Congressional Research Service
Informing the legislative debate since 1914

Legal Sidebar

HALT Fentanyl Act Permanently Controls Fentanyl-Related Substances

July 29, 2025

On July 17, 2025, President Trump signed into law the Halt All Lethal Trafficking of Fentanyl Act (HALT Fentanyl Act). Among other things, the HALT Fentanyl Act permanently placed certain *fentanyl-related substances* (FRS)—a class of compounds chemically related to the powerful synthetic opioid fentanyl—in Schedule I of the Controlled Substances Act (CSA). Before the enactment of the HALT Fentanyl Act, FRS had been subject to temporary CSA control since February 2018.

This Legal Sidebar provides an overview of FRS control and the HALT Fentanyl Act, then discusses selected considerations for Congress related to the regulation of FRS and other opioids.

The CSA and Controlled Substance Regulation

The CSA regulates drugs and other substances—whether medical or recreational, legally or illicitly distributed—that pose a risk of abuse and dependence. The Drug Enforcement Administration (DEA), an agency within the Department of Justice, is the federal agency primarily responsible for implementing and enforcing the CSA.

Substances become subject to the CSA through placement in one of five lists, known as Schedules I through V. Controlled substances in Schedule I are subject to the most stringent controls, as they are deemed to have a high potential for abuse and no currently accepted medical use. It is legal to produce, dispense, and possess Schedule I substances only in the context of federally approved scientific studies. Substances in Schedules II through V have accepted medical uses and have been deemed to pose progressively lower risks of abuse and dependence. Those substances may be used for medical purposes, generally by prescription. Anybody who handles a controlled substance, other than an ultimate user, must register with DEA and comply with CSA registration requirements, which include security and reporting obligations.

Either Congress or the DEA administrator can place a substance in a CSA schedule, move a substance to a different schedule, or remove a substance from the schedules. Congress can take those scheduling actions by enacting legislation. DEA, for its part, may make permanent scheduling decisions through a formal rulemaking process and can also temporarily place substances in Schedule I on an emergency basis.

Congressional Research Service
https://crsreports.congress.gov
LSB11343

Fentanyl is in Schedule II, as it has recognized medical uses related to pain management. Some specific substances chemically related to fentanyl are controlled in Schedule I if they do not have currently accepted medical uses or in Schedule II if they do. Cough medicines containing small amounts of another opiate, codeine, are in Schedule V. (Many other prescription drugs are not controlled substances subject to the CSA.)

A substance not specifically designated for control in Schedules I through V may still be subject to the CSA as a *controlled substance analogue*. Under the relevant statutory provisions, a substance that has an effect or chemical composition similar to a controlled substance in Schedule I or II and is intended for human consumption is treated as a controlled substance in Schedule I. Unscheduled synthetic opioids related to fentanyl may qualify as controlled substance analogues. DEA has stated that, as a practical matter, regulating those substances as controlled substance analogues may allow for less effective control than if the substances are specifically scheduled under the CSA. Prior to February 2018, substances now classified as FRS were subject to CSA control, if at all, as controlled substance analogues.

Temporary Scheduling of Fentanyl-Related Substances

On February 6, 2018, DEA issued a temporary scheduling order (FRS TSO) that placed certain FRS in Schedule I for two years based on a finding that control was necessary to avoid an imminent hazard to public safety. While previous scheduling actions by both DEA and Congress generally identified specific substances or lists of several discrete substances for control, the FRS TSO instead imposed controls on a broad class of "fentanyl-related substances" that meet specific criteria related to their chemical structures. The class of FRS does not include fentanyl itself, which remains in Schedule II, or other fentanyl analogues that have been individually scheduled.

While the class of FRS is finite, it includes thousands of chemicals. As discussed in more detail in a previous Legal Sidebar, the effects, potential for abuse and dependence, and medical utility of many of those substances are unknown, which appears to have prevented DEA from undertaking permanent regulatory scheduling of the full class of FRS. Stakeholders—including officials at DEA and the Department of Health and Human Services (HHS)—called on Congress to permanently schedule FRS through legislation. In the meantime, DEA continued to take temporary and permanent scheduling actions with respect to certain specific fentanyl analogues, including some FRS subject to the FRS TSO.

On February 6, 2020, Congress enacted the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act. That legislation did not permanently schedule the class of FRS. Instead, it temporarily extended the FRS TSO until May 6, 2021. Congress subsequently extended the temporary scheduling several times while considering numerous legislative proposals that would have permanently scheduled FRS.

The HALT Fentanyl Act

The HALT Fentanyl Act became law on July 17, 2025. The primary purpose of the Act is to "amend the [CSA] with respect to the scheduling of [FRS]." Section 1 of the HALT Fentanyl Act is the short title. Section 4 contains certain technical corrections to the CSA, and Section 5 directs the Attorney General to issue rules to implement the HALT Fentanyl Act. As discussed below, other sections of the Act impose permanent controls on FRS and establish new registration requirements for research involving Schedule I controlled substances more generally.

FRS Control

Section 2 of the HALT Fentanyl Act amends a section of the CSA, 21 U.S.C. § 812, to permanently add to Schedule I the class of FRS defined in the FRS TSO. Section 2 expressly provides that substances that are

individually scheduled shall not be considered FRS. This section further authorizes the Attorney General to publish in the *Federal Register* a list of substances that satisfy the definition of FRS but provides that the absence of a substance from any such list "does not negate the control status of the substance under this schedule" if the substance fits the definition of FRS.

Section 6 of the HALT Fentanyl Act amends a provision of the CSA, 21 U.S.C. § 841, and a related provision of the Controlled Substances Import and Export Act, 21 U.S.C. § 960, to provide expressly that quantity-based mandatory minimum prison sentences that apply to certain offenses involving analogues of fentanyl also apply to offenses involving FRS.

Section 7 of the Act provides that "the amendments made by this Act apply beginning as of the date of enactment of this Act" and that nothing in the Act "may be construed as evidence that ... [an FRS] is not an analogue of [fentanyl]" for purposes of certain mandatory minimum sentencing provisions of the CSA. It further states that "Congress agrees with the interpretation of the [CSA] in United States v. McCray, 346 F. Supp. 3d 363 (W.D.N.Y. 2018)." *McCray* concerned the application of a CSA mandatory minimum sentencing provision to an offense involving a fentanyl analogue. A previous Legal Sidebar discusses the significance of *McCray* to FRS scheduling legislation.

Schedule I Research

Section 3 of the HALT Fentanyl Act contains multiple provisions designed to streamline research with Schedule I controlled substances. The section applies generally to Schedule I substances, including but not limited to FRS. Section 3(a) amends 21 U.S.C. § 823 to create a simplified registration process for researchers whose research is (1) funded by HHS or the Department of Veterans Affairs or (2) done under an Investigational New Drug (IND) exemption from the Food and Drug Administration (FDA). Under the new process, the researcher may submit a notice to DEA containing the controlled substance to be used in the research, the quantity of the substance to be used, demonstration that one of the above criteria is met (e.g., the grant or project number and identification of the funding agency or the IND application number), and demonstration that the researcher is allowed to do the research under the law of the state where the research will be conducted. Researchers currently registered to conduct research with Schedule I or II controlled substances may begin their new research within 30 days of the notice to DEA. For a researcher without a current registration, DEA must act within 45 days of receiving all required information either to register the applicant or issue an order for the applicant to show cause why registration should not be denied.

Section 3(b) of the Act amends 21 U.S.C. § 822 to clarify that, under certain conditions, individuals in an institution with a DEA-registered researcher may perform research on a controlled substance in the same schedule without being separately registered. The registered researcher must inform DEA of the identities of all such persons conducting research without separate registrations, authorize them to participate, and affirm that any acts involving controlled substances by such individuals will be attributed to the registered researcher.

Section 3(c) adds a subsection to § 822 providing that a single DEA registration may cover controlled substances research in multiple locations so long as all the sites are under the control of the same institution and are in the same city or county and so long as the researcher notifies DEA of each site before the site is used for research or storage of the controlled substances. It authorizes DEA to issue regulations to ensure effective controls against diversion of substances at these sites.

Section 3(d) clarifies that a new DEA inspection is not needed if a registrant applies to research an additional controlled substance under the same or a less restrictive schedule.

Section 3(e) allows researchers who have Schedule I research registrations to continue to conduct research with newly added Schedule I substances on which they have been conducting research. Those

researchers must apply within 90 days of scheduling for a registration (or a modification of the existing registration) to work on the newly scheduled substance, but the research may continue uninterrupted until the application is withdrawn or until DEA issues a show-cause order proposing to deny the application.

Section 3(f) adds a new subsection under § 822 providing that a DEA-registered researcher is not required to obtain a separate registration to manufacture a controlled substance if the manufactured quantities are small and are produced for purposes of the research and the researcher notifies DEA of the manufacturing activities and the quantities of the substance in question. It allows for the creation of different forms of the substance consistent with the research and further allows dosage form development studies to be performed in order to apply to FDA for an IND exemption. It also specifies that it does not provide authority to grow marijuana.

Section 3(g) requires that, if DEA determines that research applications involving certain controlled substances should be "considered under a process, or subject to criteria, different from the process or criteria applicable to applications to conduct research with other controlled substances in the same schedule," DEA shall make that determination public.

Considerations for Congress

Following enactment of the HALT Fentanyl Act, Congress could take additional actions with respect to the regulation of FRS and other synthetic opioids. As discussed above, the FRS TSO, as permanently codified by the HALT Fentanyl Act, defines covered FRS based on their chemical structure. Some have argued that this legal definition may be both overinclusive (because it may include inactive substances) and underinclusive (because it may exclude potentially dangerous opioids that are not chemically related to fentanyl or that involve chemical modifications not listed in the FRS TSO).

Regulating fentanyl analogues using the FRS TSO's definition of FRS is not the only option for Congress. While multiple recent legislative proposals have taken that approach, other proposals from the 116th-119th Congresses have offered differing approaches to scheduling fentanyl analogues. For instance, the Modernizing Drug Enforcement Act of 2019 would have amended the CSA to add to Schedule I "mu opioid receptor agonists"—a class of opioids (including morphine) that is defined by the molecular reactions that produce their effects. The SIFT Act of 2023 would have scheduled certain specific fentanyl analogues, as well as the class of FRS defined in the FRS TSO.

Some recent legislative proposals, including the SAFE Act from the 119th Congress and the SIFT Act and TEST Act from the 118th Congress, would provide a process for expedited rescheduling or descheduling of any FRS that were later found to pose little or no risk of abuse. The HALT Fentanyl Act does not include an expedited rescheduling provision. DEA retains the authority to schedule, reschedule, and deschedule specific substances, including substances currently classified as FRS, through its usual regulatory scheduling process. Congress can also change the status of FRS as a class or individually via legislation.

Another consideration for Congress related to FRS is what criminal penalties should apply to offenses involving those substances. The CSA imposes mandatory minimum sentences for some offenses involving Schedule I controlled substances. No mandatory minimum penalty attaches to a first conviction for simple possession or manufacture, distribution, and possession with intent to distribute most Schedule I controlled substances. However, minimum sentences apply to second and subsequent offenses and offenses resulting in death or serious injury. Additionally, under CSA provisions that predate the temporary scheduling of FRS, mandatory minimum sentences apply to the manufacture, distribution, and possession with intent to distribute large amounts of fentanyl or "any analogue" of fentanyl. Commentators have debated how these provisions should apply to FRS. Some have raised criminal justice concerns, asserting that individuals may face criminal liability for unwitting possession of fentanyl analogues or that Schedule I status may give rise to harsh mandatory minimum penalties under the CSA.

Other commentators and law enforcement officials seek more stringent controls of fentanyl analogues to combat the opioid crisis.

Prior to enactment of the HALT Fentanyl Act, various legislative proposals offered differing options for how FRS should fit into the CSA's criminal enforcement and sentencing regimes. The HALT Fentanyl Act expressly provides that mandatory minimum sentences apply to certain offenses involving FRS. By contrast, the Federal Initiative to Guarantee Health by Targeting Fentanyl Act and the SAFE Act would provide that those mandatory minimums do not apply to FRS. The SAFE Act would also allow for resentencing if a defendant is convicted of an offense involving an FRS that is later rescheduled or descheduled. A proposal from the 117th Congress, the Ending the Fentanyl Crisis Act of 2021, would have applied more stringent control to fentanyl analogues, imposing penalties for "scheduled or unscheduled" fentanyl analogues and reducing the amounts of those substances required to trigger mandatory sentences.

Author Information

Joanna R. Lampe
Legislative Attorney

Disclaimer