



# Department of Justice

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**STATEMENT OF THE  
U.S. DEPARTMENT OF JUSTICE**

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**BEFORE THE**

**COMMITTEE ON THE JUDICIARY  
UNITED STATES SENATE**

**FOR A HEARING ENTITLED**

**THE COUNTDOWN: FENTANYL ANALOGUES & THE EXPIRING  
EMERGENCY SCHEDULING ORDER**

**PRESENTED**

**JUNE 4, 2019**

**Statement of the  
Department of Justice  
Before the United States Senate  
Committee on the Judiciary  
For a Hearing Entitled “The Countdown:  
Fentanyl Analogues & the Expiring Emergency Scheduling Order”  
June 4, 2019**

Chairman Graham, Ranking Member Feinstein, and Members of the Committee: thank you for the opportunity to discuss the dangers posed by illicit fentanyl and its analogues and the challenges the Department of Justice (Department) and Drug Enforcement Administration (DEA) face when holding traffickers accountable. The Department and DEA appreciate the Committee’s interest in this important topic.

It is well-known that overdose deaths in the United States have been on the rise and have already reached record levels. While the most recent provisional overdose death data published by the Centers for Disease Control and Prevention (CDC) indicate that deaths have plateaued and that we are finally starting to see a slow decrease, deaths from synthetic opioids continue to rise. While a number of factors appear to be contributing to this public health crisis, one of the chief causes is the proliferation of illicitly produced, potent substances structurally related to fentanyl, commonly called “fentanyl analogues” or “fentanyl-like substances.” Fentanyl is approximately 100 times more potent than morphine, and the substances structurally related to fentanyl tend to be even more potent. Because of fentanyl’s low dosage range and potency, one kilogram of fentanyl purchased in China for \$3,000 - \$5,000 can generate upwards of \$1.5 million in revenue on the illicit market – and is enough to potentially kill 500,000 people by overdose. The lethality of fentanyl is virtually unmatched. It is 30-50 times more potent than heroin, which is quite lethal in its own right. That unmatched lethality is not reflected in sentencing ranges for fentanyl trafficking, which punish dealers of fentanyl and fentanyl-like substances less severely than sellers of less lethal drugs.

However, licit fentanyl is an important treatment agent in the practice of medicine and is utilized for its potent analgesic effects. Because of its potency, careful dosing and titration are essential. Some forms of the drug are indicated for use in people who have high opioid tolerance. Due to their high potential for abuse, fentanyl and various fentanyl-like substances were controlled in Schedule I or Schedule II of the Controlled Substances Act (CSA) on a substance-by-substance basis. Unfortunately, clandestine chemists have with relative ease created new synthetic variations of fentanyl by introducing minor structural modifications, resulting in new, non-controlled fentanyl-like substances. *These substances are specifically engineered to skirt U.S. law.*

Whether delivered via mail, express consignment, or through Mexico, China is the principal source country of fentanyl-like substances and other synthetic opioids, producing most illicit fentanyl and fentanyl-like substances that reach U.S. users. DEA works closely with China to bring attention to and help combat the rise of illicit fentanyl and fentanyl analogues. Because

of this robust engagement, China has made great strides in this space, and, on April 1, 2019, announced the class-wide control of fentanyl-like substances effective May 1, 2019.

In addition to China, many countries have experienced their own ongoing public safety challenges caused by the rapid emergence of fentanyl-like substances. DEA's temporary actions are the catalyst for communication with a number of international counterparts who are interested in following our example and implementing a similar class-based control for fentanyl-related substances. The Department, DEA, and ultimately the United States are leading from the front with our efforts to establish controls on fentanyl-like substances as a class on an emergency basis and did so, by utilizing authority provided by Congress in the Comprehensive Crime Control Act of 1984. The action is believed to have saved many lives related to the unpredictable nature of fentanyl-related substances by removing an incentive for traffickers to attempt to circumvent the control, and thus, reducing supply on the illicit market. However, this potentially life-saving temporary scheduling action, absent extension, expires soon. Absent an approach to permanently schedule these dangerous, lethal substances as a class, in just 248 days from today, they will again fall out of our controls. Should the temporary order expire, it will result in negative outcomes for our communities and users.

## **DEA'S TEMPORARY EMERGENCY SCHEDULING OF FENTANYL-LIKE SUBSTANCES**

DEA utilizes its regulatory authority to place many synthetic substances into the CSA, pursuant to the aforementioned temporary scheduling authority. As provided by Congress, Factors 4, 5, and 6 of the eight Factor Analysis are considered for temporary control to make the finding that a substance poses an imminent hazard to public safety. Once a substance is temporarily placed in Schedule I, DEA may move towards permanent control by requesting a scientific and medical evaluation, and a scheduling recommendation, from the Department of Health and Human Services (HHS). DEA and HHS also gather and analyze additional information in order to consider the eight factors for permanent control. Since March 2011, DEA has utilized this authority on 23 occasions to place 68 synthetic drugs temporarily (emergency control) into Schedule I, including 17 fentanyl-like substances. In comparison, over the first 25 years (1985-2010) after Congress created this authority, DEA utilized it a total of 13 times to control 25 substances. The process is workable but is highly reactive, lagging behind the dynamic pace of illicit drug producers and distributors.

In recognition of the unprecedented escalation in opioid-related overdoses, as well as the White House directive to declare the opioid crisis a national public health emergency,<sup>1</sup> on February 6, 2018, DEA used its authority under Section 201 of the CSA<sup>2</sup> to place all non-scheduled fentanyl-like substances into Schedule I *temporarily*, on an emergency basis, for two

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<sup>1</sup> *President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis*, The White House Office of the Press Secretary, Oct. 26, 2017, <https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis>.

<sup>2</sup> 21 U.S.C. § 811(h)(1).

years to combat this practice.<sup>3</sup> As a result, anyone who possesses, imports, distributes, or manufactures any illicit, fentanyl-like substance is subject to criminal prosecution in the same manner as any other Schedule I controlled substance. This makes it easier for federal agents to seize fentanyl-like substances and, investigate traffickers of these substances, and for prosecutors to prosecute such traffickers.

The positive impacts in the 15 months since implementation are significant. The class control has substantially slowed the rate at which new fentanyl-related substances are introduced to, and are encountered in, the illicit market. Prior to this action, DEA observed a rapid and continuous emergence of new fentanyl-like substances each time it scheduled a fentanyl-like substance. Under the temporary emergency scheduling order, there is little incentive for drug trafficking organizations to invent new substances in the fentanyl family for the purpose of evading DEA's control. Specifically, DEA laboratories have not encountered any new fentanyl analogue substances in the first quarter Fiscal Year (FY) 2019 and is currently analyzing data for the second quarter of FY 2019. DEA's experience under the relatively short temporary scheduling regime is proof of concept that class-wide scheduling of fentanyl-related substances produces solid law enforcement results, while it has a positive impact on the application process. As a result instead of research based on individual substances, the process allows for research on an entire class of compounds. It must be noted that expiration of a temporary class-wide scheduling results in the termination of this streamlined process, which results in research reverting to an individual substance-by-substance application.

## **DEPARTMENT OF JUSTICE INTERACTIONS WITH CHINESE COUNTERPARTS**

### *China: Government Action and Cooperation*

As part of the Administration's whole of government approach, the Department and DEA, which has an active Beijing-based country office, have engaged Chinese counterparts on the control of emerging fentanyl-like substances and other new psychoactive substances. When China controls a drug or precursor chemical, we see a significant drop in the use of that substance for illicit purposes in the United States. It is through these bilateral communications and bridge building efforts that we can work to reduce the supply of illegal substances around the world.

On April 1, 2019, China announced that it would schedule fentanyl-like substances as a class, effective May 1, 2019; the Department understands that the action is now in place. This will help prevent chemical work-arounds by clandestine synthetic opioid producers in China, and will allow the United States and China to cooperate on a broader range of cases. Like DEA's temporary scheduling order of fentanyl-like substances, this is a novel approach in China, and responsive to our Nation's unprecedented opioid threat. Indeed, officials from the Ministry of

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<sup>3</sup> Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188 (Feb. 6, 2018), <https://www.federalregister.gov/documents/2018/02/06/2018-02319/schedules-of-controlled-substances-temporary-placement-of-fentanyl-related-substances-in-schedule-i>. There is a possibility of extending temporary scheduling for one additional year if proceedings are underway for permanent scheduling. 21 U.S.C. § 811(h)(2).

Public Security Narcotics Control Board in China had indicated that their scheduling process was long and complicated, that China had always scheduled one drug at a time pursuant to its law, and that any change in that process would be groundbreaking for China.

As the opioid threat continues, the Department and DEA are committed to working with Chinese officials through well-established bilateral efforts: liaison presence; the Counter-Narcotics Working Group, Bilateral Drug Intelligence Working Group, regular meetings of scientists; and enhancing collaboration with DEA's interagency partners stationed abroad and in the United States. The Department is encouraged by China's recent class-wide controls of fentanyl-like substances.

## **LEGAL IMPLICATIONS OF EXPIRATION OF TEMPORARY SCHEDULING**

DEA's emergency temporary scheduling action controlling fentanyl-like substances will expire on February 6, 2020, absent further action. At that time, any substance that meets the definition of a fentanyl-like substance but has not completed the multi-step, dual-agency review process, including HHS scientific and medical evaluation and recommendation to permanently place under the CSA on a substance-by-substance basis, will no longer appear on a controlled substance schedule. Re-scheduling of such substances may encounter regulatory obstacles, and trafficking of such substances would then have to be prosecuted under the Controlled Substance Analogue Enforcement Act of 1986 (Analogue Act, enacted at 21 U.S.C. § 802(32) (definition) and § 813(operative)).

### *Regulatory Challenges*

Upon the expiration of class-wide scheduling, DEA will utilize all available tools to protect the public, continuing to collect information on incidents of trafficking and harm to prioritize the most harmful and persistent of fentanyl-like substances for scheduling on a substance-by-substance basis. As per previous experience, it will remain critical to rapidly identify new encounters of these substances and connect them to their harm and lethality. This remains a significant challenge for public health and law enforcement in a rapidly evolving illicit market where traffickers outpace our ability to determine the potential harm of newly developed analogues. However, in doing so the Department would enter uncharted legal and regulatory terrain. It is unknown whether a newly encountered fentanyl-like substance, having just been allowed to lapse from the class scheduling regime, could later be quickly subject to temporary control. The Department will continue to evaluate all options to best protect the public; however, the introduction of new fentanyl-related substances will only result in additional deaths and continuing the cycle of problematic opioid use.

### *Law Enforcement: Investigation and Prosecution*

If class scheduling of fentanyl-like substances expires, the overall effect on law enforcement activities by DEA, U.S. Immigration and Customs Enforcement Homeland Security Investigations, and others, as well as on Department prosecutions, is unknown, but may be significant. DEA expects savvy clandestine manufacturers and traffickers to respond to the re-

emerging gap in U.S. law by again producing novel fentanyl-like substances. This is the normal response of traffickers who wish to avoid prosecution and still profit from peddling poison, and is consistent with previous attempts to circumvent reactive substance-specific control measures. While China has, helpfully, taken the bold step of scheduling all fentanyl-related substances, we run the risk that manufacturers and drug traffickers may move operations to other countries.

In terms of investigations and prosecutions, if the temporary emergency scheduling order lapses without permanent scheduling, the Department would once again have to rely on the Analogue Act to bring fentanyl traffickers to justice. These cases require several elements of proof that are either presumed, or simply not relevant to routine controlled substance prosecutions. To prevail, the government must prove:

1. that the substance involved in the case was intended for human consumption;
2. that the substance is a “controlled substance analogue,” which in turn requires proof of the following “prongs”:
  - a. it has a substantially similar chemical structure as a Schedule I or II controlled substance – in this case fentanyl; and
  - b. it either (i) has a substantially similar effect on the central nervous system (*i.e.*, psychoactive effect) as a Schedule I or II controlled substance – in this case fentanyl – or (ii) in a particular case, was intended or represented as having such an effect.

All of these elements must be proven to a jury beyond a reasonable doubt.

Given the applicable law and issues of proof, Analogue Act prosecutions are time-consuming, resource-intensive, and difficult for investigators, drug testing laboratories, prosecutors, courts, juries, and the entire criminal justice system. Court filings can be technical and voluminous, and cases often involve a “battle of experts” on complex chemical and scientific issues. While the government has a very good track record in Analogue Act prosecutions, the results in these cases are not predictable or necessarily consistent among cases and courts. Because a factual finding that a substance is an analogue of a controlled substance in a particular case has no precedential impact, each case can lead to disparate results.

The potential adverse consequences of a lapse in scheduling of fentanyl-related substances go beyond a simple return to the *status quo ante*, before the DEA class scheduling action. Proof of the unique elements just noted could become more difficult. Though the Department is confident in the need, urgency, and legal and factual basis to invoke emergency and temporary scheduling of fentanyl-like substances, a lapse in class scheduling, could be seized upon to argue that the class scheduling action was not warranted in the first instance. This problem would affect two classes of prosecutions: (1) cases charging substances that were scheduled at the time of the offense only by virtue of the class scheduling action, and (2) cases charging substances that would no longer be scheduled at the time of the offense, as a result of the lapse, and would therefore be charged under a controlled substance analogue theory. Prosecution expert witnesses – often DEA Scientists – testifying that the chemical structure and pharmacological effect of the analogue in question is similar to fentanyl (or another scheduled

substance) could be confronted with contrary conclusions. This is a recipe for confusion and potential trial losses.

Complications inherent in the charging and proof of a case involving a fentanyl-like substance that was temporarily scheduled, then de-scheduled will arise if the class-wide scheduling order is not made permanent. These scenarios would unnecessarily introduce additional complexity into these cases, and would potentially confuse jurors. As the United States is facing unprecedented overdose deaths and the Administration is working to pull our Nation out of the opioid epidemic, it would be prudent to avoid these factual and legal issues, especially when the substance at stake is something as potent and dangerous as a fentanyl analogue.

## **LEGAL SIGNIFICANCE OF LEGISLATIVE SCHEDULING OF FENTANYL-LIKE SUBSTANCES**

A legislative solution to adopt class scheduling of fentanyl-related substances would remove any legal uncertainty surrounding the authority of the Attorney General, through DEA, to schedule fentanyl-like substances. Implicit in the structure and text of the CSA's scheduling authority is the concept that specifically identified substances are scheduled one at a time. The Department is confident that the DEA temporary scheduling action would withstand judicial scrutiny, but it remains an untested approach. Temporary scheduling actions, while not subject to direct judicial review, are subject to challenges. One or more rulings invalidating fentanyl class scheduling would yield confusing and possibly devastating consequences, both in pending cases and post-conviction. Congressional action would resolve this issue and permanently address the United States' response to these deadly fentanyl-like substances. Class scheduling of fentanyl-like substances is an urgent and necessary first step. This situation highlights the need to next address the scheduling system on a more comprehensive basis to avoid having this situation reoccur when the next broad class of dangerous analogues is developed, as we know it will, by savvy illicit drug manufacturers seeking to avert current controlled substances scheduling authorities.

## **CONCLUSION**

Absent extension, DEA's temporary class scheduling of fentanyl-related substances expires on February 6, 2020, at which time any substances that have not been permanently scheduled will fall outside the CSA drug schedule. As a result, the Department and DEA would enter relatively unknown territory. Temporary class control has been shown to be very effective in substantially reducing the number of fentanyl analogue encounters in the United States.

The class of fentanyl-like substances needs to be categorically and permanently scheduled. A solution that prevents fentanyl-like substances from falling out of control is essential to continue tackling the opioid epidemic our Nation currently faces, and the Department and DEA firmly believe that a solution can be found that will achieve this goal while also accommodating interests in continued research on these substances.

Thank you for the opportunity to testify today and we look forward to continuing to work with Congress to find solutions necessary to address the threats posed by illicit fentanyl and its analogues.