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# Comparison of Proposed Legislation Concerning Fentanyl-Related Substances

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## Comparison of Proposed Legislation Concerning Fentanyl-Related Substances

On February 6, 2018, the Drug Enforcement Administration (DEA) issued a temporary scheduling order that placed certain “fentanyl-related substances” (FRS) in Schedule I of the Controlled Substances Act (CSA) for two years. Placing a drug or other substance in Schedule I reflects a finding that the substance has no currently accepted medical use and a high potential for abuse. While previous scheduling actions by both DEA and Congress identified a specific substance or a list of several discrete substances for control, the FRS temporary scheduling order instead imposed controls on a broad class of FRS that met specific criteria related to their chemical structure. Although that class of substances is finite, it includes thousands of different chemicals.

For multiple reasons, including the statutory and practical limitations on DEA’s scheduling authority, Congress has extended the FRS temporary scheduling order several times, most recently on December 29, 2022. The order is now set to expire on December 31, 2024.

This report compares the treatment of FRS under two bills introduced during the 118<sup>th</sup> Congress: the Save Americans from the Fentanyl Emergency Act (SAFE Act, H.R. 568) and the Halt All Lethal Trafficking of Fentanyl Act (HALT Fentanyl Act, H.R. 467). The report discusses both proposals in relation to current law under the CSA. This report focuses on these two bills due to planned floor activity for the week of May 22, 2023, and the similarities between the two bills.

**R47572**

May 24, 2023

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This report compares the treatment of certain fentanyl-related substances (FRS) under two bills introduced during the 118<sup>th</sup> Congress: the Save Americans from the Fentanyl Emergency Act (SAFE Act, H.R. 568) and the Halt All Lethal Trafficking of Fentanyl Act (HALT Fentanyl Act, H.R. 467). The report discusses both proposals in relation to current law under the Controlled Substances Act (CSA).<sup>1</sup> The report focuses on these two bills due to planned floor activity for the week of May 22, 2023, and the similarities between the two bills.

As background, on February 6, 2018, the Drug Enforcement Administration (DEA) issued a temporary scheduling order that placed certain FRS in Schedule I under the CSA for two years.<sup>2</sup> The order defined FRS as follows:

(i) Fentanyl-related substance means any substance not otherwise listed under another Administration Controlled Substance Code Number, and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355], that is structurally related to fentanyl by one or more of the following modifications:

(A) Replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(B) Substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxyl, halo, haloalkyl, amino or nitro groups;

(C) Substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;

(D) Replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or

(E) Replacement of the N-propionyl group by another acyl group.<sup>3</sup>

DEA subsequently began permanent scheduling proceedings for certain specific FRS but not for the full class of FRS.<sup>4</sup> Before DEA completed those proceedings, on February 6, 2020, Congress enacted the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (P.L. 116-114), which extended the temporary scheduling order until May 6, 2021.<sup>5</sup> Congress has since extended the temporary scheduling order several times, often through appropriations law:

- The Extending Temporary Emergency Scheduling of Fentanyl Analogues Act (P.L. 117-12) extended the temporary scheduling order until October 22, 2021.
- The Extending Government Funding and Delivering Emergency Assistance Act (P.L. 117-43) extended the temporary scheduling order until January 28, 2022.

<sup>1</sup> 21 U.S.C. § 801 et seq. For more information on the Controlled Substances Act, see CRS Report R45948, *The Controlled Substances Act (CSA): A Legal Overview for the 118th Congress*, by Joanna R. Lampe. This report refers to the version of the SAFE Act introduced in the House on January 26, 2023, and the version of the HALT Fentanyl Act reported in the House on May 17, 2023.

<sup>2</sup> DEA, Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5,188 (Feb. 6, 2018). Fentanyl itself is in Schedule II, as it has recognized medical uses. Multiple non-pharmaceutical substances chemically related to fentanyl are controlled in Schedule I. *See generally* 21 C.F.R. §§ 1308.11-1308.12.

<sup>3</sup> 83 Fed. Reg. at 5191-92 (brackets in original).

<sup>4</sup> *See, e.g.*, DEA, Schedules of Controlled Substances: Placement of Four Specific Fentanyl-Related Substances in Schedule I, 86 Fed. Reg. 14,707 (Mar. 18, 2021) (proposed action).

<sup>5</sup> S. 3201 (116th Cong. 2020).

- The Further Extending Government Funding Act (P.L. 117-70) extended the temporary scheduling order until February 18, 2022.
- The Further Additional Extending Government Funding Act (P.L. 117-86) extended the temporary scheduling order until March 11, 2022.
- The Extension of Continuing Appropriations Act, 2022 (P.L. 117-95), extended the temporary scheduling order until March 15, 2022.
- The Consolidated Appropriations Act, 2022 (P.L. 117-103), extended the temporary scheduling order until December 31, 2022.
- Most recently, the Consolidated Appropriations Act, 2023 (P.L. 117-328), extended the temporary scheduling order until December 31, 2024.

Absent further legislative or administrative action,<sup>6</sup> the full class of FRS is to remain in Schedule I until December 31, 2024, and is subject to all restrictions and penalties applicable to Schedule I substances until that date. If the temporary scheduling expires, FRS would no longer be scheduled under the CSA as a class, though they may still be subject to control as controlled substance analogues.<sup>7</sup> DEA (or Congress) may also continue to schedule specific FRS.

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<sup>6</sup> As mentioned, DEA has continued to individually schedule specific fentanyl analogues that were included in the class of FRS. However, DEA and the Department of Justice (DOJ) have indicated that they are unable to keep pace with the onset of new fentanyl analogues and scheduling of these substances, and DOJ has asked that Congress schedule all FRS as a class. See DEA, *Statement of the U.S. Department of Justice Before the House Energy and Commerce Committee, Subcommittee on Health, U.S. House of Representatives for a Hearing Entitled, The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances*, December 2, 2021, [https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/2022/08/09/2021.012.02\\_doj\\_statement\\_re\\_overdose\\_crisis\\_frs.pdf](https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/2022/08/09/2021.012.02_doj_statement_re_overdose_crisis_frs.pdf).

<sup>7</sup> For further discussion of regulation of controlled substance analogues, see CRS Legal Sidebar LSB10865, *Recent Developments in Opioid Regulation Under the Controlled Substances Act*, by Joanna R. Lampe.

**Table 1** contains a CRS comparison of the current law regarding FRS (including temporary scheduling), the law if Congress were to enact the SAFE Act, and the law if Congress were to enact the HALT Fentanyl Act.

**Table I. Comparison of the SAFE Act and the HALT Fentanyl Act with Current Federal Law**

| Current Law/Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | SAFE Act (H.R. 568)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | HALT Fentanyl Act (H.R. 467)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| <p><b>21 C.F.R. § 1308.11 Schedule I.</b><br/>                     21 C.F.R. § 1308.11(h) provides for temporary scheduling of “Fentanyl-related substances, their isomers, esters, ethers, salts and salts of isomers, esters and ethers.” Pursuant to P.L. 117-328, the temporary scheduling of FRS is currently in effect until December 31, 2024.<br/>                     21 C.F.R. § 1308.11(i) defines FRS as outlined above. Fentanyl itself and some related chemicals, including some that would otherwise qualify as FRS, have been individually controlled in Schedules I and II on a permanent basis. The definition of FRS includes only substances not individually scheduled. Thus, the classification of fentanyl and specific controlled substances related to fentanyl would not change under either bill or if the temporary scheduling of FRS expires.</p> | <p><b>Sec. 2. Class Scheduling of Fentanyl-Related Substances.</b><br/>                     This section would amend the CSA, 21 U.S.C. § 812(c), to add FRS to Schedule I permanently in a new subsection, Schedule I(e). The proposal uses a definition of FRS that is substantially the same as the current definition, defining FRS as a class based on their chemical structure.<br/>                     The bill would expressly provide that substances that are individually scheduled, rescheduled, or removed from control shall not be considered FRS. It would further provide that FRS shall not be subject to specified quantity-based mandatory minimum penalties. Section 3 of the bill, discussed below, would also limit the applicability of mandatory minimums for FRS.<br/>                     The proposal would authorize the Attorney General (as delegated to DEA) to publish a list of individual substances that meet the definition of FRS. It would provide that “[t]he absence of a substance on any such list does not negate the control status of such substance if the substance meets the criteria” for treatment as FRS. Thus, it appears such a list would be intended to provide notice of some substances that qualify as FRS without limiting the class of covered substances.</p> | <p><b>Sec. 2. Class Scheduling of Fentanyl-Related Substances.</b><br/>                     This section would amend the CSA, 21 U.S.C. § 812(c), to add FRS to Schedule I permanently in a new subsection, Schedule I(e). The proposal uses a definition of FRS that is substantially the same as the current definition, defining FRS as a class based on their chemical structure.<br/>                     The bill would expressly provide that substances that are individually scheduled shall not be considered FRS.<br/>                     The proposal would authorize the Attorney General (as delegated to DEA) to publish a list of individual substances that meet the definition of FRS. Similar to the SAFE Act, it would provide that “[t]he absence of a substance from [such a list] does not negate the control status of the substance under this schedule if the substance satisfies the definition of the term ‘fentanyl-related substance.’”<br/>                     Unlike the SAFE Act, the HALT Fentanyl Act would not exempt FRS from quantity-based mandatory minimum sentences.</p> |
| <p><b>21 U.S.C. § 841 Prohibited acts A.</b><br/>                     21 U.S.C. § 841(b)(1)(A)(vi) imposes a mandatory minimum sentence of 10 years in prison for offenses including the manufacture, distribution, or possession with intent to distribute 400 grams or more of a mixture or substance containing a detectable amount of fentanyl or 100 grams or more of a mixture or substance containing any analogue of fentanyl.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p><b>Sec. 3. Penalty Provisions with Respect to Fentanyl-Related Substances—Domestic Offenses.</b><br/>                     The SAFE Act would amend 21 U.S.C. § 841(b)(1)(A)(vi) to apply a 10-year mandatory minimum prison sentence to offenses involving</p> <ul style="list-style-type: none"> <li>• 400 grams or more of a mixture or substance containing a detectable amount of fentanyl or</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p><b>Sec. 5. Penalties.</b><br/>                     The HALT Fentanyl Act would amend 21 U.S.C. § 841(b)(1)(A)(vi) and 21 U.S.C. § 841(b)(1)(B)(vi) to provide expressly that quantity-based mandatory minimum prison sentences that currently apply to certain offenses involving analogues of fentanyl also apply to offenses involving “fentanyl-related substance[s].”</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

| Current Law/Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | SAFE Act (H.R. 568)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | HALT Fentanyl Act (H.R. 467)                                                                                                                                                                                                                |
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| <p>21 U.S.C. § 841(b)(1)(B)(vi) imposes a mandatory minimum sentence of five years in prison for offenses including the manufacture, distribution, or possession with intent to distribute 40 grams or more of a mixture or substance containing a detectable amount of fentanyl or 10 grams or more of a mixture or substance containing any analogue of fentanyl.</p> <p>While this statute does not define what constitutes an analogue of fentanyl, it appears that FRS may be treated as analogues of fentanyl for purposes of these provisions.</p> <p>Other aggravating factors, such as repeated offenses or causing serious bodily injury or death, may also yield mandatory minimum sentences.</p> | <ul style="list-style-type: none"> <li>• 100 grams or more of a mixture or substance containing a detectable amount of any analogue of fentanyl <i>that is in Schedule I or II or treated as a Schedule I controlled substance</i> pursuant to the CSA’s analogue controlled substance provision, <i>except for a FRS in Schedule I(e).</i></li> </ul> <p>The bill would also amend 21 U.S.C. § 841(b)(1)(B)(vi) to apply a five-year mandatory minimum prison sentence to offenses involving</p> <ul style="list-style-type: none"> <li>• 40 grams or more of a mixture or substance containing a detectable amount of fentanyl or</li> <li>• 10 grams or more of a mixture or substance containing a detectable amount of any analogue of fentanyl <i>that is in Schedule I or II or treated as a Schedule I controlled substance</i> pursuant to the CSA’s analogue controlled substance provision, <i>except for a FRS in Schedule I(e).</i></li> </ul> <p>The effect of these amendments would be to state expressly that the quantity-based mandatory minimum penalties for fentanyl analogues apply to fentanyl analogues in Schedules I and II and unscheduled substances related to fentanyl that qualify as controlled substance analogues under 21 U.S.C. § 813. It would also exempt offenses involving FRS in Schedule I(e) from mandatory minimum sentences based on the quantity of drugs at issue. Other aggravating factors could still yield mandatory minimums for certain FRS offenses.</p> |                                                                                                                                                                                                                                             |
| <p><b>21 U.S.C. § 960 Prohibited acts A.</b></p> <p>21 U.S.C. § 960(b)(1)(F) imposes a mandatory minimum sentence of 10 years in prison for offenses including unauthorized export or import of 400 grams or more of a mixture or substance containing a detectable amount of fentanyl or 100 grams or more</p>                                                                                                                                                                                                                                                                                                                                                                                              | <p><b>Sec. 4. Penalty Provisions with Respect to Fentanyl-Related Substances—Import and Export Offenses.</b></p> <p>The SAFE Act would amend 21 U.S.C. § 960(b)(1)(F) to apply a 10-year mandatory minimum prison sentence to offenses involving</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p><b>Sec. 5. Penalties.</b></p> <p>The HALT Fentanyl Act would amend 21 U.S.C. § 960(b)(1)(F) and 21 U.S.C. § 960(b)(2)(F) to provide expressly that quantity-based mandatory minimum prison sentences that currently apply to certain</p> |



| Current Law/Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | SAFE Act (H.R. 568)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | HALT Fentanyl Act (H.R. 467)                                                                                      |
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| <p>of a mixture or substance containing any analogue of fentanyl.</p> <p>21 U.S.C. § 960(b)(2)(F) imposes a mandatory minimum sentence of five years in prison for offenses including unauthorized export or import of 40 grams or more of a mixture or substance containing a detectable amount of fentanyl or 10 grams or more of a mixture or substance containing any analogue of fentanyl.</p> <p>While this statute does not define what constitutes an analogue of fentanyl, it appears that FRS may be treated as analogues of fentanyl for purposes of these provisions.</p> <p>Other aggravating factors, such as repeated offenses or causing serious bodily injury or death, may also yield mandatory minimum sentences.</p> | <ul style="list-style-type: none"> <li>• 400 grams or more of a mixture or substance containing a detectable amount of fentanyl or</li> <li>• 100 grams or more of a mixture or substance containing a detectable amount of any analogue of fentanyl <i>that is in Schedule I or II or treated as a Schedule I controlled substance pursuant to the CSA’s analogue controlled substance provision, except for a FRS in Schedule I(e).</i></li> </ul> <p>The bill would also amend 21 U.S.C. § 960(b)(2)(F) to apply a five-year mandatory minimum prison sentence to offenses involving</p> <ul style="list-style-type: none"> <li>• 40 grams or more of a mixture or substance containing a detectable amount of fentanyl or</li> <li>• 10 grams or more of a mixture or substance containing a detectable amount of any analogue of fentanyl <i>that is in Schedule I or II or treated as a Schedule I controlled substance pursuant to the CSA’s analogue controlled substance provision, except for a FRS in Schedule I(e).</i></li> </ul> <p>The effect of these amendments would be to state expressly that the quantity-based mandatory minimum penalties for fentanyl analogues apply to fentanyl analogues in Schedules I and II and unscheduled substances related to fentanyl that qualify as controlled substance analogues under 21 U.S.C. § 813. It would also exempt offenses involving FRS in Schedule I(e) from mandatory minimum sentences based on the quantity of drugs at issue. Other aggravating factors could still yield mandatory minimums for certain FRS offenses.</p> | <p>offenses involving analogues of fentanyl also apply to offenses involving “fentanyl-related substance[s].”</p> |

| Current Law/Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | SAFE Act (H.R. 568)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | HALT Fentanyl Act (H.R. 467)                                                                                                                                                                                                                                                                        |
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| <p><b>Rescheduling or descheduling.</b></p> <p>Either Congress or DEA can schedule, reschedule, or deschedule a controlled substance, including FRS. Congress can take scheduling actions through legislation. DEA makes permanent scheduling decisions through an administrative process outlined in 21 U.S.C. § 811 that involves participation by other agencies and the public. DEA’s permanent scheduling decisions can take years to consider and finalize. When Congress adds, removes, or amends the schedule of a controlled substance, DEA implements the legislative schedule change through rulemaking.</p> | <p><b>Sec. 5. Removal from Schedule I of Fentanyl-Related Substances.</b></p> <p>The SAFE Act would add a new subsection to 21 U.S.C. § 811 providing special procedures for expedited descheduling or rescheduling of FRS deemed to pose a limited potential for abuse.</p> <p>If the Secretary of Health and Human Services determines that a FRS has a potential for abuse that is less than the substances in Schedule V and submits to DEA a scientific and medical evaluation supporting its conclusion, the bill would require DEA to remove the substance from the CSA schedules within 90 days.</p> <p>If the Secretary determines that an FRS has a potential for abuse that is less than the substances in Schedules I and II and submits to DEA a scientific and medical evaluation supporting its conclusion, the bill would require DEA to move the substance to Schedule III within 90 days.</p> <p>The bill lists certain information the Secretary may use in evaluating the potential for abuse of a FRS. The bill would also authorize petitions for rescheduling of an FRS to be considered pursuant to the foregoing expedited procedures. It contains an exception to the expedited descheduling or rescheduling process if a substance is required to be controlled under the United States’ international treaty obligations.</p> <p>The bill contains a rule of construction specifying that it does not limit DEA’s ability to deschedule or reschedule FRS pursuant to the existing generally applicable procedures. It also states that descheduling pursuant to this section does not preclude DEA from later imposing new controls.</p> | <p><b>No related provision.</b></p> <p>The HALT Fentanyl Act would not provide for expedited descheduling or rescheduling of FRS. It would remain possible for Congress to change the status of FRS via legislation or for DEA to do so through generally applicable CSA scheduling procedures.</p> |

| Current Law/Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | SAFE Act (H.R. 568)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | HALT Fentanyl Act (H.R. 467)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| <p><b>Convictions involving removed or rescheduled substances.</b></p> <p>Multiple provisions of the CSA, including 21 U.S.C. § 841(b) (discussed above), impose criminal penalties for violations of the CSA involving Schedule I substances in general or fentanyl analogues specifically. There is currently no CSA provision that allows a federal court to vacate or reduce a sentence for a defendant convicted of an offense involving a FRS (or any controlled substance) that has since been removed from control or moved to a less stringent schedule.</p> <p><b>21 U.S.C. § 823 Registration requirements.</b></p> <p>Even if a practitioner has a DEA registration for research on Schedule II-V substances, the registrant must obtain a separate DEA registration for Schedule I substances. 21 U.S.C. § 823(g) requires DEA registrant applications for research with Schedule I substances to be referred to the Department of Health and Human Services (HHS; authority delegated to the Food and Drug Administration [FDA]). FDA then determines the qualifications and competency of each practitioner requesting registration as well as the merits of the research protocol. FDA, in determining the merits of each research protocol, must consult with DEA regarding effective procedures to adequately safeguard against diversion of the controlled substances from legitimate medical or scientific use.</p> <p><b>21 U.S.C. § 822 Persons required to register.</b></p> <p>21 U.S.C. § 822(a) and (b) require that every individual using a controlled substance in research must have a registration to do so. 21 U.S.C. § 822(c) provides several exceptions to the registration requirement, such as for those who are employees of individuals who are registered.</p> | <p><b>Sec. 6. Past Cases Involving Removed or Rescheduled Substances.</b></p> <p>The SAFE Act would allow a federal court to vacate or reduce a sentence (following a motion by the defendant, federal government, or the federal court itself) for a defendant who has been convicted of an offense involving an FRS that has since been descheduled or moved to any schedule other than Schedule I or II. The defendant would not be required to attend the hearing during which the court considers vacating or reducing his or her sentence.</p> <p><b>Sec. 7. Registration Requirements Related to Research.</b></p> <p><b>(a) Alternative Registration Process for Schedule I Research.</b> The SAFE Act would create a simplified process for those whose research is (1) funded by HHS or the Department of Veterans Affairs, or (2) done under an Investigative New Drug (IND) exemption from FDA. Under the new process, the researcher would submit a notice to DEA containing only the following information: the identity of 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.</p> <p>Researchers currently registered to conduct research with Schedule I or II controlled substances would be permitted to begin their new research within 30 days. For a researcher without a current registration, DEA would be directed to 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.</p> | <p><b>No related provision.</b></p> <p>The HALT Fentanyl Act would not provide for vacatur or reduction of the sentence of a defendant convicted of an offense involving an FRS (or any controlled substance) that is removed from control or moved to a less stringent schedule.</p> <p><b>Sec. 3. Registration Requirements Related to Research.</b></p> <p>The HALT Fentanyl Act's provisions designed to streamline research with Schedule I controlled substances, contained in subsections 3(a) through 3(g), are substantively the same as subsections 7(a) through 7(g) of the SAFE Act.</p> |

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**Current Law/Regulation**

21 U.S.C. § 822(e) requires a separate registration for each principal location where the registrant handles controlled substances.

Under DEA regulations, 21 C.F.R. § 1301.18, if a DEA registrant wants to conduct research beyond the variations provided in the registrant's approved protocol, the registrant must submit three copies of a supplemental protocol describing the new research. DEA processes supplemental protocols in the same manner as original research protocols.

Under 21 U.S.C. § 822, manufacturing and research registrations are separate, although researchers may conduct limited manufacturing as a coincident activity of their research registration without obtaining separate manufacturing registrations under certain circumstances.

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**SAFE Act (H.R. 568)****(b) Separate Registrations Not Required for Additional Researcher in Same Institutions.**

Registration exceptions under § 822(c) do not necessarily apply to researchers in the same institution as the Schedule I registrant (unless they are agents or employees of individuals who are registered). This would add a subsection to § 822 which would clarify that, under certain conditions, individuals in an institution with a registered researcher may perform research without being separately registered if performing research on a controlled substance in the same schedule. The registered researcher would be required to inform DEA of the identities of all such persons conducting research without a separate registration, authorize them to participate, and affirm that any acts involving controlled substances by such individuals will be attributed to the registered researcher.

**(c) Single Registration for Related Research Sites.**

The proposal would add a subsection to § 822, which would establish that a single registration would cover multiple locations for the research or storage of controlled substances 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 would specifically authorize DEA regulations to ensure effective controls against diversion of substances at these sites.

**(d) New Inspection Not Required in Certain Situations.** While current law does not require a new inspection if a registrant applies to research an additional controlled substance under the same or a less restrictive schedule, this new subsection would clarify that a new inspection is not needed under this circumstance. It would not, however, prevent DEA

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**HALT Fentanyl Act (H.R. 467)**

from conducting inspections deemed necessary to maintain diversion control.

**(e) Continuation of Research on Substances Newly Added to Schedule I.** This new subsection under § 822 would allow 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. These researchers would have to apply within 90 days for a registration (or a modification of the existing registration) to work on the newly scheduled substance, but the research could continue uninterrupted until the application is withdrawn or until DEA issues a show-cause order proposing to deny the application.

**(f) Treatment of Certain Manufacturing Activities as Coincident to Research.**

This new subsection under § 822 would more generally make clear that a DEA-registered researcher would not be required to obtain a separate manufacturing registration if the manufactured quantities are small and are produced for purposes of the research and if the researcher notifies DEA of the manufacturing activities and the quantities of the substance in question. It would allow the creation of different forms of the substance consistent with the research, and it would allow dosage form development studies performed in order to apply to FDA for an IND exemption. It would also specify that it does not provide authority to grow marijuana.

**(g) Transparency Regarding Special Procedures.**

This new subsection under § 822 would require DEA to make public which substances are subject to special processes or criteria, what special processes or criteria apply to these substances, and how those

| Current Law/Regulation                                                                                                                                                                                                                                                                                  | SAFE Act (H.R. 568)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | HALT Fentanyl Act (H.R. 467)                                                                                                        |
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| <p><b>21 U.S.C. § 821 Rules and regulations.</b><br/>Under 21 U.S.C. § 821, the Attorney General (authority delegated to DEA) is authorized to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.</p> | <p>processes or criteria differ from those that apply to other substances on the same schedule.</p> <p><b>Sec. 8. Rulemaking.</b><br/>This section would require DEA to issue rules implementing the law within one year of enactment and authorize DEA to issue such rules as interim final rules. An interim final rule issued by DEA under this subsection would become immediately effective as an interim final rule without requiring DEA to demonstrate good cause but would be required to give interested persons the opportunity to comment and to request a hearing. The bill would then require a final rule to be issued in accordance with the Administrative Procedure Act (5 U.S.C. § 553).</p>                                       | <p><b>Sec. 4. Rulemaking.</b><br/>This section of the HALT Fentanyl Act is substantively the same as section 8 of the SAFE Act.</p> |
| <p><b>No related provision.</b></p>                                                                                                                                                                                                                                                                     | <p><b>Sec. 9 GAO Report.</b><br/>This section would require the Government Accountability Office (GAO) to consult with HHS, DOJ, the Department of Homeland Security, the Department of State, the Office of National Drug Control Policy, the medical and scientific research community, the law enforcement community, and the civil rights and criminal justice reform communities and to publish a report analyzing the implementation and impact of permanent FRS class scheduling. GAO would be required to analyze the impact on FRS research, removal and rescheduling actions, the effects on illicit FRS manufacturing and trafficking, criminal sentences related to FRS, and the proliferation of new controlled substance analogues.</p> | <p><b>No related provision.</b><br/>The HALT Fentanyl Act would not require a GAO report.</p>                                       |

| Current Law/Regulation | SAFE Act (H.R. 568)   | HALT Fentanyl Act (H.R. 467)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------------|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| No related provision.  | No related provision. | <p><b>Sec. 6. Applicability; Other Matters.</b></p> <p>This section would provide that the HALT Fentanyl Act is effective upon enactment. It would further provide that the Act may not be construed as evidence that, with respect to conduct occurring before the date of the enactment, an FRS is not an analogue of fentanyl. Finally, this section would express the sense of Congress that “[t]he Congress agrees with the interpretation of the Controlled Substances Act (21 U.S.C. 801 et seq.) in <i>United States v. McCray</i>, 346 F. Supp. 3d 363 (2018).”<sup>a</sup></p> |

**Source:** Table created by CRS based on bills introduced in the 118<sup>th</sup> Congress.

**Notes:** Section I (Short Title) of each bill was excluded because it contains only the bill title.

- a. In *McCray*, a district court held that an “analogue of fentanyl” subject to quantity-based mandatory minimum sentences under 21 U.S.C. § 841(b) need not be a “controlled substance analogue” as defined under 21 U.S.C. § 802(32). 346 F. Supp. 3d 363, 365 (W.D.N.Y. 2018).

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