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Listed Chemicals and Federal Regulation of Controlled Substance Precursors

The Controlled Substances Act (CSA) regulates pharmaceutical and non-pharmaceutical drugs and other substances that pose a risk of abuse and dependence. The CSA authorizes the manufacture, distribution, and possession of controlled substances for legitimate medical and scientific purposes, subject to government registration and regulatory controls designed to prevent misuse and diversion. It also imposes criminal penalties for unauthorized activities involving controlled substances.

In addition to controlled substances, the CSA regulates *listed chemicals*—certain substances that can be used to illicitly manufacture controlled substances. Listed chemicals include some controlled substance precursors as well as certain reagents and solvents used in the manufacturing process. Like controlled substances, listed chemicals are subject to CSA regulatory requirements, and unlawful activities involving listed chemicals may give rise to civil or criminal liability.

What Are Listed Chemicals?

The CSA divides listed chemicals into two categories, known as List I and List II. *List I chemicals* are defined as chemicals designated by the Drug Enforcement Administration (DEA) 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. 21 U.S.C. § 802(34). *List II chemicals* are DEA-designated chemicals not included in List I that, in addition to legitimate uses, are used in manufacturing a controlled substance in violation of the CSA (without the additional requirement of being important to the manufacture). *Id.* § 802(35).

Many List I chemicals are precursor chemicals that are key ingredients used to produce controlled substances. For instance, ephedrine is a List I chemical that is a precursor to the Schedule II controlled substance methamphetamine. Other List I chemicals are precursors to controlled substances such as fentanyl, lysergic acid diethylamide (LSD), and 3,4-Methylenedioxymethamphetamine (known as MDMA, molly, or ecstasy). List I also includes substances such as phosphorous and iodine, which are used as reagents during controlled substance manufacturing. While List II includes some precursor chemicals, most List II chemicals are either reagents or solvents used to produce controlled substances. Examples include acetone, hydrochloric acid, and sulfuric acid.

The CSA also imposes specific controls on *scheduled listed chemical products*, which are products lawfully sold as nonprescription drugs that contain any of the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine. 21 U.S.C. § 802(45). As one example, pseudoephedrine is sometimes sold without a prescription as a nasal decongestant.

While many listed chemicals are controlled substance precursors, the CSA separately provides for control of *immediate precursors*. To control a substance as an immediate precursor, DEA must find by regulation that the substance is the “principal compound used” in producing a controlled substance or made “primarily for use” in such production, is “an immediate chemical intermediary” used to manufacture the controlled substance (essentially a chemical stepping stone to the controlled substance), and must be controlled to prevent or limit such manufacture. 21 U.S.C. § 802(23). The CSA authorizes DEA to include an immediate precursor in the same schedule as the controlled substance it is used to produce or in any less restrictive schedule. *Id.* § 811(e). Scheduled immediate precursors are regulated as controlled substances, not as listed chemicals. For more information on regulation of controlled substances under the CSA, see CRS Report R45948, *The Controlled Substances Act (CSA): A Legal Overview for the 117th Congress*, by Joanna R. Lampe.

Regulation of Listed Chemicals

Some of the CSA’s regulatory requirements for listed chemicals differ from the requirements for controlled substances, and some depend on whether a chemical is in List I or List II.

Under 21 U.S.C. § 822(a), “Every person who manufactures or distributes any controlled substance or list I chemical,” or who proposes to do so, must register with DEA. 21 U.S.C. § 823(i) sets out specific criteria for registering applicants to distribute List I chemicals. DEA may deny, revoke, or suspend a registration on various grounds, including if a registrant has materially falsified any application filed under the CSA; committed a felony involving a controlled substance or List I chemical; had a state license or registration suspended, revoked, or denied; or committed acts that would render registration “inconsistent with the public interest.” *Id.* § 824(a). The CSA does not require DEA registration to manufacture or distribute List II chemicals.

Another section of the CSA, 21 U.S.C. § 830, imposes specific requirements on transactions involving listed chemicals (as well as transactions involving machines used to form substances into tablets or capsules). Among other things:

- Regulated parties must maintain records of covered transactions, 21 U.S.C. § 830(a);
- Regulated parties must submit reports to DEA about suspicious transactions, including transactions “involving an extraordinary quantity of a listed chemical” or “an uncommon method of payment or delivery,” *id.* § 830(b)(1)(A);
- Sales of any scheduled listed chemical product to a retail purchaser may not exceed set amounts in a single day, *id.* § 830(d);
- Scheduled listed chemical products sold at retail must be placed “behind-the-counter,” meaning that “the seller places the product such that customers do not have direct access to the product before the sale is made” (the product need not actually be placed behind a counter and may be “stored in a locked cabinet that is located in an area ... to which customers do have direct access”), *id.* § 830(e)(1)(A)(i); and
- Most sales of scheduled listed chemical products must be recorded in a logbook—“a written or electronic list of such sales that identifies the products by name, the quantity sold, the names and addresses of purchasers, and the dates and times of the sales,” *id.* § 830(e)(1)(A)(ii).

DEA has issued regulations to implement the CSA’s requirements related to listed chemicals. *See, e.g.*, 21 C.F.R. Parts 1309, 1310, 1313 & 1314.

21 U.S.C. § 842(a)(12), (13), and (15) prohibit sales of scheduled listed chemical products in violation of applicable regulatory requirements. 21 U.S.C. § 842(a)(14) prohibits unauthorized disclosure of information in logbooks of listed chemical transactions and refusal to provide a logbook to federal, state, or local law enforcement authorities. Violations may result in a civil fine of up to \$25,000. DEA may also prohibit a regulated entity that violates 21 U.S.C. § 842(a)(12) or (13) from selling any scheduled listed chemical product. While most violations of Section 842 are not crimes, knowing violations may be prosecuted as criminal offenses, subject to a fine and up to a year in prison. *Id.* § 842(c)(2)(A).

Listed Chemical Offenses

In addition to the foregoing, some other unauthorized activities involving listed chemicals are crimes that can lead to fines and imprisonment. Among other things, 21 U.S.C. § 841(c) prohibits possessing a listed chemical “with intent to manufacture a controlled substance except as authorized” under the CSA. It also prohibits distributing reportable

amounts of a listed chemical in small units “with the intent of causing the evasion of the [CSA’s] recordkeeping or reporting requirements.”

Under 21 U.S.C. § 841(f), possession of a listed chemical in knowing violation of the applicable recordkeeping or reporting requirements is punishable by a fine and up to year in prison. Knowing distribution of a listed chemical in violation of any other provision of the CSA is punishable by a fine and imprisonment for up to five years.

21 U.S.C. § 843(a)(4)(B) makes it an offense to present false or fraudulent identification when receiving or purchasing a listed chemical. 21 U.S.C. § 843(a)(9) makes it unlawful to distribute, import, or export a List I chemical without the required registration. A first offense is punishable by a fine and up to four years in prison. A person convicted of a felony violation of Section 843 involving a listed chemical may also be enjoined from engaging in any transaction involving a listed chemical for not more than 10 years. *Id.* § 843(e).

Among other things, 21 U.S.C. § 844(a) makes it unlawful for a person knowingly or intentionally to possess any List I chemical obtained pursuant to a registration that is no longer effective. It also prohibits knowing or intentional purchases of scheduled listed chemical products in excess of certain amounts. A first offense is subject to imprisonment for not more than one year and a minimum fine of \$1,000.

Considerations for Congress

Controlled substance precursors have been regulated under the CSA since Congress enacted the statute in 1970, and Congress has periodically modified the applicable regulatory regime. For instance, Congress passed legislation imposing controls on scheduled listed chemical products in 2006, seeking to target List I chemicals that can be used to manufacture methamphetamine illegally. More recently, listed chemical regulation has attracted attention in the context of the opioid epidemic, as policymakers seek to control chemicals used to manufacture illicit fentanyl and other synthetic opioids.

Congress has substantial power to change the laws that apply to listed chemicals and could do so in several ways. First, Congress could pass legislation to add or remove specific substances from control as listed chemicals, and it has done so in the past. Second, Congress could change the substantive CSA provisions that apply to listed chemicals. Third, Congress could enact legislation outside the scope of the CSA to impose legal consequences for activities involving listed chemicals. As one example, the Fentanyl Sanctions Act, 21 U.S.C. §§ 2301–2335, enacted as part of the National Defense Authorization Act for FY2020, directs the President to impose sanctions on foreign persons involved in trafficking “listed chemicals that are synthetic opioids” or “active pharmaceutical ingredients or chemicals that are used in the production of controlled substances that are synthetic opioids.”

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