Department of Justice

STATEMENT OF THE
U.S. DEPARTMENT OF JUSTICE

BEFORE THE

HOUSE ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

THE OVERDOSE CRISIS: INTERAGENCY PROPOSAL TO COMBAT ILLICIT FENTANYL-RELATED SUBSTANCES

PRESENTED

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Statement of the U.S. Department of Justice
Before the House Energy and Commerce Committee
Subcommittee on Health
For a Hearing Entitled
"The Overdose Crisis: Interagency Proposal
to Combat Illicit Fentanyl-Related Substances"
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Ms. Chairwoman, Representative Guthrie, distinguished members of the Committee—thank you for holding this hearing and for providing the Department of Justice ("Department") the opportunity to share our views in strong support of the Administration's legislative proposal to permanently schedule fentanyl-related substances (FRS) as a class.

The Department supports the Administration's approach to reducing the supply and availability of illicitly manufactured FRS, while protecting civil rights and reducing barriers to scientific research. The Administration's legislative proposal for class-wide scheduling of FRS will continue to prohibit FRS as Schedule I substances in the United States, which will deter manufacturers and traffickers from attempting to flood our communities with these substances. At the same time, the Administration's proposal will address important research and criminal justice concerns. The proposal would subject defendants who import or traffic FRS domestically to the advisory penalties set forth under the United States Sentencing Guidelines without subjecting them to new quantity-based mandatory minimum penalties or affecting existing fentanyl and fentanyl analogue mandatory minimums. In addition, the proposal would preserve the Drug Enforcement Administration's (DEA) ability to individually schedule FRS substances as Schedule I controlled substances, using the traditional administrative scheduling process. Once scheduled, any such fentanyl related compound would be subject to the same mandatory minimums applicable to "any analogue of fentanyl" under the Controlled Substances Act, just as under current law, *see* 21 U.S.C. §§ 841(b)(1)(A)(vi) and (B)(vi); 21 U.S.C. §§ 960(b)(1)(F) and (b)(2)(F).

The permanent scheduling of FRS is critical to the safety and health of our communities and class-wide scheduling provides a vital tool to combat overdose deaths in the United States. The Department believes that the balanced approach to FRS presented in the Administration's proposal will achieve our core public safety and health imperatives, preserve prosecutorial equities, and send the necessary deterrent message to drug traffickers around the world.

Class-Wide Scheduling of FRS is Imperative to Protect Public Health and Safety

The Centers for Disease Control and Prevention (CDC) estimates that there were more than 100,000 overdose deaths in the United States during the 12-month period ending in April of 2021, an increase of approximately 28% from the 78,056 deaths during the same period the year before.[1] Experts interpreting the data report that synthetic opioids, primarily fentanyl, cause the majority of the deaths. Fentanyl is 50 to 100 times more potent than morphine, and 50 times

[1] CDC, National Center for Health Statistics, Drug Overdose in the U.S. Top 100,000 Annually, November 17, 2021.

more potent than heroin. Just 2 milligrams, the amount that fits on the tip of a pin, can be lethal. Fentanyl analogues can be even more potent than fentanyl itself.

Some clarification of terms and substances at issue is useful to understand the legal and regulatory framework that gives rise to the need for class-wide scheduling of FRS. Fentanyl is a prescription opioid analgesic first approved by the Food and Drug Administration (FDA) in 1968. For purposes of the law, fentanyl analogues can be thought of as licit (legally produced, though still subject to diversion, trafficking, and misuse) and illicit (produced from the outset for illegal trafficking and abuse). On the licit side, several formulations of pharmaceutical fentanyl exist, including among others injectable products, buccal tablets to be inserted in the user's cheek, transdermal patches, and sublingual sprays and tablets. Over the decades, analogues of fentanyl have been developed for medical use in humans (*e.g.*, remifentanil, alfentanil, and sufentanil) and animals (*e.g.*, carfentanil and thiafentanil). Because these pharmaceutical products have accepted use in treatment in the United States, they are placed in Schedule II of the Controlled Substances Act. Licitly produced fentanyl products can be diverted and trafficked just like any drug of abuse, but these products also have legitimate uses, though they are limited and specialized compared to many other drug products. On the illicit side, clandestine drug traffickers, sometimes working with prospective customers, have also developed fentanyl analogues simply to avoid regulatory controls and thus detection and prosecution. The Department, through authority delegated to DEA, controls these substances when encountered, but the process has many steps and takes time, and the agency must prioritize the most prevalent, persistent, and harmful fentanyl analogues. If a fentanyl analogue is not scheduled, manufacturing and distribution offenses may still be prosecuted under the Controlled Substance Analogue Enforcement Act of 1986 ("Analogue Act"), if it is proven that the substance was intended for human consumption. However, as discussed below, such prosecutions require proof of several elements to a jury or judge and are cumbersome and resource intensive. The danger of illicit fentanyl analogues, the nefarious ingenuity of underground chemists, and the extreme public health danger of these products, gave rise to the need for class-wide scheduling of substances that DEA, in a regulation effective on February 6, 2018, first defined as "fentanyl-related substances" (FRS). These substances are described by chemical modifications to the fentanyl molecule in ways that would be expected to result in a psychoactive compound. By definition, FRS are currently non-scheduled substances. A substance that would meet the definition of an FRS may later be scheduled; once scheduled, by definition they are no longer FRS but controlled substances.

The Department believes that permanent class scheduling of FRS is essential to protecting Americans from the proliferation of these deadly synthetic opioids. Before the February 2018 emergency class-wide scheduling of FRS, the DEA had to continually race to schedule fentanyl analogues individually, in an effort to keep pace with cartels and drug traffickers who were making new fentanyl formulations, using different precursor and pre-precursor chemical compositions specifically to avoid controls. During the 22-month period between May 2016 and February 2018, the DEA individually scheduled 16 distinct, newly created fentanyl analogues. Unfortunately, it was not uncommon for the DEA to encounter a new fentanyl analogue within weeks of announcing the scheduling of a previously encountered fentanyl analogue, sometimes associated with a cluster of overdoses. The DEA is continuing its thorough work of individually scheduling fentanyl analogues, as they are encountered. Class-

wide scheduling allows law enforcement to respond to the manufacturing, importation, and trafficking of those illicitly manufactured analogues of fentanyl that are not yet individually scheduled before they are even produced and distributed by drug traffickers.

Recent experience has demonstrated the success of class-wide scheduling in reducing the availability of FRS, to the benefit of law enforcement, and in turn the American public. As the Government Accountability Office (GAO) has recently found, after the United States class-scheduled FRS on February 6, 2018, through DEA administrative action, and after China imposed class controls on May 1, 2019, that law enforcement encounters of fentanyl analogues not individually scheduled by name plummeted, falling nearly 90%, from 7,058 encounters in 2016 through 2017, to 787 encounters in 2018 through 2019.[2] The number of new FRS encountered by law enforcement has also declined significantly, though less dramatically, from 32 in 2016 through 2018 to just 12 from February 2018 to July 2020.

While scheduling is not the only factor in reducing the proliferation of FRS, permanent class-wide scheduling of FRS is a critical step to enable our laws to keep pace with the evolving and dynamic synthetic drug market. Keeping class-wide scheduling in place is vital to securing the health and safety of Americans against a new wave of deadly fentanyl analogues, and it will send a strong message to critical partner nations, as well as drug traffickers.

The Department's experience has also been that the Analogue Act is not an adequate substitute for class-wide scheduling. While the Department can prosecute— and has prosecuted— trafficking crimes involving FRS through the Analogue Act, that statute is not a regulatory tool. Rather, it requires untrained juries to evaluate scientific submissions from multiple, competing experts, and to perform a regulatory-like function but on a case-by-case basis. Outcomes have not always been consistent among courts, or among circuits, and the process is time consuming and inefficient. Federal prosecutors have achieved excellent results using the Analogue Act when necessary, but with the unprecedented overdose epidemic facing us today, it would be prudent to avoid the factual and legal complications attendant to Analogue Act prosecutions. In addition, the clear delineation of modifications to the fentanyl molecule in the definition of FRS provides clear notice to the public. Our federal criminal justice system has given greater emphasis to uniformity and fairness since the Sentencing Reform Act of 1984. In keeping with these principles, the Department believes Congress should schedule all FRS as a class, to provide for equal treatment across judicial districts and circuits.

Finally, while some skeptics have expressed the view that FRS class scheduling will subject many more people to prosecutions that result in mandatory minimum sentences, the Department's experience has not demonstrated that outcome. During the time period that class-wide scheduling of FRS has been in effect, mandatory minimums attached to FRS have not played a significant role in federal prosecutions. According to the Department's records of

[2] GAO, Synthetic Opioids, Considerations for the Class-Wide Scheduling of Fentanyl-Related Substances, April 2021, at 18 ("Our analysis of DEA data on these reports show that encounters with fentanyl analogues that were not individually scheduled by name—which is what class-wide scheduling was intended to target—decreased from 7,058 reports in 2016 and 2017 to 787 reports in 2018 and 2019. This decrease coincided with DEA's class-wide scheduling order in February 2018 and the individual scheduling of 11 fentanyl analogues shortly before DEA's order.").

federal case filings across U.S. Attorneys' Offices, during the time between February 6, 2018 (when FRS were administratively scheduled by DEA) and December 31, 2020, there were only eight federal prosecutions of FRS substances, and only three involved a quantity of FRS that could trigger a mandatory minimum. While some of these cases involved more than one defendant— and one unusual case involved 22 defendants— the majority of defendants in all of the cases were not sentenced to a mandatory minimum term. Permanent scheduling is expected to continue to reduce proliferation of these substances, thereby reducing the overall number of prosecutions.

Department Support for the Administration Proposal

The Administration's proposal for class-wide scheduling of FRS would create a new statutory class of substances—"fentanyl related substances"—and specify that FRS shall be treated as Schedule I drugs under the Controlled Substances Act (CSA), but shall not be subject to enhanced quantity-based sentences applicable to "any analogue of fentanyl" (the CSA uses the long scientific name for fentanyl) for the purposes of title 21, sections 841(b)(1)(A) and (b)(1)(B). This means that domestic drug-trafficking crimes involving FRS (other than those specifically exempted or listed under another schedule) would be punishable under section 841(b)(1)(C) of title 21, which does not contain quantity-based mandatory minimum penalties. Mandatory minimum penalties would be retained for (1) any individually scheduled "analogue of fentanyl," whether scheduled before or after this proposal is enacted, as per the text of sections 841(b)(1)(A) and (B); and (2) where death or serious bodily injury results from the use of a trafficked FRS under (b)(1)(C). The applicable U.S. Sentencing Guidelines for FRS as fentanyl analogues would not be affected.

Although scheduling an entire class of a substance is a relatively rare action, the Administration's proposal here appropriately seeks to avoid unintended criminal justice consequences by excluding FRS from quantity-based mandatory minimum penalties. For the reasons set forth below, the Department believes that the Administration's proposal reflects a balanced approach to the imposition of criminal penalties that will enable the Department to continue to meet its law enforcement mission and hold criminal wrongdoers accountable.

First, not imposing quantity-based mandatory minimums on FRS is anticipated to have an overall negligible effect on federal cases. As noted above, the Department has found only eight cases with FRS charges from the time temporary class scheduling was adopted in 2018 through December 2020, of which only a handful included charges that could have resulted in quantity-driven mandatory minimums. Specifically, publicly available information about those eight cases shows that in only three was FRS charged in a sufficient quantity that it could have triggered a mandatory minimum sentence. But in two of the cases, nearly every defendant was also charged with trafficking additional drugs—such as heroin, methamphetamine, or individually scheduled fentanyl analogues—which independently would have triggered a mandatory minimum sentence, irrespective of the FRS. As reflected by these cases, mandatory minimums attached to FRS have not played a significant role in federal prosecutions during the time that class-wide scheduling of FRS has been in effect.

Second, the proposal would not preclude the DEA from individually scheduling the most harmful and prevalent FRS, as the DEA currently does, using the traditional administrative scheduling process set forth by the CSA. For example, if DEA were to continually encounter a specific FRS in the community and determine that it warrants individual scheduling, the DEA could move to schedule it—and the FRS would then be treated as a "fentanyl analogue" under the CSA. In fact, even during the time that class-wide scheduling has been in effect, the DEA continued individually scheduling the most prevalent, persistent, and harmful FRS, and a number of such scheduling actions are currently in the pipeline. Only a few FRS that have been encountered by law enforcement remain unscheduled, and many are in the pipeline for permanent scheduling. Of course, these actions only concern those substances which have been *encountered*. It is difficult to estimate how many FRS may start appearing and being encountered if class-wide scheduling expires. Previous DEA testimony highlighted the myriad of ways that new fentanyl analogues (FRS) may be synthesized:

> New fentanyl analogues can be designed easily and synthesized by using the same chemistry as that to make fentanyl and simply replacing one or more of the chemicals used in the synthetic process. For example, a group of fentanyl analogues (e.g., acetyl fentanyl, acryl fentanyl, butyryl fentanyl, furanyl fentanyl) can by synthesized from 4-anilino-N-phenethylpiperidine (4-ANPP), a Schedule II immediate precursor to fentanyl. The same idea can be, and has been, applied to other sections of fentanyl's chemical structure. Using this pathway, different chemicals can be used to create structural modifications to the chemical structure of fentanyl.[3]

Third, the Administration proposal does not propose changes to the current Sentencing Guidelines, which treat FRS like an individually scheduled "fentanyl analogue."[4] Tracking the CSA, the Drug Quantity Table in the sentencing guidelines is calibrated so that a given base offense level is triggered by one-quarter of the quantity of fentanyl analogues versus fentanyl. The Administration proposal would not alter the treatment of FRS as fentanyl analogues, for the purposes of the Drug Quantity Table, nor would it alter the potential enhancements and factors that judges are permitted to consider when imposing sentences. Besides being advisory, unlike mandatory minimums, the Sentencing Guidelines provide guidance to the courts on accounting for the full range of factors characterizing the offender's conduct in the offense.

Fourth, the Administration proposal retains the potential imposition of a mandatory minimum penalty where death or serious bodily injury results from the trafficking of an FRS, as is the case for any other Schedule I and II controlled substance under 21 U.S.C. § 841(b)(1)(C). According to a U.S. Sentencing Commission study reviewing fiscal year 2019 data, this mandatory minimum was infrequently applied across all drug cases (less than 1% of the time).[5] Where this mandatory minimum for death or serious bodily injury did apply, it was applied in a much higher

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[3] Demetra Ashley, Acting Administrator, DEA, Comment to U.S. Sentencing Commission on Fentanyl & Fentanyl Analogues in Response to 82 FR 47322, November 13, 2017, p.1."

[4] USSG §2D1.1(c) (Drug Quantity Table), n. (J), promulgated by Amendment 807, effective Nov. 1, 2018.

[5] U.S. Sentencing Comm'n., Fentanyl and Fentanyl Analogues, Federal Trends and Trafficking Patterns, January 2021, at 36.

proportion of cases involving fentanyl offenders (6.1%, n=54) and an even higher proportion involving fentanyl analogue offenders (8.2%, n=19) than in cases involving other drug offenders (0.1%, n=25).[6] Accordingly, where this rarely imposed punishment does apply, it is fair to conclude that the facts that warrant a significant sentence have been proven beyond a reasonable doubt—namely, that the death or serious bodily injury would not have occurred "but-for" the FRS, or that the FRS, if consumed with other substances, was independently sufficient to have caused the death or serious bodily injury.[7]

Finally, two additional aspects of the Administration proposal are important to safeguarding against unwarranted outcomes. First, the proposal includes an off-ramp process, overseen by the Department of Health and Human Services, to identify and remove or reschedule any individual FRS that is found not to have a high potential for abuse, as defined in the Controlled Substances Act. And second, the proposal contains a provision that would enable federal courts to vacate or reduce the sentence of a person convicted of an offense involving an individual FRS that is subsequently removed or rescheduled from Schedule I.

Conclusion

Class-wide control of fentanyl-related substances has been a critical tool in the Department's fight against the fentanyl epidemic. The Department believes that the Administration's proposal regarding FRS scheduling reflects a balanced approach that will promote public safety and health, deter the proliferation of these deadly substances, enable the Department to pursue FRS trafficking crimes and seek appropriate penalties, and at the same time, guard against unintended consequences in connection with criminal justice and continued research. The Department looks forward to working with Congress to permanently schedule FRS.

[6] *Id.*

[7] *Burrage v. United States*, 134 S.Ct. 881, 892, 571 U.S. 204, 218-19 (2014) ("We hold that, at least where use of the drug distributed by the defendant is not an independently sufficient cause of the victim's death or serious bodily injury, a defendant cannot be liable under the penalty enhancement provision of 21 U.S.C. § 841(b)(1)(C) unless such use is a but-for cause of the death or injury.").