

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Hearing: “Fentanyl: The Next Wave of the Opioid Crisis”
March 21, 2017
Questions for the Record

Questions for the Record for Dr. Debra Houry, Director, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC)

Chairman Tim Murphy

1. A [Huffington Post article](#) in January commented that many hospital Emergency Departments or related hospital sections do not yet test for fentanyl in the systems of potential victims. How prevalent does that situation continue to be, and what steps are being taken to rectify it?

Answer: CDC does not have national data on the percentage of emergency departments that test for fentanyl or fentanyl analogs, but historical reports suggest that many hospitals do not test for synthetic opioids such as fentanyl.ⁱ In the emergency department (ED) setting, where the focus is on immediate resuscitation and restoration of vital signs, knowing the specific form of opioid involved in an overdose has little clinical relevance unless the opioid has a long half-life, such as methadone. Clinical diagnosis of opioid overdose is sufficient to begin appropriate treatment, and naloxone is titrated to whatever level is necessary to achieve an adequate response. A rapid drug screening panel, using immunoassay technology, is often conducted in the ED setting for suspected overdose cases, and is used to provide objective evidence of opioid overdose, but a positive screening test is unlikely to be sent for confirmatory testing which would allow for the specific opioid, such as fentanyl, to be identified. Such testing is expensive, and the results would only be available after the ED patient has been discharged. Some EDs have elected to add a rapid immunoassay test specific to fentanyl into their standard drug screen panel, but many may not be aware of the availability of this rapid test. Furthermore, a rapid fentanyl immunoassay test may or may not detect the various fentanyl analogs now available, leading to false negative results. There are example of hospitals in jurisdictions with high levels of fentanyl use and overdose, such as in Rhode Island, beginning to test for fentanyl.ⁱⁱ

- a. **How does this impact data reporting and collection in hospital settings?**

Answer: Because we do not know the percentage of emergency departments testing for fentanyl and whether this percent is increasing or decreasing over time, it is difficult to assess national trends in fentanyl-related overdoses. This has been a limitation of previous national estimates of fentanyl non-fatal overdoses.ⁱⁱⁱ In April 2017, CDC began to receive preliminary data on emergency department visits related to drug overdoses on a quarterly basis from 11 states^{iv} as part of the CDC Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality funding announcement.^v Although the data contain preliminary information on the emergency department visit, analyses will be conducted to estimate how often emergency departments appear to be testing and detecting fentanyl-related overdoses.

- b. **How can we improve data collection and reporting to ensure we are getting complete and accurate information?**

Answer: CDC is addressing the problem in at least two ways. First, CDC is raising awareness about the increasing problem of fentanyl-related overdoses and identifying states and jurisdictions strongly impacted.^{vi} This highlights the importance of responding and tracking nonfatal fentanyl-related overdoses in those jurisdictions. Second, CDC has recommended and is working with 12 states funded through the CDC Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality funding announcement to develop rapid methods for identifying drug overdose outbreaks using existing data from emergency department and emergency medical services.^{vii} This project will help assess the current data collected on nonfatal overdoses by emergency departments and identify opportunities to improve surveillance of emergency department visits related to fentanyl-related overdoses.

- 2. There is a wide variation in the reporting of overdose statistics from state to state, and even county to county. However, committee staff located a county in Illinois (Will County, in suburban Chicago) that now tracks “Accidental Overdoses” by date of death, cause of death (fentanyl and/or other drugs), and personal demographics like race, sex, and age. How helpful is this for legal and medical entities? If useful, could this reporting format be evaluated for recommendation as a prototype for other communities and states?**

Answer: CDC believes that the information collected in Will County would be extremely helpful if it were collected on all death certificates of drug overdose deaths in the US. It also substantially aligns with current federal efforts to improve and enhance fatal and nonfatal drug overdose data collections. This information is useful to public health, medical, and legal entities, as it helps researchers, investigators, health care providers (for both clinical and behavioral health), and public health practitioners to understand and identify drug use risks, appropriate clinical and behavioral care, and public health interventions.

The US death certificate is designed to collect all of the information on drug overdose deaths being collected by Will County. However, data quality issues, especially with regard to the reporting of specific drugs can be a challenge when interpreting drug overdose statistics.^{viii} After a drug overdose death is investigated, the investigator (usually a medical examiner or coroner) certifies the cause of death (e.g., drug poisoning [overdoses]) and should also include details and circumstances such as the specific drugs contributing to the death (e.g., heroin and cocaine). However, the quality of information regarding specific drugs involved with drug overdoses varies substantially across states and counties. Nationally, drugs are unspecified for approximately 1 in 5 drug overdose deaths in the US. The percent of overdose death certificate data with information on at least one drug varies substantially across states (from 48 percent to nearly 100 percent in 2014).^{ix}

There are multiple national and state efforts underway to address these issues that align with the effort in Will County. Currently, CDC is partnering with the Association of State and Territorial Health Officials (ASTHO) on a project to improve drug specificity on death certificates. This project will gather individual perspectives about the importance of death certificate data in public health practice, the issues affecting the quality of mortality data, and identify potential solutions and benchmark indicators for improved data quality. This project builds on ongoing work by CDC’s National Center for Health Statistics (NCHS) to improve the quality of drug overdose death information. Additionally, NCHS has built text search tools that can be used to identify drug overdose related to specific drugs such as fentanyl.^x Finally, the CDC Enhanced State

Surveillance of Opioid-Involved Morbidity and Mortality announcement funds 12 states to collect complete toxicology findings and death scene evidence collected on all opioid-related overdose deaths starting in July 2016. This will allow the 12 states and CDC to better track drug specific mortality.^{xi}

3. Have new priorities been established to inform or assist the states in distinguishing fentanyl overdoses and deaths from other opioids? If so, where and how are they implemented?

Answer: Yes, and CDC is assisting states in four ways. First, in response to the sharp increases in the supply of illicitly-manufactured fentanyl (IMF) and fentanyl-related drug overdose deaths in 2014, CDC changed its method for calculating overdose deaths related to opioid analgesics to exclude overdose deaths that may have involved IMF.^{xii} The calculation change was widely distributed and is reflected in the current indicators CDC uses to track the progress of its state prevention efforts. Second, CDC was involved in Epidemiological Investigations ([Epi-Aids](#)) in Ohio and Massachusetts where the broad distribution of IMF is driving increases in opioid-related overdose deaths. Ohio now separately tracks fentanyl-related overdose deaths.^{xiii} In Massachusetts, CDC collaborated with the Massachusetts Department of Health to estimate the percent of fentanyl-related overdose deaths that were suspected to involve IMF versus pharmaceutical fentanyl.^{xiv} In addition to informing targeted prevention efforts in Massachusetts, the methodology can be applied in other states. Third, CDC is partnering with the Association of State and Territorial Health Officials (ASTHO) on a project to improve drug specificity on death certificates. This project will gather individual perspectives about the importance of death certificate data in public health practice, the issues affecting the quality of mortality data, and identify potential solutions and benchmark indicators for improved data quality. This project builds on ongoing work by the National Center for Health Statistics (NCHS), within CDC, to improve the quality of drug overdose death information. Additionally, NCHS has built text search tools that can be used to identify drug overdose related to specific drugs such as fentanyl.^{xv} Finally, the CDC Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality announcement funds 12 states to collect complete toxicology findings and death scene evidence collected on all opioid-related overdose deaths starting in July 2016. This will allow the 12 states and CDC to track fentanyl-related overdose deaths and deaths related to fentanyl analogs such as acetyl fentanyl and carfentanil when coroners and medical examiners test for analogs.^{xvi} In addition, the 12 states may be able to estimate deaths related to IMF using the methodology developed in Massachusetts if sufficient death scene evidence was documented.

4. In your statement, you refer to “effective PDMPs [Prescription Drug Monitoring Programs]” and how you have made them timelier and easier to use in interstate communication. How have you improved or enhanced this process, and can you cite examples?

Answer: CDC has funded 42 states and Washington, D.C., to combat the prescription drug overdose epidemic through state programs. Funded states are using various methods to maximize the effectiveness of their PDMPs. For example, Arizona has upgraded their PDMP software so the time it takes for patient prescription information to be updated in the system has been reduced from 7 days to 1 to 3 days. The reduction in the time between data entry and the system being updated allows prescribers to more accurately calculate a patient’s morphine milligram equivalent (MME) dose, enabling providers to more easily recognize patients who

may be at risk for overdose and provide better care.

Another example is Kentucky. In December 2015, Kentucky began integrating morphine equivalent information into patient PDMP reports. With the help of CDC funding, Kentucky PDMP patient reports now contain an Active Cumulative Morphine Equivalent (ACME) number. If the ACME is 100 or greater, a warning symbol appears along with a note that increased clinical vigilance may be appropriate. This functionality increases a doctor's ability to provide safe and effective care to their patients. Following the enhancement of the PDMP reports, a 2% decrease was seen in high opioid prescribing to adults, and a remarkable 25% reduction in opioid prescribing to youth aged 0-17 between the last quarter of 2015 and the end of the first quarter of 2016.

CDC funds have been used to launch a pilot project in Tennessee and Kentucky to examine the added value of interstate PDMP data sharing. The project will assess the extent to which data sharing across states enhances each state's ability to identify and respond effectively to high-risk patients.

5. One response given in localities is that the need and availability of Naloxone is ever-present. Given the unknown need for quantities on hand for paramedics, etc., since there can be no set amount to counteract a given overdose – how can this need be effectively addressed?

Answer: There are two factors to ensure that adequate naloxone will be available to responders to manage overdose, particularly in locations where fentanyl is present. The first is to ensure limited supplies of naloxone are prioritized to locations where they are most needed, and the second is to consider making higher dose formulations of naloxone available to responders. Improved surveillance can assist with the first goal, which is best served by a combination of data from public health and public safety. Monitoring of ED and EMS data for spikes in overdose and spikes in naloxone administrations can help to identify hotspots where naloxone resources can be directed, along with data from public safety, which identifies changes in the illicit drug market. Due to the recognition that multiple administrations of naloxone are often necessary to revive a fentanyl overdose in the field,^{xvii} the FDA has recently convened an Advisory Committee to assess the most appropriate doses of naloxone that should be made available for use in the field, as well as criteria for assessing the most appropriate dose to utilize in advance of an overdose event.^{xviii}

a. The state of Virginia has even gone so far as to mandate its access to all state residents. How has this type of response helped the crisis?

Answer: HHS and international health organizations recommend providing naloxone kits to laypersons who use opioids, who might witness an opioid overdose, to patients in substance use treatment programs, to persons leaving prison and jail, and as a component of responsible opioid prescribing.^{xix} An interrupted time series analysis during 2002–2009 found that opioid overdose death rates were reduced in Massachusetts communities where overdose education and nasal naloxone distribution was implemented.^{xx} One strategy to improve access and distribution of naloxone to community members is to implement a Standing Order for naloxone. This strategy has been recently implemented in Virginia, and allows pharmacists in Virginia to recommend and dispense naloxone to

those deemed to be at significant risk of opioid overdose, without a prescription from a physician. The strategy has been implemented in a number of other states, and has been demonstrated to increase the availability and use of naloxone among community members.^{xxi}

6. In your written testimony you state that CDC has funded 12 states for Enhanced State Surveillance of Opioid-Involved Mortality. What are the criteria for funding for these states?

Answer: The criteria for funding states for the Enhanced State Surveillance of Opioid-Involved Mortality was based on a competitive application process where states were scored based on their burden and their ability to:

- a) Increase the timeliness of aggregate nonfatal opioid overdose reporting.
- b) Increase the timeliness of fatal opioid overdose and associated risk factor reporting.
- c) Disseminate surveillance findings to key stakeholders working to prevent or respond to opioid overdoses.

The number of states funded was based on the appropriation for the activity.

7. Your written testimony mentions that CDC is connected to 44 states at present regarding prevention efforts and surveillance activities, with the goal of expanding to all 50 states. What can you tell us about the six states not yet connected, and what hurdles need to be cleared to achieve their involvement?

Answer: The six states that are not yet supported directly by CDC funds are: Florida, Texas, Iowa, Mississippi, North Dakota, and Wyoming. Although these states do not currently receive funding, we provide non-monetary programmatic resources (that are available to any state) upon request. Examples include CDC's Opioid Indicators Toolkit and recordings of technical assistance webinars and training events. By providing these resources, our goal is to ensure all states have and can utilize the Indicators Toolkit, and recordings of technical assistance webinars and training events.

We also plan to work directly with the six states by inviting them to CDC-funded opioid overdose training academies, which are designed to: 1) include state teams comprised of key players, such as the governor's office, public health, Medicaid, law enforcement, treatment providers, and health systems leaders; 2) teach best practices related to partnerships, data systems, and evidence-based interventions; and 3) develop a state plan that includes key agencies and most impactful interventions. These academies have been very successful in the past when executed with a partner who can ensure that the right state-level leaders come to the training and can offer follow-up assistance afterwards. Both the National Governors Association and the National Network of Public Health Institutes could potentially offer these trainings in conjunction with CDC.

8. How can real-time monitoring of the fentanyl threat be expanded?

**Please note this question is from NIDA's QFRs, but is best addressed by CDC. CDC's response is below.*

Answer: A top priority in stopping the fentanyl epidemic is to create a national surveillance system that will give a full picture of the epidemic in real-time. We are currently funding 12 states under the Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality program to improve tracking and reporting of illicit opioid overdoses, including fentanyl, as part of this surveillance system. It allows CDC to monitor changing trends and issues related to this epidemic, such as deaths from heroin containing illicitly manufactured fentanyl, and to understand how the epidemic evolves over time. If the program was expanded to all 50 states, we could have a true national snapshot of nonfatal and fatal opioid-involved overdoses. This could give us more timely information on geographic areas experiencing sharp increases so we could respond more quickly with responses tailored to that outbreak. It could also give us information on decreases of overdoses which would help us rapidly identify successful intervention efforts.

The Honorable Buddy Carter

- 1. The Ensuring Patient Access and Effective Drug Enforcement Act of 2016 was signed into law on April 19, 2016. This Act requires a report to Congress not later than one year after enactment identifying among other things, obstacles to legitimate patient access to controlled substances, and how collaboration among federal, state, and local law enforcement agencies and industry can benefit patients and prevent diversion and abuse of controlled substances. HHS is tasked with submitting the report to Congress in coordination and collaboration with a number of other federal agencies, including the Drug Enforcement Administration. Please provide us with an update of the status of the report.**

Answer: This is outside of CDC's purview; however, HHS will follow up with your office for a response.

ⁱ For additional information https://www.samhsa.gov/data/sites/default/files/report_2083/ShortReport-2083.html .

ⁱⁱ For additional information <http://www.providencejournal.com/news/20170404/as-overdoses-surge-many-ri-hospitals-start-testing-for-fentanyl-in-ers> .

ⁱⁱⁱ For additional information https://www.samhsa.gov/data/sites/default/files/report_2083/ShortReport-2083.html .

^{iv} Although 12 states are funded through the ESOOS program, only 11 states are submitting ED data. States have the option to submit ED or EMS data or both. Ten of the 12 states are submitting both ED and EMS data. Oklahoma is not submitting ED data, and Missouri is not submitting EMS data.

^v For additional information <https://www.cdc.gov/drugoverdose/foa/state-opioid-mm.html> .

^{vi} For additional information <https://emergency.cdc.gov/han/han00384.asp> and <https://www.cdc.gov/mmwr/volumes/65/wr/mm6533a2.htm> .

^{vii} For additional information <https://emergency.cdc.gov/han/han00395.asp>, <https://emergency.cdc.gov/han/han00384.asp>, <https://www.cdc.gov/mmwr/volumes/66/wr/mm6614a2.htm> and <https://www.cdc.gov/drugoverdose/foa/state-opioid-mm.html> .

^{viii} For additional information <http://www.cste.org/blogpost/1084057/246934/Announcing-New-Recommendations-for-Epidemiologists-to-Improve-Reporting-of-Drug-Overdose-Deaths-on-Death-Certificates> .

^{ix} For additional information https://www.cdc.gov/nchs/data/health_policy/unspecified_drugs_by_state_2013-2014.pdf and <http://s3.documentcloud.org/documents/1151267/heroin-project-2014-study-on-overdose-deaths.pdf> .

^x For additional information https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_10.pdf and https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_09.pdf .

^{xi} For additional information <https://www.cdc.gov/drugoverdose/foa/state-opioid-mm.html> .

^{xii} For additional information <https://www.cdc.gov/drugoverdose/data/analysis.html> .

^{xiii} For additional information <https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2015-Overdose-Data/2015-Ohio-Drug-Overdose-Data-Report-FINAL.pdf?la=en> .

^{xiv} For additional information <https://www.cdc.gov/mmwr/volumes/66/wr/mm6614a2.htm> .

^{xv} For additional information https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_10.pdf and https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_09.pdf .

^{xvi} For additional information <https://www.cdc.gov/drugoverdose/foa/state-opioid-mm.html> .

^{xvii} For additional information <https://www.cdc.gov/mmwr/volumes/66/wr/mm6614a2.htm> and <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6234a5.htm> .

^{xviii} For additional information <https://www.fda.gov/AdvisoryCommittees/Calendar/ucm516000.htm>

^{xix} For additional information <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm>, <https://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf> , and http://www.who.int/substance_abuse/publications/management_opioid_overdose/en/ and <https://addiction.surgeongeneral.gov/surgeon-generals-report.pdf>.

^{xx} Additional information available at <http://www.bmj.com/content/346/bmj.f174.long>

^{xxi} Davis, CS et al, Legal Changes to increase access to naloxone for opioid overdose reversal in the U.S., Drug and Alcohol Dependence, 2015 Dec 1;157:112-20 <https://www.ncbi.nlm.nih.gov/pubmed/26507172>