Temporary Emergency Scheduling and Testing of Fentanyl Analogues Act of 2022 (TEST Act)

Senator Cory A. Booker

[W]e have gathered up an entire class of substances, uncreated, that within that class of substance, there may be substances that either have medical merit or are not the least bit harmful. They're not any more harmful than water.

Office of National Drug Control Policy, House Hearing on the Regulation of Fentanyl-Related Substances, Dec. 2, 2021

Since 2018, as our country has faced an increase in opioid overdoses, Congress has extended temporary class-wide scheduling of fentanyl-related substances on Schedule I of the Controlled Substances Act. Schedule I is reserved for the most harmful drugs with no medical use, which carry the harshest criminal penalties and barriers to scientific research. Yet, according to provisional data from the Centers for Disease Control and Prevention, U.S. overdose deaths involving synthetic opioids other than methadone increased 23 percent between 2020 and 2021 alone, from 58,000 to 71,000.

It is apparent that temporary scheduling has not proven to be an effective solution to the country's grim overdose crisis.

Class-wide scheduling has placed fentanyl-analogues into Schedule I without the scientific and medical evaluation for pharmacological effect that is required for controlled substances. This approach accepts that helpful, harmful, and harmless substances alike can be preemptively treated as equally harmful, thereby disregarding basic principles of evidence and pharmacology.

The failure to test fentanyl analogues jeopardizes the discovery of potential new therapeutic treatments and antidotes.

As of December 2021, the Drug Enforcement Administration (DEA) has identified approximately 44 fentanyl-related substances and the Food and Drug Administration has studied the pharmacology for about 25 of these substances. The FDA found that, among the 25 studied substances, one substance had no pharmacological effect and could even be a life-saving treatment like naloxone. Despite these findings, the DEA has not made public the studies, and the DEA is not required to test the rest of the group.

Every day that passes without studying these substances is another day that we fail to address the public health crisis we face.

The TEST Act will extend the temporary class-wide scheduling for two years during which time the Department of Justice will be required to conduct a scientific and medical evaluation of the fentanyl-related substances it has encountered to date but not yet tested. The bill also eases research requirements so that the science and medical communities can study and develop treatments for fentanyl-related substances.

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Section by Section

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The TEST Act will extend the temporary class-wide scheduling for two years, during which time the Department of Justice will be required to conduct a scientific and medical evaluation of fentanyl-related substances. The bill also streamlines evaluation requirements so that the science and medical communities work to develop treatments for fentanyl-related substances:

Section 3 of the TEST Act extends the temporary class-wide scheduling of fentanyl-related substances for two years.

Section 4 of the TEST Act requires the Department of Justice to evaluate the fentanyl-related substances that it has encountered but not yet evaluated. The bill gives 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.

Section 5 of the TEST Act amends the Controlled Substances Act so that fentanyl-related substances can more quickly be evaluated and properly scheduled according to pharmacological effect. This includes:

- **Evaluation for pharmacological effect**: Currently, the Secretary of Health and Human Services must conduct an eight-factor scientific and medical evaluation to make a scheduling recommendation. The TEST Act narrows the evaluation factors to four, allowing fentanyl-related substances to more quickly be evaluated and properly scheduled according to their pharmacological effect.

- **Removal and rescheduling**: The TEST Act requires the Attorney General to remove fentanyl-related substances with no potential for abuse from the schedules. It also requires the Attorney General to place into a lower schedule any fentanyl-related substance that has a potential for abuse that is less than the drugs or other substances in schedules I and II.

- **Public access to scientific and medical information**: To date, the Attorney General has tested dozens of fentanyl-related substances without making the evaluations and recommendations public. The TEST Act requires the Attorney General to publish the evaluations and recommendations for those fentanyl-related substances that have already been tested.

- **Expands research opportunities**: Schedule I substances are subject to stringent research requirements that impede scientific study. The TEST Act eases the registration requirements for researchers to study fentanyl-related substances

for medical or therapeutic uses and to make science-based scheduling recommendations.

- **Funding**: The TEST Act authorizes appropriations of $50,000,000 to the Department of Health and Human Services to evaluate fentanyl-related substances as required by the bill.

Section 6 of the TEST Act requires the Attorney General to notify any person who has been convicted or sentenced for an offense related to a fentanyl-related substance that is subsequently removed from the schedules, or rescheduled to a lower schedule that carries a lower criminal penalty, of the change.