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

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

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

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

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

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

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

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Prescription drugs play a vital role in American public health. The Centers for Disease Control and Prevention (CDC) estimates that during 2015 and 2016 over 45% of Americans had used one or more prescription drugs in the last 30 days.¹ But unfettered access to drugs may pose serious public health risks. The CDC reports that in 2018 over 67,000 Americans died of overdoses of prescription and nonprescription drugs.² The Controlled Substances Act³ (CSA or the Act) seeks to balance those competing considerations.⁴ The CSA regulates *controlled substances*—prescription and nonprescription drugs and other substances that are deemed to pose a risk of abuse and dependence.⁵ By establishing rules for the proper handling of controlled substances⁶ and imposing penalties for any illicit production, distribution, or possession of such substances,⁷ the Act seeks to protect the public health from the dangers of controlled substances while also ensuring that patients have access to pharmaceutical controlled substances for legitimate medical purposes.⁸

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

Background and Scope of the CSA

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

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

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

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

⁴ *See id.* §§ 801(1), (2).

⁵ *See id.* §§ 802(6), 811.

⁶ *See id.* §§ 821-832.

⁷ *See id.* §§ 841-865.

⁸ *See id.* §§ 801(1), (2).

⁹ *See infra* “Background and Scope of the CSA” and “Other Regulatory Schemes.”

¹⁰ *See infra* “Classification of Controlled Substances.”

¹¹ *See infra* “Registration Requirements.”

¹² *See infra* “Trafficking Provisions.”

¹³ *See infra* “Legal Considerations for the 117th Congress.”

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

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

The CSA regulates certain drugs²¹—whether medical or recreational, legally or illicitly distributed—that are found to pose a risk of abuse and dependence.²² In enacting the CSA, Congress recognized two competing interests related to drug regulation. On one hand, many drugs “have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.”²³ On the other hand, “illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.”²⁴ Accordingly, the Act simultaneously aims to protect public health from the dangers of controlled substances while also ensuring access to controlled substances for legitimate purposes.

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

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

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

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

¹⁷ *Id.* at 600-03.

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

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

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

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

²² See 21 U.S.C. §§ 811, 812.

²³ *Id.* § 801(1).

²⁴ *Id.* § 801(2).

²⁵ See *id.* §§ 821-832.

²⁶ *Id.* §§ 841-865.

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

Other Regulatory Schemes

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

²⁷ *Id.* § 811.

²⁸ *Id.* § 829; *see also infra* “Prescriptions.”

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

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

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

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

³³ *See* 21 U.S.C. § 802(6).

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

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

³⁶ 21 U.S.C. §§ 301-399i.

³⁷ *Id.* § 331(a).

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

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

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

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

³⁸ *Id.* § 352.

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

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

⁴¹ 21 U.S.C. § 351.

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

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

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

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

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

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

⁴⁸ Kreit, *supra* note 44 at 628.

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

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

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

Classification of Controlled Substances

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

Overview of Schedules

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

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

⁵⁰ Kreit, *supra* note 44 at 629.

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

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

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

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

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

⁵⁶ 21 U.S.C. § 812.

⁵⁷ See *infra* “Scheduling Procedures.”





⁵⁸ See *id.*

⁵⁹ 21 U.S.C. § 812.

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

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

Figure 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 prescription fentanyl and illicit fentanyl. Prescription fentanyl and several related medications are in Schedule II. Numerous nonprescription fentanyl analogues are in Schedule I.

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

⁷ 21 U.S.C. § 812(b)(3).

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

⁹ 21 U.S.C. § 812(b)(4).

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

¹¹ 21 U.S.C. § 812(b)(5).

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

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

Analogues and Listed Chemicals

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

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

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

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

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

⁶³ *Id.* § 802(32).

⁶⁴ *Id.* § 813(a).

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

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

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

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

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

Scheduling Procedures

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

Legislative Scheduling

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

⁶⁶ 21 C.F.R. § 1300.02(b18).

⁶⁷ *Id.* § 1300.02(b19).

⁶⁸ *Id.* § 1310.02(a).

⁶⁹ *Id.* § 1310.02(b).

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

⁷¹ *Id.* § 830.

⁷² 21 U.S.C. §§ 802(34), (35).

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

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

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

Administrative Scheduling

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

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

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

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

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

⁷⁸ 21 U.S.C. § 811(a).

⁷⁹ 21 C.F.R. § 1308.43.

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

⁸¹ 21 U.S.C. § 811(b).

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

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

⁸⁴ *Id.* § 811(b).

⁸⁵ *Id.*

⁸⁶ *Id.*

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

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

Emergency Scheduling

Ordinary DEA scheduling decisions are made through notice-and-comment rulemaking and can take years to consider and finalize.⁹⁵ Recognizing that in some cases faster scheduling may be appropriate, Congress amended the CSA through the Comprehensive Crime Control Act of 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

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

⁸⁸ *Id.* § 812(b).

⁸⁹ 5 U.S.C. § 500, et seq.

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

⁹¹ *See id.* § 877.

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

⁹³ 21 U.S.C. § 877.

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

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

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

⁹⁷ 21 U.S.C. § 811(h)(1).

⁹⁸ 21 U.S.C. § 811(h)(1).

⁹⁹ *Id.* § 811(h)(3).

¹⁰⁰ *Id.* § 811(h)(4).

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

DEA has recently used its emergency scheduling power to temporarily control certain analogues to the opioid fentanyl¹⁰⁵ and several synthetic cannabinoids.¹⁰⁶

International Treaty Obligations

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

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

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

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

¹⁰² *Id.* § 811(h)(2).

¹⁰³ *Id.* § 811(h)(5).

¹⁰⁴ *Id.* § 811(h)(6).

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

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

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

¹⁰⁸ *Id.* art. 36.

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

¹¹⁰ *Id.* art. 2(1)(7).

¹¹¹ 21 U.S.C. § 811(d)(1).

¹¹² *Id.*

Registration Requirements

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

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

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

Entities Required to Register

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

¹¹³ See *id.* § 822.

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

¹¹⁵ 21 U.S.C. § 822(a).

¹¹⁶ 21 C.F.R. § 1300.02(b)(24).

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

¹¹⁸ See *infra* “Obligations of Registrants.”

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

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

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

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

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

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

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

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

¹²³ 21 U.S.C. § 822(a)(2).

¹²⁴ *Id.* § 822(a)(1).

¹²⁵ *Id.* § 822(e)(1).

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

¹²⁷ *Id.* § 823(a)-(f).

¹²⁸ *Id.*

¹²⁹ 21 C.F.R. §§ 1301.13(c), (d).

¹³⁰ *Id.* § 1301.52.

¹³¹ *Id.* § 1301.52(b).

Obligations of Registrants

Recordkeeping and Reporting

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

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

Inspections

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

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

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

¹³⁴ 21 U.S.C. § 828(c)(2).

¹³⁵ *Id.* § 828(c)(1).

¹³⁶ *Id.* § 832.

¹³⁷ 21 C.F.R. § 1304.74(b).

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

¹³⁹ 21 U.S.C. § 822(f).

¹⁴⁰ 21 C.F.R. § 1316.13.

¹⁴¹ 21 U.S.C. § 880(c).

¹⁴² *Id.* § 880(d)(1).

¹⁴³ *Id.*

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

Security

The CSA's implementing regulations require all registrants to "provide effective controls and procedures to guard against theft and diversion of controlled substances."¹⁴⁵ The regulations establish specific physical security requirements, which vary depending on the type of registrant and the classification of the controlled substance at issue.¹⁴⁶ For example, practitioners¹⁴⁷ subject to CSA registration must store controlled substances "in a securely locked, substantially constructed cabinet."¹⁴⁸ In addition to those physical security requirements, practitioners may not "employ, as an agent or employee who has access to controlled substances" any person who has been convicted of a felony related to controlled substances, had an application for CSA registration denied, had a CSA registration revoked, or surrendered a CSA registration for cause.¹⁴⁹ Registered non-practitioners must store controlled substances in Schedules I and II in a safe, steel cabinet, or vault that meets certain specifications.¹⁵⁰ Non-practitioners must further ensure that controlled substance storage areas are "accessible only to an absolute minimum number of specifically authorized employees."¹⁵¹

Quotas

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

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

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

¹⁴⁵ 21 C.F.R. § 1301.71.

¹⁴⁶ *Id.* §§ 1301.72-76.

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

¹⁴⁸ 21 C.F.R. §§ 1301.75(a), (b).

¹⁴⁹ *Id.* § 1301.76(a).

¹⁵⁰ 21 C.F.R. § 1301.72(a).

¹⁵¹ *Id.* § 1301.72(d).

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

¹⁵³ *Id.* §§ 826(b), (c).

¹⁵⁴ *Id.* § 826(i).

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

Prescriptions

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

Enforcement and Penalties

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

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

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

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

¹⁵⁷ *Id.* § 829(c).

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

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

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

¹⁶¹ 21 U.S.C. § 824(a).

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

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

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

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

Trafficking Provisions

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

Prohibitions

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

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

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

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

¹⁶⁵ 21 U.S.C. § 842(c)(1).

¹⁶⁶ *Id.* § 842(c)(2)(A).

¹⁶⁷ *Id.* § 842(c)(2)(D).

¹⁶⁸ See *id.* §§ 841-865.

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

¹⁷⁰ *Id.* § 841(a)(1).

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

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

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

Enforcement and Penalties

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

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

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

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

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

¹⁷⁴ *See, e.g., id.* §§ 841(b).

¹⁷⁵ *Id.* § 849.

¹⁷⁶ *Id.* § 860.

¹⁷⁷ *Id.* § 859.

¹⁷⁸ *Id.* § 858.

¹⁷⁹ *Id.* § 863.

¹⁸⁰ *Id.* § 848.

¹⁸¹ *Id.* § 846.

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

¹⁸³ 423 U.S. 122, 133 (1975).

¹⁸⁴ *Id.* at 124.

effect, he acted as a large-scale ‘pusher’—not as a physician.”¹⁸⁵ Appellate courts have relied on *Moore* to uphold convictions of a pharmacist who signed thousands of prescriptions for sale through an online pharmacy¹⁸⁶ and a practitioner who “freely distributed prescriptions for large amounts of controlled substances that are highly addictive, difficult to obtain, and sought after for nonmedical purposes.”¹⁸⁷ But several courts have cautioned that a conviction under *Moore* requires more than a showing of mere professional malpractice. For instance, the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) has held that the prosecution must prove that the defendant “acted with intent to distribute the drugs *and with intent to distribute them outside the course of professional practice*,” suggesting that specific intent must be established with respect to the defendant’s failure to abide by professional norms.¹⁸⁸

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

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

¹⁸⁵ *Id.* at 142-43.

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

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

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

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

¹⁹⁰ See Press Release, DOJ, Manhattan U.S. Attorney And DEA Announce Charges Against Rochester Drug 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.

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

¹⁹² 21 U.S.C. § 844(a).

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

The CSA is not the only means to target misconduct related to the distribution of pharmaceutical and nonpharmaceutical controlled substances. Rather, such conduct can give rise to liability under numerous other provisions of federal and state law. For example, drug companies may face administrative sanctions or criminal charges under the FD&C Act.¹⁹⁶ Companies and individuals may also be subject to federal criminal charges under the Racketeer Influenced and Corrupt Organizations Act¹⁹⁷ or the Federal Anti-Kickback Statute.¹⁹⁸ Those statutes notably formed part of the basis for the significant settlement between DOJ and opioid manufacturer Purdue Pharma in 2020.¹⁹⁹ And manufacturers and distributors of opioids currently face numerous civil suits under federal and state law based on the companies' marketing and distribution of prescription opioids.²⁰⁰

Legal Considerations for the 117th Congress

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

Opioid Crisis

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

¹⁹³ *Id.* § 841(b)(1)(A).

¹⁹⁴ *Id.* § 841(b).

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

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

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

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

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

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

drugs.²⁰¹ Some opioids have legitimate medical purposes, primarily related to pain management, while others have no recognized medical use.²⁰² Both pharmaceutical opioids (such as oxycodone, codeine, and morphine) and nonpharmaceutical opioids (such as heroin) may pose a risk of abuse and dependence and may be dangerous or even deadly in excessive doses.²⁰³ The CDC reports that overdoses of prescription and nonprescription opioids claimed over 50,000 lives in 2019.²⁰⁴ CDC researchers further estimate that the misuse of prescription opioids alone cost the United States \$78.5 billion in 2013.²⁰⁵

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

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

²⁰² *Id.*

²⁰³ *Id.*

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

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

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

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

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

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

²¹⁰ Pub. L. No. 115-271, §§ 3201-04.

²¹¹ *Id.* § 3241.

²¹² *Id.* § 3282.

²¹³ *Id.* §§ 3291-92.

Notwithstanding the flurry of recent legal changes, numerous legislative proposals in the 116th Congress sought to address the opioid crisis by further amending the CSA.²¹⁴ For example, the DEA Enforcement Authority Act of 2019²¹⁵ would have made it easier for DEA to suspend a registration. Specifically, the bill would have lowered the threshold for what constitutes imminent danger, allowing suspension upon a finding of “*probable cause* that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration,” rather than the current statutory requirement of “*a substantial likelihood of an immediate threat* that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.”²¹⁶ In addition, the John S. McCain Opioid Addiction Prevention Act²¹⁷ would have required medical practitioners applying for new or renewed CSA registration to certify that they will not prescribe more than a seven-day supply of opioids for the treatment of acute pain.²¹⁸ The LABEL Opioids Act²¹⁹ would have amended the CSA to require that opioids in Schedules II through V bear labels warning that they can cause dependence, addiction, and overdose. Failure to comply with the labeling requirements would have violated the CSA’s registration requirements.²²⁰ Other proposals sought to improve treatment of opioid use disorder.²²¹

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

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

²¹⁵ S. 424, 116th Cong. (2019).

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

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

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

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

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

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

²²² For additional discussion of fentanyl regulation, see *infra* “Analogue Fentanyl.”

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

and overdose.²²⁴ The Ending the Fentanyl Crisis Act of 2019²²⁵ would have amended the CSA to reduce the amounts of fentanyl required to constitute a trafficking offense.²²⁶ That bill would have also increased penalties applicable to offenses involving fentanyl and provided separate procedures for emergency scheduling of synthetic opioids.²²⁷ The Screening All Fentanyl-Enhanced Mail Act of 2019²²⁸ sought to require screening of all inbound international mail and express cargo from high-risk countries to detect and prevent the importation of illicit fentanyl and other synthetic opioids. Finally, the Blocking Deadly Fentanyl Imports Act²²⁹ aimed to gather information about the production of illicit fentanyl in foreign countries and to withhold bilateral assistance from countries that fail to enforce certain controlled substance regulations.

Analogue Fentanyl

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

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

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

²²⁵ S. 1724, 116th Cong. (2019).

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

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

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

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

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

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

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

²³³ See 21 C.F.R. §§ 1308.11, 1308.12.

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

used its emergency scheduling authority²³⁵ to impose temporary controls on 74 synthetic drugs, including 17 fentanyl-like substances.²³⁶

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

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

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

²³⁵ See *supra* “Emergency Scheduling.”

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

²³⁷ See *supra* “Analogues and Listed Chemicals.”

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

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

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

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

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

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

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

²⁴⁵ See *supra* note 239.

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

February 2020.²⁴⁷ However, on February 6, 2020, Congress enacted the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which extended the temporary scheduling of fentanyl-related substances until May 6, 2021.²⁴⁸ Absent further legislative or administrative action, substances subject to the legislation will remain in Schedule I until that date and will be subject to all restrictions and penalties applicable to Schedule I substances. After the expiration date, the substances at issue will no longer be scheduled under the CSA but may still be subject to control as controlled substance analogues. Notably, fentanyl itself and certain other related chemicals are permanently controlled in Schedules I and II.²⁴⁹ The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act does not affect those classifications.

Several proposals in the 116th Congress sought to permanently schedule fentanyl analogues. For instance, the Stopping Overdoses of Fentanyl Analogues Act²⁵⁰ would have permanently added to Schedule I certain specific synthetic opioids, as well as the whole category of “fentanyl-related substances,” as defined in the February 2018 emergency scheduling order. The Modernizing Drug Enforcement Act of 2019²⁵¹ would have amended the CSA to add to Schedule I all “mu opioid receptor agonists” not otherwise scheduled, subject to certain exceptions.²⁵² One of the sponsors of the Modernizing Drug Enforcement Act stated that the bill’s aim was “to automatically classify drugs or other substances that act as opioids, such as synthetic fentanyl, as a schedule I narcotic based on their chemical structure and functions,” avoiding the need for such substances to be individually scheduled.²⁵³

Marijuana Policy Gap

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

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

²⁴⁷ *Id.* at 5188.

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

²⁴⁹ See 21 C.F.R. §§ 1308.11, 1308.12.

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

²⁵¹ H.R. 2580, 116th Cong. (2019).

²⁵² Mu opioid receptor agonists are a class 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 Press Release, Rep. Phil Roe, Roe, Suozzi Reintroduce the Modernizing Drug Enforcement Act (May 8, 2019), <https://roe.house.gov/news/documentsingle.aspx?DocumentID=400515>.

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

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

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

In each budget cycle since FY2014 Congress has passed an appropriations rider prohibiting DOJ from using taxpayer funds to prevent the states from “implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.”²⁵⁸ The current appropriations rider is in effect through September 30, 2021.²⁵⁹ Several courts have interpreted the appropriations rider to bar DOJ from expending any appropriated funds to prosecute activities involving marijuana that are conducted in “strict compliance” with state law.²⁶⁰ For example, in *United States v. Evans*, the Ninth Circuit upheld the prosecution of two individuals involved in the production of medical marijuana who smoked marijuana as they processed plants for sale.²⁶¹ Although state law permitted medical marijuana use by “qualifying patients,” the court concluded that the defendants failed to show they were “qualifying patients,” and thus they could be prosecuted because their personal marijuana use did not strictly comply with state medical marijuana law.²⁶²

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

²⁵⁶ *Id.*

²⁵⁷ See, e.g., *Gonzales v. Raich*, 545 U.S. 1, 29 (2004). See also CRS Legal Sidebar LSB10482, *State Marijuana “Legalization” and Federal Drug Law: A Brief Overview for Congress*, by Joanna R. Lampe. Notably, however, not all CBD is subject to the CSA. The 2018 Farm Bill exempted “hemp”—cannabis and cannabis derivatives containing very low levels of tetrahydrocannabinol (THC)—from control under the CSA. See 21 U.S.C. § 802(16)(B)(i). Accordingly, CBD that meets those requirements is no longer a federally controlled substance. CBD remains subject to federal regulation under the FD&C Act, and FDA has taken the position that CBD is a drug that may not lawfully 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.

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

²⁵⁹ See *id.* § 5.

²⁶⁰ See *United 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).

²⁶¹ 929 F.3d 1073, 1076-79 (9th Cir. 2019). See also *United States v. Kleinman*, 880 F.3d 1020, 1027-30 (9th Cir. 2017) (prosecution was proper because sales of marijuana to out-of-state customers violated state law); *United 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).

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

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

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

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

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

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

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

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

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

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

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

²⁷¹ 18 U.S.C. § 922.

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

Numerous proposals in the 116th Congress aimed to address issues related to the marijuana policy gap. Some proposals targeted specific issues that arise from the divergence between federal and state law. For instance, the Secure And Fair Enforcement Banking Act of 2019 (SAFE Banking Act)²⁷³ sought to protect depository institutions that provide financial services to cannabis-related businesses from regulatory sanctions. The Ensuring Safe Capital Access for All Small Businesses Act of 2019²⁷⁴ would have made certain loan programs of the Small Business Administration (SBA) available to cannabis-related businesses.²⁷⁵

Other proposals sought to address the marijuana policy gap more broadly by attempting to mitigate any conflict between federal and state law. For example, the State Cannabis Commerce Act²⁷⁶ would have taken an approach similar to the current DOJ appropriations rider with respect to all federal agencies. While that bill would not have altered the scope of the CSA's restrictions on marijuana, it would have prevented any federal agency from using appropriated funds "to prevent any State from implementing any law of the State that . . . authorizes the use, distribution, possession, or cultivation of marijuana" within the state. The Strengthening the Tenth Amendment Through Entrusting States Act (STATES Act)²⁷⁷ would have amended the CSA to provide that most provisions related to marijuana "shall not apply to any person acting in compliance with State law relating to the manufacture, production, possession, distribution, dispensation, administration, or delivery" of marijuana. The STATES Act would have removed the risk of federal criminal prosecution under the CSA for individuals and entities whose marijuana-related activities comply with state law, but the bill did not specifically address the potential consequences of such activity under other areas of federal law. The Responsibly Addressing the Marijuana Policy Gap Act of 2019²⁷⁸ would have removed marijuana-related activities that comply with state law from the scope of the CSA and also sought to address specific collateral consequences of such activities, including access to banking services, bankruptcy proceedings, and certain tax deductions.

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

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

marijuana.

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

²⁷⁴ H.R. 3540, 116th Cong. (2109).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

²⁸⁸ *Id.*

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

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

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

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

²⁹⁰ H.R. 171, 116th Cong. (2019).

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

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

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

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

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

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

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

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

Clinical Research and Use of Schedule I Substances

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

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

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

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

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

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

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

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

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

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

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

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

³⁰⁴ See *supra* “Marijuana Policy Gap.”

³⁰⁵ See Lizzy Acker, *Oregon Becomes First State to Legalize Psychedelic Mushrooms*, 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.

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

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

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

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

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

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

In December 2020, DEA issued a final rule (based on its August 2019 proposal) governing registration for bulk marijuana manufacturers.³¹³ The final rule provides that the DEA Administrator “may grant an application for a registration to manufacture marijuana . . . only if he determines that such registration is consistent with the public interest and with United States obligations under the Single Convention.”³¹⁴ The rule further provides that “[a]ll registered manufacturers who cultivate cannabis shall deliver their total crops of cannabis” to DEA, and the agency “shall purchase and take physical possession of such crops as soon as possible” and “have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks [of cannabis] other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations.”³¹⁵ The rule also allows DEA to delegate some of its responsibilities, such as storage and trading of cannabis, to “appropriately registered persons.”³¹⁶ The effective date of the final rule is January 19, 2021.³¹⁷ As of January 2021, DEA had not registered any additional marijuana manufacturers.

As it did with the Improving Regulatory Transparency for New Medical Therapies Act, Congress could pass further legislation to guide DEA’s consideration of applications to manufacture marijuana for research purposes. For instance, the Medical Cannabis Research Act of 2019³¹⁸ would have aimed to increase the number of licenses to produce cannabis for research purposes by requiring DEA to approve at least three additional manufacturers within a year of passage. Congress could also legislate more broadly to facilitate research involving controlled substances. For example, a proposed amendment to the appropriations bill for FY2020 would have eliminated the appropriations rider restricting the use of federal funding for research involving Schedule I substances.³¹⁹ That amendment, which would have applied to research involving all Schedule I controlled substances, was intended to facilitate research involving not only marijuana but also psilocybin, MDMA, and other Schedule I drugs that might have legitimate medical uses.³²⁰

³¹¹ *Id.*

³¹² DEA Notice at 44,921.

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

³¹⁴ *Id.* at 82,353.

³¹⁵ *Id.*

³¹⁶ *Id.*

³¹⁷ *Id.*

³¹⁸ H.R. 601, 116th Cong. (2019).

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

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

COVID-19 Pandemic

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

Supply of Controlled Substances

The COVID-19 pandemic has increased the demand for certain controlled substances for legitimate medical purposes.³²³ In particular, Schedule II controlled substances such as fentanyl and hydromorphone are used to relieve pain relief associated with intubation for patients on ventilators.³²⁴ The CSA requires DEA to set aggregate production quotas for controlled substances in Schedules I and II and for certain listed chemicals.³²⁵ DEA set the quotas for 2020 in December 2019.³²⁶ As COVID-19 spread in the United States in the spring of 2020, health care providers became worried that existing supplies would be inadequate for the unprecedented number of patients needing artificial ventilation and asked DEA to increase production quotas.³²⁷ In April 2020, DEA published a final order adjusting the 2020 production quotas for certain Schedule II controlled substances, including fentanyl and hydromorphone, and the List I chemicals ephedrine and pseudoephedrine.³²⁸

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

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

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

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

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

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

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

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

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

³²⁹ See *id.* at 20,304-05.

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

³³¹ William Wan & Heather Long, “Cries for Help”: Drug Overdoses Are Soaring During the Coronavirus Pandemic,

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

Telehealth Services

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

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

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

³³² *See id.* §§ 801(1), (2).

³³³ S. 4058, 116th Cong. (2020).

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

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

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

³³⁷ 21 U.S.C. § 829(e).

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

³³⁹ 21 U.S.C. §§ 829(e)(2), 802(54).

Act³⁴⁰ when the practice “involves patients located in such areas, and such controlled substances, as the [HHS] Secretary, with the concurrence of the Attorney General, designates.”³⁴¹ On January 31, 2020, the HHS Secretary issued a determination that a public health emergency exists under the Public Health Service Act “[a]s a result of confirmed cases of 2019 Novel Coronavirus.”³⁴² Subsequently, citing the CSA’s exception for telehealth services during a declared public health emergency, DEA issued guidance on its website authorizing the use of telemedicine.³⁴³ DEA stated that on March 16, 2020, the HHS Secretary (with the concurrence of the acting DEA Administrator) applied the public health emergency exception to “all schedule II-V controlled substances in all areas of the United States.” Thus, subject to applicable federal and state laws and other conditions,³⁴⁴ from March 16, 2020, until the expiration of the public health emergency related to COVID-19, DEA-registered practitioners anywhere in the United States may prescribe any pharmaceutical controlled substance via telemedicine without conducting an in-person medical evaluation.³⁴⁵

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

³⁴⁰ 42 U.S.C. § 247d.

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

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

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

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

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

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

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

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