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The Controlled Substances Act (CSA): A Legal Overview for the 118th Congress

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The Controlled Substances Act (CSA): A Legal Overview for the 118th Congress

The Controlled Substances Act (CSA) establishes a unified legal framework to regulate certain drugs that are deemed to pose a risk of abuse and dependence. The CSA may apply to drugs that are medical or recreational, legally or illicitly distributed, but the statute does not apply to all drugs. Rather, it applies to 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*—precursor 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. The agency may also place a substance under temporary control on an emergency basis if the substance poses an imminent hazard to public safety. In addition, DEA may designate a substance for control if required by the United States' international treaty obligations. In the alternative, Congress may place a substance under control by statute.

The CSA simultaneously aims to ensure that patients have access to pharmaceutical controlled substances for legitimate medical purposes while also seeking to protect public health from the dangers of controlled substances diverted into or produced for the illicit market. To accomplish those two goals, the statute creates two overlapping legal schemes. *Registration provisions* require entities working with controlled substances to register with DEA and take various steps to prevent diversion and misuse of controlled substances. *Trafficking provisions* establish penalties for the production, distribution, and possession of controlled substances outside the legitimate scope of the registration system. DEA is primarily responsible for enforcing the CSA's registration provisions and works with the Criminal Division of the Department of Justice to enforce the Act's trafficking provisions. Violations of the registration provisions generally are not criminal offenses, but certain serious violations may result in criminal prosecutions 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 Congress, significant legal developments related to controlled substances regulation occurred via executive branch actions, court decisions, and enacted federal and state legislation. Members of Congress also introduced a number of proposals to amend the CSA in various ways. For instance, the 117th Congress confronted ongoing issues related to the opioid epidemic, including the regulation of the powerful opioid fentanyl and its analogues and the legality of supervised consumption sites. Recent years also saw developments in marijuana law and policy, including a 2022 presidential grant of clemency for federal and D.C. marijuana possession offenses and a growing divergence between federal and state marijuana laws. Members of the 117th Congress reintroduced legislation such as the MORE Act (H.R. 3617) and introduced the Cannabis Administration and Opportunity Act (S. 4591), both of which would have removed marijuana from control under the CSA. 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, expand medical practitioners' ability to prescribe controlled substances via telemedicine, and address sentencing disparities between CSA offenses involving crack and powder cocaine.

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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 2015 and 2018 estimated that over 48% of Americans had used one or more prescription drugs in the last 30 days.¹ But both pharmaceutical and non-pharmaceutical drugs may also pose serious public health risks. The CDC reports that 106,699 Americans died of drug overdoses in 2021.² The Controlled Substances Act³ (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 substances⁶ 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 118th 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 issues related to the response to the opioid epidemic, the growing divergence between the status of marijuana under federal and state law, legal limits on clinical research and medical use of certain controlled substances, CSA

¹ See CDC, Therapeutic Drug Use, <https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm> (last visited Dec. 28, 2022).

² See Merianne Rose Spencer, et al., *Drug Overdose Deaths in the United States, 2001-2021*, NCHS DATA BRIEF No. 457 (Dec. 2022).

³ 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. See 21 U.S.C. § 802(12); *id.* § 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.”

regulation of prescribing controlled substances via telemedicine, and criminal sentences for CSA offenses involving crack cocaine.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, and report certain information to regulators.²⁴ *Trafficking provisions* establish penalties for the production,

¹³ See *infra* “Legal Considerations for the 118th 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 See Quinn & McLaughlin, *supra* note 14 at 593.

¹⁷ *Id.* at 600-03.

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

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

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

²¹ See 21 U.S.C. §§ 811, 812.

²² *Id.* § 801(1).

²³ *Id.* § 801(2).

²⁴ See *id.* §§ 821-832.

distribution, and possession of controlled substances outside the legitimate scope of the registration system.²⁵

The CSA does not apply to all drugs. As discussed below, substances must generally be identified for control (either individually or as a class) to fall within the scope of the Act.²⁶ For medical drugs, the CSA primarily applies to prescription drugs, not drugs available over the counter.²⁷ Moreover, the statute does not apply to all prescription drugs but rather to a subset of those drugs deemed to warrant additional controls.²⁸ As for non-pharmaceutical drugs, well-known recreational drugs such as marijuana, cocaine,²⁹ 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.³⁰ Some recreational drugs are not classified as federally controlled substances.³¹ Alcohol and tobacco, which might otherwise qualify as drugs potentially warranting control under the CSA, are explicitly excluded from the scope of the Act,³² as is hemp that meets certain statutory requirements.³³ Finally, it is possible for legitimate researchers and illicit drug manufacturers to formulate new drugs not listed in any of the Act's schedules. Even if those drugs are similar to existing controlled substances, they may fall outside the scope of the CSA unless they are classified as controlled substances.³⁴ In some cases, however, substances not specifically listed in the CSA's schedules may nonetheless be subject to CSA regulation as *controlled substance analogues*.³⁵

²⁵ *Id.* §§ 841-865.

²⁶ *Id.* § 811.

²⁷ *Id.* § 829; *see also infra* "Prescriptions." The U.S. Food and Drug Administration also regulates pharmaceutical drugs, including pharmaceutical controlled substances, under the Federal Food, Drug, and Cosmetic Act. *See infra* "Federal Food, Drug, and Cosmetic Act."

²⁸ The Drug Enforcement Administration (DEA) has estimated that 10%-11% of all drug prescriptions written in the United States are for controlled substances. *See* DEA, Dispensing of Controlled Substances to Residents at Long Term Care Facilities, 75 Fed. Reg. 37,463, 37,464 (June 29, 2010).

²⁹ 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); *see also infra* "Overview of Schedules."

³⁰ The full schedules are promulgated at 21 C.F.R. §§ 1308.11-1308.15.

³¹ For example, *Salvia divinorum* (an herb with hallucinogenic effects) and kratom (a tropical tree whose leaves may have either stimulant or sedative effects depending on dosage) are not subject to the CSA at this writing, although DEA has identified them as "drugs of concern." DEA, DRUGS OF ABUSE: A DEA RESOURCE GUIDE, 84-85 (2017).

³² *See* 21 U.S.C. § 802(6).

³³ *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).

³⁴ *See The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order: Hearing Before the Sen. Comm. on the Judiciary*, 116th Cong. 1, 4 (2019) (statement of the U.S. Dep't of Justice) [hereinafter, DOJ Testimony]; *see also* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea.

³⁵ *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).³⁶ The U.S. Food and Drug Administration (FDA) is the agency primarily responsible for enforcing the FD&C Act, which, among other things, prohibits the “introduction or delivery for introduction into interstate commerce of any ... drug ... that is adulterated or misbranded.”³⁷ The FD&C Act defines misbranding broadly: a drug is considered misbranded if, among other things, its labeling, advertising, or promotion “is false or misleading in any particular.”³⁸ Unlabeled drugs are considered misbranded,³⁹ as are prescription drugs that FDA has not approved, including imported drugs.⁴⁰ The FD&C Act provides that a drug is deemed to be adulterated if, among other things, it “consists in whole or in part of any filthy, putrid, or decomposed substance,” “it has been prepared, packed, or held under insanitary conditions,” its container is made of “any poisonous or deleterious substance,” or its strength, quality, or purity is not as represented.⁴¹

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

State Laws Addressing Controlled Substances

With respect to both pharmaceutical and non-pharmaceutical drugs, many drugs subject to the CSA are also subject to state controlled substance laws.⁴⁴ Such state laws often mirror federal law, and they are relatively uniform across jurisdictions because almost all states have adopted a version of a model statute called the Uniform Controlled Substances Act (UCSA).⁴⁵ However,

³⁶ 21 U.S.C. §§ 301-399i.

³⁷ *Id.* § 331(a).

³⁸ *Id.* § 352.

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

⁴⁰ *See, e.g., In re Canadian Import Antitrust Litigation*, 470 F.3d 785, 788-90 (8th Cir. 2006); *United States v. Patwardhan*, 422 Fed. App'x 614, 616-17 (9th Cir. 2011). 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).

⁴¹ 21 U.S.C. § 351.

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

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

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

⁴⁵ Richard L. Braun, *Uniform Controlled Substances Act of 1990*, 13 CAMPBELL L. REV. 365, 365 (1991) (The UCSA

states are free to modify the UCSA, and have done so to varying extents.⁴⁶ Moreover, the model statute does not specify sentences for violations, so penalties for state controlled substance offenses vary widely.⁴⁷

There is not a complete overlap between drugs subject to federal and state controlled substance laws for several reasons. First, states may elect to impose controls on substances that are not subject to the CSA.⁴⁸ For example, some states have controlled the fentanyl analogues benzylfentanyl and therylfentanyl, but those substances are not currently scheduled under the CSA.⁴⁹ 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.⁵⁰ Third, states may decide not to impose state controls on substances subject to the CSA, or they may choose to impose modified versions of federal controls at the state level.⁵¹

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

Classification of Controlled Substances

The heart of the CSA is its system for classifying controlled substances, as nearly all the obligations and penalties that the Act establishes flow from the classification system.⁵⁵ Drugs

“has been the basic law pertaining to control of narcotic drugs in forty-six (46) states.”)

⁴⁶ For example, Arkansas has adopted the UCSA but added a sixth schedule for “substances that are determined to be inappropriately classified by placing them in Schedules I through V.” Ark. Code Ann. § 5-64-213. In addition, the UCSA classifies marijuana as a Schedule I controlled substance subject to stringent controls; however, many states have passed laws decriminalizing some or all marijuana use. See *infra* “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).

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

⁴⁸ Kreit, *supra* note 44 at 628.

⁴⁹ See, e.g., *United States v. Guerrero*, 910 F.3d 72, 75 (2d Cir. 2018) (discussing difference in scheduling between federal law and Arizona law); *McCoy v. United States*, 707 F.3d 184 (2d Cir. 2013) (same with respect to Connecticut law). Benzylfentanyl and therylfentanyl were temporarily placed under federal control in 1985, but the temporary scheduling expired in 1986, and DEA has determined that the substances are “essentially inactive, with no evidence of abuse potential.” DEA, *Correction of Code of Federal Regulations: Removal of Temporary Listing of Benzylfentanyl and Therylfentanyl as Controlled Substances*, 75 Fed. Reg. 37,300, 37,300 (June 29, 2010).

⁵⁰ Kreit, *supra* note 44 at 629.

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

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

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

⁵⁴ DEA and DOJ sometimes do not enforce federal controlled substances law with respect to state-legal activities that violate the CSA. Reasons for this include the exercise 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.

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

become subject to the CSA by being placed in one of five lists, referred to as *schedules*.⁵⁶ Either the administrator of the Drug Enforcement Administration (DEA)—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.⁵⁷ As discussed below, scheduling decisions by Congress and DEA follow different procedures.⁵⁸

Overview of Schedules

The CSA establishes five categories of controlled substances, referred to as Schedules I through V.⁵⁹ The schedule on which a controlled substance is placed determines the level of restriction imposed on its production, distribution, and possession, as well as the penalties applicable to any improper handling of the substance.⁶⁰ As **Figure 1** describes, when DEA places substances under control by regulation, the agency assigns each controlled substance to a schedule based on its medical utility and its potential for abuse and dependence.

⁵⁶ 21 U.S.C. § 812.

⁵⁷ *See infra* “Scheduling Procedures.”

⁵⁸ *See id.*

⁵⁹ 21 U.S.C. § 812.

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

Figure I. CSA Scheduling Criteria

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

Notes:

¹ 21 U.S.C. § 812(b)(1).

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

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

⁴ 21 U.S.C. § 812(b)(2).

⁵ The CSA distinguishes between 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.⁶¹ Notably, because substances in Schedule I have no accepted medical use, it is only legal to produce, dispense, and possess those substances in the context of federally approved scientific studies.⁶²

Analogues and Listed Chemicals

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

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

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

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

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

⁶¹ See *John Doe, Inc. v. DEA*, 484 F.3d 561, 563 (D.C. Cir. 2007).

⁶² See 21 U.S.C. § 823(f); see also *Gonzales v. Raich*, 545 U.S. 1, 14 (2004).

⁶³ *Id.* § 802(32).

⁶⁴ *Id.* § 813(a).

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

⁶⁶ 21 C.F.R. § 1300.02(b18).

⁶⁷ *Id.* § 1300.02(b19).

known as “ecstasy” or “molly”), and other drugs.⁶⁸ List II chemicals include, among others, solvents such as acetone, hydrochloric acid, and sulfuric acid.⁶⁹

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

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

Scheduling Procedures

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

Legislative Scheduling

Perhaps the most straightforward way to change a substance’s legal status under the CSA is for Congress to pass legislation to place a substance under control, alter its classification, or remove it from control. The procedural requirements for administrative scheduling discussed in the 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).

Congress has 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.⁷⁵ More recently, in February 2020, Congress enacted the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which placed a broad class of fentanyl analogues in Schedule I on a temporary basis.⁷⁶

⁶⁸ *Id.* § 1310.02(a).

⁶⁹ *Id.* § 1310.02(b).

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

⁷¹ *Id.* § 830.

⁷² 21 U.S.C. §§ 802(34), (35).

⁷³ *See, e.g.*, *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).

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

⁷⁵ *See* P.L. 112-144, 126 Stat. 1130 (2012).

⁷⁶ P.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.”

Administrative Scheduling

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

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

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

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

⁷⁸ 21 U.S.C. § 811(a).

⁷⁹ 21 C.F.R. § 1308.43.

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

⁸¹ 21 U.S.C. § 811(b).

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

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

⁸⁴ *Id.* § 811(b).

⁸⁵ *Id.*

⁸⁶ *Id.*

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

⁸⁸ *Id.* § 812(b).

⁸⁹ 5 U.S.C. § 500, et seq.

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

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

Emergency Scheduling

Ordinary DEA scheduling decisions made through notice-and-comment rulemaking can take years to consider and finalize.⁹⁵ Recognizing that in some cases faster scheduling may be appropriate, Congress amended the CSA through the Comprehensive Crime Control Act of 1984⁹⁶ to allow the DEA Administrator to place a substance in Schedule I temporarily when “necessary to avoid an imminent hazard to the public safety.”⁹⁷ Before issuing a temporary scheduling order, the DEA Administrator must provide 30 days’ notice to the public and the Secretary of HHS stating the basis for temporary scheduling.⁹⁸ In issuing a temporary scheduling order, the DEA Administrator must consider only a subset of the factors relevant to permanent scheduling: the history and current pattern of abuse of the substance at issue; the scope, duration, and significance of abuse; and the risk to the public health.⁹⁹ The DEA Administrator must also consider any comments from the Secretary of HHS.¹⁰⁰

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

⁹¹ *See id.* § 877.

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

⁹³ 21 U.S.C. § 877.

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

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

⁹⁶ P.L. 98-473, 98 Stat. 1976 (1984).

⁹⁷ 21 U.S.C. § 811(h)(1).

⁹⁸ 21 U.S.C. § 811(h)(1).

⁹⁹ *Id.* § 811(h)(3).

¹⁰⁰ *Id.* § 811(h)(4).

¹⁰¹ P.L. 112-144, 126 Stat. 993 (2012).

¹⁰² 21 U.S.C. § 811(h)(2). As originally enacted, the Comprehensive Crime Control Act of 1984 authorized temporary scheduling for up to one year, with a possible extension for up to six months if permanent scheduling proceedings were pending. *See* 98 Stat. 2072.

¹⁰³ *Id.* § 811(h)(5).

¹⁰⁴ *Id.* § 811(h)(6).

DEA has recently used its emergency scheduling power to temporarily control a large class of analogues to the opioid fentanyl,¹⁰⁵ other synthetic opioids,¹⁰⁶ and several synthetic cannabinoids.¹⁰⁷

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.¹⁰⁸ 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.¹⁰⁹

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.¹¹⁰ 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.¹¹¹

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.”¹¹² 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.¹¹³

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

¹⁰⁵ See DEA, Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188 (Feb. 6, 2018); see also *infra* “Fentanyl Analogues.”

¹⁰⁶ See DEA, Schedules of Controlled Substances: Temporary Placement of Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene in Schedule I, 87 Fed. Reg. 21,556 (Apr. 12, 2022).

¹⁰⁷ See DEA, Schedules of Controlled Substances: Temporary Placement of 5F-EDMBPINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 into Schedule I, 84 Fed. Reg. 15,505 (Apr. 16, 2019).

¹⁰⁸ 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”).

¹⁰⁹ *Id.* art. 36.

¹¹⁰ United Nations Convention on Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543.

¹¹¹ *Id.* art. 2(1)(7).

¹¹² 21 U.S.C. § 811(d)(1).

¹¹³ *Id.*

user, becomes subject to a comprehensive system of regulatory requirements.¹¹⁴ The goal of the regulatory scheme is to create a “closed system” of distribution in which only authorized handlers may distribute controlled substances.¹¹⁵ 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,¹¹⁶ are referred to as *registrants*.¹¹⁷ DEA has described the movement of a pharmaceutical controlled substance from the manufacturer to the patient as follows:

[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.¹¹⁸

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.¹¹⁹ Thus, the registration system aims to ensure that any controlled substance is always accounted for and under the control of a DEA-registered person until it reaches a patient or is destroyed.¹²⁰

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.¹²¹ 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.”¹²² 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.¹²³

¹¹⁴ See *id.* § 822.

¹¹⁵ DEA, Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,235, 16,237 (Mar. 31, 2010).

¹¹⁶ 21 U.S.C. § 822(a).

¹¹⁷ 21 C.F.R. § 1300.02(b)(24).

¹¹⁸ DEA, Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration, 74 Fed. Reg. 3480, 3481 (Jan. 21, 2009).

¹¹⁹ See *infra* “Obligations of Registrants.”

¹²⁰ See DEA, Definition and Registration of Reverse Distributors, 70 Fed. Reg. 22,591, 22,591 (May 2, 2005).

¹²¹ 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 imposing registration requirements for importers and exporters of controlled substances).

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

¹²³ 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

Manufacturers and distributors of controlled substances, such as pharmaceutical companies, must register with DEA annually.¹²⁴ 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.¹²⁵ 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.¹²⁶ Special registration is required for certain activities, including operating an opioid treatment program such as a methadone clinic.¹²⁷

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.¹²⁸ 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) that are the focus of the application. However, the requirements generally serve to help DEA determine whether the applicant has demonstrated the capacity to maintain effective controls against diversion and comply with applicable laws.¹²⁹

The registration of an individual or organization expires at the end of the registration period unless it is renewed.¹³⁰ Registration also ends when the registrant dies, ceases legal existence, or discontinues business or professional practice.¹³¹ A registration cannot be transferred to someone else without the express, written consent of the DEA Administrator.¹³²

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.¹³³ In addition, a controlled substance in Schedule I or II may be distributed only pursuant to a written order from the recipient of the

purposes of the CSA's trafficking provisions, "even if there is no commercial scheme involved").

¹²⁴ 21 U.S.C. § 822(a)(2).

¹²⁵ *Id.* § 822(a)(1).

¹²⁶ *Id.* § 822(e)(1).

¹²⁷ *Id.* § 823(g); *see also* CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*, by Johnathan H. Duff.

¹²⁸ *Id.* § 823(a)-(f).

¹²⁹ *Id.*

¹³⁰ 21 C.F.R. §§ 1301.13(c), (d).

¹³¹ *Id.* § 1301.52.

¹³² *Id.* § 1301.52(b).

¹³³ 21 U.S.C. § 827; 21 C.F.R. Part 1304.

substance.¹³⁴ Copies of each order form must be transmitted to DEA.¹³⁵ Records of orders must be preserved for two years and made available for government review upon request.¹³⁶

Registrants are also required to “design and operate a system to identify suspicious orders” and to notify DEA of any suspicious orders they detect.¹³⁷ DEA regulations provide that “[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”¹³⁸ That list is not exhaustive, however—courts have suggested that orders may be suspicious if, for example, a pharmacy mostly sells controlled substances rather than a more typical mix of controlled and non-controlled medications, many customers pay for controlled substances with cash, or pharmacies purchase drugs at a price higher than insurance would reimburse.¹³⁹

Inspections

The CSA permits the DEA Administrator to inspect the establishment of any registrant or applicant for registration.¹⁴⁰ 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.”¹⁴¹ Absent the consent of the registrant or special circumstances such as an imminent danger to health or safety, a warrant is required for inspection.¹⁴² “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.”¹⁴³ Issuance of a warrant requires probable cause.¹⁴⁴ 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.¹⁴⁵

Security

The CSA’s implementing regulations require all registrants to “provide effective controls and procedures to guard against theft and diversion of controlled substances.”¹⁴⁶ The regulations establish specific physical security requirements, which vary depending on the type of registrant and the classification of the controlled substance at issue.¹⁴⁷ For example, practitioners¹⁴⁸ subject

¹³⁴ 21 U.S.C. § 828; 21 C.F.R. Part 1305.

¹³⁵ 21 U.S.C. § 828(c)(2).

¹³⁶ *Id.* § 828(c)(1).

¹³⁷ *Id.* § 832.

¹³⁸ 21 C.F.R. § 1304.74(b).

¹³⁹ *See* *Masters Pharms. Inc. v. DEA*, 861 F.3d 206, 220 (D.C. Cir. 2017).

¹⁴⁰ 21 U.S.C. § 822(f).

¹⁴¹ 21 C.F.R. § 1316.13.

¹⁴² 21 U.S.C. § 880(c).

¹⁴³ *Id.* § 880(d)(1).

¹⁴⁴ *Id.*

¹⁴⁵ *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).

¹⁴⁶ 21 C.F.R. § 1301.71.

¹⁴⁷ *Id.* §§ 1301.72-76.

¹⁴⁸ 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

to CSA registration must store controlled substances “in a securely locked, substantially constructed cabinet.”¹⁴⁹ 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.¹⁵⁰ Registered non-practitioners must store controlled substances in Schedules I and II in a safe, steel cabinet, or vault that meets certain specifications.¹⁵¹ Non-practitioners must further ensure that controlled substance storage areas are “accessible only to an absolute minimum number of specifically authorized employees.”¹⁵²

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.¹⁵³ 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.¹⁵⁴ 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.¹⁵⁵ DEA sets production quotas annually and can adjust the quotas for a calendar year based on changes in demand.¹⁵⁶

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.”¹⁵⁷

he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.” 21 U.S.C. § 802(21). The Act and its implementing regulations do not define the term “non-practitioner,” but it appears to include registrants not engaged in the practice of medicine, such as manufacturers and distributors.

¹⁴⁹ 21 C.F.R. §§ 1301.75(a), (b).

¹⁵⁰ *Id.* § 1301.76(a).

¹⁵¹ 21 C.F.R. § 1301.72(a).

¹⁵² *Id.* § 1301.72(d).

¹⁵³ 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. 20, 2021), https://www.deadiversion.usdoj.gov/schedules/orangebook/j_chemlist_regulated.pdf.

¹⁵⁴ *Id.* §§ 826(b), (c).

¹⁵⁵ *Id.* § 826(i).

¹⁵⁶ *See* 21 C.F.R. § 1303.13. *See also, e.g.*, DEA, Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020, 84 Fed. Reg. 66,014, (Dec. 2, 2019) (setting aggregate production quotas for 2020); DEA, Adjustments to Aggregate Production Quotas for Certain Schedule II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine and Pseudoephedrine for 2020, in Response to the Coronavirus Disease 2019 Public Health Emergency, 85 Fed. Reg. 20,302 (Apr. 10, 2020) (adjusting aggregate production quotas for 2020 to meet increased need due to the COVID-19 pandemic).

¹⁵⁷ 21 U.S.C. § 952. The Controlled Substances Import and Export Act also imposes controls on the exportation of controlled substances, but does not establish specific export quotas. *See id.* § 953.

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.¹⁵⁸ The Act does not mandate that Schedule V substances be distributed by prescription, but such substances may be dispensed only “for a medical purpose.”¹⁵⁹ 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.¹⁶⁰

Enforcement and Penalties

DEA is the federal agency primarily responsible for enforcing the CSA’s registration requirements.¹⁶¹ 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.¹⁶²

The DEA Administrator may suspend or revoke a registration (or deny an application for registration) on several bases, including findings that a registrant or applicant has falsified application materials, been convicted of certain felonies, or “committed such acts as would render his registration ... inconsistent with the public interest.”¹⁶³ 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.¹⁶⁴ 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.”¹⁶⁵ To illustrate, those conditions may be satisfied when a practitioner prescribes

¹⁵⁸ *Id.* §§ 829(a), (b). Substances in Schedule I may not be dispensed by prescription because they have no accepted medical use.

¹⁵⁹ *Id.* § 829(c).

¹⁶⁰ *Cf.*, e.g., Ga. Code Ann. § 16-13-29.2 (permitting the State Board of Pharmacy to allow the sale of Schedule V controlled substances without a prescription); Fla. Stat. Ann. § 893.08 (permitting the sale of Schedule V controlled substances over-the-counter by a registered pharmacist, if a prescription is not required under the FD&C Act).

¹⁶¹ *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).

¹⁶² *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.”

¹⁶³ 21 U.S.C. § 824(a).

¹⁶⁴ *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 APA. *See, e.g.*, *Volkman v. DEA*, 567 F.3d 215, 219 (6th Cir. 2006).

¹⁶⁵ 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, P.L. 114-145, 130 Stat. 354 (2016). Those amendments made it more difficult for DEA to issue immediate suspensions. Previously, the Act simply provided that “[t]he Attorney General [through the DEA Administrator] may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety.” 21 U.S.C. § 824(d) (2000). As amended, the Act limits DEA’s discretion by requiring a specific finding of “imminent threat [of] death, serious bodily harm, or abuse of a controlled substance.” 21 U.S.C. § 824(d)(2); *see also* Scott Higham & Lenny

controlled substances outside the usual course of professional practice without a legitimate medical purpose in violation of state and federal controlled substances laws.¹⁶⁶

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.¹⁶⁷ 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.¹⁶⁸ 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.¹⁶⁹

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*.¹⁷⁰ Although the word “trafficking” may primarily call to mind the illegal distribution of recreational drugs, the CSA’s trafficking provisions in fact apply to a wide range of illicit activities involving either pharmaceutical or non-pharmaceutical controlled substances.¹⁷¹

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,¹⁷² 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;¹⁷³

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

¹⁶⁶ 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.

¹⁶⁷ 21 U.S.C. § 842(c)(1).

¹⁶⁸ *Id.* § 842(c)(2)(A).

¹⁶⁹ *Id.* § 842(c)(2)(D).

¹⁷⁰ See *id.* §§ 841-865.

¹⁷¹ See, e.g., *id.* §§ 841, 844 (criminalizing the manufacture, distribution, and possession of “a controlled substance,” except as authorized by the CSA).

¹⁷² *Id.* § 841(a)(1).

¹⁷³ *Id.* §§ 802(15) (“‘manufacture’ means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container”); 802(22) (“‘production’ includes the

- **Distribution or dispensing** of a controlled substance;¹⁷⁴
- **Possession** of a controlled substance with or without intent to distribute.¹⁷⁵

Penalties for the foregoing offenses vary based on the type and amount of the controlled substance in question.¹⁷⁶ Other sections of the CSA define more specific offenses, such as distributing controlled substances at truck stops or rest areas,¹⁷⁷ at schools,¹⁷⁸ or to people under age 21;¹⁷⁹ endangering human life while manufacturing a controlled substance;¹⁸⁰ selling drug paraphernalia;¹⁸¹ 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.¹⁸² An attempt or conspiracy to commit any offense defined under the Act also constitutes a crime.¹⁸³

Enforcement and Penalties

DOJ enforces the CSA’s trafficking provisions by bringing criminal charges against alleged violators.¹⁸⁴ 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 Act.¹⁸⁵ The Court in *Moore* held that physicians registered under the CSA can be prosecuted under the Act’s general drug trafficking provisions “when their activities fall outside the usual course of professional practice.”¹⁸⁶

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

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

¹⁷⁴ *Id.* § 841(a)(1). “Dispensing” refers to delivery of a controlled substance by a registered practitioner, including prescribing or administering a pharmaceutical controlled substance, while “distribution” refers to other delivery of a controlled substance. *Id.* §§ 802(10), 802(11).

¹⁷⁵ *Id.* §§ 841(a)(1) (criminalizing possession with intent to manufacture, distribute, or dispense, a controlled substance, except as authorized under the Act); *id.* § 844(a) (making it unlawful “knowingly or intentionally to possess a controlled substance,” unless the substance was obtained in a manner authorized by the CSA).

¹⁷⁶ *See, e.g., id.* §§ 841(b).

¹⁷⁷ *Id.* § 849.

¹⁷⁸ *Id.* § 860.

¹⁷⁹ *Id.* § 859.

¹⁸⁰ *Id.* § 858.

¹⁸¹ *Id.* § 863.

¹⁸² *Id.* § 848.

¹⁸³ *Id.* § 846.

¹⁸⁴ Trafficking that involves smuggling may also implicate the Controlled Substances Import and Export Act, 21 U.S.C. §§ 951-971, and/or the Maritime Drug Law Enforcement Act, 46 U.S.C. §§ 70501-70508.

¹⁸⁵ 423 U.S. 122, 133 (1975).

¹⁸⁶ *Id.* at 124.

effect, he acted as a large-scale ‘pusher’—not as a physician.”¹⁸⁷ Appellate courts have relied on *Moore* to uphold convictions of a pharmacist who signed thousands of prescriptions for sale through an online pharmacy¹⁸⁸ 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.”¹⁸⁹ 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.¹⁹⁰

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.¹⁹¹ 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.”¹⁹² 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.¹⁹³

For decades, DOJ has brought criminal trafficking charges against doctors and pharmacists who dispensed pharmaceutical controlled substances outside the usual course of professional practice.¹⁹⁴ In April 2019, DOJ for the first time brought criminal trafficking charges against a pharmaceutical company—Rochester Drug Cooperative—and two of its executives based on the company’s sale of the opioids oxycodone and fentanyl to pharmacies that illegally distributed the drugs.¹⁹⁵ Similarly, in July 2019, a federal grand jury indicted two former executives at the

¹⁸⁷ *Id.* at 142-43.

¹⁸⁸ *See* *United States v. Nelson*, 383 F.3d 1227, 1230 (10th Cir. 2004).

¹⁸⁹ *United States v. McIver*, 470 F.3d 550, 564 (4th Cir. 2006).

¹⁹⁰ *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”).

¹⁹¹ 142 S. Ct. 2370 (2022).

¹⁹² *Id.* at 2375.

¹⁹³ *Id.* at 2382.

¹⁹⁴ *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>.

¹⁹⁵ *See* Press Release, DOJ, Manhattan U.S. Attorney And DEA Announce Charges Against Rochester Drug Cooperative 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. In 2022, a federal jury convicted the company’s former CEO of conspiring to

pharmaceutical distributor Miami-Luken, Inc., among others, for conspiracy to violate the CSA's trafficking provisions.¹⁹⁶

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.¹⁹⁷ 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.¹⁹⁸ Penalties increase for second or subsequent offenses, or if death or serious bodily injury results from the use of the controlled substance.¹⁹⁹ 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.²⁰⁰

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.²⁰¹ Companies and individuals may also be subject to federal criminal charges under the Racketeer Influenced and Corrupt Organizations Act²⁰² or the Federal Anti-Kickback Statute.²⁰³ Those statutes notably formed part of the basis for the significant settlement between DOJ and opioid manufacturer Purdue Pharma in 2020.²⁰⁴ And manufacturers and distributors of opioids currently face numerous civil suits

distribute unlawfully oxycodone and fentanyl and conspiring to defraud DEA. Press Release, DOJ, 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>.

¹⁹⁶ 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).

¹⁹⁷ 21 U.S.C. § 844(a).

¹⁹⁸ *Id.* § 841(b)(1)(A).

¹⁹⁹ *Id.* § 841(b).

²⁰⁰ 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 Section 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.

²⁰¹ 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.

²⁰² See, e.g., Press Release, DOJ, Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering (Oct. 26, 2017); Gabrielle Emmanuel and Katie Thomas, *Opioid Company Executives Convicted of Racketeering*, N.Y. TIMES, May 3, 2019, at B1.

²⁰³ 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).

²⁰⁴ Purdue Pharma LP pled guilty to violating the Federal Anti-Kickback Statute and conspiracy to defraud the United

under federal and state law based on the companies' marketing and distribution of prescription opioids.²⁰⁵

Legal Considerations for the 118th Congress

Drug regulation has received significant attention from Congress in recent years. 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 supervised injection sites should be allowed under the CSA. In addition, policymakers have confronted a growing divergence between the status of marijuana under state and federal law, considered whether and how to facilitate clinical research involving Schedule I controlled substances, proposed legislation that would expand access to controlled substances via telemedicine, and debated reforms to criminal sentences for controlled substance offenses involving cocaine. The remainder of this report focuses on these and other particular topics that may be of interest to the 118th Congress.

Opioid Epidemic

One salient current issue in the realm of controlled substance regulation is the opioid epidemic.²⁰⁶ Opioids are drugs derived from the opium poppy or emulating the effects of opium-derived drugs.²⁰⁷ Some opioids have legitimate medical purposes, primarily related to pain management, while others have no recognized medical use.²⁰⁸ Both pharmaceutical opioids (such as oxycodone, codeine, and morphine) and non-pharmaceutical opioids (such as heroin) may pose a risk of abuse and dependence and may be dangerous or even deadly in certain doses.²⁰⁹ The CDC reports that overdoses involving opioids claimed over 80,800 lives in 2021.²¹⁰ CDC researchers further estimate that the costs of opioid use disorder and fatal opioid overdoses exceeded \$1 trillion in 2017.²¹¹

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,

States; the company and its shareholders also settled civil claims brought by the United States. *See id.*

²⁰⁵ *See, e.g.*, National Prescription Opiate Litigation, No. 17-MD-2804 (N.D. Ohio Dec. 12, 2017); *see also* CRS Legal Sidebar LSB10365, *Overview of the Opioid Litigation and Related Settlements and Settlement Proposals*, by Wen W. Shen; CRS Legal Sidebar LSB10226, *State and Local Governments Pursue Judicial Solutions to the Opioid Epidemic*, by Jennifer A. Staman.

²⁰⁶ 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.

²⁰⁷ *See* CRS Report R44987, *The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions*, by Lisa N. Sacco and Erin Bagalman. Technically, the term “opiates” refers to natural compounds found in the opium poppy, while the term “opioids” refers to synthetic compounds that emulate the effects of opiates, but commentators often use the term “opioids” to refer to both categories of substances, and this report adopts that usage. *See id.*

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ *See* CDC, U.S. Overdose Deaths In 2021 Increased Half as Much as in 2020 – But Are Still Up 15% (May 11, 2022), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm.

²¹¹ *See* Curtis S. Florence, et al., *The Economic Burden of Opioid Use Disorder and Fatal Opioid Overdose in the United States, 2017*, 218 DRUG & ALCOHOL DEPENDENCE (Jan. 2021).

Congress enacted the Comprehensive Addiction and Recovery Act of 2016 (CARA)²¹² and the 21st Century Cures Act (Cures Act).²¹³ CARA authorized grants to address issues related to the opioid crisis including abuse prevention and education, law enforcement, and treatment.²¹⁴ The Cures Act, among other things, provided additional funding to states combating opioid addiction.²¹⁵ 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.²¹⁶ Key amendments to the CSA under the SUPPORT Act included provisions expanding access to medication-assisted treatment for opioid addiction,²¹⁷ specifying the factors for determining whether a controlled substance analogue is intended for human consumption,²¹⁸ revising the factors DEA considers when establishing opioid production quotas,²¹⁹ and codifying the definition of “suspicious order” and outlining the CSA’s suspicious order reporting requirements.²²⁰

Building on these far-reaching enactments, the 116th and 117th Congresses enacted legislation seeking to address specific facets of the opioid crisis. Some of that legislation is discussed in the following subsections, along with selected recent proposals for reform.

Fentanyl Analogues

One issue that garnered significant attention in the 116th and 117th Congresses 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.²²¹ Many legal pharmaceutical drugs are synthetically produced.²²² 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 similar but stronger effects—but have chemical structures that have been slightly modified to circumvent existing drug laws.²²³

²¹² P.L. 114-198, 130 Stat. 695 (2016).

²¹³ P.L. 114-255, 130 Stat. 1033 (2016).

²¹⁴ See CRS Report R45449, *The SUPPORT for Patients and Communities Act (P.L.115-271): Medicare Provisions*, coordinated by Suzanne M. Kirchhoff.

²¹⁵ See *id.*

²¹⁶ P.L. 115-271, 132 Stat. 3894 (2018); see also CRS Report R45449, *The SUPPORT for Patients and Communities Act (P.L.115-271): Medicare Provisions*, coordinated by Suzanne M. Kirchhoff; CRS Report R45423, *Public Health and Other Related Provisions in P.L. 115-271, the SUPPORT for Patients and Communities Act*, coordinated by Elayne J. Heisler and Johnathan H. Duff; CRS Report R45405, *The SUPPORT for Patients and Communities Act (P.L. 115-271): Food and Drug Administration and Controlled Substance Provisions*, coordinated by Agata Bodie.

²¹⁷ P.L. 115-271, §§ 3201-04. 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.

²¹⁸ P.L. 115-271, § 3241. 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.”

²¹⁹ P.L. 115-271, § 3282. See also *supra* “Quotas.”

²²⁰ P.L. 115-271, §§ 3291-92. See also *supra* “Recordkeeping and Reporting.”

²²¹ See CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea.

²²² See, e.g., Kevin R. Campos, et al., *The Importance of Synthetic Chemistry in the Pharmaceutical Industry*, SCIENCE, Jan. 18, 2019.

²²³ Synthetic drugs that slightly modify the molecular structures of controlled substances to circumvent existing drug

One particular public concern in this area relates to synthetic opioids, including fentanyl analogues.²²⁴ Prescription fentanyl is a Schedule II controlled substance; multiple non-pharmaceutical substances related to fentanyl are controlled in Schedule I.²²⁵ 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.²²⁶ DEA has stated that, between March 2011 and January 2020, the agency used its emergency scheduling authority²²⁷ to impose temporary controls on 74 synthetic drugs, including 17 fentanyl-like substances.²²⁸

Even if not individually scheduled under the CSA, substances related to fentanyl may be subject to DEA control as controlled substance analogues.²²⁹ However, DOJ has stated that analogue prosecutions can be burdensome because they raise “complex chemical and scientific issues.”²³⁰ 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.²³¹ 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.²³² DOJ has therefore argued that permanent scheduling of fentanyl analogues can reduce uncertainty and aid enforcement.²³³

The 116th and 117th 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 scheduling order (Fentanyl TSO) that temporarily placed in Schedule I a class of “fentanyl-related substances.”²³⁴ 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 fentanyl-related substances that met specific criteria related to their chemical structures. That class of substances is finite, but it

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.

²²⁴ See, e.g., Press Release, U.S. Atty. 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>.

²²⁵ See 21 C.F.R. §§ 1308.11, 1308.12.

²²⁶ See CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea.

²²⁷ See *supra* “Emergency Scheduling.”

²²⁸ 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 emergency scheduling authority to control additional synthetic opioids. See DEA, Schedules of Controlled Substances: Temporary Placement of Isotonitazene in Schedule I, 85 Fed. Reg. 51,342 (Aug. 20, 2020); DEA, Schedules of Controlled Substances: Temporary Placement of Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene in Schedule I, 87 Fed. Reg. 21,556 (Apr. 12, 2022).

²²⁹ See *supra* “Analogues and Listed Chemicals.”

²³⁰ DOJ Testimony, *supra* note 34 at 5.

²³¹ 21 U.S.C. §§ 802(32), 813; see also DOJ Testimony, *supra* note 34 at 5.

²³² See CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea.

²³³ DOJ Testimony, *supra* note 34 at 5.

²³⁴ DEA, Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188 (Feb. 6, 2018). The emergency scheduling order applies to “any substance not otherwise [subject to the CSA] that is structurally related to fentanyl by one or more [specified] modifications.” *Id.* at 5191-92.

includes thousands of chemicals.²³⁵ As one researcher testified before Congress, the effects, potential for abuse and dependence, and medical utility of many of those substances are unknown.²³⁶ Perhaps because of those uncertainties, DEA did not initiate permanent scheduling of the class of substances subject to the Fentanyl TSO,²³⁷ though the agency has continued to take temporary and permanent scheduling actions with respect to specific fentanyl analogues, including selected fentanyl-related substances subject to the Fentanyl TSO.²³⁸

The Fentanyl TSO was set to expire in February 2020.²³⁹ 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 fentanyl-related substances until May 6, 2021.²⁴⁰ Congress has since extended the temporary scheduling several times, most recently through December 31, 2024.²⁴¹

Absent further legislative or administrative action, substances subject to the Fentanyl TSO will remain in Schedule I and subject to all restrictions and penalties applicable to Schedule I substances until the December 2024 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.²⁴² 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 and 117th 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.²⁴³ Others would have scheduled the class of fentanyl-related substances subject to the Fentanyl TSO plus certain specific substances.²⁴⁴

²³⁵ *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).

²³⁶ *See Fentanyl Analogues: Perspectives on Classwide Scheduling: Hearing Before the House Comm. on the Judiciary*, 116th Cong. 4 (2020) (statement of Sandra D. Comer).

²³⁷ 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 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.

²³⁸ *See* DEA, Schedules of Controlled Substances: Placement of Four Specific Fentanyl-Related Substances in Schedule I, 86 Fed. Reg. 14,707 (Mar. 18, 2021).

²³⁹ DEA, Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188, 5188 (Feb. 6, 2018).

²⁴⁰ P.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, *An Expiration Date for Temporary Control of Fentanyl Analogues*, by Joanna R. Lampe.

²⁴¹ P.L. 117-328, div. O, § 601.

²⁴² *See* 21 C.F.R. §§ 1308.11, 1308.12.

²⁴³ *See, e.g.*, Protecting Americans from Fentanyl Trafficking Act of 2022, S. 3457, 117th Cong. (2022); 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).

²⁴⁴ *See, e.g.*, Stopping Overdoses of Fentanyl Analogues Act, H.R. 2209, 117th Cong. (2021); S. 1006, 117th Cong.

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 scheduling²⁴⁵ or would have provided for expedited descheduling if a fentanyl-related substance were found not to pose a risk of abuse and dependence.²⁴⁶ In addition, based on concerns that individuals prosecuted for trafficking in fentanyl-related substances might face harsh penalties 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 fentanyl-related substances.²⁴⁷

A key challenge 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 structures. On one hand, not all analogues of fentanyl have effects similar to fentanyl itself,²⁴⁸ 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.²⁴⁹ 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.²⁵⁰

Congress could also consider alternative approaches to class-wide scheduling. For example, a proposal during the 116th Congress, the Modernizing Drug Enforcement Act of 2019,²⁵¹ 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.²⁵² That approach might avoid the concerns about scope of control noted above. It is not clear 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.²⁵³

(2021). *See also* Stopping Overdoses of Fentanyl Analogues Act, H.R. 2935, 116th Cong. (2019); S. 1622, 116th Cong. (2019).

²⁴⁵ *See, e.g.*, HALT Fentanyl Act, H.R. 6184, 117th Cong. (2021); S. 3336, 117th Cong. (2021); SIFT Act of 2021, H.R. 2041, 117th Cong. (2021).

²⁴⁶ *See, e.g.*, SAFE Act of 2022, H.R. 6946, 117th Cong. (2022).

²⁴⁷ *See, e.g., id.*; Federal Initiative To Guarantee Health by Targeting Fentanyl Act, H.R. 3269, 117th Cong. (2021).

²⁴⁸ To illustrate, DEA previously temporarily scheduled two fentanyl analogues before determining that the substances were “essentially inactive.” *See* DEA, Correction of Code of Federal Regulations: Removal of Temporary Listing of Benzylfentanyl and Thenyfentanyl as Controlled Substances, 75 Fed. Reg. 37,300, 37,300 (June 29, 2010).

²⁴⁹ *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>.

²⁵⁰ *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).

²⁵¹ H.R. 2580, 116th Cong. (2019).

²⁵² 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).

²⁵³ *See supra* note 231.

Supervised Consumption Sites

Another prominent legal issue arising from the opioid epidemic concerns the legality of supervised consumption sites under the CSA. Supervised consumption sites (sometimes also called safe injection sites) are facilities that pursue a harm reduction strategy by permitting the use of controlled substances in the presence of staff who can administer overdose-reversal medications, distributing medical supplies such as sterile syringes, and offering referrals to social services including substance use treatment.²⁵⁴ In recent years, courts and policymakers have considered whether a provision of the CSA that prohibits “[m]aintaining drug-involved premises,” 21 U.S.C. § 856 (Section 856), bars the operation of supervised consumption sites.

Congress first enacted Section 856 in 1986 in response to concerns about “crack houses”—premises where illicit drugs such as crack cocaine were manufactured, stored, distributed, and used.²⁵⁵ Congress amended the provision in 2003 to target facilities that hosted “raves,” where attendees distributed and used drugs such as MDMA.²⁵⁶

Section 856 imposes two criminal prohibitions. The first, contained in Section 856(a)(1), prohibits an entity from maintaining premises for its own drug-related activities.²⁵⁷ The second, Section 856(a)(2), prohibits making premises available for drug-related activity by third parties.²⁵⁸ Supervised consumption sites and their staff generally do not produce, distribute, or otherwise handle drugs, so legal questions related to such facilities center on Section 856(a)(2).²⁵⁹

In 2018, a nonprofit called Safehouse announced plans to open a supervised consumption site in Philadelphia. The United States sued Safehouse to block the proposed facility, arguing that the supervised consumption site would violate Section 856.²⁶⁰ On January 12, 2021, in *United States v. Safehouse*, the U.S. Court of Appeals for the Third Circuit agreed with the government.²⁶¹ A majority of the three-judge panel held that Safehouse need not “have the purpose that its visitors use drugs” but rather “need only ‘knowingly and intentionally’ open its site to visitors who come ‘for the purpose of ... using’ drugs.”²⁶² The court also concluded that, in “offer[ing] visitors a space to inject themselves with drugs,” Safehouse would violate Section 856 because the

²⁵⁴ See, e.g., Safehouse, The Safehouse Model, <https://www.safehousephilly.org/about/the-safehouse-model> (last visited Dec. 30, 2022); see also Substance Abuse and Mental Health Services Administration, Harm Reduction, <https://www.samhsa.gov/find-help/harm-reduction> (last visited Dec. 30, 2022); Jeffery C. Mays & Andy Newman, *Nation’s First Supervised Drug-Injection Sites Open in New York*, N.Y. TIMES (Nov. 30, 2021).

²⁵⁵ See Anti-Drug Abuse Act of 1986, P.L. 99-570, § 1841 (1986); see also, e.g., Nina Feldman, *In Philadelphia, Judges Rule Against Opening ‘Supervised’ Site To Inject Opioids*, NPR (Jan. 14, 2021).

²⁵⁶ See Protect Act, P.L. 108-21 § 608 (2003).

²⁵⁷ 21 U.S.C. § 856(a)(1) (providing that it shall be unlawful to “knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance”).

²⁵⁸ 21 U.S.C. § 856(a)(2) (providing that it shall be unlawful to “manage or control any place ... and knowingly and intentionally rent, lease, profit from, or make available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance”).

²⁵⁹ See, e.g., Safehouse, Frequently Asked Questions, <https://www.safehousephilly.org/frequently-asked-questions> (last visited Dec. 30, 2022).

²⁶⁰ See Press Release, DOJ, Civil Lawsuit Filed to Seek Judicial Declaration that Drug Injection Site Is Illegal Under Federal Law (Feb. 6, 2019), <https://www.justice.gov/usao-edpa/pr/civil-lawsuit-filed-seek-judicial-declaration-drug-injection-site-illegal-under-federal>.

²⁶¹ 985 F.3d 225 (3d Cir. 2021).

²⁶² *Id.* at 232.

organization “itself has a significant purpose that its visitors use heroin, fentanyl, and the like.”²⁶³ In response to Safehouse’s argument that this application was not what Congress intended when it enacted and amended Section 856, the majority held that the text of the statute was clear, so the court need not look beyond the text to other indicia of congressional intent.²⁶⁴

One member of the Third Circuit panel dissented. Senior Judge Roth contended that the text of Section 856 is ambiguous and that the majority erred in construing the ambiguous text in a way that imposed broad criminal liability.²⁶⁵ She would have also held that Safehouse lacked the requisite intent to violate Section 856 because it “is not motivated at least in part by a desire for unlawful drug activity to occur and ... in fact wants to reduce drug activity.”²⁶⁶ The Supreme Court declined to review the Third Circuit’s decision.²⁶⁷

As of January 2023, Safehouse has not commenced operation. However, other states and localities have begun considering whether to authorize such facilities. During the Safehouse litigation, there were already multiple reports of a supervised consumption site operating in secret in an undisclosed location, and local governments and other organizations outside Philadelphia had begun to consider similar facilities.²⁶⁸ In July 2021, Rhode Island enacted legislation authorizing supervised consumption sites under state law.²⁶⁹ The Illinois, Massachusetts, and New Mexico state legislatures have also considered legislation related to supervised consumption sites.²⁷⁰ The California legislature passed legislation in 2022 that would have allowed supervised consumption sites to operate on a trial basis in three cities,²⁷¹ but the governor vetoed it, expressing concerns that the legislation might inadvertently “[w]orsen[] drug consumption challenges” in those cities.²⁷²

In November 2021, two supervised consumption sites began operating openly in New York City with the approval of the city government.²⁷³ The city reported that the sites were used 2,000 times in their first three weeks of operation and averted at least 59 potential overdose deaths.²⁷⁴ While DOJ actively opposed the operation of supervised consumption sites under the Trump Administration, to date the Biden Administration has not sought to invoke the CSA against such facilities. In February 2022, DOJ stated that it was “evaluating supervised consumption sites,

²⁶³ *Id.* at 238.

²⁶⁴ *Id.* at 238-39.

²⁶⁵ *Id.* at 244- 45 (Roth, S.J., dissenting).

²⁶⁶ *Id.* at 251 (Roth, S.J., dissenting).

²⁶⁷ *Safehouse v. Dept. of Justice*, 142 S. Ct. 345 (2021).

²⁶⁸ *See, e.g.*, Ronnie Cohen, *Drug Users Find Safety, Community in Underground Injection Facility*, REUTERS (Jan. 12, 2018); Lenny Bernstein, *A Secret, Supervised Place Where Users Can Inject Drugs Has Been Operating in the U.S. for Three Years*, WASH. POST (Aug. 8, 2017); Gabrielle Masson, *Massachusetts General Hosts Mock Safe Injection Site*, BECKER’S HOSP. REV. (Oct. 16, 2019).

²⁶⁹ R.I. Stat. § 23-12.10-1 et seq; *see also* Aaron Warnick, *Rhode Island Approves Nation’s First Sites for Safe Drug Injection Use*, THE NATION’S HEALTH (Oct. 2021).

²⁷⁰ H.B. 100, 102nd Gen. Assembly (Ill. 2022); S. 1258, 192nd Gen. Ct. (Mass. 2021); H.B. 123, 55th Leg. (N.M. 2021).

²⁷¹ S.B. 57, 2021-22 Reg. Sess. (Ca. 2021).

²⁷² *See* Cheri Mossburg, *Newsom Vetoes Bill Proposing Safe Drug Injection Sites in California*, CNN (Aug. 22, 2022).

²⁷³ Press Release, NYC Dept. of Health & Mental Hygiene, *Overdose Prevention Centers Averted 59 Overdoses in First Three Weeks of Operation* (Dec. 21, 2021), <https://www.nyc.gov/site/doh/about/press/pr2021/overdose-prevention-centers-prevent-59-deaths.page>.

²⁷⁴ *Id.*

including discussions with state and local regulators about appropriate guardrails for such sites, as part of an overall approach to harm reduction and public safety.”²⁷⁵

In the meantime, uncertainty remains as to the legality of supervised consumption sites under the CSA. Congress could wait to see if other courts address the issue, or it could seek to resolve that uncertainty by enacting legislation. If Congress decided to allow supervised consumption sites to operate, it could consider the breadth of such authorization. One option would be to exempt supervised consumption sites from CSA control entirely. Alternatively, Congress might choose to exempt from federal prosecution facilities operating in compliance with state and local law, as it has done with state-sanctioned medical marijuana through a series of appropriations riders.²⁷⁶ Another option would be for Congress to impose specific registration requirements for supervised consumption sites under the CSA, as it has done for entities that administer medication-assisted treatment for opioid use disorder.²⁷⁷

If Congress decided not to allow supervised consumption sites, it could amend Section 856 to prohibit those facilities explicitly, as it did with respect to other activities in 2003,²⁷⁸ or enact separate legislation to ban supervised consumption sites. Congress could also withhold federal spending from supervised consumption sites.²⁷⁹ For example, a proposal during the 117th Congress would have prohibited federal funds from being “used by any Federal agency to operate or control ... an injection center” that violates Section 856.²⁸⁰ Others would have limited the availability of federal funds to states, localities, Indian tribes, and other entities that operate supervised consumption sites in violation of Section 856.²⁸¹

Other Proposals Related to Opioid Regulation

In addition to the proposals discussed above, numerous other legislative proposals in the 117th Congress sought to address the opioid crisis by amending the CSA.²⁸² For instance, the LABEL Opioids Act would have required certain opioid medications subject to the CSA to bear a “clear,

²⁷⁵ *Justice Department Signals It May Allow Supervised Injection Sites*, CBS NEWS N.Y. (Feb. 8, 2022).

²⁷⁶ See *infra* “Appropriations Limitations.”

²⁷⁷ See 21 U.S.C. § 823(h); see also CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*, by Johnathan H. Duff.

²⁷⁸ See Protect Act, P.L. 108-21 § 608 (2003).

²⁷⁹ For background on Congress’s spending power, see Cong. Rsch. Serv., *Overview of Spending Clause*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S8-C1-2-1/ALDE_00013356/ (last visited Dec. 30, 2022).

²⁸⁰ Crack is Whack Act, H.R. 6741, § 2, 117th Cong. (2022).

²⁸¹ See Stop Injection Sites for Illegal Drugs Act of 2022, H.R. 7029, 117th Cong. (2022); Defund de Blasio’s Injection Sites Act of 2021, H.R. 6159, 117th Cong. (2021).

²⁸² 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.

concise warning that the opioid dispensed can cause dependence, addiction, and overdose.”²⁸³ 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.”²⁸⁴ 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.²⁸⁵ The Harm Reduction Through Community Engagement Act of 2022 would have imposed additional registration requirements for opioid treatment programs.²⁸⁶ The Opioid QuOTA Act of 2021 would have required publication of the annual quotas that apply to each registered opioid manufacturer.²⁸⁷

Other proposals would have amended CSA provisions that impose criminal penalties for unauthorized activities involving opioids.²⁸⁸ Some proposals sought to increase criminal penalties for certain fentanyl-related offenses, imposing life in prison or the death penalty.²⁸⁹ Others would have lowered the amounts of fentanyl or fentanyl analogues required to trigger existing mandatory minimum sentences.²⁹⁰ 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.²⁹¹ Another proposal would have authorized special agents of Homeland Security Investigations to perform certain enforcement functions under the CSA.²⁹²

Federal and State Marijuana Regulation

Another topic that raised a number of legal considerations for the 117th Congress is the increasing divergence between federal and state marijuana regulation.²⁹³ As of January 2023, 21 states, two territories, and the District of Columbia have passed laws removing prohibitions on medical and recreational marijuana use by adults age 21 or older.²⁹⁴ Thirty-seven states have passed laws permitting medical use of marijuana. Another 10 states authorize medical use of cannabis derivatives, such as cannabidiol (CBD), that contain low levels of tetrahydrocannabinol

²⁸³ H.R. 1026, 117th Cong. (2021); S. 2353, 117th Cong. (2021).

²⁸⁴ S. 2235, 117th Cong. (2021).

²⁸⁵ H.R. 1384, 117th Cong. (2021); S. 445, 117th Cong. (2021).

²⁸⁶ H.R. 8917, 117th Cong. (2021).

²⁸⁷ H.R. 6150, 117th Cong. (2021); S. 3327, 117th Cong. (2021).

²⁸⁸ For general discussion of the CSA’s trafficking provisions, see *supra* “Trafficking Provisions.”

²⁸⁹ See, e.g., Fentanyl Trafficker Elimination Act, H.R. 6439, 117th Cong. (2022); Death Penalty for Dealing Fentanyl Act of 2022, H.R. 8228, 117th Cong. (2022).

²⁹⁰ 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).

²⁹¹ See, e.g., Zero Tolerance for Deceptive Fentanyl Trafficking Act, S. 4984, 117th Cong. (2022); Stop Pills That Kill Act, H.R. 8175, 117th Cong. (2022); S. 4151, 117th Cong. (2022).

²⁹² Homeland Security Fentanyl Enforcement Act, H.R. 9093, 117th Cong. (2022).

²⁹³ See generally CRS Report R44782, *The Evolution of Marijuana as a Controlled Substance and the Federal-State Policy Gap*, coordinated by Lisa N. Sacco.

²⁹⁴ See Nat’l Conference of State Legislatures, *State Medical Marijuana Laws* (Nov. 9, 2022), <http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>.

(THC).²⁹⁵ However, marijuana is a Schedule I controlled substance under federal law, and state marijuana legislation has no effect on that status.²⁹⁶

As discussed below, certain legal and practical considerations limit federal prosecutions of individuals and businesses involved in the state-legal marijuana industry.²⁹⁷ 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,²⁹⁸ and those businesses may be ineligible for certain federal tax deductions.²⁹⁹ The involvement of income from a marijuana-related business may also prevent a bankruptcy court from approving a bankruptcy plan.³⁰⁰ For individuals, some CSA violations involving marijuana may have adverse immigration consequences.³⁰¹ Illicit drug use or convictions may limit individuals' eligibility for

²⁹⁵ *Id.*

²⁹⁶ *See, e.g.,* Gonzales v. Raich, 545 U.S. 1, 29 (2004). *See also* CRS Legal Sidebar LSB10482, *State Marijuana "Legalization" and Federal Drug Law: A Brief Overview for Congress*, by Joanna R. Lampe. Notably, however, not all CBD is subject to the CSA. The 2018 Farm Bill exempted "hemp"—cannabis and cannabis derivatives containing very low levels of THC—from control under the CSA. *See* 21 U.S.C. § 802(16)(B)(i). Accordingly, CBD that meets those requirements is no longer a federally controlled substance. CBD remains subject to federal regulation under the FD&C Act, and FDA has taken the position that CBD is a drug that may not lawfully be added to foods or marketed as a dietary supplement. *See* Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Signing of the Agriculture Improvement Act and the Agency's Regulation of Products Containing Cannabis and Cannabis-Derived Compounds (Dec. 20, 2018); *see also* Sean M. O'Connor & Erika Lietzan, *The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling*, 68 AM. U. L. REV. 823 (2019); CRS In Focus IF11250, *FDA Regulation of Cannabidiol (CBD) Consumer Products*, by Agata Bodie and Renée Johnson.

²⁹⁷ *See infra* "Appropriations Limitations."

²⁹⁸ Anti-money laundering laws prohibit, *inter alia*, "conduct[ing] or attempt[ing] to conduct ... a financial transaction which in fact involves the proceeds of specified unlawful activity ... with the intent to promote the carrying on of specified unlawful activity" 18 U.S.C. §§ 1956(a). For a full list of predicate offenses, see the "Specified Unlawful Activities" section of CRS Report RL33315, *Money Laundering: An Overview of 18 U.S.C. § 1956 and Related Federal Criminal Law*, by Charles Doyle. For further discussion of banking law issues related to the marijuana policy gap, see the "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.

²⁹⁹ *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.

³⁰⁰ 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 a 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 a 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).

³⁰¹ *See* 8 U.S.C. § 1427(a) (providing that no person shall be naturalized unless that person, among other things, "has been and still is a person of good moral character"); 8 C.F.R. § 316.10(b)(2) ("An applicant shall be found to lack good moral character if during the statutory period the applicant ... [v]iolated any law of the United States, any State, or any foreign country relating to a controlled substance, provided that the violation was not a single offense for simple possession of 30 grams or less of marijuana").

federal student financial aid and other benefits.³⁰² Federal law also prohibits the possession of firearms or ammunition by any person who is “an unlawful user of or addicted to any controlled substance.”³⁰³ Furthermore, people who use marijuana, even for medical purposes, generally enjoy little or no legal protection from adverse employment consequences.³⁰⁴

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.”³⁰⁵ The current appropriations rider is in effect through September 30, 2023.³⁰⁶ Several federal courts have interpreted the appropriations rider to bar DOJ from expending any appropriated funds to prosecute activities involving marijuana that are conducted in “strict compliance” with state law.³⁰⁷ For example, in the 2019 case *United States v. Evans*, the Ninth Circuit upheld the prosecution of two individuals involved in the production of medical marijuana who smoked marijuana as they processed plants for sale.³⁰⁸ 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.³⁰⁹

More recently, in the 2022 case *United States v. Bilodeau*, the First Circuit held that the rider also bars prosecution in some cases where defendants did not strictly comply with state medical marijuana law.³¹⁰ 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.”³¹¹ Thus, the First Circuit concluded that requiring strict compliance with state law would likely chill state-legal medical marijuana

³⁰² See CRS Legal Sidebar LSB10556, *The MORE Act: House Plans Historic Vote on Federal Marijuana Legalization*, by Joanna R. Lampe; CRS Report R42394, *Drug Testing and Crime-Related Restrictions in TANF, SNAP, and Housing Assistance*, by Maggie McCarty et al.

³⁰³ 18 U.S.C. § 922.

³⁰⁴ 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>.

³⁰⁵ P.L. 117-328, div. B, § 531. The appropriations rider enumerates the specific states and territories to which it applies. The list excludes the three states that have not decriminalized medical marijuana use.

³⁰⁶ See *id.* § 5.

³⁰⁷ See *United States v. McIntosh*, 833 F.3d 1163, 1178 (9th Cir. 2016); *Duval v. United States*, 372 F. Supp. 3d 544, 555-56 (E.D. Mich. 2019); *Sandusky v. Goetz*, 2018 WL 6505803 at *4-5 (D. Colo. Dec. 11, 2018); *United States v. Jackson*, 2019 WL 3239844 at *6-8 (E.D. Pa. June 5, 2019).

³⁰⁸ 929 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 States 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).

³⁰⁹ *Evans*, 929 F.3d at 1078-79 (9th Cir. 2019).

³¹⁰ 24 F.4th 705 (2022).

³¹¹ *Id.* at 713.

activities and prevent the states from giving effect to their medical marijuana laws.³¹² 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."³¹³ 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.³¹⁴

It remains to be seen whether and how the difference in reasoning between the Ninth Circuit and the First Circuit will make a practical difference in federal marijuana prosecutions.³¹⁵ Congress 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 marijuana³¹⁶ 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 has typically not prosecuted individuals who possess marijuana for personal use on private property but instead has "left such lower-level or localized marijuana activity to state and local authorities through enforcement of their own drug laws."³¹⁷ 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."³¹⁸ In recent years, DOJ has pursued marijuana prosecutions in the context of large-scale trafficking operations or gang-related activity.³¹⁹ The Biden Administration DOJ has not issued formal guidance on marijuana policy,

³¹² *Id.* at 713-14.

³¹³ *Id.* at 714.

³¹⁴ *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.*

³¹⁵ 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 target individuals and organizations that have clearly 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." *Id.* at 718 (Barron, J., concurring).

³¹⁶ *See, e.g.*, State Cannabis Commerce Act, H.R. 3546, 116th Cong. (2019); S. 2030, 116th Cong. (2019); *cf.* STATES Act, H.R. 2093, 116th Cong. (2019); S. 1028, 116th Cong. (2019) (proposal to amend the CSA to provide that most provisions related to marijuana "shall not apply to any person acting in compliance with State law relating to the manufacture, production, possession, distribution, dispensation, administration, or delivery" of marijuana).

³¹⁷ U.S. Government Accountability Office, *State Marijuana Legalization: DOJ Should Document Its Approach to Monitoring the Effects of Legalization*, GAO-16-1, 9 (Dec. 2015).

³¹⁸ Memorandum from Jefferson B. Sessions, Attorney Gen., U.S. Dep't of Justice, on Marijuana Enforcement to all United States Attorneys (Jan. 4, 2018), <https://www.justice.gov/opa/press-release/file/1022196/download>.

³¹⁹ *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),

but Attorney General Merrick Garland has indicated that the agency will not prioritize prosecuting individuals for personal use of marijuana.³²⁰

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.³²¹ President Biden’s invocation of the clemency power means that people who committed simple possession of marijuana before the date of the proclamation may not be prosecuted or punished for the offense under the relevant provisions of the CSA or the D.C. Code.³²²

Several factors limit the scope of the pardon. First, it applies only to violations of federal and D.C. law and does 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.³²³ Second, the pardon applies only to simple possession of marijuana, which the federal government rarely prosecutes.³²⁴ It does not apply to other marijuana-related CSA offenses such as manufacture, distribution, or possession with intent to distribute or to other federal crimes.³²⁵

<https://www.justice.gov/usao-ct/pr/indictment-charges-bridgeport-gang-members-drug-trafficking-committing-4-murders>.

³²⁰ See, e.g., *Hearing Before the Sen. Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies*, 117th Cong. (Apr. 26, 2022) (testimony of Atty. 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.”).

³²¹ Joseph R. Biden, A Proclamation on Granting Pardon for the Offense of Simple Possession of Marijuana (Oct. 6, 2022).

³²² 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.

³²³ 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>.

³²⁴ 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, https://www.usc.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).

³²⁵ The USSC reports that 425 people were convicted of possessing marijuana and possessing other illicit drugs. USSC, Number of Federal Offenders Convicted Only of 21 U.S.C. § 844 Involving Marijuana and Other Drugs, Fiscal Years 1992 – 2021, https://www.usc.gov/sites/default/files/pdf/news/press-releases-and-news-advisories/news-advisories/20221012_Updated-News-Advisory-Data-Analysis.pdf#page=2. In addition, 585 people were convicted of simple possession of marijuana and one or more other crimes. USSC, Number of Federal Offenders Convicted of 21 U.S.C. § 844 Involving Only Marijuana Who Also Have Other Convictions, Fiscal Years 1992 – 2021, https://www.usc.gov/sites/default/files/pdf/news/press-releases-and-news-advisories/news-advisories/20221012_Updated-News-Advisory-Data-Analysis.pdf#page=3. Those people would remain liable for the

Third, the pardon by its terms “does not apply to individuals who were non-citizens not lawfully present in the United States at the time of their offense.”³²⁶ Fourth, the pardon applies only to offenses committed before the proclamation.³²⁷ Thus, while DOJ is currently not prioritizing prosecuting low-level marijuana offenses, the October 2022 pardon does not prevent prosecution of future offenses if the current Administration or a future Administration adopts a different policy. Fifth, the pardon may not remove all legal consequences of marijuana possession, because it does not expunge convictions.³²⁸ Moreover, some collateral consequences of marijuana-related activities do not depend on a person being charged with or convicted of a CSA violation.³²⁹

In addition, and most fundamentally, the pardon does not change the status of marijuana under federal law. The President lacks the power to make such a change unilaterally.³³⁰ In announcing the grant of clemency, President Biden directed the Attorney General to review the classification of marijuana under the CSA.³³¹ Such review is one way the federal government could change the status of the substance consistently with relevant separation-of-powers principles and the CSA’s procedural requirements.³³² Any agency action in response to that directive would likely occur through notice-and-comment rulemaking and would be subject to judicial review³³³ and applicable international treaty obligations.³³⁴

Proposed Marijuana Legislation

Numerous proposals introduced in the 117th Congress 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.³³⁵

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 marijuana offenses.” USSC, *Final Priorities for Amendment Cycle*, 87 Fed. Reg. 67,756, 67,756 (Nov. 9, 2022).

³²⁶According 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: SIMPLE POSSESSION OF DRUGS IN THE FEDERAL CRIMINAL JUSTICE SYSTEM* 5-6 (Sept. 2016). Among offenders sentenced for marijuana possession in FY2013, over 94% of those arrested at the border were 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.

³²⁷The 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).

³²⁸ *See* DOJ, *Presidential Proclamation on Marijuana Possession* (Nov. 2, 2022), <https://www.justice.gov/pardon/presidential-proclamation-marijuana-possession>.

³²⁹ *See supra* notes 298-304 and accompanying text.

³³⁰ *See* CRS Legal Sidebar LSB10655, *Does the President Have the Power to Legalize Marijuana?*, by Joanna R. Lampe.

³³¹ Joseph R. Biden, *A Proclamation on Granting Pardon for the Offense of Simple Possession of Marijuana* (Oct. 6, 2022).

³³² *See, e.g.,* *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 585 (1952); 21 U.S.C. § 811.

³³³ *See* 21 U.S.C. § 877.

³³⁴ The relevant treaties are not self-executing and do not directly bind Congress or private parties, but the CSA requires DEA to schedule substances as needed to satisfy the United States’ treaty obligations. *See* 21 USC § 811(d)(1) (“If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations[.]”); *see also supra* “International Treaty Obligations.”

³³⁵ *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,

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.³³⁶ Among other things, it would have also removed some collateral consequences for marijuana-related activities,³³⁷ imposed a 5% tax on cannabis products,³³⁸ and used revenues from the tax to fund certain grant programs for disadvantaged individuals and “individuals adversely impacted by the War on Drugs.”³³⁹ The MORE Act passed the House in April 2022 but did not pass the Senate.³⁴⁰

Another descheduling proposal, the Cannabis Administration and Opportunity Act, would have removed from Schedule I marijuana and THC derived from the cannabis plant.³⁴¹ It would have also provided for expungement of certain past marijuana convictions,³⁴² 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.³⁴³ In addition, among other things, it would have provided guidance for regulation of cannabis products under the FD&C Act.³⁴⁴ It would also have imposed a 10%-25% tax on cannabis products³⁴⁵ and used revenues from the tax to fund programs including small business development, community reinvestment, and opioid abuse treatment.³⁴⁶ Other legislative proposals from the 117th Congress would likewise have removed marijuana from control under the CSA.³⁴⁷

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.³⁴⁸ To address this, some descheduling proposals also include provisions designed to address past criminal convictions related to marijuana.³⁴⁹ Second, removing marijuana from the ambit of the CSA

https://constitution.congress.gov/browse/essay/artI-S8-C3-1/ALDE_00013403/ (last visited Jan. 3, 2023).

³³⁶ H.R. 3617, §§ 3, 10, 117th Cong. (2021).

³³⁷ *Id.* §§ 7-9.

³³⁸ *Id.* § 5.

³³⁹ *Id.* §§ 5-6.

³⁴⁰ 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* 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.

³⁴¹ S. 4591, § 101, 117th Cong. (2022).

³⁴² *Id.* § 311.

³⁴³ *Id.* § 112.

³⁴⁴ *Id.* § 501.

³⁴⁵ *Id.* § 401.

³⁴⁶ *Id.* §§ 301-03.

³⁴⁷ *See, e.g.*, 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); *see also* Marijuana Justice Act of 2019, H.R. 1456, 116th Cong. (2019); S. 597, 116th Cong. (2019).

³⁴⁸ *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).

³⁴⁹ Other legislative proposals from the 117th Congress would also have allowed for expungement or sealing of certain federal marijuana convictions. *See, e.g.*, Marijuana Misdemeanor Expungement Act, H.R. 8557, (2022); 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 2021, H.R. 6129, 117th Cong. (2021). *See also, e.g.*,

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.³⁵⁰ 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 116th Congress would have imposed new federal regulations on marijuana akin to those applicable to alcohol and tobacco.³⁵¹ Fourth, reducing or removing federal restrictions on marijuana might be inconsistent with certain treaty obligations of the United States.³⁵² The applicable treaties are not self-executing,³⁵³ meaning that they do not have the same status as judicially enforceable domestic law.³⁵⁴ However, failure to abide by its treaty obligations could expose the United States to diplomatic consequences.³⁵⁵

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).

³⁵⁰ 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. Congress could also enact legislation to alter FDA regulation of cannabis-based products. For example, the Legitimate Use of Medicinal Marijuana Act, 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.

³⁵¹ See, e.g., Regulate Marijuana Like Alcohol Act, H.R. 420, 116th Cong. (2019).

³⁵² See *supra* “International Treaty Obligations.” The United States is a party to the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971. 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). Nonetheless, cannabis and its derivatives remain subject to restrictions under the international drug control treaties that may be inconsistent with legalization of marijuana, particularly for recreational purposes. 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.

³⁵³ 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 is also not self-executing.

³⁵⁴ See *Medellin*, 552 U.S. at 527 (“A non-self-executing treaty, by definition, is one that was ratified with the understanding that it is not to have domestic effect of its own force.”). For additional background on the legal effect of self-executing and non-self-executing treaties, see CRS Report RL32528, *International Law and Agreements: Their Effect upon U.S. Law*, by Stephen P. Mulligan, at 15.

³⁵⁵ 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 that 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).

As an alternative to descheduling, some recent proposals would have maintained marijuana as a controlled substance but moved it to a less restrictive schedule, potentially allowing it to be dispensed by prescription for medical purposes.³⁵⁶ Congress could also continue to regulate marijuana as a Schedule I controlled substance subject to specific exceptions. For instance, several legislative proposals during the 116th Congress would have left marijuana in Schedule I but limited enforcement of federal marijuana law in states that have legalized marijuana.³⁵⁷ In the 117th Congress, the Small and Homestead Independent Producers Act of 2022 (H.R. 8825) would have allowed shipment of marijuana within and between states that have legalized the substance.³⁵⁸

Some recent proposals would have addressed specific legal consequences of marijuana's Schedule I status. For example, the SAFE Banking Act of 2021, which passed the House in April 2021, sought to protect depository institutions that provide financial services to cannabis-related businesses from regulatory sanctions.³⁵⁹ Other proposals sought to ensure marijuana businesses' access to insurance and other financial resources,³⁶⁰ facilitate federally approved clinical research involving marijuana,³⁶¹ or enable veterans to access information about or use medical marijuana.³⁶² Additional proposals would have removed collateral legal consequences of marijuana-related activities for individuals in areas such as immigration,³⁶³ gun ownership,³⁶⁴ and federally assisted housing.³⁶⁵

While most recent proposals would have relaxed federal regulation of marijuana, Congress could also impose more stringent controls. For instance, one recent proposal would have prohibited the use of benefits under the Temporary Assistance for Needy Families block grant at any store that offers marijuana for sale.³⁶⁶ Other proposals would seek to address the issues of marijuana impairment in the workplace³⁶⁷ or driving under the influence of marijuana and other substances.³⁶⁸

³⁵⁶ See, e.g., Marijuana 1-to-3 Act of 2021, H.R. 365, 117th Cong. (2012); Legitimate Use of Medicinal Marijuana Act, H.R. 171, 116th Cong. (2019); Compassionate Access Act, H.R. 715, 115th Cong. (2017).

³⁵⁷ 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); S. 1028, 116th Cong. (2019); Responsibly Addressing the Marijuana Policy Gap Act of 2019, H.R. 1119, 116th Cong. (2019); S. 421, 116th Cong. (2019).

³⁵⁸ H.R. 8825, 117th Cong. (2022).

³⁵⁹ H.R. 1996, 117th Cong. (2021); S. 910, 117th Cong. (2021).

³⁶⁰ CLAIM Act, H.R. 2068, 117th Cong. (2021); 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).

³⁶¹ See, e.g., 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 Substances."

³⁶² See, e.g., Veterans Equal Access Act, H.R. 8197, 117th Cong. (2022); Fully Informed Veteran Act of 2021, H.R. 3601, 117th Cong. (2021); Veterans Medical Marijuana Safe Harbor Act, H.R. 2588, 117th Cong. (2021); Veterans Cannabis Use for Safe Healing Act, H.R. 430, 117th Cong. (2021).

³⁶³ Destigmatizing in Immigration Act, H.R. 1614, 117th Cong. (2021).

³⁶⁴ Gun Rights And Marijuana Act, H.R. 2830, 117th Cong. (2021).

³⁶⁵ Marijuana in Federally Assisted Housing Parity Act of 2021, H.R. 3212, 117th Cong. (2021).

³⁶⁶ Welfare for Needs not Weed Act, H.R. 4536, 117th Cong. (2021).

³⁶⁷ H.R. 8591, 117th Cong. (2022).

³⁶⁸ 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).

Clinical Research and Use of Schedule I Substances

Another issue that received significant attention during the 117th Congress was the possibility that certain Schedule I controlled substances, especially marijuana and psilocybin, may have medical benefits. As a legal matter, Schedule I status limits researchers' ability to conduct clinical research involving these substances and patients' ability to access such substances for medical purposes. Because substances in Schedule I have no accepted medical use under the CSA, it is only legal to produce, dispense, and possess those substances in the context of federally approved scientific studies.³⁶⁹ In addition, federal law limits the use of federal funding for such research: a rider to the appropriations law for FY2023 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.”³⁷⁰

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.³⁷¹ 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.³⁷² But, more recently, it appears that a gap may be developing with respect to other Schedule I substances. On November 3, 2020, voters in Oregon approved a ballot measure authorizing the use of psilocybin for medical purposes under state law.³⁷³ The same day, District of Columbia voters passed a ballot measure deprioritizing the enforcement of criminal prohibitions on certain psychedelic plants and fungi.³⁷⁴ 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

³⁶⁹ See 21 U.S.C. § 823(f); see also *Gonzales v. Raich*, 545 U.S. 1, 14 (2004).

³⁷⁰ P.L. 117-328, div. H, § 509.

³⁷¹ 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>.

³⁷² See *supra* “Federal and State Marijuana Regulation.”

³⁷³ See Lizzy Acker, *Oregon Becomes First State to Legalize Psychedelic Mushrooms*, OREGONIAN, Nov. 3, 2020. Through a separate ballot measure, Oregonians voted to decriminalize possession of small amounts of certain Schedule I and II controlled substances, including cocaine, heroin, oxycodone and methamphetamines. See Cleve R. Wootson Jr. and Jaclyn Peiser, *Oregon Decriminalizes Possession of Hard Drugs, as Four Other States Legalize Recreational Marijuana*, WASH. POST, Nov. 4, 2020.

³⁷⁴ See Justin Wm. Moyer, *D.C. Voters Approve Ballot Question to Decriminalize Psychedelic Mushrooms*, WASH. POST, Nov. 3, 2020. The D.C. ballot measure does not repeal criminal laws related to psychedelic plants and fungi but rather provides that prosecution for the use and sale of such substances shall be “among the Metropolitan Police Department’s lowest law enforcement priorities.” *Id.* The ballot measure appears to have been tailored to comply with a federal appropriations rider that prohibits the District of Columbia from expending any federal funds “to enact or carry out any law, rule, or regulation to legalize or otherwise reduce penalties associated with the possession, use, or distribution of any schedule I substance under the Controlled Substances Act[.]” P.L. 116-93 Div. C, § 909, 133 Stat. 2317 (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.

establishment of centers for the therapeutic use of psilocybin and psilocyn.³⁷⁵ As with state marijuana laws, these changes in D.C. and state law do not alter the status of the affected Schedule I controlled substances under the federal CSA.³⁷⁶

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 complained that marijuana from that source was deficient in both quality and quantity.³⁷⁷ In 2015, Congress passed the Improving Regulatory Transparency for New Medical Therapies Act, which imposed deadlines on DEA to issue notice of each application to manufacture Schedule I substances for research and then act on the application.³⁷⁸ Following years of delay and related court challenges,³⁷⁹ 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.³⁸⁰ It also provided notice of the 33 applications DEA had received to manufacture Schedule I controlled substances for research purposes, and stated that DEA would review all pending applications and grant “the number that the agency determines is necessary to ensure an adequate and uninterrupted supply of the controlled substances at issue under adequately competitive conditions.”³⁸¹

In December 2020, DEA issued a final rule governing registration for bulk marijuana manufacturers.³⁸² The final rule provides that the DEA Administrator “may grant an application for a registration to manufacture marihuana ... only if he determines that such registration is consistent with the public interest” and with U.S. treaty obligations.³⁸³ 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.”³⁸⁴ The rule also allows DEA to delegate some of its responsibilities, such as storage and trading of cannabis, to “appropriately registered persons.”³⁸⁵ After issuing the final rule, DEA began to issue registrations to additional manufacturers. As of January 2023, DEA has registered seven marijuana manufacturers.³⁸⁶

³⁷⁵ See Danica Jefferies, Colorado Just Legalized ‘Magic Mushrooms,’ an Idea That’s Growing Nationwide, CNBC (Nov. 12, 2022).

³⁷⁶ See CRS Legal Sidebar LSB10482, *State Marijuana “Legalization” and Federal Drug Law: A Brief Overview for Congress*, by Joanna R. Lampe.

³⁷⁷ See Pet. for Writ of Mandamus at 13-15, *In re* Scottsdale Research Inst., No. 19-1120 (D.C. Cir. June 6, 2019).

³⁷⁸ P.L. 114-89, 129 Stat.703 (2015); 21 U.S.C. § 823(i)(2). “Manufacturing” of controlled substances includes growing marijuana. See, e.g., DEA, Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana, 84 Fed. Reg. 44,920 (Aug. 27, 2019) [hereinafter, DEA Notice].

³⁷⁹ See generally Pet. for Writ of Mandamus, *In re* Scottsdale Research Inst., No. 19-1120 (D.C. Cir. June 6, 2019).

³⁸⁰ DEA Notice at 44,921.

³⁸¹ *Id.*

³⁸² See DEA, *Controls To Enhance the Cultivation of Marihuana for Research in the United States*, 85 Fed. Reg. 82,333 (Dec. 18, 2020).

³⁸³ *Id.* at 82,353.

³⁸⁴ *Id.*

³⁸⁵ *Id.*

³⁸⁶ DEA, Marihuana Growers Information, <https://www.deadiversion.usdoj.gov/drugreg/marihuana.htm> (last visited Jan. 3, 2022)

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.³⁸⁷ Among other things, the Act created specialized, expedited procedures for DEA approval of marijuana research and manufacture of marijuana for research purposes.³⁸⁸

Other proposals during the 117th Congress sought to facilitate federally approved clinical research involving marijuana³⁸⁹ or enable veterans to access information about or use medical marijuana.³⁹⁰ Congress could also legislate more broadly to facilitate 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 substances.³⁹¹ 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.³⁹²

Telehealth Services

The spread of COVID-19 in the United States beginning in early 2020 altered the daily lives of millions of Americans and raised a wide range of legal issues.³⁹³ One area where the pandemic has had a lasting effect on the CSA's regulatory framework is the practice of telemedicine.³⁹⁴

As the COVID-19 pandemic limited individuals' ability or desire to seek medical care in person, the demand for telehealth services increased.³⁹⁵ However, the CSA limits the circumstances in which health care providers may prescribe controlled substances via telemedicine. The CSA provides that most pharmaceutical controlled substances may be dispensed only pursuant to a valid prescription,³⁹⁶ and a valid prescription must generally be predicated on an in-person

³⁸⁷ P.L. 117-215 (2022).

³⁸⁸ For additional discussion of the Act, see CRS Legal Sidebar LSB10859, *Recent Developments in Marijuana Law*, by Joanna R. Lampe.

³⁸⁹ See, e.g., 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 Substances."

³⁹⁰ See, e.g., Veterans Equal Access Act, H.R. 8197, 117th Cong. (2022); Fully Informed Veteran Act of 2021, H.R. 3601, 117th Cong. (2021); Veterans Medical Marijuana Safe Harbor Act, H.R. 2588, 117th Cong. (2021); Veterans Cannabis Use for Safe Healing Act, H.R. 430, 117th Cong. (2021).

³⁹¹ H.Amdt. 85, 117th Cong. (2021). The amendment was not adopted.

³⁹² See 166 Cong. Rec. H4074 (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.").

³⁹³ See CRS Legal Sidebar LSB10433, *Legal Issues Related to the COVID-19 Outbreak: An Overview*, coordinated by Caitlain Devereaux Lewis. For discussion of DEA's role in responding to the COVID-19 pandemic, see CRS Insight IN11321, *COVID-19: The Drug Enforcement Administration's Regulatory Role*, by Lisa N. Sacco.

³⁹⁴ Telemedicine is also subject to regulation under legal authorities other than the CSA. See CRS Report R46239, *Telehealth and Telemedicine: Frequently Asked Questions*, by Victoria L. Elliott.

³⁹⁵ Lisa M. Koonin, et al., *Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic — United States, January–March 2020*, MORBIDITY AND MORTALITY WEEKLY REPORT, Oct. 30, 2020.

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

medical evaluation.³⁹⁷ A practitioner who has previously evaluated a patient in person may prescribe the patient a controlled substance via telemedicine.³⁹⁸ By contrast, a practitioner who has not evaluated a patient in person may prescribe controlled substances via telemedicine only in more limited circumstances, including at the request of a practitioner who has conducted an in-person evaluation when that practitioner is unavailable, when a patient is being treated in a CSA-registered facility, when the practitioner has obtained a special telemedicine registration from DEA, during a medical emergency situation, or during a public health emergency.³⁹⁹

With respect to the last option, the CSA authorizes the use of telemedicine during a public health emergency declared by the HHS Secretary under Section 319 of the Public Health Service Act⁴⁰⁰ when the practice “involves patients located in such areas, and such controlled substances, as the [HHS] Secretary, with the concurrence of the Attorney General, designates.”⁴⁰¹ On January 31, 2020, the HHS Secretary issued a determination that a public health emergency exists under the Public Health Service Act “[a]s a result of confirmed cases of 2019 Novel Coronavirus.”⁴⁰² Subsequently, citing the CSA’s exception for telehealth services during a declared public health emergency, DEA issued guidance on its website authorizing the use of telemedicine to prescribe “all schedule II-V controlled substances in all areas of the United States.”⁴⁰³ Thus, subject to applicable federal and state laws and other conditions,⁴⁰⁴ from March 16, 2020, until the expiration of the public health emergency related to COVID-19, DEA-registered practitioners anywhere in the United States may prescribe any pharmaceutical controlled substance via telemedicine without conducting an in-person medical evaluation.⁴⁰⁵

Numerous proposals before the 116th and 117th Congresses sought to increase access to telehealth care during the COVID-19 pandemic or maintain advances in telemedicine after the pandemic ends. For instance, the Telehealth Extension and Evaluation Act would have extended expanded access to telehealth services for two years after the expiration of the COVID-19 emergency declaration.⁴⁰⁶ The Telehealth Act, introduced in the 116th Congress, would have

³⁹⁷ 21 U.S.C. § 829(e).

³⁹⁸ 21 U.S.C. § 829(e)(2); *see also* DEA, COVID-19 Information Page, <https://www.dea/diversion.usdoj.gov/coronavirus.html> (accessed Dec. 2, 2020).

³⁹⁹ 21 U.S.C. §§ 829(e)(2), 802(54).

⁴⁰⁰ 42 U.S.C. § 247d.

⁴⁰¹ 21 U.S.C. § 802(54)(D). The statute provides that “such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of title 5,” *i.e.*, the APA. *Id.* § 802(54)(D)(ii).

⁴⁰² Alex M. Azar II, Determination that a Public Health Emergency Exists (Jan. 31, 2020), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>. The determination has been renewed multiple times, most recently in January 2023. Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists (Jan. 11, 2023), <https://aspr.hhs.gov/legal/PHE/Pages/covid19-11Jan23.aspx>.

⁴⁰³ DEA, COVID-19 Information Page, <https://www.dea/diversion.usdoj.gov/coronavirus.html> (accessed Jan. 6, 2023).

⁴⁰⁴ The applicable conditions for the use of telemedicine to prescribe controlled substances during the current public health emergency are: (1) the prescription is “issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice,” (2) the “telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system,” and (3) the prescribing practitioner is acting in accordance with applicable federal and State laws.

⁴⁰⁵ DEA specifically noted: “If the prescribing practitioner has previously conducted an in-person medical evaluation of the patient, the practitioner may issue a prescription for a controlled substance after having communicated with the patient via telemedicine, or any other means, regardless of whether a public health emergency has been declared by the Secretary of Health and Human Services, so long as the prescription is issued for a legitimate medical purpose and the practitioner is acting in the usual course of his/her professional practice. In addition, for the prescription to be valid, the practitioner must comply with applicable Federal and State laws.”

⁴⁰⁶ S. 3593, 117th Cong. (2022); H.R. 7573, 117th Cong. (2022).

allowed practitioners to prescribe controlled substances in Schedule III or Schedule IV based on a telehealth visit.⁴⁰⁷ A number of other legislative proposals in the 116th and 117th Congresses sought to address regulation of telemedicine outside the scope of the CSA.⁴⁰⁸ If similar proposals are introduced in the 118th Congress, legislators may consider whether they would affect the prescribing of controlled substances via telemedicine and whether they should include specific provisions related to the CSA.

Cocaine Sentencing

The 117th Congress also saw significant legal developments related to sentencing for cocaine offenses under the CSA.⁴⁰⁹ Congress placed cocaine in Schedule II when it enacted the CSA in 1970.⁴¹⁰ The CSA as enacted did not distinguish between powder and crack cocaine. However, in response to concerns about a “crack epidemic” in the mid-1980s, Congress amended the CSA in 1986 to impose mandatory minimum sentences for certain offenses involving cocaine.⁴¹¹ While the minimum sentences applied to both powder and crack cocaine, the amount of each substance required to trigger the mandatory minimum varied by a ratio of 100 to 1.⁴¹² Offenses involving smaller amounts or an unspecified amount of cocaine (whether powder or crack) were also subject to criminal penalties but did not carry a mandatory minimum prison term.

After the 1986 legislation was enacted, some commentators and stakeholders raised concerns that the disparity between the thresholds for powder and crack cocaine was too great and that crack offenders were disproportionately Black, creating a “perception of unfairness.”⁴¹³ In response, Congress enacted the Fair Sentencing Act of 2010, which, among other things, raised the amounts of crack required to trigger mandatory minimum sentences, reducing the disparity between the thresholds for powder and crack cocaine to a ratio of approximately 18 to 1.⁴¹⁴ The Fair Sentencing Act applied to future cases and cases that were pending on the date of enactment but did not apply to cases in which a sentence had already been imposed.

⁴⁰⁷ H.R. 7992, 116th Cong. (2020). Legislative proposals to reform CSA regulation of telemedicine are not limited to addressing the COVID-19 pandemic. For instance, the METH Addiction Act, S. 2244, 116th Cong. (2019), would have amended the CSA to allow community addiction treatment facilities and community mental health facilities to register to dispense controlled substances through the practice of telemedicine. *See also* Improving Access to Remote Behavioral Health Treatment Act of 2019, H.R. 4131, 116th Cong. (2019).

⁴⁰⁸ *See, e.g.*, Ensuring Telehealth Expansion Act of 2021, H.R. 341, 117th Cong. (2021); Telehealth Expansion Act of 2021, H.R. 5981, 117th Cong. (2021); S. 1704, 117th Cong. (2021); Greater Access to Telehealth Act, H.R. 8489, 117th Cong. (2022); Advancing Telehealth Beyond COVID-19 Act of 2021, H.R. 4040, 117th Cong. (2021); Mental Health Telemedicine Expansion Act, H.R. 1301, 116th Cong. (2019); VA Mission Telehealth Clarification Act, S. 3643, 116th Cong. (2020); Telehealth Modernization Act, H.R. 8727, 116th Cong. (2020).

⁴⁰⁹ For additional discussion of cocaine sentencing under the CSA, see CRS Legal Sidebar LSB10611, *Crack Cocaine Offenses and the First Step Act of 2018: Overview and Implications of Terry v. United States*, by Michael A. Foster and Joanna R. Lampe; CRS In Focus IF11965, *Cocaine: Crack and Powder Sentencing Disparities*, by Lisa N. Sacco and Kristin Finklea.

⁴¹⁰ Pub. L. No. 91-513, 84 Stat. 1236 (1970).

⁴¹¹ P.L. 99-70, 100 Stat. 3207-2 (1986).

⁴¹² For example, offenses involving 5 kilograms of cocaine powder or 50 grams of cocaine base (i.e., crack) carried a mandatory 10-year sentence, and offenses involving 500 grams of cocaine powder or 5 grams of cocaine base carried a mandatory five-year sentence.

⁴¹³ *Terry v. United States*, 141 S. Ct. 1858, 1861 (2021) (quoting USSC, *Special Report to the Congress: Cocaine and Federal Sentencing Policy* 195-197 (Feb. 1995)).

⁴¹⁴ P.L. 111-220, 124 Stat. 2373 (2010); *see also* 21 U.S.C. § 841.

In 2018, Congress enacted the First Step Act, which made the Fair Sentencing Act’s changes to crack sentences retroactive and permitted persons convicted and sentenced prior to passage of the Fair Sentencing Act to seek resentencing.⁴¹⁵ The First Step Act applied to any “covered offense,” defined in part as “a violation of a Federal criminal statute, the statutory penalties for which were modified by” the Fair Sentencing Act provision that altered the crack-to-powder ratio for purposes of the relevant CSA offenses.⁴¹⁶

Federal courts divided on the question of which statutory penalties were “modified by” the Fair Sentencing Act such that an offense subject to such penalties would constitute a “covered offense” and specifically whether offenders convicted under the lowest tier prior to changes made by the Fair Sentencing Act could seek retroactive resentencing.⁴¹⁷ The Supreme Court resolved the split in a 2021 decision in *Terry v. United States*.⁴¹⁸ In *Terry*, the Court concluded unanimously that the Fair Sentencing Act did not modify the statutory penalties for cocaine offenses under the lowest penalty tier.⁴¹⁹ That holding means that crack offenders convicted prior to enactment of the Fair Sentencing Act may not seek resentencing if they were not subject to a mandatory minimum sentence.

Following the Supreme Court’s decision in *Terry*, Members of the 117th Congress considered whether to expand resentencing opportunities for crack offenses committed before the enactment of the Fair Sentencing Act. It appears that at least some Members of Congress who supported the First Step Act intended the legislation to reach broadly and encompass all crack offenders.⁴²⁰ Additionally, some commentators have argued that it would be incongruous or arbitrary to allow resentencing for individuals convicted of offenses involving large amounts of crack while leaving in place sentences involving smaller amounts of the substance.⁴²¹

More generally, the 117th Congress considered whether to alter or eliminate the disparity in sentencing thresholds between crack and powder cocaine. Congress originally imposed lower quantity thresholds for crack offenses based on concerns that crack was cheaper, more potent, more addictive, and overall more dangerous than other forms of cocaine.⁴²² Some stakeholders argue that the current 18-to-1 ratio is not justified on scientific or public safety grounds and disproportionately affects Black offenders.⁴²³ If Congress elected to modify the threshold amounts

⁴¹⁵ P.L. 115-391, 132 Stat. 5194 (2018).

⁴¹⁶ *Id.* § 404.

⁴¹⁷ Compare *United States v. Smith*, 954 F. 3d 446, 450 (1st Cir. 2020) and *United States v. Woodson*, 962 F. 3d 812, 816 (4th Cir. 2020) with *United States v. Birt*, 966 F. 3d 257, 264 (4th Cir. 2020).

⁴¹⁸ 141 S. Ct. 1858.

⁴¹⁹ *Id.* at 1860.

⁴²⁰ For instance, four Senators who were lead sponsors and drafters of the 2018 legislation filed an amicus brief in *Terry*, arguing that the First Step Act “authorizes relief to everyone who had been sentenced for crack-cocaine offenses before the Fair Sentencing Act became effective, including individuals with low-level crack offenses” that did not carry mandatory minimum sentences. Br. of Amici Curiae Sens. Durbin, Grassley, Booker, and Lee, *Terry v. United States*, No. 20-5904 (Feb. 19, 2021).

⁴²¹ See, e.g., Br. of Amici Curiae Ams. for Prosperity Foundation 20, *Terry v. United States*, No. 20-5904 (Feb. 19, 2021); Ekow Yankah, *Unanimous Ruling on Crack-Cocaine Disparity is Heavy on Text, Light on History*, SCOTUSBLOG (June 16, 2021), <https://www.scotusblog.com/2021/06/unanimous-ruling-on-crack-cocaine-disparity-is-heavy-on-text-light-on-history/>.

⁴²² USSC, COCAINE AND FEDERAL SENTENCING POLICY 9 (May 2002).

⁴²³ See, e.g., Press Release, Nat’l Dist. Attys Assoc., Nation’s Largest Prosecutor Organization Endorses Ending the Disparity in Sentencing Between Crack and Powder Cocaine (Feb. 24, 2021).

that trigger mandatory minimum sentences under the CSA, it could also consider whether those changes should apply retroactively.

A proposal before the 117th Congress entitled the Eliminating a Quantifiably Unjust Application of the Law Act (EQUAL Act) sought to address both the retroactivity question presented in *Terry* and the sentencing disparity.⁴²⁴ With respect to the sentencing disparity between crack and powder cocaine, the EQUAL Act would have repealed the CSA provisions that impose mandatory minimum sentences for offenses involving crack.⁴²⁵ Because crack also falls within the broader category of cocaine, certain crack offenses would remain subject to mandatory minimum sentences. However, the quantity of crack required to trigger a mandatory minimum sentence would no longer be lower than the quantity of other forms of cocaine. With respect to retroactivity, the EQUAL Act would have authorized resentencing of any “defendant who, before the date of enactment of [the EQUAL] Act, was convicted or sentenced for a Federal offense involving cocaine base.”⁴²⁶ That language appears to include offenders who were convicted of crack offenses that did not carry mandatory minimum sentences.

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⁴²⁴ S. 79, 117th Cong. (2021); H.R. 1693, 117th Cong. (2021).

⁴²⁵ *Id.* § 2(a), (b).

⁴²⁶ *Id.* § 2(c)(2).