedule I, 87 Fed. Reg. 21556 (Apr. 12, 2022); Schedules of Controlled Substances: Extension of Temporary Placement of Butonitazene, Flunitazene, and Metodesnitazene in Schedule I of the Controlled Substances Act, 89 Fed. Reg. 25517 (Apr. 11, 2024).

[117] *See* 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. 15505 (Apr. 16, 2019).

[118] *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").

[119] *Id.* art. 36.

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.[120] 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.[121]

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."[122] 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.[123]

Registration Requirements

Once a substance is brought within the scope of the CSA through one of the scheduling processes discussed above, almost any person or organization that handles that substance, except for the end user, becomes subject to a comprehensive system of regulatory requirements.[124] The goal of the regulatory scheme is to create a "closed system" of distribution in which only authorized persons may handle controlled substances.[125] Central to the closed system of distribution is the requirement that individuals or entities that work with controlled substances register with DEA. Those covered entities, which include manufacturers, distributors, practitioners, and pharmacists,[126] are referred to as *registrants*.[127] DEA has described the movement of a pharmaceutical controlled substance from the manufacturer to the patient thus:

> [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.[128]

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.[129] Thus, the registration system aims to ensure

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

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

[122] 21 U.S.C. § 811(d)(1).

[123] *Id.*

[124] *See id.* § 822.

[125] Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16236, 16237 (Mar. 31, 2010).

[126] 21 U.S.C. § 822(a).

[127] 21 C.F.R. § 1300.02(b)(24).

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

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

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.[130]

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.[131] 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."[132] Ultimate users and other entities exempt from the CSA's registration provisions can still violate the Act's criminal trafficking provisions if they engage in unauthorized activities.[133]

Manufacturers and distributors of controlled substances, such as pharmaceutical companies, must register with DEA annually.[134] 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.[135] Registrations specify the extent to which registrants may manufacture, possess, distribute, or dispense controlled substances, and each registrant may engage only in the specific activities covered by its registration. In some instances, applicants must obtain more than one registration to comply with the CSA. For example, separate registrations are required for each principal place of business where controlled substances are manufactured, distributed, imported, exported, or dispensed.[136] Special registration is required for certain activities, including operating an opioid treatment program such as a methadone clinic.[137]

The CSA directs the DEA administrator to issue a registration if it would be consistent with the public interest, and the Act outlines the criteria the DEA administrator must consider when evaluating the public interest.[138] The criteria vary depending on (1) whether the applicant is a manufacturer, distributor, researcher, or practitioner and (2) the classification of the controlled substance(s) subject to 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.[139]

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[130] *See* Definition and Registration of Reverse Distributors, 70 Fed. Reg. 22591, 22591 (May 2, 2005).

[131] 21 U.S.C. § 822; 21 C.F.R. Part 1301. *See also* 21 U.S.C. § 957 (provision of the Controlled Substances Import and Export Act, Pub. L. 91-513, tit. III, 84 Stat. 1285 (1970) (codified as amended at 21 U.S.C. §§ 951–71), imposing registration requirements for importers and exporters of controlled substances).

[132] 21 U.S.C. § 822(c)(3). *See also id.* § 802(25) (defining "ultimate user" as a "person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household"). DEA has explained that ultimate users need not register because the controlled substances in their possession "are no longer part of the closed system of distribution and are no longer subject to DEA's system of corresponding accountability." Definition and Registration of Reverse Distributors, 68 Fed. Reg. 41222, 41226 (July 11, 2003). Some other exemptions are specified by statute, *see* 21 U.S.C. §§ 822(c)(1), (2); or by regulation, *see* 21 C.F.R. §§ 1301.22–.24.

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

[134] 21 U.S.C. § 822(a)(2).

[135] *Id.* § 822(a)(1).

[136] *Id.* § 822(e)(1).

[137] *Id.* § 823(g); *see also* CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*, by Johnathan H. Duff (2019).

[138] 21 U.S.C. § 823(a)–(f).

[139] *Id.*

The registration of an individual or organization expires at the end of the registration period unless it is renewed.[140] Registration also ends if revoked by DEA[141] or when the registrant dies, ceases legal existence, or discontinues business or professional practice.[142] A registration cannot be transferred to someone else without the express, written consent of the DEA administrator.[143]

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.[144] In addition, subject to limited exceptions, a controlled substance in Schedule I or II may only be distributed pursuant to a written order from the recipient of the substance.[145] Copies of each order form must be transmitted to DEA.[146] Records of orders must be preserved for two years and made available for government review upon request.[147] Many transactions involving controlled substances are tracked in the Automation of Reports and Consolidated Orders System (ARCOS), an automated drug reporting system maintained by DEA.[148]

Registrants are also required to "design and operate a system to identify suspicious orders" and to notify DEA of any suspicious orders they detect.[149] DEA regulations that apply to non-practitioners provide that "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[150] That list is not exhaustive. Courts have suggested that orders may be suspicious if, for example, a pharmacy mostly sells controlled substances rather than a more typical mix of controlled and non-controlled medications, many customers pay for controlled substances with cash, or pharmacies purchase drugs at a price higher than insurance would reimburse.[151] DEA initiated rulemaking on suspicious order reporting in 2020 but, as of January 2025, has not issued a final rule.[152] The agency issued a guidance document on suspicious order reporting in 2023 stating that DEA-

[140] 21 C.F.R. § 1301.13(c), (d).

[141] *Id.* § 1301.36. The fact that a registrant allows its registration to expire or otherwise terminate during the pendency of an enforcement action does not impact DEA's jurisdiction or prerogative under the CSA to adjudicate the action to finality. *See* Jeffrey D. Olsen, M.D.; Decision and Order, 84 Fed. Reg. 68474, 68476–68479 (Dec. 16, 2019). For additional discussion of revocation of registration, see *infra* "Enforcement and Penalties."

[142] 21 C.F.R. § 1301.52.

[143] *Id.* § 1301.52(b).

[144] 21 U.S.C. § 827; 21 C.F.R. Part 1304.

[145] 21 U.S.C. § 828; 21 C.F.R. Part 1305.

[146] 21 U.S.C. § 828(c)(2).

[147] *Id.* § 828(c)(1).

[148] DEA, *Automation of Reports and Consolidated Orders System (ARCOS)*, DOJ, https://www.deadiversion.usdoj.gov/arcos/arcos.html (last visited Jan. 13, 2025).

[149] *Id.* § 832.

[150] 21 C.F.R. § 1304.74(b).

[151] *See* Masters Pharmas. Inc. v. DEA, 861 F.3d 206, 220 (D.C. Cir. 2017). *Masters* concerned the alleged failure of a pharmaceutical distributor to report to DEA suspicious orders for controlled substances and to take other precautions to ensure that those medications would not be diverted into illegal channels. *See id.* at 211–12. Pharmacies themselves have a corresponding responsibility to ensure that they are filling legitimate prescriptions. *See* 21 C.F.R. § 1306.04(a).

[152] Suspicious Orders of Controlled Substances, 85 Fed. Reg. 69282 (proposed Nov. 2, 2020).

registered manufacturers or distributors are not required to set quantitative thresholds for orders of controlled substances.[153]

Inspections

The CSA permits the DEA administrator to inspect the establishment of any registrant or applicant for registration.[154] DEA regulations express the agency's intent "to inspect all manufacturers of controlled substances listed in Schedules I and II and distributors of controlled substances listed in Schedule I once each year," and other manufacturers and distributors of controlled substances "as circumstances may require."[155] Absent the consent of the registrant or special circumstances such as an imminent danger to health or safety, a warrant is required for inspection.[156] "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."[157] Issuance of a warrant requires probable cause.[158] 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.[159]

Security

The CSA's implementing regulations require all registrants to "provide effective controls and procedures to guard against theft and diversion of controlled substances."[160] The regulations establish specific physical security requirements, which vary depending on the type of registrant and the classification of the controlled substance at issue.[161] For example, practitioners[162] subject to CSA registration must store controlled substances "in a securely locked, substantially constructed cabinet."[163] In addition to those physical security requirements, practitioners may not "employ, as an agent or employee who has access to controlled substances," any person who has been convicted of a felony related to controlled substances, had an application for CSA registration denied, had a CSA registration revoked, or surrendered a CSA registration for cause.[164] Registered non-practitioners must store controlled substances in Schedules I and II in a

[153] DEA, DIVERSION CONTROL DIVISION, GUIDANCE DOCUMENT: DEA-REGISTERED MANUFACTURER AND DISTRIBUTOR ESTABLISHED CONTROLLED SUBSTANCE QUANTITATIVE THRESHOLDS AND THE REQUIREMENT TO REPORT SUSPICIOUS ORDERS (Jan. 20, 2023), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-065)(EO-DEA258)_Q_A_SOR_and_Thresholds_(Final).pdf.

[154] 21 U.S.C. § 822(f).

[155] 21 C.F.R. §1316.13.

[156] 21 U.S.C. § 880(c).

[157] *Id.* § 880(d)(1).

[158] *Id.*

[159] *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).

[160] 21 C.F.R. § 1301.71.

[161] *Id.* §§ 1301.72–76.

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

[163] 21 C.F.R. § 1301.75(a), (b). A securely locked closet or room may satisfy this requirement if sufficient to prevent theft or diversion. *See, e.g.*, Ajay S. Ahuja, M.D.; Decision and Order, 84 Fed. Reg. 5479, 5493–94 (Feb. 21, 2019).

[164] *Id.* § 1301.76(a).

safe, steel cabinet, or vault that meets certain specifications.[165] Non-practitioners must further ensure that controlled substance storage areas are "accessible only to an absolute minimum number of specifically authorized employees."[166]

Quotas

To prevent the production of excess amounts of controlled substances, which may increase the likelihood of diversion, the CSA directs DEA to set aggregate production quotas for controlled substances in Schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine.[167] 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.[168] 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.[169] DEA sets production quotas annually and can adjust the quotas for a calendar year based on changes in demand.[170]

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."[171]

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.[172] The Act does not mandate that Schedule V substances be distributed by prescription, but such substances may be dispensed only "for a medical purpose."[173] As a practical matter, Schedule V substances are usually dispensed pursuant to a prescription due to separate requirements under the FD&C Act or state law.[174] DEA regulations provide that a prescription for a controlled substance "must be

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[165] 21 C.F.R. § 1301.72(a).

[166] *Id.* § 1301.72(d).

[167] 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 controlled substances such as methamphetamine or amphetamine. *See* DEA, LISTED CHEMICALS REGULATED UNDER THE CONTROLLED SUBSTANCES ACT (Dec. 31, 2024), https://www.deadiversion.usdoj.gov/schedules/orangebook/j_chemlist_regulated.pdf.

[168] 21 U.S.C. § 826(b), (c).

[169] *Id.* § 826(i).

[170] *See* 21 C.F.R. § 1303.13. *See also, e.g.*, Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020, 84 Fed. Reg. 66014, (Dec. 2, 2019) (setting aggregate production quotas for 2020); Adjustments to Aggregate Production Quotas for Certain Schedule II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine and Pseudoephedrine for 2020, in Response to the Coronavirus Disease 2019 Public Health Emergency, 85 Fed. Reg. 20302 (Apr. 10, 2020) (adjusting aggregate production quotas for 2020 to meet increased need due to the COVID-19 pandemic).

[171] 21 U.S.C. § 952. The Controlled Substances Import and Export Act, Pub. L. 91-513, tit. III, 84 Stat. 1285 (1970), (codified as amended at 21 U.S.C. §§ 951–71), also imposes controls on the exportation of controlled substances, but does not establish specific export quotas. *See* 21 U.S.C. § 953.

[172] 21 U.S.C. § 829(a), (b). Substances in Schedule I may not be dispensed by prescription because they have no accepted medical use in treatment in the United States.

[173] *Id.* § 829(c).

[174] *Cf., e.g.*, GA. CODE § 16-13-29.2 (2023) (permitting the State Board of Pharmacy to allow the sale of Schedule V (continued...)

issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[175] Both practitioners who prescribe controlled substances and pharmacists who fill controlled substance prescriptions bear responsibility for ensuring compliance with the applicable requirements.[176]

Enforcement and Penalties

DEA is the federal agency primarily responsible for enforcing the CSA's registration requirements.[177] DEA may take formal or informal administrative action to enforce the registration requirements, including issuing warning letters, suspending or revoking an entity's registration, and imposing fines.[178] The DEA administrator's decisions related to CSA registrations are published in the *Federal Register*.[179]

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 materially falsified his application, has been convicted of certain felonies, does not have state authority to handle controlled substances, or has "committed such acts as would render his registration … inconsistent with the public interest."[180] 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.[181] 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."[182] To illustrate, those conditions may be satisfied when a practitioner prescribes controlled substances outside the usual course of professional practice, without a legitimate medical purpose, and

controlled substances without a prescription); FLA. STAT. § 893.08 (2024) (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).

[175] 21 C.F.R. § 1306.04(a).

[176] *Id.*

[177] *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, Pub. L. No. 91-513, 84 Stat. 1236).

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

[179] *See, e.g.*, Ajay S. Ahuja, M.D.; Decision and Order, 84 Fed. Reg. 5479, 5493–94 (Feb. 21, 2019).

[180] 21 U.S.C. §§ 823, 824(a).

[181] *Id.* § 824(c), (d). Enforcement actions based on imminent danger are not subject to these requirements, but DEA provides an administrative review process for any denial, suspension, or revocation of registration, and a registrant may seek judicial review of the agency's final decision under the Administrative Procedure Act, ch. 324, 60 Stat. 237 (1946) (as amended). *See, e.g.*, Volkman v. DEA, 567 F.3d 215, 219 (6th Cir. 2006).

[182] 21 U.S.C. § 824(d)(2). Congress added the opportunity to submit a corrective plan and the standard for determining whether an imminent danger to the public health or safety exists through the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, 130 Stat. 354 (2016). Those amendments made it more difficult for DEA to issue immediate suspensions. Previously, the CSA 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 CSA 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.

beneath the applicable standard of care in violation of state and federal controlled substances laws.[183]

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.[184] However, in the event of a knowing violation, DOJ may bring criminal charges against both individual and corporate registrants. Potential penalties vary depending on the offense. For example, a first criminal violation of the registration requirements by an individual is punishable by a fine or up to a year in prison.[185] If "a registered manufacturer or distributor of opioids" commits knowing violations such as failing to report suspicious orders for opioids or maintain effective controls against diversion of opioids, the registrant may be punished by a fine of up to $500,000 for each registration violation.[186]

Trafficking Provisions

In addition to the registration requirements outlined above, the CSA contains provisions that define offenses involving the production, distribution, and possession of controlled substances outside the legitimate confines of the registration system—what this report refers to as the Act's *trafficking provisions*.[187] Although the word "trafficking" may primarily call to mind the illegal distribution of recreational drugs, the CSA's trafficking provisions apply to a wide range of illicit activities involving either pharmaceutical or non-pharmaceutical controlled substances.[188]

Prohibitions

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

- **Manufacture** of a controlled substance,[189] which includes the synthesis of a controlled substance that is a chemical, the cultivation of a controlled substance that is a plant, or the processing or packaging of a controlled substance;[190]

[183] *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.

[184] 21 U.S.C. § 842(c)(1).

[185] *Id.* § 842(c)(2)(A).

[186] *Id.* § 842(c)(2)(D).

[187] *See id.* §§ 841–865.

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

[189] *Id.* § 841(a)(1).

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

- **Distribution** or **dispensing** of a controlled substance;[191]
- **Possession** of a controlled substance with or without intent to distribute.[192]

Penalties for the foregoing offenses vary based on the type and amount of the controlled substance in question.[193] Other sections of the CSA define more specific offenses, such as distributing controlled substances at truck stops or rest areas,[194] at schools,[195] or to people under age 21;[196] endangering human life while manufacturing a controlled substance;[197] selling drug paraphernalia;[198] and engaging in a "continuing criminal enterprise"—that is, an ongoing drug dealing operation that involves at least five other people and provides the defendant with substantial income or resources.[199] An attempt or conspiracy to commit any offense defined under the Act also constitutes a crime.[200]

Enforcement and Penalties

DOJ enforces the CSA's trafficking provisions by bringing criminal charges against alleged violators.[201] 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 the 1975 case *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 CSA.[202] The Court in *Moore* held that physicians registered under the CSA can be prosecuted under the CSA's general drug trafficking provisions "when their activities fall outside the usual course of professional practice."[203]

Numerous judicial opinions provide guidance on what sorts of conduct fall outside the usual course of professional practice. The defendant in *Moore* was a registered doctor who distributed large amounts of methadone with inadequate patient exams and no precautions against misuse or diversion. The Court held that "[t]he evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of 'professional practice'" because, "[i]n practical effect, he acted as a large-scale 'pusher'—not as a physician."[204] Appellate courts have relied on

[191] 21 U.S.C. § 841(a)(1). "Dispensing" refers to delivery of a controlled substance by a registered practitioner, including prescribing or administering a pharmaceutical controlled substance, while "distribution" refers to other delivery of a controlled substance. *Id.* § 802(10), (11).

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

[193] *See, e.g.*, *id.* § 841(b).

[194] *Id.* § 849.

[195] *Id.* § 860.

[196] *Id.* § 859.

[197] *Id.* § 858.

[198] *Id.* § 863.

[199] *Id.* § 848.

[200] *Id.* § 846.

[201] Trafficking that involves smuggling may also implicate the Controlled Substances Import and Export Act, Pub. L. 91-513, tit. III, 84 Stat. 1285 (1970) (codified as amended at 21 U.S.C. §§ 951–971), and/or the Maritime Drug Law Enforcement Act, Pub L. No. 96-350, 94 Stat. 1159 (1980) (codified as amended at 46 U.S.C. §§ 70501–70508).

[202] 423 U.S. 122, 133 (1975).

[203] *Id.* at 124.

[204] *Id.* at 142–43.

Moore to uphold convictions of a pharmacist who signed thousands of prescriptions for sale through an online pharmacy[205] 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."[206] However, several courts cautioned that a conviction under *Moore* requires more than a showing of mere professional malpractice. For instance, the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) has held that the prosecution must prove that the defendant "acted with intent to distribute the drugs *and with intent to distribute them outside the course of professional practice*," suggesting that specific intent must be established with respect to the defendant's failure to abide by professional norms.[207]

In the 2022 case *Ruan v. United States*, the Supreme Court clarified the mental state required to convict a medical practitioner for violation of the CSA's trafficking provisions.[208] The Court held that, "[a]fter a defendant produces evidence that he or she was authorized to dispense controlled substances"—that is, that he or she was registered to do so under the CSA—"the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so."[209] This means that the government must show that a CSA registrant knowingly or intentionally dispensed a controlled substance not for a legitimate medical purpose or in a manner that was not in the usual course of professional practice.[210]

For decades, DOJ has brought criminal trafficking charges against practitioners who dispensed pharmaceutical controlled substances outside the usual course of professional practice, without a legitimate medical purpose, and beneath the applicable standard of care.[211] In April 2019, DOJ for the first time brought criminal trafficking charges against a pharmaceutical company that distributed controlled substances—Rochester Drug Cooperative—and two of its executives based on the company's sale of the opioids oxycodone and fentanyl to pharmacies that illegally dispensed the drugs.[212] Similarly, in July 2019, a federal grand jury indicted two former

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

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

[207] 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").

[208] 597 U.S. 450 (2022).

[209] *Id.* at 454.

[210] *Id.* at 466–67.

[211] *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.

[212] *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 (2019). In 2022, a federal jury convicted the company's former CEO of conspiring to distribute unlawfully oxycodone and fentanyl and conspiring to defraud DEA. Press Release, DOJ, (continued...)

executives at the pharmaceutical distributor Miami-Luken, Inc., among others, for conspiracy to violate the CSA's trafficking provisions.[213]

Violations of the CSA's trafficking provisions are criminal offenses that may give rise to large fines and significant prison time. Penalties vary according to the offense and may further vary based on the type and amount of the controlled substance at issue. Unauthorized simple possession of a controlled substance may prompt a minimum fine of $1,000 and a term of up to a year in prison.[214] Distribution of large quantities of certain drugs—including specific Schedule I controlled substances such as heroin and LSD and specific Schedule II controlled substances such as cocaine and methamphetamine—carries a prison sentence of 10 years to life and a fine of up to $10 million for an individual or a fine of up to $50 million for an organization.[215] Penalties increase for second or subsequent offenses, or if death or serious bodily injury results from the use of the controlled substance.[216] Compared with the civil penalties available for violations of the CSA's registration provisions, the Act's criminal trafficking provisions generally entail greater potential liability—particularly for individual defendants—but also require prosecutors to show that a violation was intentional.[217]

The CSA is not the only means to target misconduct related to the distribution of pharmaceutical and non-pharmaceutical 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.[218] Companies and individuals may also be subject to federal criminal charges under the Racketeer Influenced and Corrupt Organizations Act[219] or the Federal Anti-Kickback Statute.[220] Those statutes notably formed part of the basis for the significant settlement between DOJ and opioid manufacturer Purdue Pharma

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Laurence Doud, Former CEO of Pharmaceutical Distributor, Convicted of Conspiring to Distribute Controlled Substances and Defrauding the DEA (Feb. 2, 2022), https://www.justice.gov/usao-sdny/pr/laurence-doud-former-ceo-pharmaceutical-distributor-convicted-conspiring-distribute.

[213] *See* Indictment, United States v. Rattini, No. 19-cr-00081 (S.D. Ohio July 17, 2019). DOJ dropped the charges against Miami-Luken and its executives following the Supreme Court's decision in *Ruan*. *See* Order Granting Mot. Dismiss, United States v. Rattini, No. 19-cr-00081 (S.D. Ohio Aug. 11, 2022).

[214] 21 U.S.C. § 844(a).

[215] *Id.* § 841(b)(1)(A).

[216] *Id.* § 841(b).

[217] A civil violation of the CSA's recordkeeping and reporting requirements requires only a showing of negligence. *See* 21 U.S.C. § 842(a)(5). A violation of § 842 may be a crime punishable by a fine and not more than a year in prison if "prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed." *Id.* § 842(c)(2)(A). 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.

[218] *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 (2018).

[219] Racketeer Influenced and Corrupt Organizations Act (RICO), Pub. L. No. 90-452, tit. IX, § 901(a), 84 Stat. 941. *See, e.g.*, Press Release, DOJ, Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering (Oct. 26, 2017), https://www.justice.gov/opa/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering; Gabrielle Emmanuel and Katie Thomas, *Opioid Company Executives Convicted of Racketeering*, N.Y. TIMES, May 3, 2019, at B1.

[220] *See, e.g.*, Press Release, DOJ, Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family (Oct. 21, 2020), https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid.

in 2020.[221] And manufacturers and distributors of opioids have faced numerous civil suits under federal and state law based on the companies' marketing and distribution of prescription opioids.[222]

Legal Considerations for the 119th Congress

Controlled substances regulation has received significant attention from Congress in recent years. Policymakers have confronted a growing divergence between the status of marijuana under state and federal law and considered whether and how to facilitate clinical research involving Schedule I controlled substances. In addition, the opioid epidemic and various federal, state, and local efforts to respond to the crisis have raised a number of legal and policy questions, including how to regulate synthetic opioids related to fentanyl and whether to control xylazine, a veterinary drug that is sometimes misused by humans either alone or in combination with opioids.

Federal and State Marijuana Regulation

One topic that raised a number of legal considerations for the 118th Congress is the increasing divergence between federal and state marijuana regulation.[223] The CDC reports that as of February 2024, 24 states, three territories, and the District of Columbia have passed laws removing prohibitions on medical and recreational marijuana use by adults age 21 or older.[224] Thirty-eight states, three territories, and D.C. have passed laws permitting medical use of marijuana; another nine states authorize medical use of cannabis derivatives, such as cannabidiol (CBD), that contain low levels of tetrahydrocannabinol (THC).[225] However, marijuana is a Schedule I controlled substance under federal law, and state marijuana legislation has no effect on that status.[226]

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[221] *See id.* DOJ, PLEA AGREEMENT WITH PURDUE PHARMA L.P. (Oct. 20, 2020), https://www.justice.gov/opa/press-release/file/1329576/dl (Purdue Pharma LP pled guilty to violating the Federal Anti-Kickback Statute and conspiracy to defraud the United States); *see* DOJ, PURDUE PHARMA L.P. SETTLEMENT AGREEMENT (Oct 21, 2020), https://www.justice.gov/opa/press-release/file/1329571/dl, and DOJ, SACKLER SETTLEMENT AGREEMENT (Oct 21, 2020), https://www.justice.gov/opa/press-release/file/1329736/dl (the company and its shareholders also settled civil claims brought by the United States).

[222] *See, e.g.*, National Prescription Opiate Litigation, No. 17-MD-2804 (N.D. Ohio Dec. 12, 2017); *see also* CRS Legal Sidebar LSB10365, *Overview of the Opioid Litigation and Related Settlements and Settlement Proposals*, by Wen W. Shen (2019); CRS Legal Sidebar LSB10226, *State and Local Governments Pursue Judicial Solutions to the Opioid Epidemic*, by Jennifer A. Staman (2018).

[223] *See generally* CRS Report R44782, *The Evolution of Marijuana as a Controlled Substance and the Federal-State Policy Gap*, coordinated by Lisa N. Sacco (2022).

[224] *See* CDC, *State Medical Cannabis Laws* (Feb. 16, 2024), https://www.cdc.gov/cannabis/about/state-medical-cannabis-laws.html.

[225] *Id.* The Commonwealth of the Northern Mariana Islands has generally legalized marijuana regardless of whether it is for medical or recreational use and does not have a regulatory program specific to medical marijuana. The CDC therefore does not include the Northern Marianas in its list of jurisdictions that have legalized medical marijuana. *Id.*

[226] *See, e.g.*, Gonzales v. Raich, 545 U.S. 1, 29 (2004). *See also* CRS Legal Sidebar LSB10482, *State Marijuana "Legalization" and Federal Drug Law: A Brief Overview for Congress*, by Joanna R. Lampe (2024). Notably, however, CBD is not subject to the CSA. The 2018 Farm Bill exempted "hemp"—cannabis and cannabis derivatives containing very low levels of THC—from control under the CSA. *See* 21 U.S.C. § 802(16)(B)(i). Accordingly, CBD products that meet those requirements are 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), https://www.fda.gov/news-events/press-
(continued...)

As discussed below, certain legal and practical considerations limit federal prosecutions of individuals and businesses involved in the state-legal marijuana industry.[227] However, regardless of whether they are subject to criminal prosecution, marijuana users and participants in the state-legal marijuana industry may face collateral consequences arising from the federal prohibition of marijuana. Various federal laws impose legal consequences based on criminal activity, including violations of the CSA. For example, even if authorized under state law, marijuana businesses may be unable to access banking services due to federal anti-money laundering laws,[228] and those businesses may be ineligible for certain federal tax deductions.[229] The involvement of income from a marijuana-related business may also prevent a bankruptcy court from approving a bankruptcy plan.[230] For individuals, some CSA violations involving marijuana may have adverse immigration consequences.[231] Illicit drug use or convictions may limit individuals' eligibility for federal student financial aid and other benefits.[232] Federal law prohibits the possession of firearms or ammunition by any person who is "an unlawful user of or addicted to any controlled

announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys; 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) Consumer Products*, by Agata Bodie and Renée Johnson (2020).

[227] *See infra* "Appropriations Limitations."

[228] 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 (2017). For further discussion of banking law issues related to the marijuana policy gap, see the "Federal Financial Laws and Financial Services for Marijuana Businesses" section of CRS Report R44782, *The Evolution of Marijuana as a Controlled Substance and the Federal-State Policy Gap*, coordinated by Lisa N. Sacco (2022).

[229] *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."). *See generally* CRS Report R46709, *The Application of Internal Revenue Code Section 280E to Marijuana Businesses: Selected Legal Issues*, by Milan N. Ball (2021).

[230] 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); *In re* Basrah Custom Design, Inc., 600 B.R. 368 (Bankr. E.D. Mich. 2019) (dismissing bankruptcy case where the court determined that the debtor sought "to enable its owner to profit from a marijuana business" that violated the CSA).

[231] *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) (2024) ("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").

[232] *See* CRS Legal Sidebar LSB10556, *The MORE Act: House Plans Historic Vote on Federal Marijuana Legalization*, by Joanna R. Lampe (2020); CRS Report R42394, *Drug Testing and Crime-Related Restrictions in TANF, SNAP, and Housing Assistance*, by Maggie McCarty et al. (2016).

substance."[233] Furthermore, people who use marijuana, even for medical purposes, generally enjoy little or no legal protection from adverse employment consequences.[234]

Federal laws other than the CSA may limit states' discretion in enacting marijuana laws. For instance, some provisions of state medical marijuana laws have been challenged under the Constitution's Dormant Commerce Clause, which prohibits states from enacting laws that discriminate against or unduly burden interstate commerce.[235]

Appropriations Limitations

Congress has addressed the divergence between federal and state marijuana law in part by limiting enforcement of the CSA against certain state-legal activities related to medical marijuana. In each budget cycle since FY2015, Congress has passed an appropriations rider prohibiting DOJ from using taxpayer funds to prevent the states from "implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana."[236] The current appropriations rider is in effect through March 14, 2025.[237]

On its face, the appropriations rider bars DOJ from taking legal action against the states directly to prevent them from promulgating or enforcing medical marijuana laws. In addition, federal courts have held that the rider prohibits certain federal prosecutions of private individuals or organizations that produce, distribute, or possess marijuana in accordance with state medical marijuana laws. Criminal defendants have invoked the rider before trial, seeking either the dismissal of their indictments or injunctions barring prosecution.[238]

Following a decision of the Ninth Circuit in the 2016 case *United States v. McIntosh*, several federal courts have interpreted the appropriations rider to bar DOJ from expending any appropriated funds to prosecute activities involving medical marijuana that are conducted in "strict compliance" with state law.[239] For example, in one 2019 case, the Ninth Circuit upheld the prosecution of two individuals involved in the production of medical marijuana who smoked

[233] 18 U.S.C. § 922.

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

[235] *Compare* Northeast Patients Grp. v. United Cannabis Patients and Caregivers of Maine, 45 F.4th 542 (1st Cir. 2022) (holding that the Maine Medical Marijuana Act's residency requirement violates the dormant Commerce Clause) *with* Jensen v. Md. Cannabis Admin., 719 F. Supp. 3d 466 (D. Md. 2024) ("join[ing] with those courts across the country that have found that the dormant Commerce Clause does not apply to state recreational cannabis laws"). *See also* Cong. Rsch. Serv., *Overview of Dormant Commerce Clause*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S8-C3-7-1/ALDE_00013307/ (last visited Jan. 13, 2025).

[236] Consolidated Appropriations Act, 2024, Pub. L. No. 118-42, div. C, § 531, 138 Stat. 25, 174 (2024). The appropriations rider is sometimes known as the "Rohrabacher-Farr Amendment" or the "Rohrabacher-Blumenauer Amendment." *See, e.g.*, United States v. Sirois, 119 F. 4th 143, 146 & n.1. The rider enumerates the specific states and territories to which it applies. The list excludes the three states that have not decriminalized medical marijuana use.

[237] American Relief Act, 2025, Pub. L. 118-158, div. A, § 101 (Dec. 21, 2024).

[238] By contrast, courts have generally declined to apply the rider outside the context of initial criminal prosecutions. For instance, the Ninth Circuit has held that the provision does not "impact[ ] the ability of a federal district court to restrict the use of medical marijuana as a condition of probation." United States v. Nixon, 839 F.3d 885, 886 (2016). In a 2024 decision, the U.S. Court of Appeals for the Eighth Circuit assumed that the rider might bar revocation of supervised release in some circumstances, but held that it did not apply to the case at bar because the challenger "engaged in unlawful conduct, even under Iowa's medical-marijuana regime." United States v. Doolin, 93 F.4th 1094, 1096 (2024).

[239] United States v. McIntosh, 833 F.3d 1163, 1178 (9th Cir. 2016); *see also* Duval v. United States, 372 F. Supp. 3d 544, 555–56 (E.D. Mich. 2019); Sandusky v. Goetz, No. 18-CV-01436-GPG, 2018 WL 6505803, at *4–5 (D. Colo. Dec. 11, 2018), rev'd and remanded, 944 F.3d 1240 (10th Cir. 2019); U.S. v. Jackson, 388 F. Supp. 3d 505, 506–08 (E.D. Pa. 2019).

marijuana as they processed plants for sale.[240] Although state law permitted medical marijuana use by "qualifying patients," the court concluded that the defendants failed to show they were qualifying patients, and thus they could be prosecuted because their personal marijuana use did not strictly comply with state medical marijuana law.[241]

More recently, in the 2022 case *United States v. Bilodeau*, the U.S Court of Appeals for the First Circuit (First Circuit) declined to follow the Ninth Circuit and held that the rider also bars prosecution in some cases where defendants did not strictly comply with state medical marijuana law.[242] The First Circuit noted that the text of the rider does not explicitly require strict compliance with state law and that, given the complexity of state marijuana regulations, "the potential for technical noncompliance [with state law] is real enough that no person through any reasonable effort could always assure strict compliance."[243] Thus, the First Circuit concluded that requiring strict compliance with state law would likely chill state-legal medical marijuana activities and prevent the states from giving effect to their medical marijuana laws.[244] However, the court also rejected the defendants' argument that the rider "must be read to preclude the DOJ, under most circumstances, from prosecuting persons who possess state licenses to partake in medical marijuana activity."[245] Ultimately, the First Circuit held that the rider bars CSA prosecution in at least some cases where the defendant has committed minor technical violations of state medical marijuana laws, but it declined to "fully define [the] precise boundaries" of its alternative standard.[246]

In November 2024, the First Circuit issued another decision applying the medical marijuana appropriations rider. In *United States v. Sirois*, two criminal defendants argued that the rider should bar their prosecutions because they were in "substantial compliance" with state medical marijuana law.[247] The government did not contest the substantial compliance standard.[248] Applying that standard, the court held that the prosecutions could go forward because the defendants failed to show by a preponderance of the evidence that they were in substantial compliance with state law.[249]

It remains to be seen whether and how the differences in reasoning between the Ninth Circuit and the First Circuit will make a practical difference in federal marijuana prosecutions.[250] Congress

[240] United States v. Evans, 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).

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

[242] 24 F.4th 705 (2022).

[243] *Id.* at 713.

[244] *Id.* at 713–14.

[245] *Id.* at 714.

[246] *Id.* at 715. On the record before it, the court concluded that "the defendants' cultivation, possession, and distribution of marijuana aimed at supplying persons whom no defendant ever thought were qualifying patients under Maine law" and that a CSA conviction in those circumstances would not "prevent Maine's medical marijuana laws from having their intended practical effect." *Id.*

[247] 119 F.4th 143, 152 (1st Cir. 2024).

[248] *Id.*

[249] *Id.* at 153.

[250] In theory, the First Circuit's analysis could make it easier for defendants to invoke the appropriations rider to bar federal prosecutions, because they could do so even if they had not been in strict compliance with state law. In practice, however, resource limitations and enforcement priorities have historically meant that federal marijuana prosecutions (continued...)

has the power to enact legislation adopting its preferred interpretation of the rider or otherwise clarifying its scope. Congress could also expand the scope of the rider to bar prosecution of other state-legal activities involving marijuana[251] or limit or repeal the rider.

Executive Branch Policy and Simple Possession Pardon

Notwithstanding the appropriations rider, activities that fall outside the scope of state medical marijuana laws remain potentially subject to federal prosecution. This includes all state-legal activities involving recreational marijuana. As a practical matter, 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."[252] 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."[253] In recent years, DOJ has pursued marijuana prosecutions in the context of large-scale trafficking operations or gang-related activity.[254] The Biden Administration DOJ did not issue formal guidance on marijuana policy, but Attorney General Merrick Garland indicated that the agency would not prioritize prosecuting individuals for personal use of marijuana.[255]

On October 6, 2022, President Biden issued a proclamation granting "a full, complete, and unconditional pardon" to "all current United States citizens and lawful permanent residents" who had committed or been convicted of simple possession of marijuana under the CSA or a related provision of the D.C. Code.[256] On December 22, 2023, President Biden issued an additional pardon to all current U.S. citizens and lawful permanent residents who had committed or been

target individuals and organizations that clearly have not complied with state medical marijuana law. Thus, one of the First Circuit judges who considered *Bilodeau* agreed with the panel's interpretation of the rider but wrote a concurrence noting that, in practice, the First Circuit's standard might not be "materially different from the one that the Ninth Circuit applied." *Bilodeau*, 24 F.4th at 718 (Barron, J., concurring).

[251] *See, e.g.*, State Cannabis Commerce Act, H.R. 3546, 116th Cong. (2019); State Cannabis Commerce Act, S. 2030, 116th Cong. (2019); *cf.* STATES 2.0 Act, H.R. 6673, 118th Cong. (2023) (would have amended the CSA so that, subject to certain exceptions, it "shall not apply" to marijuana-related activities that comply with state law); STATES Act, H.R. 2093, 116th Cong. (2019); STATES Act, S. 1028, 116th Cong. (2019).

[252] U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-1, STATE MARIJUANA LEGALIZATION: DOJ SHOULD DOCUMENT ITS APPROACH TO MONITORING THE EFFECTS OF LEGALIZATION 9 (2015).

[253] Memorandum from Jefferson B. Sessions, Attorney Gen., U.S. DOJ, to all U.S. Attorneys, on Marijuana Enforcement (Jan. 4, 2018), https://www.justice.gov/opa/press-release/file/1022196/download.

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

[255] *See, e.g.*, A Review of the President's Fiscal Year 2023 Funding Request for the U.S. Department of Justice: *Hearing Before the Sen. Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies*, 117th Cong. (2022) (testimony of Att'y. Gen. Merrick B. Garland) ("I think I laid this out actually also in my confirmation hearing and my view hasn't really changed since then, and that is that the Justice Department has almost never prosecuted use of marijuana and that's not an efficient use of the resources given the opioid and methamphetamine epidemic that we have.").

[256] Proclamation No. 10467, 87 Fed. Reg. 61441 (Oct. 6, 2022).

convicted of "the offense of simple possession of marijuana, attempted simple possession of marijuana, or use of marijuana" under the CSA, the D.C. Code, or related federal regulations.[257]

President Biden's invocations of the clemency power mean that people who committed simple possession or use of marijuana or attempted to commit those offenses before the issuance of the proclamations may not be prosecuted or punished for the offenses under the relevant provisions of the CSA or the D.C. Code.[258]

Several factors limit the scope of the pardons. First, they apply only to violations of federal and D.C. law and do not affect other state law marijuana offenses, because the President has no direct power to change state law or compel the states to adopt federal policies.[259] Second, the pardons apply only to simple possession of marijuana and related low-level offenses, which the federal government rarely prosecutes.[260] They do not apply to other marijuana-related CSA offenses such as manufacture, distribution, or possession with intent to distribute or to other federal crimes.[261]

Third, the pardons by their terms do not apply to "individuals who were non-citizens not lawfully present in the United States at the time of their offense."[262] Fourth, the pardons apply only to

[257] Proclamation No. 10688, 88 Fed. Reg 90083 (Dec. 28, 2023). On January 17, 2025, President Biden commuted the sentences of nearly 2,500 individuals who had been convicted of non-violent drug offenses. That grant of clemency was not limited to marijuana offenders and applied to "individuals who received lengthy sentences based on discredited distinctions between crack and powder cocaine, as well as outdated sentencing enhancements for drug crimes." Statement from President Joe Biden on Additional Clemency Actions (Jan. 17, 2025), https://www.whitehouse.gov/briefing-room/statements-releases/2025/01/17/statement-from-president-joe-biden-on-additional-clemency-actions/.

[258] Although the District of Columbia has its own criminal code, its criminal justice system has some overlap with the federal system and is subject to the President's clemency power. For additional information on the President's clemency power, see CRS Report R46179, *Presidential Pardons: Overview and Selected Legal Issues*, by Michael A. Foster (2020).

[259] *See id*. "Constraints on the Pardon Power." In announcing the pardon, President Biden also encouraged state governors to grant clemency for state offenses. While some governors have taken such steps or expressed willingness to do so, in some states, governors cannot independently grant clemency. *See, e.g.*, David Montgomery, *Governors Split on Biden's Call to Pardon Low-Level Pot Offenders*, PEW (Oct. 28, 2022), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/10/28/governors-split-on-bidens-call-to-pardon-low-level-pot-offenders. The pardon also does not apply to offenses under the Uniform Code of Military Justice. *See, e.g.*, Michael Lee, *Biden's Pardon of Marijuana Offenses Won't Apply to Military*, FOX NEWS (Oct. 9, 2022), https://www.foxnews.com/politics/bidens-pardons-marijuana-offenses-wont-apply-military.

[260] The U.S. Sentencing Commission (USSC) reports that about 7,700 people subject to the pardon were convicted of only simple possession since FY1992, none of whom were in federal custody at the time of the grant of clemency. USSC, NUMBER OF FEDERAL OFFENDERS CONVICTED ONLY OF 21 U.S.C. § 844 INVOLVING MARIJUANA, FISCAL YEARS 1992 – 2021 (Oct. 12, 2022), https://www.ussc.gov/sites/default/files/pdf/news/press-releases-and-news-advisories/news-advisories/20221012_Updated-News-Advisory-Data-Analysis.pdf. In FY2021, 117 people subject to the pardon were convicted of only simple possession. *See id.* Additional individuals convicted of simple possession were not subject to the pardon. *See* USSC, WEIGHING THE CHARGES: SIMPLE POSSESSION OF DRUGS IN THE FEDERAL CRIMINAL JUSTICE SYSTEM 6 (Sept. 2016), https://www.ussc.gov/sites/default/files/pdf/research-and-publications/research-publications/2016/201609_Simple-Possession.pdf.

[261] The USSC reports that 425 people were convicted of possessing marijuana and possessing other illicit drugs, USSC, NUMBER OF FEDERAL OFFENDERS, *supra* note 259. In addition, 585 people were convicted of simple possession of marijuana and one or more other crimes. USSC, NUMBER OF FEDERAL OFFENDERS, *supra* note 259. Those people would remain liable for the other offenses. After the pardon was announced, the USSC issued policy priorities including "consideration of possible amendments to the [Sentencing] Guidelines Manual relating to criminal history to address ... the impact of simple possession of marihuana offenses." Final Priorities for Amendment Cycle, 87 Fed. Reg. 67756, 67756 (Nov. 9, 2022).

[262] According to a 2016 USSC report, the vast majority of federal marijuana possession arrests occur at the border between the United States and Mexico and involve non-citizens. *See* USSC, WEIGHING THE CHARGES, *supra* note 259, at 5–6. Among offenders sentenced for marijuana possession in FY2013, over 94% of those arrested at the border were (continued...)

offenses committed before the proclamations.[263] Thus, while DOJ is currently not prioritizing prosecuting low-level marijuana offenses, the October 2022 and December 2023 pardons do not prevent prosecution of future offenses if the current Administration or a future Administration adopts a different policy. Fifth, the pardons may not remove all legal consequences of marijuana possession, because they do not expunge convictions.[264] Moreover, some collateral consequences of marijuana-related activities do not depend on a person being charged with or convicted of a CSA violation.[265]

In addition, and most fundamentally, the pardons did not change the status of marijuana under federal law. The President lacks the power to make such a change unilaterally.[266] In announcing the first grant of clemency, President Biden directed the Attorney General to review the classification of marijuana under the CSA.[267] DOJ subsequently announced a proposal to reschedule marijuana, which is discussed further below.[268]

It remains to be seen what approach President Trump's second Administration will take toward marijuana regulation. During President Trump's first Administration, DOJ rescinded Obama Administration guidance deprioritizing enforcement against low-level marijuana offenses.[269] Nonetheless, the number of DEA marijuana arrests fell every year during the first Trump Administration.[270]

DOJ Proposal to Reschedule Marijuana

On May 21, 2024, DOJ published in the *Federal Register* a notice of proposed rulemaking (NPRM) proposing to move marijuana from Schedule I to Schedule III.[271] The agency held an initial public hearing on the proposal in December 2024.[272] As of the date of publication of this report, it is unknown whether DOJ will finalize the proposal and, if so, what controls the agency would impose on marijuana.[273]

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not U.S. citizens. *Id.* at 6. To the extent those individuals were not lawfully present in the country, they would not benefit from the pardon.

[263] The Supreme Court has explained that the President may issue a pardon "at any time after [an offense's] commission, either before legal proceedings are taken, or during their pendency, or after conviction and judgment." *Ex parte* Garland, 71 U.S. 333, 380 (1866).

[264] *See* DOJ, Office of the Pardon Attorney, *Presidential Proclamation on Marijuana Possession, Attempted Possession, and Use* (December 16, 2024), https://www.justice.gov/pardon/presidential-proclamation-marijuana-possession.

[265] *See supra* "Enforcement and Penalties."

[266] *See* CRS Legal Sidebar LSB10655, *Does the President Have the Power to Legalize Marijuana?*, by Joanna R. Lampe (2021).

[267] Proclamation No. 10467, 87 Fed. Reg. 61441 (Oct. 6, 2022).

[268] *See infra* "DOJ Proposal to Reschedule Marijuana."

[269] Jefferson B. Sessions, *supra* note 253.

[270] *See* DOJ, FEDERAL JUSTICE STATISTICS, 2022 (Jan. 2024), https://bjs.ojp.gov/document/fjs22.pdf.

[271] Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597 (proposed May 21, 2024). While scheduling is generally initiated by DEA, the marijuana NPRM indicated that DOJ was initiating the process and at times included views of both DEA and DOJ. *See, e.g.*, *id.* at 44601.

[272] *DEA to Hold Hearing on the Rescheduling of Marijuana*, DEA (Nov. 26, 2024), https://www.dea.gov/stories/2024/2024-11/2024-11-26/dea-hold-hearing-rescheduling-marijuana.

[273] The NPRM indicated that DOJ might place marijuana in Schedule III while also posing additional, substance-specific controls as required to comply with the United States' international treaty obligation. *See* Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44620 (proposed May 21, 2024).

Moving marijuana from Schedule I to Schedule III, without other legal changes, would not bring the state-legal medical or recreational marijuana industry into compliance with federal controlled substances law. With respect to medical marijuana, a key difference between placement in Schedule I and placement in Schedule III is that substances in Schedule III have an accepted medical use and may lawfully be dispensed by prescription, while substances in Schedule I cannot.[274] However, prescription drugs must be approved by FDA. Although FDA has approved some drugs derived from or related to cannabis, marijuana itself is not an FDA-approved drug.[275] Moreover, if one or more marijuana products obtained FDA approval, manufacturers and distributors would need to register with DEA and comply with regulatory requirements that apply to Schedule III controlled substances in order to handle those products.[276] Users of medical marijuana would need to obtain valid prescriptions for the substance from medical providers, subject to federal legal requirements that differ from existing state regulatory requirements for medical marijuana.[277]

Rescheduling marijuana would not affect the medical marijuana appropriations rider discussed above.[278] Thus, so long as the current rider remains in effect, participants in the state-legal medical marijuana industry who comply with state law would be shielded from federal prosecution. If the rider were to lapse or be repealed, these persons would again be subject to prosecution at the discretion of DOJ. With respect to the manufacture, distribution, and possession of *recreational* marijuana, if marijuana were moved to Schedule III, such activities would remain illegal under federal law and potentially subject to federal prosecution regardless of their status under state law.

Some criminal penalties for CSA violations depend on the schedule in which a substance is classified.[279] If marijuana were moved to Schedule III, applicable penalties for some offenses would be reduced.[280] By contrast, some CSA penalties apply to activities involving marijuana specifically, including certain quantity-based mandatory minimum sentences.[281] Those substance-specific penalties would not change as a result of rescheduling. Similarly, the Medical Marijuana and Cannabidiol Research Expansion Act imposed some registration requirements related to research that apply specifically to marijuana.[282] Those requirements would not change if marijuana were rescheduled.

One significant legal change if marijuana were rescheduled relates to the taxation of marijuana-related businesses. Section 280E of the Internal Revenue Code prohibits deduction of business expenses of any trade or business that "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."[283] As the provision applies only to activities involving substances in Schedule I or II, moving marijuana from

[274] *See* 21 U.S.C. § 829.

[275] *See FDA and Cannabis: Research and Drug Approval Process*, FDA (Feb. 24, 2023), https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process.

[276] *See supra* "Registration Requirements."

[277] *See* 21 U.S.C. § 829.

[278] *See supra* "Appropriations Limitations."

[279] *See, e.g.*, 21 U.S.C. § 841(b)(1)(C).

[280] *See id.* A criminal prohibition on advertising Schedule I controlled substances would cease to apply to marijuana if it were moved to Schedule III. *See id.* § 843(c).

[281] *See, e.g., id.* § 841(b)(1)(A).

[282] Pub. L. 117-215, 136 Stat. 2257 (2022).

[283] 26 U.S.C. § 280E.

Schedule I to Schedule III would allow marijuana businesses to deduct business expenses on federal tax filings. Another change is that DEA would no longer need to set annual quotas for the manufacture of marijuana, because the CSA does not require the agency to set annual production quotas for Schedule III controlled substances.[284] Other collateral legal consequences would continue to attach to unauthorized marijuana-related activities.[285]

Proposed Marijuana Legislation

Numerous proposals introduced in the 116th-118th Congresses would have changed how the federal government regulates marijuana. Congress has broad power to regulate marijuana or relax federal regulation of the substance as part of its authority over interstate commerce.[286] As discussed above, DOJ is currently considering moving marijuana to Schedule III via administrative rulemaking.[287] If Congress wishes to change the legal status of marijuana, it could do so before or after DOJ makes any final scheduling decision.

Several recent proposals would have removed marijuana from control under the CSA. One high-profile descheduling proposal, the Marijuana Opportunity Reinvestment and Expungement Act (MORE Act), would have removed marijuana and THC from control under the CSA and required expungement of past convictions for many federal marijuana offenses.[288] Among other things, it also would have removed some collateral consequences for marijuana-related activities,[289] imposed a 5% tax on cannabis products,[290] and used revenues from the tax to fund certain grant programs for disadvantaged individuals and "individuals adversely impacted by the War on Drugs."[291] The MORE Act passed the House during the 117th Congress but did not pass the Senate.[292]

Another descheduling proposal, the Cannabis Administration and Opportunity Act (CAOA), would have removed from CSA control marijuana and THC derived from the cannabis plant.[293] It also would have provided for expungement of certain past marijuana convictions,[294] but it would have retained federal criminal liability for cannabis-related activities not conducted pursuant to a federal permit or authorized under the law of the states where they occur.[295] In addition, among other things, it would have provided guidance for regulation of cannabis products under the

[284] 21 U.S.C. § 826.

[285] *See* discussion *supra* notes 228–234 and accompanying text.

[286] Gonzales v. Raich, 545 U.S. 1, 15 (2004). For background on Congress's power to regulate interstate commerce, see Cong. Rsch. Serv., *Overview of Commerce Clause*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S8-C3-1/ALDE_00013403/ (last visited Jan. 13, 2023).

[287] *See supra* "DOJ Proposal to Reschedule Marijuana."

[288] MORE Act, H.R. 5601, §§ 3, 10, 118th Cong. (2023).

[289] *Id.* §§ 7–9.

[290] *Id.* § 5.

[291] *Id.* §§ 5–6.

[292] MORE Act, H.R. 3617, 117th Cong. (2021). A previous version of the MORE Act passed the House in December 2020, the first time either chamber of Congress voted on a proposal to decriminalize marijuana. *See* MORE Act of 2020, H.R. 3884, 116th Cong. (2020), *see also* Nicholas Wu, *House Will Vote on Federal Marijuana Legalization for the First Time, Bill's Future in Senate Uncertain*, USA TODAY (Sept. 4, 2020) https://www.usatoday.com/story/news/politics/2020/09/04/marijuana-house-vote-federal-legalization-first-time/5678068002/.

[293] Cannabis Administration and Opportunity Act, S. 4226, § 101, 118th Cong. (2022).

[294] *Id.* § 311.

[295] *Id.* § 112.

FD&C Act.[296] It also would have imposed a 10%-25% tax on cannabis products[297] and used revenues from the tax to fund programs including small business development, community reinvestment, and opioid abuse treatment.[298] Other legislative proposals from the 116th-118th Congresses would likewise have removed marijuana from control under the CSA.[299]

Removing marijuana from the coverage of the CSA could raise several legal considerations. First, by default, the repeal of federal criminal prohibitions rarely applies retroactively.[300] To address this, some descheduling proposals also include provisions designed to address past criminal convictions related to marijuana.[301] Second, removing marijuana from the ambit of the CSA would not affect other existing statutes and regulations that apply to the drug and thus would not bring aspects of the existing cannabis industry into compliance with federal laws such as the FD&C Act.[302] Third, Congress might enact new legislation affecting marijuana in conjunction with any legislation removing it from the scope of the CSA. For instance, legislation introduced during the 118th Congress would have amended the FD&C Act to provide for the regulation of cannabis and cannabinoid products.[303] Fourth, reducing or removing federal restrictions on marijuana might be inconsistent with certain treaty obligations of the United States.[304] The

[296] *Id.* § 501.

[297] *Id.* § 401.

[298] *Id.* §§ 301–303.

[299] *See, e.g.*, States Reform Act of 2023, H.R. 6028, 118th Cong. (2023); Homegrown Act of 2021, H.R. 2649, 117th Cong. (2021); Common Sense Cannabis Reform for Veterans, Small Businesses, and Medical Professionals Act, H.R. 3105, 117th Cong. (2021); Marijuana Justice Act of 2019, H.R. 1456, 116th Cong. (2019); Marijuana Justice Act of 2019, S. 597, 116th Cong. (2019).

[300] *See* 1 U.S.C. § 109; 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).

[301] In addition to the MORE Act and the CAOA, other legislative proposals from the 117th and 118th Congress would also have allowed for expungement or sealing of certain federal marijuana convictions. *See, e.g.*, Marijuana Misdemeanor Expungement Act, H.R. 8917, 118th Cong. (2024); Clean Slate Act of 2021, H.R. 2864, 117th Cong. (2021). Another proposal sought to facilitate expungement of state convictions. *See* Harnessing Opportunities by Pursuing Expungement Act of 2023, H.R. 2677, 118th Cong. (2023). *See also, 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).

[302] *See* Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Signing of the Agriculture Improvement Act and the Agency's Regulation of Products Containing Cannabis and Cannabis-Derived Compounds (Dec. 20, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys; *see also* CRS In Focus IF11250, *FDA Regulation of Cannabidiol (CBD) Consumer Products*, by Agata Bodie and Renée Johnson (2020). Congress could also enact legislation to alter FDA regulation of cannabis-based products. For example, the Legitimate Use of Medicinal Marihuana Act (LUMMA), H.R. 171, 116th Cong. (2019), would have provided that neither the CSA nor the FD&C Act "shall prohibit or otherwise restrict" certain activities related to medical marijuana that are legal under state law.

[303] Cannabinoid Safety and Regulation Act, S. 5243, 118th Cong. (2024). *See also* Preparing Regulators Effectively for a Post-prohibition Adult-use Regulated Environment Act of 2023, H.R. 2598, 118th Cong. (2023); Regulate Marijuana Like Alcohol Act, H.R. 420, 116th Cong. (2019).

[304] *See supra* "International Treaty Obligations." The United States is a party to the Single Convention on Narcotic Drugs, 1961, Mar. 30, 1961, 18 U.S.T. 1407 and the United Nations Convention on Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543. Both conventions require parties to impose certain controls on cannabis; however, in December 2020, the United Nations Commission on Narcotic Drugs voted to remove some of the restrictions on cannabis under the 1961 Convention. *See* Press Release, United Nations Commission on Narcotic Drugs, CND Votes on Recommendations for Cannabis and Cannabis-related Substances (Dec. 2, 2020), https://www.unodc.org/unodc/en/frontpage/2020/December/cnd-votes-on-recommendations-for-cannabis-and-cannabis-related-substances.html. Nonetheless, cannabis and its derivatives remain subject to restrictions under the (continued...)

applicable treaties are not self-executing,[305] meaning that they do not have the same status as judicially enforceable domestic law.[306] However, failure to abide by its treaty obligations could expose the United States to diplomatic consequences.[307]

As an alternative to descheduling, some recent proposals would have maintained marijuana as a controlled substance but moved it to a less restrictive schedule.[308] These proposals would generally move marijuana to Schedule III, as DOJ is currently considering doing by rulemaking.[309] If Congress moved marijuana to Schedule III by legislation, it could simultaneously consider whether to change some of the legal consequences of the substance's Schedule III status. Congress could also legislate to move marijuana to another CSA schedule, which would subject it to controls more or less stringent than those that apply to Schedule III controlled substances. As discussed above, moving marijuana to a schedule other than Schedule I would theoretically allow the substance to be dispensed by prescription for medical purposes. However, because marijuana is not currently an FDA-approved prescription drug, rescheduling alone would not allow current state-legal medical recreational marijuana markets to comply with the CSA.[310]

Congress could also continue to regulate marijuana as a Schedule I controlled substance while creating substance-specific exceptions. For instance, several legislative proposals during the 116th-118th Congresses would have left marijuana in Schedule I but limited enforcement of federal marijuana law in states that have legalized marijuana.[311] In the 117th Congress, the Small

international drug control treaties that may be inconsistent with legalization of marijuana, particularly for recreational purposes. Specifically, cannabis and cannabis resin remain in Schedule I of the 1961 Convention. United Nations Single Convention on Narcotic Drugs, 1961, List of Drugs Included in Schedule I, Mar. 30, 1961, 18 U.S.T. 1407. The 1961 Convention also contains provisions imposing specific requirements on the cultivation of cannabis. *Id.* art. 28. In addition, THC remains subject to control under the 1971 Convention. United Nations Convention on Psychotropic Substances, List of Substances in Schedule I, Feb. 21, 1971, 32 U.S.T. 543.

[305] 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.

[306] *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 (2023).

[307] *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); Jonathan Remy Nash, *Doubly Uncooperative Federalism and the Challenge of U.S. Treaty Compliance*, 55 COLUM. J. TRANSNAT'L L. 3, 21–23 (2016).

[308] *See, e.g.*, Marijuana 1-to-3 Act of 2021, H.R. 365, 117th Cong. (2012); Legitimate Use of Medicinal Marihuana Act, H.R. 171, 116th Cong. (2019); Compassionate Access Act, H.R. 715, 115th Cong. (2017).

[309] *See supra* "DOJ Proposal to Reschedule Marijuana."

[310] *See id.*

[311] Strengthening the Tenth Amendment Through Entrusting States 2.0 Act, H.R. 6673, 118th Cong. (2023); State Cannabis Commerce Act, H.R. 3546, 116th Cong. (2019); S. 2030, 116th Cong. (2019); Strengthening the Tenth Amendment Through Entrusting States Act (STATES Act), H.R. 2093, 116th Cong. (2019); STATES Act, S. 1028, (continued...)

and Homestead Independent Producers Act of 2022 would have allowed shipment of marijuana within and between states that have legalized the substance.[312]

Some other recent proposals would have addressed specific legal consequences of marijuana's Schedule I status. For example, the SAFE Banking Act,[313] a version of which passed the House in 2021,[314] sought to protect depository institutions that provide financial services to cannabis-related businesses from regulatory sanctions. A related bill called the SAFER Banking Act was introduced in the 118th Congress.[315] Other proposals sought to ensure marijuana businesses' access to insurance and other financial resources,[316] facilitate federally approved clinical research involving marijuana,[317] or enable veterans to access information about or use medical marijuana.[318] Additional proposals would have removed collateral legal consequences of marijuana-related activities for individuals in areas such as immigration,[319] gun ownership,[320] federal employment,[321] and federally assisted housing.[322]

While most recent proposals would have relaxed federal regulation of marijuana, Congress could also impose more stringent controls.[323] One proposal from the 118th Congress would have withheld certain federal funds from states in which the purchase or public possession of marijuana for recreational purposes is lawful.[324] A proposal from the 117th Congress would have prohibited the use of benefits under the Temporary Assistance for Needy Families block grant at any store that offers marijuana for sale.[325] Other proposals sought to address the issues of marijuana impairment in the workplace[326] or driving under the influence of marijuana and other

116th Cong. (2019); Responsibly Addressing the Marijuana Policy Gap Act of 2019, H.R. 1119, 116th Cong. (2019); Responsibly Addressing the Marijuana Policy Gap Act of 2019 S. 421, 116th Cong. (2019).

[312] H.R. 8825, 117th Cong. (2022).

[313] SAFE Banking Act of 2023, H.R. 2891, 118th Cong. (2023); SAFE Banking Act of 2023. S. 1323, 118th Cong. (2023).

[314] Secure And Fair Enforcement Banking Act of 2021, H.R. 1996, 117th Cong. (2021).

[315] SAFER Banking Act, S. 2860, 118th Cong. (2023).

[316] CLAIM Act, H.R. 2984, 118th Cong. (2023), CLAIM Act, S. 1359, 118th Cong. (2023); Ensuring Safe Capital Access for All Small Businesses Act of 2021, H.R. 2712, 117th Cong. (2021); CLIMB Act, H.R. 8200, 117th Cong. (2022); *see also* Ensuring Access to Counseling and Training for All Small Businesses Act of 2019, H.R. 3543, 116th Cong. (2019).

[317] *See, e.g.*, Cannabis Research Act, H.R. 8901, 118th Cong. (2024); Developing and Nationalizing Key Cannabis Research Act of 2022, H.R. 8540, 117th Cong. (2022); Medical Marijuana Research Act, H.R. 5657, 117th Cong. (2021). *See also infra* "Clinical Research and Use of Schedule I Controlled Substances."

[318] *See, e.g.*, Veterans Equal Access Act, H.R. 2431, 118th Cong. (2023); Veterans Medical Marijuana Safe Harbor Act, H.R. 2682, S. 1204, 118th Cong. (2023); Fully Informed Veteran Act of 2021, H.R. 3601, 117th Cong. (2021); Veterans Cannabis Use for Safe Healing Act, H.R. 430, 117th Cong. (2021).

[319] Destigmatizing in Immigration Act, H.R. 1614, 117th Cong. (2021).

[320] Gun Rights And Marijuana Act, H.R. 2772, 118th Cong. (2023).

[321] Cannabis Users' Restoration of Eligibility Act, H.R. 5040. 118th Cong. (2023); see also Intelligence Authorization Act for Fiscal Year 2024, S. 2103 § 805, 118th Cong. (2023).

[322] Marijuana in Federally Assisted Housing Parity Act of 2024, H.R. 7094, 118th Cong. (2024).

[323] In addition to the proposals discussed below, see Targeting and Offsetting Existing Illegal Contaminants Act, H.R. 1473, 118th Cong. (2023); Federal Lands Amplified Security for the Homeland (FLASH) Act, H.R. 9678, 118th Cong. (2024).

[324] Stop Pot Act of 2023, H.R. 5323, 118th Cong. (2023).

[325] Welfare for Needs not Weed Act, H.R. 4536 117th Cong. (2021). *See* Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. No. 104-193, tit. I, 110 Stat. 2105, 2110 (commonly referred to as Temporary Assistance for Needy Families (TANF)).

[326] H.R. 8591, 117th Cong. (2022).

substances.[327] Another proposal from the 118th Congress would have provided for congressional review of DEA rescheduling decisions related to marijuana.[328]

Clinical Research and Use of Schedule I Controlled Substances

Another issue that received significant attention during the 117th and 118th Congresses was the possibility that certain Schedule I controlled substances, especially marijuana and psilocybin, may have medical benefits. As a legal matter, Schedule I status limits researchers' ability to conduct clinical research involving these substances and patients' ability to access such substances for medical purposes. As substances in Schedule I have no accepted medical use under the CSA, it is only legal to produce, dispense, and possess those substances in the context of federally approved scientific studies.[329] In addition, federal law limits the use of federal funding for such research: a rider to the appropriations law for FY2024 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."[330]

Schedule I status under the CSA raises two key legal issues related to medical use and clinical research. First, some commentators have expressed concerns that the CSA places too many restrictions on research involving controlled substances, particularly Schedule I controlled substances that might have a legitimate medical use.[331] Barriers to research may make it difficult both to harness potential medical benefits of those substances and to disprove possible false claims of benefits that may pose a public health risk.

Second, there is a growing gulf between federal and state law with respect to Schedule I controlled substances with potential medical benefits. The gap between federal and state regulation of medical and recreational marijuana is discussed in greater detail above.[332] However, more recently, it appears that a gap may be developing with respect to other Schedule I controlled substances. On November 3, 2020, voters in Oregon approved a ballot measure authorizing the use of psilocybin for medical purposes under state law.[333] The same day, District of Columbia

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[327] Drug-Impaired Driving Education Act of 2021, H.R. 3675, 117th Cong. (2021); Impaired Driving Study Act of 2021, H.R. 3253, 117th Cong. (2021).

[328] Deferring Executive Authority Act, S. 2909, 118th Cong. (2023).

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

[330] American Relief Act, 2025, Pub. L. 118-158, div. D, § 509 (Dec. 21, 2024). The provision has been extended through March 14, 2025. *See id.*, div. A, § 101.

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

[332] *See supra* "Federal and State Marijuana Regulation."

[333] *See* Lizzy Acker, *Oregon Becomes First State to Legalize Psychedelic Mushrooms*, OREGONIAN (Nov. 3, 2020), https://www.oregonlive.com/politics/2020/11/oregon-becomes-first-state-to-legalize-psychedelic-mushrooms.html. Through a separate ballot measure, Oregonians voted to decriminalize possession of small amounts of certain Schedule I and II controlled substances, including cocaine, heroin, oxycodone and methamphetamines. *See* Cleve R. Wootson Jr. and Jaclyn Peiser, *Oregon Decriminalizes Possession of Hard Drugs, as Four Other States Legalize Recreational Marijuana*, WASH. POST (Nov. 4, 2020), https://www.washingtonpost.com/nation/2020/11/04/election-drugs-oregon-new-jersey/. The ballot measure related to possession of controlled substances was repealed in 2024. *See* Claire Rush, *Oregon Law Rolling Back Drug Decriminalization Takes Effect, Making Possession a Crime Again*, PBS NEWS (Sept. 1, 2024), https://www.pbs.org/newshour/politics/oregon-law-rolling-back-drug-decriminalization-takes-effect-making-possession-a-crime-again. Psilocybin remains available for medical use in Oregon. *See* Andrew Jacobs, *'Life-Changing' Psychedelics, for When Life Is Ending*, N.Y. TIMES (Dec. 17, 2024), https://www.nytimes.com/2024/12/17/health/psychedelic-medicine-palliative-care-end-of-life.html.

voters passed a ballot measure deprioritizing the enforcement of criminal prohibitions on certain psychedelic plants and fungi.[334] On November 8, 2022, voters in Colorado approved a ballot initiative legalizing the use of psilocybin and certain other substances by adults 21 or over and providing for the establishment of centers for the therapeutic use of psilocybin and psilocyn.[335] A number of cities have also enacted local laws deprioritizing enforcement of controlled substances offenses involving psychedelics.[336] As with state marijuana laws, these changes in D.C., state, and local law do not alter the status of the affected Schedule I controlled substances under the federal CSA.[337]

In recent years, Congress has enacted legislation designed to facilitate research involving marijuana while also retaining strict controls over the substance. For over 50 years, DEA registered one farm in the United States to legally produce marijuana for research purposes, and researchers contended that marijuana from that source was deficient in both quality and quantity.[338] In 2015, Congress passed the Improving Regulatory Transparency for New Medical Therapies Act, which imposed deadlines on DEA to issue notice of each application to manufacture Schedule I controlled substances for research and then act on the application.[339] Following years of delay and related court challenges,[340] DEA published a notice in the *Federal Register* in August 2019 announcing the agency's intent to promulgate regulations governing the manufacture of marijuana for research purposes.[341]

In December 2020, DEA issued a final rule governing registration for bulk marijuana manufacturers.[342] The final rule provides that the DEA administrator "may grant an application for a registration to manufacture marihuana … only if he determines that such registration is

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[334] *See* Justin Wm. Moyer, *D.C. Voters Approve Ballot Question to Decriminalize Psychedelic Mushrooms*, WASH. POST (Nov. 3, 2020), https://www.washingtonpost.com/local/dc-politics/dc-magic-mushrooms-result/2020/11/03/bb929e86-1abc-11eb-bb35-2dcfdab0a345_story.html. The D.C. ballot measure does not repeal criminal laws related to psychedelic plants and fungi but rather provides that prosecution for the use and sale of such substances shall be "among the Metropolitan Police Department's lowest law enforcement priorities." *Id.* The ballot measure appears to have been tailored to comply with a federal appropriations rider that prohibits the District of Columbia from expending any federal funds "to enact or carry out any law, rule, or regulation to legalize or otherwise reduce penalties associated with the possession, use, or distribution of any schedule I substance under the Controlled Substances Act[.]" Consolidated Appropriations Act, 2020, Pub. L. No. 116-93, tit. VIII, § 809, 133 Stat. 2500 (2019). The District of Columbia measure is not limited to medicinal use but was motivated in part by the possibility that psychedelic substances may provide medical benefits. *See* Justin Wm. Moyer, *D.C. Voters to Weigh in on 'Magic Mushroom' Decriminalization After Months-long Campaign*, WASH. POST (Oct. 8, 2020), https://www.washingtonpost.com/local/dc-mushroom-decriminalization/2020/10/08/b19a1a70-0712-11eb-991c-be6ead8c4018_story.html.

[335] *See* Danica Jefferies, *Colorado Just Legalized 'Magic Mushrooms,' an Idea That's Growing Nationwide*, NBC NEWS (Nov. 12, 2022), https://www.nbcnews.com/data-graphics/magic-mushrooms-psilocybin-map-colorado-us-states-rcna55980.

[336] *Psychedelic Legalization & Decriminalization Tracker*, PSYCHEDELIC ALPHA, https://psychedelicalpha.com/data/psychedelic-laws (last visited Jan. 13, 2025).

[337] *See* CRS Legal Sidebar LSB10482, *State Marijuana "Legalization" and Federal Drug Law: A Brief Overview for Congress*, by Joanna R. Lampe (2024).

[338] *See* Pet. for Writ of Mandamus at 13–15, *In re* Scottsdale Research Inst., No. 19-1120 (D.C. Cir. June 6, 2019).

[339] 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.*, Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana, 84 Fed. Reg. 44920 (Aug. 27, 2019).

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

[341] Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana, 84 Fed. Reg. 44920, 44921 (Aug. 27, 2019).

[342] *See* Controls to Enhance the Cultivation of Marihuana for Research in the United States, 85 Fed. Reg. 82333 (Dec. 18, 2020).

consistent with the public interest" and with U.S. treaty obligations.[343] The rule further provides that "[a]ll registered manufacturers who cultivate cannabis shall deliver their total crops of cannabis" to DEA, and the agency "shall purchase and take physical possession of such crops as soon as possible" and "have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks [of cannabis] other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations."[344] The rule also allows DEA to delegate some of its responsibilities, such as storage and trading of cannabis, to "appropriately registered persons."[345] After issuing the final rule, DEA began to issue registrations to additional manufacturers. As of March 2023, DEA had registered seven marijuana manufacturers.[346]

On December 2, 2022, President Biden signed into law the Medical Marijuana and Cannabidiol Research Expansion Act, which aimed to ease requirements for research involving marijuana and CBD.[347] Among other things, the Act created specialized, expedited procedures for DEA approval of marijuana research and manufacture of marijuana for research purposes.[348]

Other proposals during the 117th and 118th Congresses sought to facilitate federally approved clinical research involving marijuana[349] or enable veterans to access information about or use medical marijuana.[350] Congress also considered legislation that would have more broadly facilitated research involving controlled substances. For example, a proposed amendment to an appropriations bill for FY2022 would have eliminated the appropriations rider restricting the use of federal funding to promote the legalization of Schedule I controlled substances.[351] That amendment was intended to facilitate research involving not only marijuana but also psilocybin, MDMA, and other Schedule I drugs that might have legitimate medical uses.[352] More recently, several proposals related to fentanyl analogues also contained provisions that would relax certain registration requirements related to research on Schedule I controlled substances.[353]

[343] *Id.* at 82353.

[344] *Id.*

[345] *Id.*

[346] Nat'l Ctr. for Complementary & Integrative Health, *DEA-Approved Bulk Cannabis Suppliers*, HHS, https://www.nccih.nih.gov/grants/dea-approved-bulk-cannabis-suppliers (last visited Jan. 13, 2025).

[347] Pub. L. 117-215, 136 Stat. 2257 (2022).

[348] For additional discussion of the Act, see CRS Legal Sidebar LSB10859, *Recent Developments in Marijuana Law*, by Joanna R. Lampe (2022).

[349] *See, e.g.*, Cannabis Research Act, H.R. 8901, 118th Cong. (2024); Developing and Nationalizing Key Cannabis Research Act of 2022, H.R. 8540, 117th Cong. (2022); Medical Marijuana Research Act, H.R. 5657, 117th Cong. (2021).

[350] *See, e.g.*, Veterans Equal Access Act, H.R. 2431, 118th Cong. (2023); Veterans Medical Marijuana Safe Harbor Act, H.R. 2682, S. 1204, 118th Cong. (2023); Fully Informed Veteran Act of 2021, H.R. 3601, 117th Cong. (2021); Veterans Cannabis Use for Safe Healing Act, H.R. 430, 117th Cong. (2021).

[351] H.Amdt. 85 to H.R. 4502, 117th Cong. (2021). The amendment was not adopted.

[352] *See* 166 Cong. Rec. H4074 (daily ed. July 30, 2021) (statement of Rep. Alexandria Ocasio-Cortez) (stating that the appropriations rider "has, for a very long period of time, prevented and acted as a barricade to Federal research on certain substances—such as psilocybin, MDMA, and marijuana—in allowing us to research the applications and potential therapeutic applications of these drugs in the treatment of diseases such as PTSD, addiction, and depression.").

[353] *See* SIFT Act of 2023, H.R. 1758, 118th Cong. (2023); TEST Act, S. 1950, 118th Cong. (2023); SAFE Act, H.R. 568, 118th Cong. (2023); HALT Fentanyl Act, S. 1141, 118th Cong. 2023). For additional discussion of regulation of fentanyl analogues, see *infra* "Fentanyl Analogues."

Opioid Epidemic

Another salient current issue in the realm of controlled substance regulation is the opioid epidemic.[354] Opioids are drugs derived from the opium poppy or emulating the effects of opium-derived drugs.[355] Some opioids have legitimate medical uses, primarily related to pain management, while others have no recognized medical use.[356] Both pharmaceutical opioids (such as fentanyl, oxycodone, codeine, and morphine) and non-pharmaceutical opioids (such as heroin and some fentanyl analogues) may pose a risk of abuse and dependence and may be dangerous or even deadly in certain doses.[357] The CDC reports that overdoses involving opioids claimed over 80,800 lives in 2021.[358] The U.S. Congress Joint Economic Committee estimates that the costs of the opioid epidemic totaled nearly $1.5 trillion in 2020.[359]

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)[360] and the 21st Century Cures Act (Cures Act).[361] CARA authorized grants to address issues related to the opioid crisis including abuse prevention and education, law enforcement, and treatment.[362] The Cures Act, among other things, provided additional funding to states combating opioid addiction.[363] 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.[364] Key amendments to the CSA under the SUPPORT Act included provisions expanding access to medication-assisted treatment for opioid addiction,[365] specifying the factors

[354] For a brief overview of legal and policy issues related to the opioid epidemic, see CRS In Focus IF12260, *The Opioid Crisis in the United States: A Brief History*, by Johnathan H. Duff et al. (2022).

[355] *See* CRS Report R44987, *The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions*, by Lisa N. Sacco and Erin Bagalman (2017). Technically, the term "opiates" refers to natural compounds found in the opium poppy, while the term "opioids" refers to synthetic compounds that emulate the effects of opiates, but commentators often use the term "opioids" to refer to both categories of substances, and this report adopts that usage. *See id.*

[356] *Id.*

[357] *Id.*

[358] *See* National Center for Health Statistics, *U.S. Overdose Deaths In 2021 Increased Half as Much as in 2020 – But Are Still Up 15%*, CDC (May 11, 2022), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm.

[359] *See* JOINT ECONOMIC COMMITTEE, THE ECONOMIC TOLL OF THE OPIOID CRISIS REACHED NEARLY $1.5 TRILLION IN 2020 (Sept. 28, 2022), https://www.jec.senate.gov/public/_cache/files/67bced7f-4232-40ea-9263-f033d280c567/jec-cost-of-opioids-issue-brief.pdf.

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

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

[362] *See* CRS Report R45449, *The SUPPORT for Patients and Communities Act (P.L.115-271): Medicare Provisions*, coordinated by Suzanne M. Kirchhoff (2019).

[363] *See id.*

[364] 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 (2019); 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 (2018); CRS Report R45405, *The SUPPORT for Patients and Communities Act (P.L. 115-271): Food and Drug Administration and Controlled Substance Provisions*, coordinated by Agata Bodie (2018).

[365] Pub. L. No. 115-271, §§ 3201–04, 136 Stat. 3894, 3943–47 (2018). For additional information on medication-assisted treatment for opioid use disorder, see CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*, by Johnathan H. Duff (2019).

for determining whether a controlled substance analogue is intended for human consumption,[366] revising the factors DEA considers when establishing opioid production quotas,[367] and codifying the definition of "suspicious order" and outlining the CSA's suspicious order reporting requirements.[368]

Building on these far-reaching enactments, the 116th-118th Congresses enacted legislation seeking to address specific facets of the opioid crisis. For instance, in December 2022 Congress relaxed registration requirements for certain opioid treatment programs.[369] Additional legislation is discussed in the following subsections, along with selected recent proposals for reform.

Fentanyl Analogues

One issue that has garnered significant legislative attention in recent years is the proliferation of synthetic drugs, especially synthetic opioids. In contrast to drugs derived from natural materials such as plants, synthetic drugs are drugs that are chemically produced in a laboratory; they may have the same chemical structure as an existing natural drug or mimic the effects of an existing drug using a different chemical structure.[370] Many pharmaceutical drugs are synthetically produced.[371] On the other hand, clandestine actors seeking to circumvent existing drug laws often design synthetic drugs that mimic the effects of other drugs—or even produce stronger effects—but have chemical structures that have been slightly modified to circumvent existing drug laws.[372]

One particular public concern in this area relates to synthetic opioids, including fentanyl analogues.[373] Fentanyl is a Schedule II controlled substance, while multiple non-pharmaceutical substances related to fentanyl are controlled in Schedule I.[374] However, 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.[375] DEA has stated that, between March 2011 and January 2020, the agency used its emergency scheduling authority[376] to impose temporary controls on 74 synthetic drugs, including 17 fentanyl-like substances.[377]

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[366] Pub. L. No. 115-271, § 3241, 136 Stat. 3894, 3950 (2018). The question of whether a substance is intended for human consumption is relevant to controlled substance analogue prosecutions. *See supra* "Analogues and Listed Chemicals"; *infra* "Fentanyl Analogues."

[367] Pub. L. No. 115-271, § 3282, 136 Stat. 3894, 3954 (2018). *See also supra* "Quotas."

[368] Pub. L. No. 115-271, §§ 3291–92, 136 Stat. 3894, 3956 (2018). *See also supra* "Recordkeeping and Reporting."

[369] Restoring Hope for Mental Health and Well-Being Act, Pub. L. 117-328 tit. I, 136 Stat. 5634 of the Consolidated Appropriations Act, 2023 (2022).

[370] *See* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea (2016).

[371] *See, e.g.*, Kevin R. Campos, et al., *The Importance of Synthetic Chemistry in the Pharmaceutical Industry*, SCIENCE (Jan. 18, 2019), https://www.science.org/doi/10.1126/science.aat0805.

[372] Synthetic drugs that slightly modify the molecular structures of controlled substances to circumvent existing drug laws may also be called "designer drugs." *See* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea (2016).

[373] *See, e.g.*, Press Release, U.S. Att'y. Robert J. Higdon, Jr., et al., Congress Must Ban Fentanyl Analogues (Jan. 30, 2020), https://www.justice.gov/usao-wdnc/pr/congress-must-ban-fentanyl-analogues.

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

[375] *See* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea (2016).

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

[377] *See Fentanyl Analogues: Perspectives on Classwide Scheduling: Hearing Before the House Comm. on the Judiciary*, 116th Cong. 2 (2020) (statement of the U.S. Dep't of Justice). Since January 2020, DEA has used its (continued...)

Even if not individually scheduled under the CSA, substances related to fentanyl may be subject to DEA control as controlled substance analogues.[378] However, DOJ has stated that analogue prosecutions can be burdensome because they raise "complex chemical and scientific issues."[379] That is because liability for trafficking in controlled substance analogues requires proof that the substance at issue (1) is intended for human consumption and (2) has either a chemical structure substantially similar to the chemical structure of a Schedule I or II controlled substance or an actual or intended effect similar to or greater than that of a Schedule I or II controlled substance.[380] For fentanyl analogues that are explicitly scheduled, proof of those additional elements is not necessary. Moreover, some synthetic drugs do not meet the applicable criteria to be deemed controlled substance analogues—for example, because their effects are unpredictable or because they replicate the effects of more than one class of drugs.[381] DOJ has therefore argued that permanent scheduling of fentanyl analogues can reduce uncertainty and aid enforcement.[382]

The 116th-118th Congresses did not permanently schedule fentanyl analogues, but they did enact legislation to facilitate DEA's regulation of those substances. In February 2018, DEA issued an emergency temporary scheduling order (Fentanyl TSO) that temporarily placed in Schedule I a class of "fentanyl-related substances" (FRS).[383] While previous scheduling actions by DEA and Congress generally identified a specific substance or a list of discrete substances for control, the Fentanyl TSO instead imposed controls on a large class of substances that met specific criteria related to their chemical structure. The class of FRS is finite, but it includes thousands of chemicals.[384] As one researcher testified before Congress, the effects, potential for abuse and dependence, and medical utility of many FRS are unknown.[385] Perhaps because of those uncertainties, DEA did not initiate permanent scheduling of the full class of FRS,[386] though the

emergency scheduling authority to control additional synthetic opioids. *See* Schedules of Controlled Substances: Temporary Placement of Isotonitazene in Schedule I, 85 Fed. Reg. 51342 (Aug. 20, 2020); Schedules of Controlled Substances: Temporary Placement of Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino Etonitazene, and Protonitazene in Schedule I, 87 Fed. Reg. 21556 (Apr. 12, 2022).

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

[379] *The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order: Hearing Before the Sen. Comm. on the Judiciary*, 116th Cong. 5 (2019) (statement of the Amanda Liskamm, Director of Opioid Enforcement and Preventions Efforts, Office of the Deputy Attorney General, and Greg Cherundolo, Acting Chief of Operations, Drug Enforcement Administration, U.S. Dep't of Justice).

[380] 21 U.S.C. §§ 802(32), 813; *see also The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order: Hearing Before the Sen. Comm. on the Judiciary*, 116th Cong. 5 (2019) (statement of the Amanda Liskamm, Director of Opioid Enforcement and Preventions Efforts, Office of the Deputy Attorney General, and Greg Cherundolo, Acting Chief of Operations, Drug Enforcement Administration, U.S. Dep't of Justice).

[381] *See* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea (2016).

[382] *The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order: Hearing Before the Sen. Comm. on the Judiciary*, 116th Cong. 5 (2019) (statement of the Amanda Liskamm, Director of Opioid Enforcement and Preventions Efforts, Office of the Deputy Attorney General, and Greg Cherundolo, Acting Chief of Operations, Drug Enforcement Administration, U.S. Dep't of Justice).

[383] 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.

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

[385] *See Fentanyl Analogues: Perspectives on Classwide Scheduling: Hearing Before the House Comm. on the Judiciary*, 116th Cong. 4 (2020) (statement of Sandra D. Comer).

[386] By statute, DEA rulemaking permanently scheduling a controlled substance must be supported by certain factual findings. *See* 21 U.S.C. § 811(c). January 2020 testimony from an HHS official indicated that, given the large number of substances subject to the order, it was not feasible to make the individualized findings required to schedule each (continued...)

agency has continued to take temporary and permanent scheduling actions with respect to specific fentanyl analogues, including selected FRS subject to the Fentanyl TSO.[387]

The Fentanyl TSO was set to expire in February 2020.[388] On February 6, 2020, Congress enacted the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which extended temporary scheduling of the class of FRS until May 6, 2021.[389] Congress has since extended the temporary scheduling several times, most recently through March 31, 2025.[390]

Absent further legislative or administrative action, FRS will remain in Schedule I and subject to all restrictions and penalties applicable to Schedule I controlled substances until the March 2025 expiration date. After the expiration date, the class of substances will no longer be scheduled under the CSA but may still be subject to control as controlled substance analogues. As noted, fentanyl itself and certain specific related chemicals are permanently controlled in Schedules I and II.[391] The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act and subsequent legislation extending the temporary scheduling do not affect those classifications.

Multiple proposals in the 116th-118th Congresses sought to permanently schedule fentanyl analogues. Some of the proposals would have permanently placed the class of substances subject to the Fentanyl TSO in Schedule I.[392] Others would have scheduled the class of FRS subject to the Fentanyl TSO plus certain specific substances.[393]

Some proposals also sought to address specific concerns related to class-wide scheduling. Because the effects of some of the substances subject to the Fentanyl TSO are currently unknown, it is possible that some might have legitimate medical uses or pose little or no risk of abuse and dependence. Thus, some legislative proposals sought to facilitate research on the substances subject to class-wide scheduling[394] or would have provided for expedited descheduling if a fentanyl-related substance were found not to pose a risk of abuse and dependence.[395] In addition, based on concerns that individuals prosecuted for trafficking in FRS might face harsh penalties

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substance permanently. *Fentanyl Analogues: Perspectives on Classwide Scheduling: Hearing Before the House Comm. on the Judiciary*, 116th Cong. 4 (2020) (statement of Brett P. Giroir). Congress is not required to make the same findings to schedule a substance via legislation.

[387] *See* Schedules of Controlled Substances: Placement of Four Specific Fentanyl-Related Substances in Schedule I, 86 Fed. Reg. 14707 (Mar. 18, 2021).

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

[389] Pub. L. 116-114, 134 Stat. 103 (2020). For further discussion of the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, see CRS Legal Sidebar LSB10404, *Scheduling of Fentanyl Analogues: The New Legal Landscape*, by Joanna R. Lampe (2024).

[390] American Relief Act, 2025, Pub. L. 118-158, tit. IV, § 5105 (Dec. 21, 2024).

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

[392] *See, e.g.*, Stopping Overdoses of Fentanyl Analogues Act, S. 600, 118th Cong. (2023); SAFE Act, H.R. 568, 118th Cong. (2023); HALT Fentanyl Act, S. 1141, 118th Cong. (2023); Protecting Americans from Fentanyl Trafficking Act of 2023, H.R. 4701, 118th Cong. (2023); S. 614, 118th Cong. (2023); CEASE Overdose Act of 2022, H.R. 6713, 117th Cong. (2022); Federal Initiative To Guarantee Health by Targeting Fentanyl Act, H.R. 1910, 117th Cong. (2021); *see also* Zero Tolerance for Deceptive Fentanyl Trafficking Act, S. 3342, 116th Cong. (2020) (would have permanently added "fentanyl-related substances" to Schedule I and imposed criminal penalties for knowingly misrepresenting or knowingly marketing as another substance a mixture or substance containing fentanyl, a fentanyl analogue, or a fentanyl-related substance).

[393] *See, e.g.*, SIFT Act of 2023, H.R. 1758, 118th Cong. (2023); Stopping Overdoses of Fentanyl Analogues Act, H.R. 2209, 117th Cong. (2021); S. 1006. 117th Cong. (2021).

[394] *See, e.g.*, HALT Fentanyl Act, S. 1141, 118th Cong. (2023); SIFT Act of 2023, H.R. 1758, 118th Cong. (2023).

[395] *See, e.g.*, SAFE Act, H.R. 568, 118th Cong. (2023).

for offenses involving substances that pose little danger, some legislative proposals would have provided that mandatory minimum sentences under the CSA would not apply to those who committed certain offenses involving FRS.[396]

A key consideration in permanently scheduling fentanyl analogues is how to define the substances subject to regulation. The Fentanyl TSO identified a class of substances for control based on their chemical structure. On one hand, not all analogues of fentanyl have effects similar to fentanyl itself,[397] so defining covered substances based on chemical structure may be *overinclusive*, potentially allowing for prosecution of individuals who possess inactive substances that pose no threat to public health and safety.[398] 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.[399]

Congress could also consider alternative approaches to class-wide scheduling. For example, a proposal during the 116th Congress, the Modernizing Drug Enforcement Act of 2019,[400] would have identified covered opioids based on their effects rather than their chemical structure, amending the CSA to add to Schedule I all "mu opioid receptor agonists" not otherwise scheduled, subject to certain exceptions.[401] That approach might avoid the concerns about scope of control noted above. It is not clear if it would significantly reduce the burden that prosecutors currently face when bringing controlled substance charges related to analogues, because prosecutors would need to show that a given substance had the required effects.[402]

Other Proposals Related to Opioid Regulation

In addition to the proposals discussed above, numerous other legislative proposals in the 117th and 118th Congresses sought to address the opioid crisis by amending the CSA.[403] For instance, the LABEL Opioids Act would have required certain opioid medications subject to the CSA to bear a "clear, concise warning that the opioid dispensed can cause dependence, addiction, and

[396] *See, e.g., id.*; Federal Initiative to Guarantee Health by Targeting Fentanyl Act, H.R. 3629, 118th Cong. (2023).

[397] To illustrate, DEA previously temporarily scheduled two fentanyl analogues before determining that the substances were "essentially inactive." *See* Correction of Code of Federal Regulations: Removal of Temporary Listing of Benzylfentanyl and Thenylfentanyl as Controlled Substances, 75 Fed. Reg. 37300, 37300 (June 29, 2010).

[398] *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.

[399] *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).

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

[401] Mu opioid receptor agonists are a class of 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).

[402] *See supra* note 380.

[403] 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.*, FDA Accountability for Public Safety Act, S. 1439, 117th Cong. (2021); Protecting Americans from Dangerous Opioids Act, S. 1434, 117th Cong. (2021); 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.*, Budgeting for Opioid Addiction Treatment Act, S. 1723, 117th Cong. (2022); Opioid Treatment Surge Act, S. 1662, 116th Cong. (2019). Some proposals would direct the Secretary of Homeland Security to designate "illicit fentanyl" as a weapon of mass destruction. *See* SOS Act of 2022, H.R. 9162, 117th Cong. (2022); Fentanyl is a WMD Act, H.R. 8030, 117th Cong. (2022); *see also* CRS Insight IN11902, *Illicit Fentanyl and Weapons of Mass Destruction: International Controls and Policy Options*, by Paul K. Kerr and Liana W. Rosen (2022).

overdose."[404] The Medication Access and Training Expansion Act of 2021 would have "require[d] physicians and other prescribers of controlled substances to complete training on treating and managing patients with opioid and other substance use disorders."[405] The Mainstreaming Addiction Treatment Act of 2021 would have relaxed CSA registration requirements for practitioners who dispense narcotic drugs in Schedules III, IV, or V (such as buprenorphine) for maintenance or detoxification treatment.[406] The Harm Reduction Through Community Engagement Act of 2023 would have imposed additional registration requirements for opioid treatment programs.[407] The Opioid QuOTA Act of 2021 would have required publication of the annual quotas that apply to each registered opioid manufacturer.[408]

Other proposals would have amended CSA provisions that impose criminal penalties for unauthorized activities involving opioids.[409] Some proposals sought to increase criminal penalties for certain fentanyl-related offenses, imposing life in prison or the death penalty.[410] Others would have lowered the amounts of fentanyl or fentanyl analogues required to trigger existing mandatory minimum sentences.[411] Some proposals targeted misrepresenting the content of a substance containing fentanyl or manufacturing counterfeit substances that contain fentanyl and bear identifying marks of another product.[412] Another proposal would have authorized special agents of Homeland Security Investigations to perform certain enforcement functions under the CSA.[413]

Xylazine

Related to but distinct from Congress's response to the opioid epidemic is discussion of whether and how to control xylazine. Xylazine, sometimes colloquially called "tranq," is a sedative and analgesic that has been approved by FDA for use in animals.[414] Xylazine is not approved or intended for human use but is sometimes used by humans, either alone or in combination with other drugs of abuse such as illicit fentanyl.[415] Human use of xylazine can pose serious health risks. FDA and DEA have issued warnings about xylazine, and the Office of National Drug Control Policy officially designated fentanyl adulterated with xylazine as an emerging threat to the United States.[416] Currently, xylazine is regulated under the FD&C Act but not the CSA.[417]

[404] H.R. 1026, 117th Cong. (2021); S. 2353, 117th Cong. (2021).

[405] S. 2235, 117th Cong. (2021).

[406] H.R. 1384, 117th Cong. (2021); S. 445, 117th Cong. (2021).

[407] H.R. 2804, 118th Cong. (2023).

[408] H.R. 6150, 117th Cong. (2021); S. 3327, 117th Cong. (2021).

[409] For general discussion of the CSA's trafficking provisions, see *supra* "Trafficking Provisions."

[410] *See, e.g.*, Fentanyl Trafficker Elimination Act, H.R. 3215, 118th Cong. (2023); Death Penalty for Dealing Fentanyl Act of 2022, H.R. 1212, 118th Cong. (2023).

[411] *See, e.g.*, Fentanyl Penalties Parity Act, H.R. 5694, 117th Cong. (2021); Ending the Fentanyl Crisis Act of 2021, S. 1293, 117th Cong. (2021).

[412] *See, e.g.*, Stop Pills That Kill Act, H.R. 4105, 118th Cong. (2023); S. 1475, 118th Cong. (2023); Zero Tolerance for Deceptive Fentanyl Trafficking Act, S. 4984, 117th Cong. (2022).

[413] Homeland Security Fentanyl Enforcement Act, H.R. 9093, 117th Cong. (2022).

[414] DEA, XYLAZINE (Nov. 2022), https://www.deadiversion.usdoj.gov/drug_chem_info/Xylazine.pdf.

[415] *Id.*

[416] *FDA Alerts Health Care Professionals of Risks to Patients Exposed to Xylazine in Illicit Drugs*, FDA (Nov. 8, 2022), https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-professionals-risks-patients-exposed-xylazine-illicit-drugs; *DEA Reports Widespread Threat of Fentanyl Mixed with Xylazine*, DEA (Nov. 2022), https://www.dea.gov/alert/dea-reports-widespread-threat-fentanyl-mixed-xylazine.

[417] DEA, XYLAZINE (Nov. 2022), https://www.deadiversion.usdoj.gov/drug_chem_info/Xylazine.pdf.

Like other drugs, xylazine is also subject to regulation under state law. Several states have taken steps to regulate xylazine under state controlled substances laws.[418]

Several proposals from the 118th Congress would have regulated xylazine under the CSA. A provision of the Support for Patients and Communities Reauthorization Act, which passed the House in December 2023, would have placed xylazine in Schedule III except to the extent the substance is an FDA-approved animal drug whose "use or intended use conforms to the approved application, including the manufacturing, importation, holding, or distribution for such use."[419] The bill would have provided for tracking of xylazine in ARCOS and required DEA and FDA to prepare certain reports to Congress related to xylazine.

The Combating Illicit Xylazine Act would have amended the CSA to ban certain activities involving "xylazine for illicit uses."[420] The bill would have defined illicit uses of xylazine to include "[a]ny use in the human species" and "[a]ny use that is not a licit use." It would further have defined licit use of xylazine to include the manufacturing, importation, or use of xylazine in FDA-approved drugs or the administration of such drugs to animals. The bill did not propose to add xylazine to the schedules of controlled substances, but it would have imposed penalties for illicit activities involving xylazine equivalent to penalties for unauthorized activities involving Schedule III controlled substances. It would also have provided for ARCOS tracking of xylazine and require DEA and FDA to prepare reports to Congress related to xylazine.

In contrast to the two foregoing proposals, both of which would have increased controls on xylazine, the Fentanyl Safe Testing and Overdose Prevention Act would have amended the CSA to clarify that the possession, sale, purchase, importation, exportation, or transportation of equipment that tests drugs for the presence of fentanyl or xylazine is not included in the CSA's prohibitions on drug paraphernalia.[421]

A key consideration related to possible CSA control of xylazine is how to maintain access to the drug for legitimate veterinary purposes while preventing unauthorized human use. Xylazine is currently used legitimately on pets, wildlife, zoo animals, and livestock.[422] If xylazine were scheduled under the CSA, any person handling the substance would need to register with DEA and comply with the CSA's regulatory requirements unless the person qualified as an "ultimate user" who possessed the substance for use on "an animal owned by him or by a member of his household."[423] Some stakeholders who currently use xylazine on animals without DEA registration have raised concerns about the possible regulatory burden associated with CSA scheduling.[424]

DEA has the authority to impose CSA controls on xylazine through administrative rulemaking, subject to the CSA's substantive and procedural scheduling requirements.[425] If DEA decided to

[418] *State and Federal Actions to Respond to Xylazine*, NAT'L GOVERNORS ASSOC. (May 9, 2023), https://www.nga.org/news/commentary/state-and-federal-actions-to-respond-to-xylazine/.

[419] H.R. 4531, 118th Cong. (2023).

[420] H.R. 1839 118th Cong. (2023); S. 993 118th Cong. (2023).

[421] S. 2569, 118th Cong. (2023).

[422] *See, e.g.*, Jan Hoffman, *The Fight Over a Drug That Is Great for Horses but Horrific for Humans*, N.Y. TIMES (Apr. 20, 2023), https://www.seattletimes.com/nation-world/nation/the-fight-over-a-drug-that-is-great-for-horses-but-horrific-for-humans/.

[423] *See* 21 U.S.C. § 802(27).

[424] *See, e.g.*, Scott Maucione, *Veterinarians Worry About Their Access to Tranquilizer Xylazine with New Restrictions*, NPR (July 13, 2023), https://www.npr.org/2023/07/13/1187573893/veterinarians-worry-about-their-access-to-tranquilizer-xylazine-with-new-restric.

[425] *See supra* "Administrative Scheduling."

control xylazine under the CSA, it would need to place the substance in one of the existing CSA schedules. The agency has asserted some authority to tailor controls to specific substances, but it cannot create new schedules or implement regulations or exceptions from control that are not authorized under the CSA.[426]

If Congress determined that xylazine should be controlled under the CSA but none of the existing schedules were appropriate, it could enact legislation imposing specified controls without scheduling the substance, as proposed in the Combating Illicit Xylazine Act. It could also schedule xylazine subject to certain exceptions, as proposed in the Support for Patients and Communities Reauthorization Act. Congress has broad legal authority to amend the CSA and has previously enacted legislation imposing targeted regulations on specific substances. For instance, the CSA imposes additional registration requirements on DEA-registered opioid treatment programs and sets mandatory minimum prison sentences for offenses involving threshold quantities of certain specific controlled substances.[427] Tailored regulation such as these measures or the xylazine-related proposals discussed above would likely need to be imposed via legislation rather than DEA rulemaking.

Congress could also consider ways to regulate xylazine other than amending the CSA. The 118th Congress enacted one such piece of legislation. The TRANQ Research Act of 2023, enacted in December 2023, requires the National Institute of Standards and Technology to coordinate science and research activities regarding illicit drugs containing xylazine, novel synthetic opioids, and other substances of concern.[428] It also requires the Government Accountability Office to conduct a study on the capabilities of the federal government to detect, identify, and otherwise respond to threats posed by new psychoactive substances, such as xylazine.

Some Members of 118th Congress introduced other proposals related to xylazine outside the context of the CSA. Multiple proposals would have authorized the use of grant funds for fentanyl and xylazine test strips and, in some cases, required research with respect to test strips.[429] The Expanding Nationwide Access to Test Strips Act would have banned states from prohibiting individuals from obtaining, possessing, distributing, or using fentanyl or xylazine test strips.[430] The STOP TRANQ Act would have included the identification of countries that are significant sources of xylazine in the annual International Narcotics Control Strategy Report.[431]

[426] *See, e.g.*, DOJ, Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44620 (proposed May 21, 2024).

[427] *See* 21 U.S.C. §§ 823(a), 841(b)(1)(A).

[428] Pub. L. 118-23, 137 Stat. 125 (2023).

[429] *See, e.g.*, Test Strip Access Act of 2023, H.R. 4106, 118th Cong. (2023); Preventing Overdoses with Test Strips Act, H.R. 5801, 118th Cong. (2023); Advancing Lifesaving Efforts with Rapid Test strips for Communities Act (ALERT Communities Act, H.R. 7226, 118th Cong. (2024); ALERT Communities Act, S. 2919, 118th Cong. (2023); Support for Patients and Communities Reauthorization Act, H.R. 4531, 118th Cong. (2023).

[430] S. 2484, 118th Cong. (2023).

[431] S. 4025, 118th Cong. (2023).

Author Information

Joanna R. Lampe
Legislative Attorney

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