October 7, 2022

Senate Majority Leader Chuck Schumer
322 Hart Senate Office Building
Washington, DC 20510

Senate Minority Leader Mitch McConnell
317 Russell Senate Office Building
Washington, DC 20510

Senator Dick Durbin
Chair, Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, DC 20510

Senator Chuck Grassley
Ranking Member, Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Senate Majority Leader Schumer, Senate Minority Leader McConnell, Chairman Durbin, and Ranking Member Grassley:

We are public health organizations and science-based institutions that write to you today in support of the Temporary Emergency Scheduling and Testing of Fentanyl Analogues Act of 2022 (TEST Act). Congress has temporarily placed on Schedule I an entire class of fentanyl-related substances (FRS) and is considering making this scheduling permanent. **By making permanent the temporary classwide scheduling of FRS, Congress may inadvertently criminalize therapeutic medications similar to naloxone and other life-saving medications at a time when the U.S. is facing record numbers of overdose deaths.** Instead, we believe Congress should pass the TEST Act which can facilitate the research of FRS and ensure that substances are placed on the drug schedule according to their scientific profile and potential for abuse.

Permanent classification of FRS on Schedule 1, without first studying the pharmacological effects and epidemiological data of the individual substances, would set an alarming precedent in U.S. drug scheduling. Since 1970, the federal government has conducted a scientific evaluation of all controlled substances in order to understand if or where on the drug schedule a particular substance should be classified. In order for a substance to be placed on Schedule 1, the DEA must determine it has potential for abuse and no approved medical use. Further, the Attorney General must request a scheduling recommendation from the Secretary of HHS based on an eight-factor medical and scientific analysis.

Yet, some are advocating for the federal government to make permanent the temporary classwide scheduling of FRS on Schedule 1 without conducting individual testing of each uniquely identified chemical compound or novel substance, despite acknowledging

that not all substances are similar and harmful. In a December 2021 House hearing, the Food and Drug Administration (FDA) testified that it had identified 44 FRS and studied 25, reporting that some of the substances in the FRS class were inert, and at least one of the substances was not psychoactive and behaved like naloxone, meaning it could potentially help reverse the effects of an opioid overdose.[1] Policymakers, the scientific community, and the public still do not know what the FDA studies revealed about each of the substances nor if any efforts have been made to deschedule or reschedule the substances pursuant to the FDA's findings.

Moreover, HHS has previously undertaken a review of the FRS class, but it could not provide findings because of the vast number of hypothetical FRS and more importantly, because it had identified examples of substances in the class that acted as opioid antagonists.[2] This means that people will be deterred from FRS research and/or may potentially be incarcerated for FRS activities related to benign or even beneficial substances. This would be a devastating and consequential outcome for our communities.

To address these problems, the TEST Act will:

- Extend the temporary, emergency scheduling of FRS for 2 years after enactment to allow time for testing of FRS;
- Require the Department of Justice to publish—within 90 days of enactment— the testing results of all FRS that have already been *encountered and evaluated*;
- Require the Department of Justice to evaluate the FRS that it has *encountered but not yet evaluated*: the bill provides the Attorney General one year to solicit a scientific and medical evaluation from the Secretary of Health and Human Services, and one year for the Secretary to complete the evaluation and submit a scheduling recommendation to the Attorney General;
- Establish a pathway for the Attorney General to delist FRS that do not have potential for abuse by removing them from Schedule I;
- Establish a pathway for the Attorney General to place into a lower schedule any FRS that has a potential for abuse that is less than the drugs or other substances in schedules I and II;
- Eliminate the costly and complex restrictions on future research into FRS;

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[1] *The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce,* 117th Cong. 4 (2021) at https://www.c-span.org/video/?c4994371/user-clip-fda.

[2] Testimony of Sandra D. Comer, Ph.D., Pub. Policy Officer, Coll. on Problems & Drug Dependence, Before the Subcomm. on Crime, Terrorism & Homeland Sec., H. Comm. on the Judiciary at 3 (Jan. 28, 2020), https://docs.house.gov/meetings/JU/JU08/20200128/110392/HHRG-116-JU08-Wstate-ComerS-20200128.pdf.

- Authorize appropriations to the Secretary of Health and Human Services to conduct testing;
- Require the Attorney General to notify any person who has been convicted or sentenced for an offense related to a FRS that is subsequently removed from the schedules or rescheduled to a lower schedule that carries a lower criminal penalty of the change.

We urge you to pass the TEST Act this Congress before the temporary FRS classwide scheduling policy expires on December 31, 2022. It is misguided for the federal government to restrict research and study of FRS at a time when approximately 300 people die of a preventable overdose each day. The federal government should support research and health services. This includes studying FRS for potential treatment options and ensuring people can receive the best treatments imaginable. We need the federal government to support our efforts to help save as many lives as possible. Ensuring that federal agencies and the research community can study emerging substances for potential therapeutic value, including FRS, is a critically important component of these efforts.

Sincerely,

A New PATH
AIDS Alabama
AIDS Foundation Chicago
AIDS United
Big Cities Health Coalition
Elephant Circle
Moms United to End the War on Drugs
OpioidSettlementTracker.com