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Legal Sidebar

Scheduling of Fentanyl Analogues: The New Legal Landscape

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In the most recent change to federal law in response to the opioid crisis, on February 6, 2020, the President signed the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (the Act). The Act temporarily extended a Drug Enforcement Administration (DEA) administrative order that placed certain *fentanyl analogues—i.e.*, compounds related to the powerful synthetic opioid fentanyl—under control pursuant to the Controlled Substances Act (CSA). This Sidebar provides an overview of key legal issues related to the scheduling of fentanyl analogues and recent changes to the law.

The CSA and Controlled Substance Scheduling

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. A lower schedule number carries greater restrictions, so controlled substances in Schedule I are subject to the most stringent controls. Placement in Schedule I reflects 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 pose progressively lower risks of abuse and dependence. Fentanyl itself is in Schedule II, as it has recognized medical uses such as pain management for cancer patients. Multiple nonpharmaceutical substances related to fentanyl are controlled in Schedule I. Cough medicines containing limited amounts of the 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*. A controlled substance analogue is a substance not otherwise approved by the Food and Drug Administration (FDA) or scheduled under the CSA that has (1) a chemical structure substantially similar to that of a controlled substance in Schedule I or II, *or* (2) an actual or intended effect that is "substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect . . . of a controlled substance in schedule I or II." A substance that meets those criteria *and* is intended for human consumption is treated as a controlled substance in Schedule I. Synthetic opioids related to fentanyl may qualify as controlled substance analogues. However, as a practical matter, treatment as controlled substance analogues may allow for less effective control than if

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the substances are specifically scheduled under the CSA. The Department of Justice (DOJ), which prosecutes CSA violations, has stated that analogue prosecutions are fact-intensive and burdensome because they raise "complex chemical and scientific issues," making case outcomes unpredictable. As a result, policymakers have expressed interest in formally scheduling fentanyl analogues.

Administrative and Legislative Scheduling Procedures

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 a schedule. While Congress can take scheduling actions through the ordinary legislative process, DEA makes permanent scheduling decisions through a complex administrative process that involves participation by other agencies and the public. Before initiating scheduling proceedings, DEA must request a scientific and medical evaluation of the substance at issue. FDA prepares the evaluation and must consider eight statutory factors primarily related to the effects of the substance and its potential for abuse. Based on those factors, FDA recommends whether the substance should be controlled and, if so, in what schedule. FDA's scientific and medical factual findings are binding on DEA, and if FDA recommends against controlling the substance, DEA cannot schedule it.

Upon receipt of FDA's report, the DEA Administrator evaluates all the relevant data and determines whether the substance should be scheduled, rescheduled, or removed from control. Before placing a substance in a schedule, the DEA Administrator must make specific findings related to the substance's medical use and potential for abuse and dependence. DEA makes scheduling decisions through notice-and-comment rulemaking, meaning that interested parties must have the opportunity to submit comments, which the agency may need to respond to before the scheduling action becomes final. Once final, DEA scheduling decisions are subject to judicial review.

Permanent DEA scheduling decisions can take years to consider and finalize. Recognizing that in some cases faster scheduling may be appropriate, Congress also created an emergency scheduling procedure, allowing the DEA Administrator to place a substance in Schedule I temporarily when "necessary to avoid an imminent hazard to the public safety." Before issuing a temporary scheduling order, the DEA Administrator must provide 30 days' notice to the public and the Secretary of HHS and consider any comments from the Secretary. However, in issuing a temporary scheduling order, the DEA Administrator needs to consider only three of the eight factors relevant to permanent scheduling: (1) the history and current pattern of abuse of the substance at issue; (2) the scope, duration, and significance of abuse; and (3) the risk to the public health. A substance may be temporarily scheduled for up to two years. If permanent scheduling proceedings are pending, the DEA Administrator may extend the temporary scheduling period for one additional year. Emergency scheduling orders are not subject to judicial review.

New Changes to the Law and Considerations for Congress

On February 6, 2018, DEA issued an emergency scheduling order (Fentanyl TSO) that placed certain "fentanyl-related substances" in Schedule I for two years. While previous scheduling actions by both DEA and Congress identified a specific substance or a list of several discrete substances for control, the Fentanyl TSO instead imposed controls on a broad class of "fentanyl-related substances" because they met certain criteria related to their chemical structure. While that class of substances is finite, it includes thousands of different chemicals. As one opioid researcher recently testified before Congress, the effects, potential for abuse and dependence, and medical utility of many of those substances are unknown.

Perhaps because of these uncertainties, DEA did not initiate permanent scheduling of the class of substances subject to the Fentanyl TSO. In fact, January 2020 testimony from HHS suggested that, given the large number of substances subject to the order, it is simply not feasible for FDA and DEA to make the individualized findings required to permanently schedule each substance. In turn, without such findings, administrative action to permanently schedule the full class of fentanyl-related substances could

be subject to challenge in court. Accordingly, stakeholders including DEA and HHS have called on Congress to permanently schedule those substances as a class.

The recent legislation did not, however, permanently schedule the substances that are the subject of the Fentanyl TSO. In lieu of such action, the Act *temporarily* extended the Fentanyl TSO until May 6, 2021. Absent further legislative or administrative action, the substances subject to the Act will remain in Schedule I until that date, and will be subject to all restrictions and penalties applicable to Schedule I substances. After the expiration of the Act, the substances at issue will no longer be scheduled under the CSA but may still be subject to control as controlled substance analogues. Notably, fentanyl itself and certain other related chemicals are permanently controlled in Schedules I and II; the Act does not affect those classifications.

If Congress pursues permanent scheduling of fentanyl analogues, several legal questions may arise.

Defining Substances Subject to Control

A key challenge in scheduling fentanyl analogues is how to define the substances subject to regulation. Not all fentanyl analogues have effects like those of fentanyl itself, and there are many whose effects are unknown. As discussed above, the Fentanyl TSO, which the Act extends, defines covered substances based on their chemical structure. Critics have argued that this legal definition may be both overinclusive (by including inactive substances) and underinclusive (by excluding potentially dangerous opioids that are not chemically related to fentanyl or that involve chemical modifications not listed in the Fentanyl TSO). In light of those concerns, the Act requires the Comptroller General to conduct a study evaluating the Fentanyl TSO's definition of substances subject to control.

The Fentanyl TSO's operative legal definition is not the only option for Congress, as proposals in the 116th Congress have taken differing approaches to scheduling fentanyl analogues. For instance, the Stopping Overdoses of Fentanyl Analogues Act would permanently add to Schedule I certain specific synthetic opioids, as well as the class of "fentanyl-related substances" defined in the Fentanyl TSO. The Modernizing Drug Enforcement Act of 2019 would amend the CSA to add to Schedule I "mu opioid receptor agonists"—a class of opioids including morphine, defined by the molecular reactions that produce their effects. The SIFT Act of 2019 would schedule a class of fentanyl analogues but provide a process for expedited descheduling of substances that are later found to pose little or no risk of abuse.

Criminal Enforcement and Sentencing

Another question related to the scheduling of fentanyl analogues is how those substances will fit into the CSA's criminal enforcement and sentencing regimes. Penalties for criminal violations of the CSA vary widely based on the substance at issue, with some penalties tailored to specific substances. Sentences also depend on numerous other factors, including the amount of the substance involved and the nature of the illicit activity (*e.g.*, simple possession versus distribution). The CSA imposes mandatory minimum sentences for only 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. And, under CSA provisions that predate the Act, mandatory minimum sentences apply to the manufacture, distribution, and possession with intent to distribute large amounts of fentanyl or "any analogue" of fentanyl.

As for the mental state required to produce criminal liability, the CSA generally applies to offenses committed knowingly or intentionally. The Supreme Court has explained that prosecutors bringing charges under the CSA must prove that a defendant either knew he was dealing with "some unspecified substance listed on the federal drug schedules" or "knew the identity of the substance he possessed." For

example, "a defendant who knows he is distributing heroin but does not know that heroin is listed on the schedules" satisfies the CSA's mens rea requirement.

Applying these rules to legislation scheduling a class of fentanyl analogues has led to legal and policy debates between various stakeholders. Some commentators have raised criminal justice concerns, asserting that individuals may face criminal liability for unwitting possession of fentanyl analogues or that Schedule I status will give rise to harsh mandatory minimum penalties under the CSA. On the other hand, some commentators and law enforcement officials seek more stringent controls of fentanyl analogues to combat the opioid crisis. As discussed above, difficulties in prosecuting activities involving unscheduled fentanyl analogues under the analogue controlled substance provisions of the CSA have led to calls for placing fentanyl-related substances in Schedule I. Notably, while the Fentanyl TSO and the Act temporarily controlled fentanyl-related substances in Schedule I, neither altered the CSA's sentencing regime or the mental state requirements that apply to controlled substance offenses.

Proposals before the 116th Congress would further tailor how the CSA applies to fentanyl analogues. For instance, the Federal Initiative to Guarantee Health by Targeting Fentanyl Act would permanently schedule a class of fentanyl-related substances but provide that no minimum terms of imprisonment shall apply to those substances. By contrast, the Ending the Fentanyl Crisis Act of 2019 would apply 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.

Research Access

While fentanyl analogues may pose public health risks, some proponents, arguing that the substances may also offer medical benefits including pain management and treatment of opioid addiction or overdose, worry that placing fentanyl analogues in Schedule I may impede research into potential medical uses.

Although people sometimes colloquially refer to substances in Schedule I as "illegal drugs," the CSA does not fully ban any drugs or other substances. Schedule I controlled substances have no accepted medical use and thus may not be dispensed by prescription like other controlled substances. Nonetheless, it is legal to produce, dispense, and possess Schedule I substances in the context of federally approved scientific studies. At the same time, Schedule I status creates certain legal hurdles for would-be researchers. For example, a person who conducts research with controlled substances must comply with the CSA's registration requirements, which include security and reporting obligations. In addition, a rider to the appropriations bill for FY2020 provides that, subject to certain exceptions, no federal funds may be used for any activity that "promotes the legalization" of a Schedule I controlled substance. No court has interpreted the rider, and it is not clear whether "legalization" only includes federal descheduling or extends to moving a substance to a less restrictive CSA schedule or state decriminalization. In any event, the appropriations rider does not directly restrict research involving Schedule I controlled substances; it simply limits the availability of federal funding to support such research.

While the Act requires the Comptroller General to report on the status of research on fentanyl analogues, there are number of proposals in the 116th Congress to substantively alter the legal framework for such research. For example, the SIFT Act of 2019 would relax certain registration requirements that apply to research on Schedule I controlled substances. And a proposed amendment to the appropriations bill for FY2020 would have eliminated the appropriations rider limiting federal funding for Schedule I research.

Author Information

Joanna R. Lampe
Legislative Attorney

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