



Department of Justice

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

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BEFORE THE

**COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON CRIME, TERRORISM, AND
HOMELAND SECURITY
UNITED STATES HOUSE OF REPRESENTATIVES**

FOR A HEARING ENTITLED

**“FENTANYL ANALOGUES: PERSPECTIVES ON CLASSWIDE
SCHEDULING”**

PRESENTED

January 28, 2020

**Statement of the Department of Justice
Before the United States House Committee on the Judiciary, Subcommittee on Crime,
Terrorism, and Homeland Security
For a Hearing Entitled
“Fentanyl Analogues: Perspectives on Classwide Scheduling”
January 28, 2020**

Chairwoman Bass, Ranking Member Ratcliffe, 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) faces when holding traffickers accountable. The Department appreciates 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. From 2016 to 2017, 31 states experienced an increase in synthetic opioid overdose deaths, including Arizona, California, Georgia, New York, Ohio, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin.

Although 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-related substances.” Fentanyl is approximately 100 times more potent than morphine. 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 support 1,000 users for 2 years’ worth of abuse. 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-related 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-related 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-related substances. These substances are specifically engineered to skirt U.S. law.

Whether delivered via mail, express consignment, or through Mexico, China is a major source of fentanyl-related substances and other synthetic opioids, producing most illicit fentanyl and fentanyl-related substances that reach U.S. users. The Drug Enforcement Administration (DEA) has worked with, and continues to work 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 classwide control of fentanyl-related substances effective May 1, 2019.

The Chinese scheduling action, coupled with the DEA's regulatory authority, enacted on February 6, 2018, which placed all non-scheduled fentanyl-related substances in Schedule I temporarily, on an emergency basis, for two years, has resulted in a significant decrease in *direct* Chinese-origin fentanyl-related substances being encountered in the United States since Fiscal Year 2019.

In addition to China, many countries have experienced their own ongoing public safety challenges caused by the rapid emergence of fentanyl-related substances. The 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-related 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 9 days from today, they will again fall out of our controls. Should the temporary order expire, it will result in significant consequences for our communities.

DEA'S TEMPORARY EMERGENCY SCHEDULING OF FENTANYL-RELATED 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 toward 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 24 occasions to place 74 synthetic drugs temporarily (using emergency control) into Schedule I, including 17 fentanyl-related substances. In comparison, during 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,¹ on February 6, 2018, DEA used its authority under Section 201 of the CSA² to place all nonscheduled fentanyl-related substances into Schedule I temporarily, on an emergency basis, for two years to combat the scourge of these illicit substances.³ As a result, anyone who possesses, imports, distributes, or manufactures any illicit, fentanyl-related 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-related substances and investigate traffickers of these substances, and for prosecutors to prosecute such traffickers.

The positive impacts in the two years since implementation are significant. Since 2018, there has been a significant decline in law enforcement reports to the National Forensic Laboratory Information System (NFLIS) of substances structurally related to fentanyl, including those captured under the February 2018 class control temporary order. In the 24 months preceding the temporary order (February 2016 through January 2018), there were more than 17,500 reports of these substances to NFLIS, excluding those controlled prior to 2016. Conversely, since the temporary class control (February 2018 through December 2019), and as of January 7, 2020, there were fewer than 8,800 reports to NFLIS for substances structurally related to fentanyl, a 50 percent reduction. It should be noted that NFLIS reporting is still ongoing for 2019. The DEA attributes this significant decline to the series of control actions in recent years, culminating in the February 2018 class control. Under the temporary emergency scheduling order, there is little incentive for drug trafficking organizations to invent new substances related to fentanyl for the purpose of evading DEA's control.

DEA's experience under the relatively short temporary scheduling regime is proof of concept that classwide scheduling of fentanyl-related substances produces solid law enforcement results, while also having a positive impact on the controlled substances research application process. Instead of an application for research based on individual substances, the temporary order allows for research on an entire class of compounds for the licensee. It must be noted that expiration of a temporary classwide scheduling results in the termination of this streamlined process, which results in research reverting to an individual substance-by-substance application.

The Department and DEA worked with our colleagues at the Office of National Drug Control Policy (ONDCP) and the Department of Health and Human Services to develop a legislative solution to this problem. This proposal, which represents the Administration's intent to promote public safety by aggressively fighting the scourge of synthetic opioids, while protecting the medical community's ability to perform critical research, would permanently schedule the very substances that are the cause of so many of deaths.

¹ *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-donaldjtrump-taking-action-drug-addiction-and-opioid-crisis>.

² U.S.C. § 811(h)(1).

³ 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/schedulesofcontrolled-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).

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-related 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-related 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-related substances, this is a novel approach in China, and responsive to our Nation's unprecedented opioid threat. Indeed, officials from the Ministry of 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 remains encouraged by China's classwide controls of fentanyl-related substances.

LEGAL IMPLICATIONS OF EXPIRATION OF TEMPORARY SCHEDULING

DEA's emergency temporary scheduling action controlling fentanyl-related substances will expire on February 6, 2020, absent Congressional action. At that time, any substance that meets the definition of a fentanyl-related substance, but has not completed the multi-step, dual agency review process, which includes scientific and medical evaluation and recommendation by HHS to place permanently 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 classwide scheduling, the Department 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-related 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-related 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-like 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-related 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 manufactures and traffickers to respond to the re-emerging gap in U.S. law by again producing novel fentanyl-related 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-like substances, we run the risk that manufacturers and drug traffickers may move operations to other countries.

LEGAL SIGNIFICANCE OF LEGISLATIVE SCHEDULING OF FENTANYL-RELATED SUBSTANCES

A legislative solution to adopt class scheduling of fentanyl-like substances would remove any legal uncertainty surrounding the authority of the Attorney General, through DEA, to schedule fentanyl-related 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-related substances. Class scheduling of fentanyl-related substances is an urgent and necessary first step. This situation highlights the need to next address the scheduling system on a more comprehensive basis in order to avoid having this situation re-occur 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-like 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-related substances needs to be categorically and permanently scheduled. A solution that prevents fentanyl-related substances from falling out of control is essential to continue tackling the opioid epidemic our Nation currently faces, and the Department firmly believes 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 the Department looks forward to continuing to work with Congress to find solutions necessary to address the threats posed by illicit fentanyl and its analogues.