



United States v. McCray and Criminal Sentences for Fentanyl Analogue Offenses

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In 2018, the U.S. District Court for the Western District of New York decided *United States v. McCray*, rejecting a criminal defendant's challenge to a mandatory minimum sentence for possession with intent to distribute and distribution of an analogue of fentanyl. *McCray* has attracted the attention of some Members of Congress because it involves a question of statutory interpretation that is relevant to the regulation of fentanyl analogues.

This Legal Sidebar provides background on the regulation of fentanyl and its analogues under the Controlled Substances Act (CSA), then summarizes the district court's decision in *McCray*. The Sidebar concludes with considerations for Congress related to the *McCray* decision and the regulation of fentanyl analogues.

CSA Regulation of Fentanyl and Fentanyl Analogues

The CSA regulates drugs and other substances—whether medical or recreational, legally or illicitly distributed—that pose a risk of abuse and dependence. 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, reflecting a finding that a substance has a high potential for abuse and no currently accepted medical use. Substances in Schedules II through V have accepted medical uses and have been deemed to pose progressively lower risks of abuse and dependence.

Fentanyl is a Schedule II controlled substance under the CSA, 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 a currently accepted medical use or in Schedule II if they do. By contrast, 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.) In addition, a class of several thousand fentanyl-related substances (FRS) are temporarily controlled in Schedule I through September 30, 2025. (For additional discussion of the temporary scheduling of FRS, see this Legal Sidebar.)

A substance not specifically designated for control in Schedules I through V may be subject to the CSA as a *controlled substance analogue*. "Controlled substance analogue" is defined in 21 U.S.C. § 802(32) as a substance not otherwise approved by the Food and Drug Administration or scheduled under the CSA that

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https://crsreports.congress.gov LSB11263 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 ... of a controlled substance in schedule I or II." The definition expressly excludes any "controlled substance." A substance that meets the foregoing criteria *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, but some synthetic drugs may 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.

It is legal to handle all controlled substances, including Schedule I controlled substances, in the context of research approved by the Drug Enforcement Administration, and controlled substances in Schedules II through V can be used for medical purposes. Unauthorized activities involving controlled substances are crimes that may be subject to fines and significant prison sentences. As relevant here, 21 U.S.C. § 841 makes it a crime "to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance," except as authorized under the CSA. Section 841(b)(1) imposes mandatory minimum prison sentences for violations involving threshold quantities of certain specific controlled substances. One subsection applies a five-year mandatory minimum sentence to offenses involving "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 a detectable amount of an analogue of [fentanyl]." (The statute uses a longer chemical name for fentanyl.) Another subsection imposes a 10-year mandatory minimum sentence on offenses involving larger quantities of the same substances.

United States v. McCray

United States v. McCray involved a criminal defendant who had been charged with possessing with intent to distribute and distributing butyryl fentanyl, a Schedule I controlled substance. The government sought an enhanced sentence under the CSA provision imposing a mandatory minimum sentence for offenses involving "10 grams or more of a mixture or substance containing a detectable amount of any analogue of [fentanyl]." The defendant argued that the quantity-based mandatory minimum sentence could not apply to him. He contended that the term "analogue of [fentanyl]" in 21 U.S.C. § 841(b)(1) should be read to include only substances that meet the definition of "controlled substance analogue" in 21 U.S.C. § 802(32). Because the definition of "controlled substance analogue" expressly excludes controlled substances, and butyryl fentanyl is a Schedule I controlled substance, the defendant's interpretation of the statute would have meant that butyryl fentanyl is not an "analogue of [fentanyl]" that can trigger a quantity-based mandatory minimum sentence.

The district court rejected the defendant's interpretation. The court first noted that the CSA does not define the phrase "analogue of [fentanyl]." The court further acknowledged that, as a scheduled controlled substance, butyryl fentanyl is not a "controlled substance analogue." However, it held that, "[a]lthough the result may seem counterintuitive, this Court agrees with the government and concludes that although butyryl fentanyl is not a controlled substance analogue, it is an analogue of fentanyl."

In so holding, the court first looked to the statutory text. While "controlled substance analogue" is a defined term under the CSA, "analogue of [fentanyl]" is not. Because the latter term is not defined, the court interpreted it based on "the term's plain and ordinary meaning." Referring to a dictionary definition of analogue as "a chemical compound structurally similar to another but differing often by a single element of the same valence and group of the periodic table as the element it replaces," the court concluded that "[n]othing in the dictionary definition of analogue suggests that butyryl fentanyl cannot be an analogue of fentanyl" and that "the government may prove that butyryl fentanyl is an analogue of fentanyl" that triggers a mandatory minimum sentence.

The court held that this interpretation avoided the "unreasonable result" of applying more severe penalties to unscheduled controlled substance analogues than to substances that had specifically been scheduled because they were deemed to pose a risk of abuse. The court further reasoned that the legislative history of Section 841(b)(1) supported its conclusion, citing a House Judiciary Committee Report indicating that "when the statute was enacted, Congress considered the term 'fentanyl analogue' to be different from the more generalized term 'controlled substance analogue' even though fentanyl is a controlled substance." In light of the foregoing, the court denied the defendant's motion to dismiss the charges under the mandatory minimum provision and allowed the prosecution to go forward. The U.S. Court of Appeals for the Second Circuit affirmed the decision in *McCray*, and the U.S. Court of Appeals for the Seventh Circuit has adopted the same statutory interpretation.

Considerations for Congress

McCray involved a substance that had been individually placed in Schedule I, not an FRS subject to temporary, class-wide scheduling. The decision has nonetheless garnered attention from some legislators as Congress considers imposing permanent controls on FRS. As noted, FRS are currently controlled in Schedule I, but the control is temporary and is set to expire on September 30, 2025.

Legislation relating to FRS has been introduced in the 119th Congress in both the House and the Senate, including a bill that would amend the CSA to list FRS as Schedule I controlled substances. A number of proposals from the 118th Congress would have permanently placed the class of FRS in Schedule I. Those proposals took different approaches on whether quantity-based mandatory minimum sentences for analogues of fentanyl should apply to FRS.

A key consideration in this debate is the fact that the class of FRS includes thousands of different chemicals, and the effects, potential for abuse and dependence, and medical utility of many of those substances are unknown. It appears that some FRS may pose a significant risk of abuse, while others may be inactive or may offer potential medical benefits. Some commentators have raised concerns about the possibility of applying mandatory minimum sentences to substances that pose no risk. On the other hand, some commentators and law enforcement officials seek more stringent controls of fentanyl analogues to combat the opioid crisis. During the Biden Administration, the Department of Justice expressed support for an FRS scheduling proposal that would not include mandatory minimums. It is unclear what stance the current Trump Administration may take on the regulation of FRS.

Several recent legislative proposals would tailor how the CSA applies to fentanyl analogues. For instance, the Federal Initiative to Guarantee Health by Targeting Fentanyl Act and the SAFE Act would both permanently schedule the class of FRS but would provide that certain minimum terms of imprisonment do not apply to those substances. The SAFE Act would also allow for resentencing if a defendant was convicted of an offense involving an FRS that was later rescheduled or descheduled. The version of the HALT Fentanyl Act that passed the House in February 2025, by contrast, would expressly apply mandatory minimum sentences to FRS. The HALT Fentanyl Act further would 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, and it states that "Congress agrees with the interpretation of the [CSA] in *United States v. McCray.*" The purpose of those provisions appears to be to avoid discouraging courts from applying quantity-based mandatory minimum sentences to pre-enactment offenses involving FRS.

Outside the context of FRS regulation, the Ending the Fentanyl Crisis Act of 2021 from the 117th Congress would have applied more stringent control to fentanyl analogues, imposing quantity-based mandatory minimum penalties for "scheduled or unscheduled" fentanyl analogues and reducing the amounts of those substances required to trigger mandatory sentences.

Ultimately, because *McCray* involved a question of statutory interpretation, Congress has the power to enact legislation to endorse or reject the district court's holding in that case. (Other constitutional limits might apply. For instance, legislation that would increase criminal penalties for pre-enactment conduct would be subject to constitutional prohibitions on retroactive legislation.) Congress could also enact other legislation to clarify or modify the meaning of the term "analogue of [fentanyl]" as used in 21 U.S.C. § 841(b)(1) or to otherwise change how the CSA regulates FRS or other substances related to fentanyl.

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