U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

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The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Louis Milione, former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, before the House Energy and Commerce Subcommittee on Oversight and Investigations, on March 21 2017, for a hearing entitled "Fentanyl: The Next Wave of the Opioid Crisis." We hope that this information is of assistance to the Subcommittee.

Please do not hesitate to contact this office if we may be of additional assistance regarding this or any other matter. The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program.

Sincerely,

Stephen E. Boyd
Assistant Attorney General

Enclosure

cc: The Honorable Diana DeGette
Ranking Member, Subcommittee on Oversight and Investigations

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives

Hearing:
"Fentanyl: The Next Wave of the Opioid Crisis"
March 21, 2017

Questions for the Record

The Honorable Tim Murphy

1. **How is fentanyl more of a law enforcement challenge than prescription opioids or heroin?**

Response: Due to the extremely high potency and the techniques used to traffic fentanyl and fentanyl analogues, this group of illicit opioids presents more of a law enforcement challenge than prescription opioids or heroin. There are many fentanyl analogues ranging from 50-100 times the potency of morphine to up to 10,000 morphine's strength for carfentanil. Not all fentanyl analogues are scheduled in the U.S. Illicit manufacturers are able to chemically modify a scheduled compound to make it an unscheduled one, facilitating distribution until the modified version of the compound is scheduled. Chinese manufacturers are continually introducing new synthetic opioids into the illicit market, impacting the U.S. and other countries where the new compounds are not scheduled.

Another unique challenge associated with the trafficking and misuse of fentanyl and its analogues is their high potency and lethality. Often, neither the trafficker nor the user is able to differentiate between an effective dose and a lethal dose.

2. **Is one of the challenges to combatting fentanyl that it has so many analogues – also known as chemical variations?**

    a. **If so, how does this present a unique challenge to addressing the supply?**

Response: Small variations or modifications to fentanyl's chemical structure retain and often enhance the opioid effects. DEA continues to respond to the introduction of these chemical variants with available tools such as authorities provided under the Controlled Substance Analogue Enforcement Act ("Analogue Act") and temporary scheduling authority. Since the temporary scheduling of acetyl fentanyl in July 2015, DEA has used its temporary scheduling authority (sometimes called "emergency" scheduling because it is triggered by an Attorney General finding that temporary scheduling is "necessary to avoid an imminent hazard to the public safety") five more times to schedule an additional six fentanyl analogues, including the most recent action, to temporarily place Schedule I controls on acryl fentanyl on July 14, 2017. DEA is currently collecting information for potential additional actions. Prior to this series of actions, DEA had last used temporary scheduling authority to schedule fentanyl analogues in the mid-1980s when Congress enacted the Comprehensive Crime Control Act of 1984, which provided DEA with this

authority. In addition to its temporary (emergency) scheduling authority, DEA relies on the Analogue Act to investigate and prosecute those preying on vulnerable populations in advance of finalizing a control action.

3. **Are the pill presses that are used in fentanyl trafficking being shipped from China?**

Response: India, China, and Germany were the top three countries from which pill presses/encapsulation machines were shipped in 2015 and 2016; however, to the best of DEA's knowledge, illicit operations identified to date in 2017 used presses that had been purchased from China.

   a. **Are the pill presses being trans-shipped from China through other countries and then to the U.S.?**

Response: At present, DEA has no information regarding transshipment of pill presses from China through other countries.

   b. **Is there a concern about trans-shipment of pill presses through other countries? If so, why?**

Response: While DEA is not currently aware of transshipment of pill presses through other countries, we continue to be vigilant in identifying emerging trends that may impact drug trafficking.

4. **DEA and DHS have seized numerous pill presses with Chinese sources. They were identified as intentionally mislabeled. However, parts or components to pill presses are also being shipped. What can you tell us about such detections, and cooperation with the Chinese government?**

Response: If shipped separately, the parts of a pill press, except for the dies, do not meet the criteria for the criminal offense with respect to counterfeiting equipment under 21 U.S.C. Section 843(a)(5). Nevertheless, depending on the facts and circumstances, it could be an offense of possessing or distributing equipment with the intent to illegally produce a controlled substance (including a counterfeit) under Sections 843(a)(6) or (7). The parts are often mislabeled to avoid law enforcement and reporting requirements. DEA has had discussions regarding pill press regulations with the Chinese government, but they are not regulated in China. However, the Chinese are willing to cooperate with DEA in investigations where crimes can be tracked back to China.

5. **While we recognize that most online addresses in the U.S. for supplying fentanyl are either faked or can be altered, there continue to be legitimate (i.e. actual physical) addresses of buildings that are listed on the websites by some fentanyl suppliers. Are these addresses being screened through law enforcement databases – including (if available) the addresses of individuals linked by e-mail to respond to customer questions?**

Response: DEA seeks to investigate many leads in tracking down illicit fentanyl suppliers.

a. Do these addresses represent possible drop shipment locations?

Response: DEA is not in a position to speculate on possible links between these locations and illicit fentanyl suppliers.

b. Has this ever been investigated?

Response: As stated above, DEA seeks to investigate many leads in tracking down illicit fentanyl suppliers.

6. The detection and identification of NPP and ANPP, two of the major essential precursors - or ingredients - to making fentanyl, have been debated topics since there are legitimate laboratory and medical uses for these items. What quantities have been noted as going to labs for legitimate purposes, how are they normally ordered or created, and from where?

Response: NPP is a List I chemical controlled by DEA that is used to manufacture fentanyl and is also used in organic synthesis. ANPP is a schedule II controlled substance (an immediate precursor) which is used by the pharmaceutical industry to manufacture fentanyl.

In the U.S., those who wish to "create" (i.e.) or manufacture ANPP and fentanyl would have to obtain a Schedule II manufacturing registration from the DEA. DEA registered manufacturers would then apply for an individual manufacturing quota. The Aggregate Production Quota (APQ) is the total amount of a controlled substance that can be manufactured in a calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States for lawful export requirements, and for the establishment and maintenance of reserve stocks. The 2016 APQ for ANPP was 2,950 kilograms and for fentanyl was 2,300 kilograms. Those wishing to manufacture NPP would obtain List I chemical manufacturing registration from DEA and report their manufacturing activities to DEA on a yearly basis. DEA has not received any such reports.

a. Are other precursors being considered for identification as illegal substances?

Response: DEA actively monitors for precursor modifications through established programs and investigations. As a new chemical or synthetic route is identified, DEA collects information and evaluates the details for a possible chemical control. There is process established under the CSA to regulate a chemical that provides for engagement with the chemical industry. Through our domestic and international chemical control efforts, DEA is able to respond to changes in precursor chemicals to disrupt the clandestine manufacture of controlled substances. In March 2017, DEA with the State Department secured the international control of two fentanyl precursors.

7. A recent drug bust in Chicago discovered that there were almost 200,000 phone calls placed to one phone line in six months, or about 1,000 calls per day. This data helped DEA and local police detect and arrest the offenders. What kinds of similar or other data-sharing and related techniques have been/are available to assist law enforcement?

Response: DEA has established 77 Tactical Diversion Squads (TDS) in 43 states, the District of Columbia and the Caribbean. The TDS groups' primary function is to investigate the diversion of controlled substances from the legal market to the illicit market. TDSs are comprised of DEA Special Agents, Diversion Investigators, State, local, and tribal Task Force Officers, and other federal law enforcement agencies (e.g., HHS-OIG and FBI agents). DEA works very closely with state and local law enforcement agencies across the country in sharing information, data, and resources to help combat the opioid epidemic.

DEA has a number of reporting mechanisms that it can analyze to develop investigative leads. Internally, the Automated Reports and Consolidated Orders System (ARCOS), the Unlawful Medical Products Internet Reporting Entries (UMPIRE), and the 877-RxABUSE hotline are all resources that DEA may rely on to establish leads relating to the potential diversion of controlled substances.

The DEA Analysis and Response Tracking System (DARTS) for DEA users, and the De-confliction and Information Coordination Endeavor (DICE) system for non-DEA users, help support data-sharing and de-confliction efforts to assist law enforcement. These tools allow law enforcement personnel to check if others are gathering the same types of information. These tools maximize coordination and information sharing among law enforcement agencies and allow for immediate field de-confliction, which enhances ongoing investigations and ensures officer safety when "blue-on-blue" investigative actions are uncovered.

8. **Since carfentanil is the deadliest of all fentanyl analogues, what can be said about areas where it has been detected consistently?**

Response: DEA is unaware of any specific areas where carfentanil has been consistently detected.

a. **What about sources and types of production?**

Response: Carfentanil is approved by the Food and Drug Administration for use in veterinary medicine and is a Schedule II substance in the United States. From 2014-2016, there have been no U.S. manufacture or imports of veterinary products containing carfentanil. During the same time period, there was no manufacturing of carfentanil for analytical standards, but these analytical standards were imported about 15 times. In 2017, DEA set the APQ at 10 grams and issued manufacturer quotas to three separate companies to manufacture analytical standards. The quantity of the drug needed for legitimate medical use is established by quota, and distributors and users are registered. DEA has not encountered diversion of the lawful carfentanil drug product. Rather, the appearance of the substance on the illicit drug market is through sources of production in Chinese laboratories, where the compounds are produced and then purchased and shipped to the United States from dark web illicit marketplaces.

b. **Where have localized spikes in deaths (and in seizures) been most pronounced?**

Response: Overall, the drug overdose death rate increased significantly from 12.3 per 100,000 in 2010 to 16.3 in 2015. Death rates have increased in 30 states and Washington, D.C., and have remained stable in 19 states. During 2015, a total of 52,404 persons in the United States died from a drug overdose, an increase from 47,055 in 2014; among these deaths, 33,091

(63.1%) involved an opioid, an increase from 28,647 in 2014. The age-adjusted opioid-involved death rate increased by 15.6%, from 9.0 per 100,000 in 2014 to 10.4 in 2015. According to CDC initial estimates, there were more than 64,000 overdose deaths in 2016, or approximately 175 per day. More than 34,500 (54%) of these deaths were caused by opioids. The sharpest increase in drug overdose deaths was fueled by a surge in fentanyl and fentanyl analogues (synthetic opioids) overdoses, accounting for more than 20,000 (31%) of these deaths.[i]

Numerous reports of fentanyl and other synthetic opioid deaths and encounters have originated in the Midwest and Northeast and the issue continues to evolve, affecting new communities across the United States. It is anticipated that these highly addictive and lethal substances are in additional communities and those encounters may be underreported. Drug overdoses are complex events. DEA continues to respond to overdose clusters and work with local, tribal and State public health officials to triangulate information to a specific drug causing the overdose event. In response to these overdoses, DEA has utilized emergency scheduling authority to control numerous fentanyl analogues. As the trend of encountering new synthetic opioids continues, additional and centralized reporting of overdose events would assist DEA in its response time.

Since the demand for fentanyl and fentanyl analogues remains high, DEA continues to engage with foreign counterparts to reduce the supply. DEA has engaged extensively with China and has shared information regarding carfentanil encounters. China's subsequent control of carfentanil on March 1, 2017, was a significant outcome. DEA and the State Department have requested the World Health Organization to review carfentanil for international control in the coming year.

9. **Most experts agree that the issue of diverted drugs has lessened in recent years, while the problem of illicit fentanyl has exploded. However, there are several types of prescription fentanyl commonly available (e.g. patches, Actiq lollipops or lozenges) that are still subject to counterfeiting and abuse. Are these types being detected or seized as illegally manufactured, and to what degree?**

Response: The diversion of licit fentanyl is not common in comparison to other pharmaceutical controlled substances such as oxycodone and hydrocodone. Furthermore, DEA is not aware at present of the illicit manufacture/counterfeiting of legitimate pharmaceutical fentanyl products, such as patches, Actiq lollipops, or lozenges. However, due to its potency, diverted fentanyl is more likely to cause an overdose than other more commonly diverted prescriptions. Should diversion of licit fentanyl be discovered, DEA will commit the resources necessary to investigate.

Illicitly-produced fentanyl has been detected in counterfeit oxycodone pills, which are being seized at a high rate. This fentanyl powder is sourced from China. North American distributors manufacture the powder into counterfeit prescription pills that are trafficked throughout the continent. The "branding" of the pills to mimic, or look like legitimate prescription pills, has resulted in the drugs being abused by witting and unwitting users.

10. **While organized crime cartels and individual internet orders have been defined as principal suppliers of illicit fentanyl, other entities have been identified. For example, biker gangs have been cited as allied with cartels as distributors in some instances,**

while significant quantities of heroin mixed with fentanyl have been discovered at dogfighting events. What can you tell us about the detection and prevalence of such alternative drug distributors?

Response: The tools needed to manufacture counterfeit pills containing fentanyls are available online and are relatively inexpensive compared to other forms of drug production, contributing to its unique level of threat. Such access paves the way for non-cartel-affiliated individuals to undertake fentanyl trafficking. Fentanyls are available for purchase online from anonymous dark net marketplaces and even overtly-operated websites. Industrial pill press machines are also widely available on the open internet. An April 2016 online search of auction websites by DEA revealed a wide variety of pill presses for sale. One pill press capable of producing 5,000 pills per hour was priced at $995, and die molds for oxycodone and Xanax® pills were for sale at $115 and $130, respectively. The availability of counterfeit prescription drugs containing fentanyls will continue to grow in the near term. The relative ease and low cost associated with obtaining the drugs and equipment needed to manufacture counterfeit pills containing fentanyls will encourage individuals, as well as large and small DTOs, to move in this direction. Additionally, non-cartel-affiliated individuals may undertake production of counterfeit pills.

11. **Regarding the detection of fentanyl pills, what kinds of commonly used techniques (or outputs) have been detected in the seizures of pills in terms of shaping from pill molds, coloring, distribution, and the like?**

Response: The source of fentanyl is primarily of non-pharmaceutical origin and has been identified in powder form as well as in solutions and tablets that mimic legitimate pharmaceutical products (i.e., counterfeit tablets). These tablets have imitated oxycodone, hydrocodone, and alprazolam pharmaceutical formulations, leading an end user to believe that the counterfeit product is a legitimate pharmaceutical product.

In 2015, there was a marked surge in the availability of non-pharmaceutical fentanyl pressed into counterfeit prescription opioids such as oxycodone. In many cases, the shape, colorings, and markings are consistent with authentic prescription medications and the presence of fentanyl only becomes known under laboratory analysis. The rise of fentanyl in counterfeit pill form exacerbates the fentanyl epidemic. Prescription pill abuse is less stigmatized than use of illegal drugs and may attract new, inexperienced drug users, thereby creating more fentanyl-dependent individuals.

12. **Since the time of China's listing of 116 illegal substances in 2015, where/have there been identification(s) of illegal manufacture and sanctions on Chinese labs?**

Response: After China's listing of substances in 2015, DEA has seen a marked decrease in these substances. DEA does not yet know the extent of sanctions placed on Chinese labs. DEA investigations have revealed various Chinese manufacturers who import illegal substances into the U.S. including fentanyl and fentanyl analogues. The Chinese government and DEA have begun coordinated investigations on Chinese manufacturers and labs. On October 17, 2017, DOJ announced indictments against two Chinese nationals and their North America-based traffickers and distributors for separate conspiracies to distribute large quantities of fentanyl and fentanyl analogues and other opiate substances in the United States.

a. Has this kind of information been shared with us by the Chinese government, or will it?

Response: DEA continues to work cooperatively with its Chinese counterparts, which includes the sharing of information related to coordinated investigations and seizures of fentanyl compounds.

13. Numerous sources state that the current fentanyl crisis is due in most part to illicit shipments and manufacturing. Yet there are several types of diverted fentanyl that have also been created illegally. Can you comment on this type of illegally made/diverted fentanyl?

Response: DEA's information indicates that fentanyl seizures are suspected to be illicitly manufactured. DEA's review of registered fentanyl manufacturers and distributors indicate it is not generally being diverted from legitimate industry. DEA continues to reassess market vulnerabilities that may allow for fentanyl diversion to fill availability shortfalls.

a. How prevalent is this? In other words, is it a significant source of the problem we are seeing right now?

Response: DEA information indicates that fentanyl diversion occurring from legitimate manufacturers and distributors is not a significant source of the problem. The data indicates that fentanyl seizures are of drugs that have been illicitly manufactured. Findings related to recent fentanyl encounters suggest that fentanyl is being pressed into pills to resemble other drug products. Although diversion of fentanyl for personal use has taken place at very low levels in the past, information from recent fentanyl encounters suggest that illicit, foreign-sourced fentanyl powder is imported and pressed into counterfeit pills in order to resemble other drug products. These counterfeit drugs are passed-off to unknowing users and often contain lethal amounts of fentanyl. There are no indications that counterfeit fentanyl drug products are being encountered on the legitimate drug market.

Illicit fentanyl is being encountered throughout the United States. Encounters at the borders include fentanyl in both powder and counterfeit tablet form or in combination with heroin or in some instances, with cocaine. DEA continues to investigate and disrupt these organizations with our federal, state, and local partners. Significant quantities of the drug have been removed from the streets and DEA will continue to utilize all tools available to disrupt and prosecute those peddling these poisons.

14. Is the diversion of Buprenorphine a significant factor also driving the opioid epidemic? What data does the DEA have regarding this diversion?

Response: Buprenorphine is a narcotic drug for which there is a significant demand in illicit channels. Given that buprenorphine is often prescribed to persons who are addicted to narcotics, it is expected that some of the buprenorphine dispensed to patients will be diverted through illegal resale. For this reason, it is controlled and its use as an addiction treatment medicine is highly regulated. However, multiple cross-sectional studies have found that the majority of people who misuse diverted buprenorphine report doing so to "self-treat" for opioid use disorder or opioid

withdrawal symptoms. In addition, buprenorphine is a partial agonist at the μ-opioid receptor, meaning it only partially activates the receptor. It poses a significantly lower risk for overdose than full agonist opioids such as oxycodone or heroin. DEA does not have data that would allow for a precise quantification of such diversion. At the same time, buprenorphine, when properly dispensed as part of an effective addiction treatment program, can be highly beneficial in leading to recovery from opioid addiction.

Buprenorphine as a partial agonist is less likely than other opioids to cause respiratory depression unless it is used in combination with other sedatives. Overdose data suggests it is less of a factor in overdose deaths than other opioids although users in treatment sometimes overdose.

When users withdraw from opioids, especially if they cannot obtain treatment on demand, they often view it acceptable to borrow or illicitly obtain drugs to prevent this withdrawal.[ii] Demand for buprenorphine as a diverted product may stem from an insufficient provider network for buprenorphine as an addiction treatment medicine.[iii] To date, fewer than 40,000 providers have taken the training and completed the special certification process to provide buprenorphine through office based treatment and most providers are not working up to capacity. One study in Ohio showed that although 466 providers were listed as offering services, nearly 1 in 5 did not actually provide treatment and more than 40% who accepted patients did not accept insurance. Until this issue is solved, buprenorphine is likely to continue to be diverted for self-treatment, to prevent withdrawal and for non-medical use.

Products combining buprenorphine with naloxone are available to produce withdrawal if patients ingest them by injection. These combination products were intentionally designed to thwart misuse and diversion and appear to be effective at this relative to buprenorphine-only products.[iv] To decrease diversion for non-medical use, the Centers for Medicare and Medicaid Services and insurers should examine their policies to ensure that patients have access to these buprenorphine formulations and that the products with pure forms of buprenorphine only intended for use under supervised administration or during pregnancy are reserved for such purposes.

New less-divertible products such as buprenorphine implants are also available and may help decrease diversion, however, they require surgery and follow-up removal and are only intended for use in stabilized patients. Policy makers should consider ways to promote their use.

The Honorable Buddy Carter

1. **In 2010, the Drug Enforcement Administration (DEA) issued an interim final rule (IFR) to allow for the electronic prescribing of controlled substances (EPCS). Since that time, DEA has acknowledged that the IFR does not allow for an unfilled prescription for a Schedule II controlled substance to be transferred or forwarded by a pharmacy to another pharmacy because the first pharmacy, for whatever reason, is unable to fill the prescription. DEA has further stated that the agency plans to address this issue when the agency issues the EPCS final rule. Considering that this unresolved issue is likely leading to delays in patient care and is acting as a barrier to the widespread adoption of EPCS, please provide an update on DEA's progress in issuing the final rule.**

Response: DEA's Interim Final Rule (IFR) on Electronic Prescriptions for Controlled Substances (EPCS) provides practitioners with the option to sign and transmit prescriptions for controlled substances electronically. Pharmacies are permitted to receive and archive electronic prescriptions. In FY 2012, DEA announced the first DEA-approved certification process for EPCS. Through December 31, 2015, DEA approved six different certification processes. The Diversion Control Program (DCP) continues to hold open dialogue with industry stakeholders in order to research, develop and implement EPCS regulations.

As the IFR stated, DEA regulations addressing the transfer of prescriptions are set forth in 21 CFR 1306.25. Consistent with the greater danger to the public health and safety associated with the diversion of Schedule II controlled substances (as compared to schedule III-V controlled substances), DEA regulations have historically not allowed for the transfer of prescriptions for Schedule II controlled substances. Nonetheless, DEA is continuing to evaluate this issue, with input from the regulated industry, to explore the possibility of amending DEA regulations to allow for the transfer of electronic prescriptions of Schedule II controlled substances in a manner consistent with effective safeguards against diversion.

The Honorable Frank Pallone, Jr.

1. **According to a December 2016 article in the Charleston Gazette-Mail, opioid wholesalers shipped mass quantities of opioid medicines that appeared to be far in excess of what certain communities in West Virginia should have received based on sound medical needs. The article said:**

   "In six years, drug wholesalers showered the state with 780 million hydrocodone and oxycodone pills, while 1,728 West Virginians fatally overdosed on those two pain killers [...] The unfettered shipments amount to 433 pain pills for every man, woman and child in West Virginia."

   a. **Has DEA been able to examine the veracity of the oversupply assertions laid out in the 2016 article?**

Response: Yes.

   b. **If DEA has found these assertions to be accurate, what action, if any, has DEA taken on this issue with respect to supply chains into West Virginia? Please include information on any joint effort with other federal, state, or local law enforcement or public health agencies.**

Response: DEA currently has two Tactical Diversion Squads (TDS) operating in Charleston, South Carolina, and Clarksburg, West Virginia, which work with state and local law enforcement. DEA established the Clarksburg TDS Group in December 2016 to help address the opioid epidemic within the state of West Virginia. DEA, working with United States Attorneys and the Department of Justice, has taken and continues to pursue criminal, administrative, and civil actions against various bad actors within the closed system of distribution, including, but not limited to, suppliers, doctors and pharmacies. Recently, DEA investigated and civilly settled significant investigations on wholesale distributors, including Amerisource Bergen, Cardinal Health, McKesson and Miami-Luken, which had supplied controlled substances into West Virginia. These settlements levied not only fines, but also imposed significant new reporting requirements on these distributors.

   c. **Similarly, has DEA identified specific public safety issues stemming from the possible oversupply of prescription drugs as described in the 2016 Charleston Gazette-Mail reporting?**

Response: Yes. DEA recently implemented its 360 Strategy in an effort to combat the nationwide opioid epidemic. This three pronged approach, including increased law enforcement operations to address violent crime, ongoing diversion control efforts, and community outreach is currently being used in West Virginia as a proactive tool to help combat the opioid crisis. Further information on DEA's 360 strategy can be found at: https://www.dea.gov/prevention/360-strategy/360-strategy.shtml

   d. **What additional insights does DEA have into the alleged practices as indicated in this reporting?**

Response: In July 2014, the State of West Virginia passed legislation requiring clinics that treat chronic pain to be licensed by the West Virginia Department of Health. Once licensed, there are additional requirements on the clinics that have significantly reduced diversion of controlled prescription drugs by doctors.

DEA issues quotas to DEA-registered bulk manufacturers and dosage form manufacturers for scientific, research and medical needs in addition to lawful exports and inventory. The databases that are used to justify and verify quota applications are nationally aggregated commercial sales and retail sales data. The regulatory requirements for quota are only at the manufacturers' level and the requirements and regulatory controls of quotas do not extend to the distributor levels. Quotas are not issued to manufacturers based on geographic areas. Sales by manufacturers to distributors are tracked by DEA through the Automated Reports and Consolidated Orders System (ARCOS), but individual distributions are not pre-approved by DEA.

Although the distributors are not covered under the Quota program, they have specific reporting requirements outlined in DEA regulations, including utilizing specific forms and report transactions to ARCOS. In addition, as DEA registrants, they are obliged by the CSA to maintain effective controls against diversion of controlled substances into illicit channels, and DEA regulations require distributors to design and operate a system to detect suspicious orders and to promptly notify DEA of any such orders. DEA has been active in enforcing that provision against national and regional controlled substance distributors.

Manufacturers also distribute the products they make, so they too are under an obligation to detect and notify of suspicious orders. A recent settlement with a large national manufacturer, Mallinckrodt plc, resulted in a civil penalty and an agreement by the company to enhance the monitoring of sales to distributors, as well as to use of available tools within the company to monitor "downstream" orders by customers of distributors who receive Mallinckrodt's drugs.

2. **MSNBC also ran a story about the substantial influx of opioids into West Virginia. More specifically, it reported on the small town of Kermit, with an estimated population of only 392 people. MSNBC reported that one pharmacy in Kermit received 9 million hydrocodone pills in two years. If this reporting is true, I am concerned we do not have sufficient systems in place to identify and respond to such dangerous trends or, if those systems do exist, they may have failed in this case. You indicated during your testimony that DEA is familiar with reports of possible oversupply of these addictive pills in West Virginia.**

   a. **Is DEA aware of the reports that one pharmacy in Kermit, West Virginia may have received 9 million hydrocodone pills over a two-year period?**

Response: Yes.

   b. **If so, what actions, if any, has DEA taken to date in response to possible oversupply in the Kermit, West Virginia case?**

Response: DEA and its State and local counterparts investigated the referenced pharmacy, which resulted in the pharmacy surrendering its DEA registration "for cause," meaning the pharmacy

voluntarily surrendered its DEA registration as a result of its alleged failure to comply with the Federal requirements pertaining to controlled substances. In addition, several doctors and nurse practitioners associated with the "pill mill" for which the pharmacy had filled prescriptions were federally prosecuted and convicted.

3. **The reports of possible oversupply of addictive opioids into West Virginia may raise additional concerns regarding whether there are systemic weaknesses in our regulatory and enforcement systems that could allow abusive oversupply patterns to go unnoticed or unaddressed.**

   a. **Has DEA identified any systemic failures surrounding the oversupply of opioids in West Virginia?**

Response: DEA has identified the need to carefully scrutinize and analyze data indicating that distributors may be supplying amounts of controlled substances disproportionate to the population size, given that it could be a data point indicative of diversion.

   b. **If yes, what issues did DEA identify? What has DEA concluded were the causes of these issues? What solutions has the DEA identified, and what efforts to date has DEA taken to implement these solutions?**

Response: As part of DEA's efforts to continue engagement with distributors, DEA conducts annual Distributor Conferences and has initiated quarterly Distributor Initiative meetings that are conducted with specific wholesalers. The purpose of these meetings is to review their data and obligations in handling controlled substances, discuss national trends involving the abuse of pharmaceutical controlled substances, discuss their "due diligence", and review ARCOS data for sales and purchases of Schedule II and III narcotic controlled substances. DEA also discusses and reviews the law and regulations pertaining to suspicious orders. At the conclusion of the Distributor Initiatives, DEA Headquarters Diversion personnel provide training to the respective field division's diversion investigators on policy changes, new systems and regulations, and other relevant information.

Additionally, specific to West Virginia, DEA increased personnel in its local field offices, including two TDS. The TDS groups combine DEA resources with those of federal, state, and local law enforcement agencies in an innovative effort to investigate, disrupt and dismantle those suspected of violating the CSA or other appropriate federal, state or local statutes pertaining to the diversion of licit pharmaceutical controlled substances. The TDS groups help coordinate with various judicial districts to maximize the effectiveness of multiple investigations and prosecutions of those involved in the diversion of pharmaceutical controlled substances.

4. **If true, the reported oversupply of these addictive pills to the State of West Virginia raises significant concern that the same problem could be occurring elsewhere.**

   a. **What monitoring systems are in place to detect potential oversupply of prescription drugs nationwide? Do we have a monitoring unit to compare to population size?**

Response: At this time, a single system does not exist to provide total distribution, usage, and prescription monitoring data and to compare that to a state or locality's population.

There are several ways in which DEA is able to monitor suspicious orders. Distributors are required to submit monthly or quarterly reports of their purchases and sales of Schedule II and Schedule III Narcotics to ARCOS. These reports are verified by DEA personnel and can be used as a tool to pinpoint areas throughout the United States in which excessive amounts of pharmaceutical controlled substances are purchased. In addition to these requirements, DEA's Diversion Regulatory Section conducts quarterly Distributors Initiatives. The ARCOS section provides data to support that initiative.

An additional tool DEA may use to further active investigations is the State-run Prescription Monitoring Programs (PMPs). Although access requirements and procedures vary by state, PMP networks can give DEA investigators the ability to access opioids prescriptions written by practitioners within all participating states. The PMPs allow DEA investigators to identify states where excessive amounts of opioids may have been dispensed in their area. Further, as noted above in response to Question 1.d, DEA-registered controlled substance distributors are obliged by the CSA to maintain effective controls against diversion of controlled substances into illicit channels, and DEA regulations require distributors to design and operate a system to detect suspicious orders and to promptly notify DEA of any such orders. DEA has been active in enforcing that provision against national and regional controlled substance distributors.

b. Does DEA have sufficient insight into the supply patterns of other states hard-hit by the opioid epidemic to identify and respond to suspicious patterns occurring elsewhere?

Response: DEA has oversight of regulatory matters under the Diversion Control Division. This oversight allows DEA personnel to conduct field regulatory investigative activities such as periodic scheduled investigations, pre-registration investigations, Order to Show Cause investigations, and theft/loss investigations, among others. The aforementioned investigations are conducted to ensure compliance with the Controlled Substances Act (CSA) and promulgated regulations found in the Code of Federal Regulations. In an effort to gain sufficient insight on areas that may face challenges with excessive opioid distribution, DEA also includes 10 pharmacies per field office as part of its yearly scheduled investigations.

DEA has the authority to reduce quota authorizations to bulk manufacturers and dosage manufacturers when it has been shown through investigations that diversion has occurred within the closed system of distribution as a result of the manufacturer not complying with the rules and regulations outlined in the CSA. However, through various investigations, DEA has determined that many of these incidents of oversupplying areas are the result of a series of primary, secondary, and even tertiary distributors selling and reselling dosage units before supplying the retail pharmacies. Although the DEA-registered distributors are not required to request quota, they are required to report transactions using DEA forms and report to ARCOS. The distributors' activities can be tracked by DEA and these issues can be addressed to each distributor in meetings, such as the Distributor Initiative Briefings. All of these tools allow for DEA to address any substantial issues/areas of concern where diversion is suspected.

[i] CDC WONDER data, retrieved from the National Institute of Health website; http://www.drugabuse.gov as reported on NIDA's website.

[ii] Kenney SR1, Anderson BJ2, Bailey GL3, Stein MD4
The relationship between diversion-related attitudes and sharing and selling buprenorphine.
Journal of Substance Abuse Treatment. 2017 Jul; 78:43-47. https://doi.org/10.1016/j.jsat.2017.04.017. Epub 2017 Apr 27.

[iii] Parran TV, Muller JZ, Chernyak E, Adelman C, Delos Reyes CM, Rowland D, Kolganov M.
Access to and Payment for Office-Based Buprenorphine Treatment in Ohio. Subst Abuse. 2017 Jun
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5473522/

[iv] Larance B1, Mattick R1, Ali R2, Lintzeris N3,4, Jenkinson R5, White N2, Kihas I1, Cassidy R1, Degenhardt L1,6.
Diversion and injection of buprenorphine-naloxone film two years post-introduction in Australia.
Drug Alcohol Rev. 2015 Oct 9. http://onlinelibrary.wiley.com/doi/10.1111/dar.12344/abstract. [Epub ahead of print]