RESPONSES TO
QUESTIONS SUBMITTED FOR THE RECORD TO
THE ACTING DIRECTOR
OFFICE OF NATIONAL DRUG CONTROL POLICY

FOLLOWING THE MARCH 21, 2017, HEARING ENTITLED,
"FENTANYL: THE NEXT WAVE OF THE OPIOID CRISIS"
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

The Honorable Tim Murphy

1. **What additional burdens is the fentanyl epidemic putting on society, the healthcare system, the criminal justice system, the emergency response system, and Federal, state, and local budgets?**

ANSWER:
Once illicit fentanyl began to emerge in pockets throughout the country, it became apparent that the United States would be facing challenges on multiple levels and experiencing additional burdens on local, state, tribal, and Federal agencies. Fentanyl outbreaks trigger rapid notification of public health and law enforcement agencies, interviews of patients and their family members to trace and limit further use or distribution of the fentanyl, immediate naloxone resupply and augmentation for emergency medical services (EMS) crews, public health alerts, and an acceleration of naloxone distribution to opioid users and their friends and families. At the Federal level, the Centers for Disease Control and Prevention (CDC), part of the Department of Health and Human Services (HHS), has sent multiple teams to investigate fentanyl-related overdose "outbreaks" in Ohio, Florida, and Massachusetts.[1, 2] This type of response to drug outbreaks is not unprecedented, but the magnitude is indicative of a greater burden than previously seen in the United States in response to earlier fentanyl overdose outbreaks.

Since October 2016, the Office of National Drug Control Policy's (ONDCP) National Heroin Coordination Group (NHCG) has collaborated with partner states in each of the four major U.S. Census regions to monitor the public health impact of the heroin and fentanyl crises and to identify emerging trends.[3] During a recent meeting, it appeared that overdose deaths involving fentanyl may be eclipsing total year-end mortality associated with overdose deaths involving heroin in a growing number of states. As some states reported in subsequent meetings, they are seeing an increase in fentanyl-related overdose deaths, which is presenting new challenges to

[1] Peterson AB, Gladden RM, Delcher C, et al. Increases in Fentanyl-Related Overdose Deaths — Florida and Ohio, 2013–2015. MMWR Morb Mortal Wkly Rep 2016; 65:844–849. DOI: http://dx.doi.org/10.15585/mmwr.mm6533a3.
[2] Somerville NJ, O'Donnell J, Gladden RM, et al. Characteristics of Fentanyl Overdose — Massachusetts, 2014–2016. MMWR Morb Mortal Wkly Rep 2017; 66:382–386. DOI: http://dx.doi.org/10.15585/mmwr.mm6614a2.
[3] Partner states that volunteered to participate: Alaska, Arizona, California, Florida, Iowa, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New Mexico, New York, Ohio, Virginia, Wisconsin, West Virginia, and Utah.

policymakers and public health and safety officials, as well as to the treatment system for people who use drugs.

Beyond the immediate public health and safety risk that a fentanyl outbreak may cause in a local community, there are other, broader challenges that exist at the Federal, state, local, and tribal levels. These include a lack of post-mortem testing standards, a dearth of medical examiners/coroners to conduct timely tests for fentanyl presence, and a lack of sufficient mechanisms to detect drugs coming into the United States.

Since there are no federally-mandated standards for conducting death investigations or nationwide mandatory rules governing the types of toxicology testing and reporting required in death investigations (post-mortem testing standards), we are unable to get an accurate national assessment of the prevalence of fentanyl-involved deaths. For the same reason, local jurisdictions also do not have a clear picture of what is happening in their own communities. With the increase in fentanyl-related deaths, many coroners and medical examiners lack the capacity to conduct thorough post-mortem testing in a timely manner. They also may not have the ability to test for fentanyl or its metabolites. Of the country's approximately 2.6 million deaths each year, medical examiners and coroners investigate approximately 500,000 because the deaths are sudden or unexpected, are suspicious or the result of violence, or the decedent lacked an attending physician. In deaths where a drug overdose is cited as the underlying cause of death, one-fifth of the death certificates in 2014 do not list the specific drug(s) involved.[4] This lack of testing and information gathered at the time of death further compounds our lack of clear, consistent data.

Detecting illicit fentanyl and its analogues at our borders, seaports, airports, and mail handling facilities is complicated and costly given the small of amount of fentanyl necessary to provide similar effects as heroin, and simply put, it is a numbers game. As a synthetic drug, fentanyl is more difficult to detect using traditional detection methods. And, with illicit fentanyl and its analogues now presenting as black tar or white powder heroin in some parts of the country, visual inspections are becoming increasingly unreliable in identifying substances. Given that Mexico and China are the two largest sources of illicit fentanyl smuggled into the United States, detection and interdiction at our nation's land borders, ports, and airports are key. However, because fentanyl can be shipped in such small quantities, it is incredibly difficult to identify amongst the high volume of incoming shipments.

As our law enforcement professionals seek to identify and respond to fentanyl-related incidents, they are confronted by the significant safety risk of coming into physical contact with the drug. To mitigate this risk, ONDCP is working with Federal, state, local, and tribal agencies to establish response protocols and to assist agencies in determining the equipment and procedures necessary to contain fentanyl incidents and protect our law enforcement, medical and rescue personnel. While this effort is ongoing, the NHCG has already worked with HHS and CDC's National Institute for Occupational Safety and Health to produce science-based handling instructions for fentanyl, which were disseminated to Federal agents and local police.

[4] Warner M, Trinidad JP, Bastian BA, Miniño AM and Hedegaard H. (2016) Drugs Most Frequently Involved in Drug Overdose Deaths: United States, 2010-2014. National Vital Statistics Report. 65(10):1-14 (December 20).

2. **Last fall, the Canadian press reported that a type of test strip to indicate the presence of fentanyl was being made widely available for a low price ($5 Canadian). These kits or test strips were first announced in Vancouver, British Columbia, but later reports have identified them to pharmacies in Winnipeg, Manitoba (the middle of Canada). Yet there appears to be little if any public reaction, response, or similar kits detected or reported in the US. Why is that?**

ANSWER:
To date, the United States has not supported making the testing of illicitly purchased drugs (at times referred to as pill testing, drug checking, or adulterant screening) more accessible. Intrinsically, the drugs being tested are illegal and their quality and content are suspect and cannot be used "safely."

Our understanding is that the test strips referenced in the question are enzyme immunoassay kits originally developed to test for the presence of fentanyl in urine, which are now being used to test for fentanyl in drug samples diluted in water. As a result, there is not a significant body of scientific evidence to determine if such test kits are accurate, if they can detect the range of fentanyl analogues necessary, or if they are an effective means of protecting users from potential overdose.

3. **Locally, Governor Hogan of Maryland announced a new initiative creating an Opioid Operational Command Center to aid in coordination of resources. How prevalent are such initiatives, and where would they be most needed?**
    a. **Where are you getting the best cooperation from the states?**
    b. **What advances have these states reported that could/would assist nationwide efforts?**
    c. **Where would such coordination need improvements?**
    d. **Would we be better off with state-by-state approach?**

ANSWER:
ONDCP is generally aware of state level efforts to address heroin and illicit fentanyl. For example, Alaska is establishing a multi-agency incident command structure, which among other activities, is working to improve information sharing, such as morbidity and mortality data and arrest information, among Federal and state law enforcement and public health agencies.

However, while ONDCP does not have a comprehensive database of state initiatives related to addressing heroin and illicit fentanyl, through the implementation of the Federal Government's Heroin Availability Response Plan (HARP), the NHCG works with 20 states that volunteered to provide data and discuss their strategies, policies, and actions on reducing the use and availability of heroin and fentanyl. Every month, a different group of states (based on geography) present on their comprehensive efforts and recent trends, which other states can then learn from and tailor their own responses to specific, local needs and challenges. The NHGC has also used information provided by states to inform the nationwide strategy and efforts to address heroin and illicit fentanyl at the Federal level. The communication venues coordinated by the

NHCG show that an all hands approach on both the Federal and state levels are necessary to turn the tide on current heroin and fentanyl trends.

Additionally, in 2015, ONDCP committed $2.5 million in High Intensity Drug Trafficking Area (HIDTA) program funds to develop the Heroin Response Strategy to respond to the Nation's heroin and opioid epidemic through combined prevention, education, intelligence, and enforcement resources to address this drug threat across 15 states (Connecticut, Delaware, Kentucky, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, and West Virginia) and the District of Columbia. The Heroin Response Strategy brings together public health, law enforcement, and other stakeholders to address the problem comprehensively. The effort is the result of a unique partnership of five regional HIDTA programs – Appalachia, New England, New York/New Jersey, Philadelphia/Camden, and Washington/Baltimore.

In 2016, ONDCP provided $3.9 million to expand the Heroin Response Strategy to include the Ohio, Michigan, and Atlanta/Carolinas HIDTAs. These HIDTAs encompass five states that have been ravaged by the negative consequences of opioid abuse, and also exhibit drug trafficking patterns that are intrinsically linked with the original 15 states and the District of Columbia of the Heroin Response Strategy.

4. **In Maryland, among other states, there are growing groups of people who are organized regarding Heroin or Opioid Awareness to help addicts and the citizenry to recognize the threat of fentanyl and fentanyl-laced heroin. What can be learned from their efforts?**
    a. **How can they be best supported by networks of local, state, and Federal assistance?**

ANSWER:
We have seen many efforts by groups across the country at all levels of government to increase awareness of illicit fentanyl and its dangers. This approach is part of not only Maryland's strategy,[5] but also many other states' overdose prevention plans. For example, Massachusetts' plan includes educating parents about signs of addiction.[6] Parental education can be valuable, as many parents report their inability to recognize addiction and their lack of knowledge of how to help their children if they are using drugs. California has developed a public dashboard on opioids, Utah has launched the "Stop the Opidemic" public awareness campaign, and other states are making their media campaign materials accessible to the public for use in their communities. Many local and national coalitions use their internet sites to provide online information.

Because of the potency of fentanyl and its analogues, as well as the various forms in which it has been encountered, it is critical for the public to learn about the dangers of illicit fentanyl and its analogues, even for experienced opioid users. Law enforcement has encountered fentanyl and its analogues in non-opioid drugs, such as cocaine and methamphetamine, and there have been

[5] Available at: http://bha.dhmh.maryland.gov/OVERDOSE_PREVENTION/Pages/Index.aspx.
[6] Available at: http://www.mass.gov/eohhs/docs/dph/stop-addiction/recommendations-of-the-governors-opioid-working-group.pdf.

anecdotal reports of fentanyl in marijuana. Fentanyl and its analogues have also been found in high quality counterfeit pills made to mimic prescribed drugs including opioids and benzodiazepines (e.g., Xanax and Valium).

Any educational or public awareness effort must be evidence-based. It also should include mechanisms for evaluation of effectiveness. Efforts should also include information about how to obtain and dispense naloxone, an opioid overdose reversal drug. Furthermore, because of the potency of fentanyl and its analogues, it is important to emphasize that additional doses may be needed to reverse a fentanyl overdose. Lastly, it is imperative that individuals using drugs, or those around them, know that overdose victims need to receive medical care if an overdose is reversed with naloxone.[7]

5. **We are aware that, on the street, when "word gets out" about a given batch of drugs being potentially deadly, it can conversely attract more customers searching for a greater high. What sources or uses of communication and education are most effective on such a level to provide adequate warnings about lethal dosage?**

ANSWER:
Since opioid tolerance varies from person to person, determining what is a "lethal dose" is not possible. A dose that may cause respiratory depression in an experienced opioid user is likely to be much larger than in an inexperienced user. It will also vary depending on body weight and other metabolic factors. Some analogues are potent enough to cause overdose in any user. Therefore, messaging focused on the lethality of the drug is not recommended.

Messaging should provide an awareness of the presence of illicit fentanyl and its analogues in the community, assistance with the identification of fentanyl, education on the risk of counterfeit pills, and information on the lethality/toxicity in general of the drug(s). These messages are important to convey to the user, health practitioner, and the community at large. This information is particularly important for non-opioid users or pill seekers, who may be unprepared for fentanyl-tainted drugs and are unlikely to know about its potency or the need for naloxone. Messaging delivered from trusted health sources and non-governmental organizations may be better received than from other sources.

6. **Is there any reason to believe that drug dealers are intentionally selling fatal doses of fentanyl on occasion to get publicity to users about the potency of their drug product?**
    a. **Similarly, due to the purity of fentanyl, is there any evidence that suggests drug dealers are intentionally selling products that contain fentanyl to intensify an addict's addiction?**

ANSWER:
Anecdotally, ONDCP has heard reports that some users and dealers were unaware they were buying or selling heroin laced with fentanyl or fentanyl alone. There are other anecdotal reports that individuals are well aware of what is being sold and what is being purchased. Fentanyl's

[7] Available at: http://www.nopetaskforce.org/overdose.php.

effects closely resemble those of heroin, but it is much more potent and its duration of action is shorter. The shorter duration of action and the rapid tolerance of the drug requires quicker escalating doses to obtain the same "high."

One state participating in HARP implementation recently stated that individual users are hearing about fentanyl's potency and are affirmatively seeking the more potent drug. There are also reports of individuals seeking to avoid fentanyl, fearing the risk of overdose. The Revere Police Department in Massachusetts has reported users switching to cocaine to attempt to avoid an overdose.

The Honorable Ryan Costello

1. How would you describe the public health and safety threat of illicitly produced fentanyl to communities throughout the nation?

ANSWER:
More than 52,000 people died from drug overdose in 2015. In 2015, overdose deaths involving a synthetic opioid other than methadone (the medical coding category that includes fentanyl) reached 9,580, an increase of 73 percent over the previous year and had tripled from 3,105 in 2013.[8] This rapid escalation in deaths involving illicit fentanyl is troubling. Illicit fentanyl also exacerbates our nation's opioid epidemic that was brought on by prescription drug misuse and heroin use, in that it also contributes to addiction, non-fatal overdoses, and opioid-exposed infants who require costly post-natal care and child welfare involvement.

Quantifying the effects of the illicit fentanyl trade on crime, and public safety as a whole, is impossible. Additionally, systemic crime is inherent in drug trafficking, which exists by definition outside the rule of law. Finally, the recent influx of illicit fentanyl draws attention and resources away from other public safety investigations by usurping law enforcement time and resources.

2. Why is the East Coast heroin market more susceptible to the risk of fentanyl overdoses?

ANSWER:
Historically, the U.S. heroin market has been divided along the Mississippi River, with the Eastern market favoring white powder heroin and the Western market dominated by black tar heroin. Because of the physical appearance of illicit fentanyl, it can be readily mixed with white powder heroin and difficult to detect by visual inspection. As a result, historically, a greater number of fentanyl-related deaths involving synthetic opioids (other than methadone) are seen in the Northeastern and Southern regions of the nation, due to the ease of combining white powder fentanyl with white powder heroin. However, recent evidence shows this paradigm may be shifting.

Law enforcement has encountered illicit fentanyl in other parts of the country in different forms. For example, recently a forensic scientist from Orange County, California, shared detailed photographs of drug evidence showing the many forms of fentanyl and its analogues presented to the laboratory, including fentanyl presented as black tar, white powder, compressed brown or white powders, rocklike substances, oxycodone, alprazolam, and other counterfeit pharmaceutical forms. The most recent evidence (April 2017) presented brown tar heroin containing methamphetamine, acetyl fentanyl, and fentanyl.

Given how increasingly unreliable visual inspection has become in accurately identifying substances, the Orange County Forensic Crime Lab instituted a new process by which all drug

[8] Centers for Disease Control and Prevention, National Health Statistics. Multiple Cause of Death 1999-2015 on CDC WONDER Online Database released 2016. Extracted by ONDCP from http://wonder.cdc.gov/mcdicd10.html, December 2016.

evidence is forensically tested and, to the extent possible, the results are shared with medical examiners/coroners and prosecutors. The shifting nature of the illicit fentanyl market may necessitate jurisdictions to review and revise their testing protocols to determine the extent of fentanyl and analogues in their communities. As detection methods improve, we will most likely see an increase in deaths attributed to fentanyl-related overdose across the country.

3. What is the appeal of adding fentanyl if it is effectively killing users? Is it less expensive to produce? Does it, in non-lethal quantities, produce a different high?

ANSWER:
Information from the Drug Enforcement Administration (DEA) suggests that illicit fentanyl is substantially more profitable than heroin because of a variety of factors. This was again reiterated at this hearing in the written testimony from DEA Assistant Administrator Louis Milione, where he stated that Mexican traffickers have seized the opportunity to enter the fentanyl market because of its profit potential. Because of its low dosage range and potency, one kilogram of fentanyl purchased in China for $3,000 – $5000 can generate upwards of $1.5 million in revenue on the illicit market.[9]

The effects on the body of fentanyl closely resemble those of heroin, but are much more potent and the duration of action is shorter. The shorter duration of action will lead a person with a substance use disorder to take the drug more frequently to maintain ongoing effects. Opioid tolerance varies from person to person; therefore, determining what is a "lethal dose" is not possible. A dose that may cause respiratory depression in an experienced opioid user is likely to be much larger than in an inexperienced user. It will also vary depending on body weight and other metabolic factors.

[9] Statement of Louis J. Milione, Assistant Administrator, Drug Enforcement Administration before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce "Fentanyl: The Next Wave of the Opioid Crisis" hearing. March 21, 2017, p.2.