Questions for the Record
Drug Enforcement Administration
Hearing before the
Committee on the Judiciary
United States Senate
"Oversight on the Ensuring Patient Access and Drug Enforcement Act."
December 12, 2017

Questions from Senator Charles Grassley

1. **Opioid distributors are required to report their sales of opioids to DEA through the ARCOS system. The distributors are also required to self-report suspicious orders. They have internal compliance functions to help them sort through what orders may be suspicious and what orders are legitimate. DEA keeps a database, ARCOS, for opioid sales data, and DEA has knowledge and data on suspicious reporting activity.**

    a. **What is ARCOS and where does DEA keep suspicious data reports? If suspicious data reports are not kept within the ARCOS database, why is that information separate from ARCOS?**
    b. **Does DEA share data on suspicious orders among the opioid distributors? If not, why? Wouldn't the sharing of information provide distributors better insight into whether the distributors should submit suspicious activity reports?**

Response: Pursuant to the Controlled Substances Act (CSA), 21 U.S.C. § 827(d)(1), and applicable Drug Enforcement Administration (DEA) regulations, manufacturers and distributors of Schedule I, II, or III narcotic controlled substances must report the manufacture, sale, purchase, loss, or other disposition of these controlled substances to DEA. The Automation of Reports and Consolidated Orders System (ARCOS) is the electronic system in which manufacturers and distributors report these transactions. ARCOS does not collect information regarding dispensing to patients at the retail level, nor does it collect inventory information except year-end inventories held by manufacturers. Registrants reported nearly 80 million ARCOS transactions in 2016.

Current regulations require DEA registrants to report Suspicious Order Reports (SORS) to their local DEA Office; there is no centralized reporting of SORS. DEA is currently working to amend its regulations in such a way that suspicious orders will be provided to a central database. Centralized reporting will allow for a more efficient review, dissemination, and investigation of suspicious activity.

While there is no single database that contains total distribution, usage, and prescription monitoring data, 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. Specifically, a unit within

DEA's Diversion Control Division, Pharmaceutical Investigations Section uses aggregated ARCOS data to identify patterns and trends in the flow of narcotic controlled substances through the closed system of drug distribution. This unit is now proactively preparing quarterly threat assessment reports for each of DEA's 22 Field Divisions to prioritize DEA's limited resources in furtherance of criminal, civil, and regulatory investigations against DEA registrants.

DEA understands that it cannot rely solely on the DEA-registered manufacturer/distributor community to report SORS to DEA to identify rogue pharmacies and doctors purchasing controlled substances. In addition, distributors registered with DEA are subject to unannounced regulatory investigations every three years. In part, these inspections allow for an accountability audit of selected controlled substances, a comparison of ARCOS records with source documents, and thorough review of all records required to be maintained pursuant to the Code of Federal Regulations. During Fiscal Year (FY) 2016, DEA conducted 352 regulatory investigations of distributors throughout the United States (for a total of 957 distributor facilities nationwide).

As part of its 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 sale and purchases of Schedule II and III narcotic controlled substances. DEA also discusses and reviews the law and regulations pertaining to suspicious orders.

2. **One of the tools at DEA's disposal when addressing issues of opioid distributors is to pursue a civil action against the distributor. If found liable as a result of a civil action, a distributor company must pay a civil penalty. The amount in civil penalties levied against drug distributors increased astronomically in 2017: in 2016, the civil penalties paid by distributors were $115,000, and in 2017, the civil penalties paid by distributors were $194,200,000. The total from 2017 is more than the previous seven years combined, which is about $148 million.**

    a. **How does DEA measure the effectiveness of civil penalties as an enforcement tool? Are civil actions and the subsequent imposition of civil penalties more helpful than ISOs in addressing drug diversion?**
    b. **Has the EPAEDEA affected DEA's ability to pursue civil penalties? If so, how?**

Response: The ultimate goal of civil penalties is to bring an errant registrant into compliance with the CSA. It can be considered effective when registrants no longer commit violations under the CSA. Immediate Suspension Orders (ISOs) are helpful when there is a legitimate need to immediately halt the actions of the registrant before harm is caused.

In regards to the Ensuring Patient Access and Effective Drug Enforcement Act (EPAEDEA) of 2016's impact on DEA's ability to pursue civil penalties, no, the EPAEDEA has not affected DEA's ability to pursue civil penalties.

3. **DEA played an active role in the passage of the EPAEDEA, and in fact "signed off" on the bill. There has been vocal opposition and demand for change from DEA since the Act's passage.**

    a. **Who at DEA was opposed to the EPAEDEA prior to its enactment?**
    b. **Who at DEA "pushed" the bill?**

Response: Former DEA Administrator Michelle Leonhart, coordinating directly with the Deputy Attorney General and the Department of Justice's (Department) Office of Legislative Affairs, met with House Judiciary Committee Chairman Goodlatte on July 23, 2014, to express DEA's very serious concerns with H.R. 4709, an earlier version of the EPAEDEA that would later pass the House under Suspension of the Rules on July 29, 2014. This bill had been considered by the House Energy & Commerce Committee a month earlier, in June 2014, and was under consideration by the House Judiciary Committee. The bill contained a significant standard for issuing ISOs by including a requirement that the Government establish that a registrant "intentionally" distributed or dispensed controlled substances in a manner that poses a present or foreseeable risk of serious adverse health consequences or death. Administrator Leonhart asserted that this definition would restrict DEA from taking action in instances of negligence, gross negligence, and reckless conduct and would completely disregard health consequences or death.

It is important to note that H.R. 4709, which was not considered in the Senate, was reintroduced in the 114th Congress on January 22, 2015, and was passed, without amendment on April 21, 2015. DEA and the Department continued their opposition to this version throughout the 114th Congress.

Following the passage of H.R. 4709, DEA and the Department began proactively engaging with Members of the Senate. In August 2014, DEA and Department staff briefed Senator Grassley, Senator Whitehouse, and Senator Leahy's staff on their concerns with the "ISO standard" that the House had passed the preceding month. During these meetings, DEA and the Department offered to provide technical assistance relating to the statutory definition for "imminent danger to the public health and safety." Throughout the 1.5 years of negotiations, DEA and the Department steadfastly stated their belief that changes to the manner in which DEA issues ISOs and Orders to Show Cause (OTSCs) were unnecessary and sought to fix a problem that did not exist.

4. **Prior to the passage of the EPAEDEA, the standard imposed on DEA to issue ISOs was not defined. Now, the Act's language requires DEA to show "immediate danger."**

    a. **Was the prior standard a "foreseeability" of imminent danger?**
    b. **If so, where did that standard arise from?**
    c. **Was that standard applied uniformly?**
    d. **Since DEA testified that the EPAEDEA has not affected DEA's enforcement capabilities, would a change in language as it pertains to the standard for issuing ISOs impact the DEA? If so, in what specific ways?**

e. **How does the current language of the Act affect DEA's capability to act in a preventative way towards diversion?**

Response: Prior to Congress' passage of EPAEDEA, the statutory term "imminent danger" was not defined in the CSA. As such, the determination of whether DEA adequately demonstrated "imminent danger" necessarily depended on the unique facts and circumstances before DEA that led DEA to issue the ISO; a standard that DEA applied consistently.

In an exchange during your initial round of questions, Ms. Ashley noted that EPAEDEA has made it harder to issue ISOs. However, in later exchanges with Senator Hatch and other Members, Ms. Ashley asserted that EPAEDEA has not had an impact on DEA's ISO authority. Consistent with Ms. Ashley's opening statement, DEA notes that the law has altered the manner in which DEA pursues ISOs. The ISO standard within EPAEDEA has not prevented DEA from enforcing existing law and using its wide array of tools to ensure the more than 1.7 million registrants are in compliance with the CSA. These include administrative actions, civil penalties, and criminal charges.

DEA supports amending EPAEDEA and continues to work with the House and Senate on any potential legislation.

5. **What tools does DEA *not* have available to it right now that it needs from Congress to help fight the Opioid epidemic?**

Response: One of the largest threats DEA is facing is combating fentanyl and other synthetic analogues. This is one of the reasons why DEA recently temporarily emergency scheduled the entire class of fentanyl substances. Any legislation that would give DEA the tools to proactively combat these deadly analogues, reduce the trafficking of synthetic drugs, and empower a more rapid response to emerging drug threats is greatly appreciated and we look forward to continuing to work with the Committee on such priorities.

6. **The Comprehensive Addiction and Recovery Act of 2016 ("CARA") allows a pharmacist to partially fill a prescription for a Schedule II Controlled Substance (such as an opioid) if all three of the following conditions are met: (1) such partial fills are not prohibited by state law, (2) a partial fill is requested by the patient or prescribing practitioner, and (3) the total quantity dispensed in partial fillings does not exceed the quantity prescribed. S.524, 114th Cong. (2016).**

    a. **In regards to this provision of CARA, can DEA legally regulate partial fill of schedule II controlled substances prescriptions?**
    b. **The Controlled Substances Act states that the partial filling of a Schedule II controlled substance is permissible only if "the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription." 21 CFR §1306.13(a). How does DEA's role through CARA agree with or conflict with this provision of the Controlled Substances Act?**
    c. **If there is no conflict between the above-mentioned provision of the Controlled Substances Act and CARA as it pertains to DEA's authority and**

regulatory powers, how does DEA intend to monitor partial fill prescriptions, particularly when a patient returns for a partial fill after receiving the initial partially filled prescription?

d. Can DEA regulate the actions of pharmacists and pharmacies directly as it relates to partial fill prescriptions?

Response: DEA agrees that the existence of clear rules regarding the partial fill of Schedule II controlled substances prescriptions plays an important role in limiting the supply of unused prescription drugs that can easily be misused or diverted. The DEA's Diversion Control Division is working on drafting a proposed rule that will implement Section 702 of the Comprehensive Addiction and Recovery Act of 2016 (CARA), which allows for the partial filling of Schedule II controlled substances under certain circumstances. This proposed rule will undergo review within the Administration to ensure that it is drafted in accordance with the applicable Executive Orders and policies. DEA intends to draft these proposed regulations so as not to conflict with current regulations governing partial fill prescriptions.

Current regulations allow pharmacists to partially fill prescriptions for Schedule II controlled substances "if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription." 21 C.F.R. § 1306.13(a). The pharmacist is required to annotate the quantity supplied on the face of a paper prescription, written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 72-hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist must notify the prescribing practitioner. No further quantity may be supplied beyond the 72-hours without a new prescription. 21 C.F.R. § 1306.13 (a).

Yes, DEA can regulate the actions of pharmacies as it relates to partial fill prescriptions, because pharmacies are DEA registrants subject to the CSA and its implementing regulations.

Questions from Ranking Member Dianne Feinstein

1. **Modify, Repeal, or Maintain the Law: Immediately following the *60 Minutes* and *Washington Post* reports, I asked DEA and the Justice Department whether the Ensuring Patient Access and Effective Drug Enforcement Act should be modified, repealed, or maintained. I also sent them specific language to consider. To date neither has responded. In your opinion, should the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 be modified, repealed, or maintained? If it should be modified, please explain how. If it should be repealed, please provide examples in which this law has negatively impacted DEA's ability to take enforcement action.**

Response: DEA supports amending EPAEDEA, and technical assistance on Senator Feinstein's draft legislation was provided by the Department on February 28, 2018. DEA continues to work with the House and Senate on any potential legislation.

2. **Enforcement Actions: Some have said that the Ensuring Patient Access and Effective Drug Enforcement Act prevents DEA from issuing immediate suspension orders. However, data provided by DEA shows that the last time an immediate suspension order was filed against a manufacturer or distributor was in 2012.**

    a. **Between 2011 and 2016, immediate suspension orders filed against pharmacies went from 21 to 4, and those filed against practitioners went from 43 to 5. These declines mostly occurred before the law passed, and as opioid overdose deaths were increasing at an alarming rate. I understand that the 2011 numbers may be artificially high because that is the year that DEA shut down an unusually high number of pill mills in Florida. Beyond this, what accounts for the decline in enforcement actions?**
    b. **Have other administrative policies within DEA, as asserted by DEA's Chief Administrative Law Judge John Mulrooney in his forthcoming Marquette Law Review article, impacted DEA's ability to take enforcement action? Please explain your response.**

Response: Although the number of ISOs has fallen, it is in part due to DEA increasing its Diversion efforts and personnel, state legislatures enacting laws to curb diversion, and a greater emphasis on assisting states in implementation of state Prescription Drug Monitoring Programs (PDMPs). For example, in response to the diversion crisis, the State of Florida enacted several laws during the 2010-2012 timeframe that directly addressed some of the root causes of the opioid epidemic. Thus, while the number of suspension orders fell, DEA suggests that it does not completely reflect other efforts of DEA and its partners in continuing programs to address this important issue.

In addition, since FY 2011, DEA's tactical diversion squads (TDS) have assumed a greater role in diversion enforcement. DEA now has 77 operational TDS groups across the United States, a significant increase (67 percent) over the 46 groups DEA had in FY 2012. TDS groups focus primarily on criminal enforcement and the results of their work often lead DEA

registrants to surrender their DEA registration for cause. In these instances, DEA is not required to initiate an administrative action to revoke the DEA registration. For example, between FY 2011 and FY 2017, a total of 6,321 registrations were voluntarily surrendered:

Fiscal Year	Voluntary Surrenders
2011	839
2012	979
2013	1,047
2014	922
2015	972
2016	786
2017	776

DEA only tracks surrenders for cause and therefore, any surrender that is reported is the result of a DEA inspection/investigation. Upon a registrant surrendering his/her registration for cause, or DEA obtaining a suspension/revocation of the registration, the registrant can no longer dispense, prescribe, or administer controlled substances, which DEA deems to be a success.

Chief Administrative Law Judge John Mulrooney does not speak for DEA; Administrative Law Judges are neutral finders of fact and not in a position to comment on policies in their personal capacity. DEA has and will continue to utilize all administrative, civil, and criminal tools available to ensure that our more that 1.7 million registrants are in compliance with the CSA.

3. **Using Data to Prevent Diversion: The Automation of Reports and Consolidated Orders System, commonly known as ARCOS, is a data collection system maintained by DEA in which drug manufacturers and distributors report their controlled substance transactions. These reports can help identify the diversion of controlled substances in to illicit channels.**

    a. **It is my understanding that there may be a 3-5 month lag between the time the information is reported to DEA and the time it ends up in the ARCOS system. If this is accurate, what accounts for this delay?**
    b. **Would sharing de-identified data with registrants that only includes information such as the total number and type of opioids going to specific pharmacies, and the total number of distributors serving specific pharmacies help prevent diversion? If distributors had information such as this, could it have helped prevent nearly 9 million oxycodone pills from being delivered by multiple distributors to a single pharmacy in West Virginia?**
    c. **Is it possible to make this data available without a legislative mandate?**

Response: ARCOS registrants (participants) must report quarterly. However, participants may elect to report more frequently on a monthly basis. Currently the split is roughly 70 percent quarterly reporters and the remaining 30 percent report on a monthly basis. A data lag is created due to inadvertent errors in reporting by ARCOS registrants that is identified by the Diversion

Control Division's AROCS unit and subsequently rectified by the registrant and reported as part of their next quarterly report.

DEA must protect the commercial information of innocent parties. It is the policy of the U.S. government—enforced by the threat of criminal sanction—to protect as confidential the business records commercial enterprises are compelled to give the government. *See* 18 U.S.C. § 1905 ("Whoever, being an officer or employee of the United States or of any department or agency thereof . . . publishes, divulges, discloses, or makes known in any manner . . . any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.'). For this reason, DEA does not generally disclose information to the public that it believes is either confidential or proprietary. An important exception to this rule is the manner in which DEA cooperates and shares information with local, State, tribal, and Federal Agencies. *See* 21 U.S.C. § 873.

Nevertheless, DEA is exploring ways to expand the use of ARCOS information to combat diversion. For example, on February 15, 2018, DEA launched a new tool within its ARCOS Online Reporting System to assist drug manufacturers and distributors with their regulatory obligations under the CSA. Specifically, the tool allows a distributor or manufacturer to enter the DEA registration number of a prospective purchaser (pharmacy, hospital, doctor, etc.) as well as the 4-digit drug code for the controlled substance the buyer wishes to purchase and the ARCOS application will return a count of the number of registrants who have sold that particular controlled substance to that prospective purchaser in the last 6-months. The goal of this tool is to provide information that will help distributors to identify red flags, while also protecting the confidential nature of the business information that registrants expect us protect.

DEA shares ARCOS information with state and local law enforcement entities pursuant to 28 C.F.R. § 0.103, on a case-specific basis, to assist in their efforts to combat diversion. DEA is in the midst of negotiations with state attorneys general to develop a framework to make ARCOS information generally available to their investigators. The Department is participating as a "friend of the court" in the ongoing Federal multi-district Litigation against opioid manufacturers and distributors that has been brought by state and local governments (In Re: *National Prescription Opiate Litigation*, N.D. Ohio Case No. 1:17-MD-2804). As part of the Department's participation, DEA is providing the parties and the Court with access to ARCOS data and other DEA information subject to a protective order that appropriately safeguards sensitive commercial information and business records.

4. **<u>Public Health Emergency Declaration</u>: On October 26, 2017, President Trump directed the Department of Health and Human Services to declare the opioid crisis a public health emergency. The declaration enables relevant agencies to reprogram**

existing Public Health Service Act funds to better address opioid overdose deaths. Has DEA reprogrammed any existing funds as a result of the public health emergency declaration?

Response: No. DEA is not a recipient of Public Health Service Act funds.

5. **The White House stated that the declaration "allows for expanded access to telemedicine services, including services involving remote prescribing of medicine commonly used for substance abuse or mental health treatment." Does this action require the Justice Department/DEA to issue new regulations? If so, is DEA currently drafting these regulations, and when will they take effect? If not, why not?**

Response: Telemedicine is currently authorized for controlled substances under certain very specific circumstances in accordance with Section 102(54) of the CSA. 21 U.S.C. § 802(54). The patient must physically go to a DEA-registered location (hospital or clinic), the prescribing practitioner who is at a location remote from the patient must be acting in the usual course of his/her practice, and this activity must be done in accordance with the applicable Federal and state laws. The practitioner must use multimedia devices, including approved audio and visual equipment at a minimum, to communicate with the patient or health care professional who is treating the patient.. If the patient does not go to a hospital or clinic, then the patient has to be in the physical presence of a DEA-registered practitioner. DEA is drafting regulations to implement the provision dealing with the special registration for telemedicine.

6. **Balance Between Ensuring Compliance and Enforcement: The Controlled Substances Act requires manufacturers and distributors of controlled substances, among others, to register with DEA. If a registrant has violated the law, DEA may respond in a number of ways. In this capacity, DEA has the opportunity to both help registrants maintain compliance with the Controlled Substances Act, as well as to take enforcement action for failure to comply.**

    a. **To what degree does DEA prioritize proactively working with its registrants to ensure compliance before it escalates to the point where enforcement action is required?**
    b. **Does DEA work with manufacturers and distributors to help them understand what constitutes a suspicious order? Please explain.**
    c. **If a manufacturer or distributor reports a suspicious order to DEA, does DEA follow up with them to tell them whether they should stop delivering opioids to a particular recipient on a permanent basis? If not, why not?**

Response: The Diversion Control Division is consistently working with its registrants to ensure compliance before it escalates to the point where enforcement action is required – through constant communication between Diversion Investigators and the registrant population as well as DEA-sponsored conferences, participation in industry conferences, as well as various other informal and formal meetings and correspondence.

Yes, DEA's Diversion Control Division has issued a variety of correspondence to manufacturers and distributors at various points to clearly explain the responsibility of the registrant to report suspicious orders, as well as what is defined as a suspicious order under currently regulations. The Diversion Control Division has also spoken on this subject at DEA-sponsored conferences that have been held specifically for manufacturers and distributors, as well as at industry-sponsored conferences.

DEA has maintained that it is up to the individual company whether or not they decide to fulfill that suspicious order and that the company should complete their own due diligence before determining whether it is a suspicious order that should be reported to DEA. It is considered part of "knowing their customer."

Questions from Senator Orrin Hatch

1. **As you know, DEA sets annual quotas, or production limits, on controlled substances. Given DEA's concerns about diversion and misuse, why didn't DEA reduce quotas for key opioids like oxycodone, oxymorphone, and hydrocordone until 2016, well after the opioid crisis was underway?**

Response: Aggregate production quotas (APQs) are established through notice and comment rulemaking procedures after an assessment of the factors described in 21 C.F.R. § 1303.1 l(b). The following outlines the considerations DEA takes into account when proposing APQs for the following year including:

1. Total net disposal of the class by all manufacturers during the current and two preceding years;
2. Trends in the national rate of net disposal of the class;
3. Total actual (or estimated) inventories of the class and of all substances manufactured from the class, and trends in inventory accumulation;
4. Projected demand for such class as indicated by procurement quotas requested pursuant to 21 C.F.R. § 1303.12; and
5. Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

In this way, the APQs represent more than retail sales resulting from prescriptions issued by practitioners nationwide. The APQs include quantities required for product development, manufacturing losses, research, exports, various categories of non-saleable materials, and inventory levels of 50 percent for bulk manufacturers. Since the APQs are determined by a number of factors (see above), the APQ values can vary based on the number and status of new products being researched (material set aside and not saleable), international contracts (for exports), manufacturers establishing contracts with backup Active Pharmaceutical Ingredient (API) suppliers, and new manufacturers entering the market conducting Food and Drug Administration (FDA) validation batches.

2. **DEA reduced the quotas for amphetamines in the 1970s, Quaaludes in the 1980s, and ephedrine more recently when it became clear that each of those substances was being abused. Why did it take DEA so long to reduce the quotas for opioids?**

Response: The APQ for the following year is established based on the best actual and forecasted data provided to DEA in a timely manner in the Spring of the previous year, from various sources as required by 21 C.F.R. § 1303.11. Throughout the course of the following calendar year, each individual manufacturer's quota request is analyzed using actual year-to-date data at the time of submission and annualized for the remainder of the calendar year.

This quota review process allows DEA to administer quota allotments based on current trends and recent changes in an individual manufacturer's national rates of disposal, FDA notifications, changes in production cycles, current inventory position, as well as yield, stability, and recall issues. *See* 21 C.F.R. § 1303.23 - 1303.26 and 1303.12. This individualized analysis typically results in lower individual quota allotments than originally predicted by DEA, which were based on actual and forecasted data received from the various sources during the initial APQ analysis completed prior to the start of the calendar year.

Since 2014, DEA has observed a decline in prescriptions written for certain Schedule II opioids. These declines have led to overall reductions in licit demand, which in turn, have directly impacted the factors DEA considers when establishing the APQs for Schedule II opioids. In October 2016, DEA announced a 25 percent reduction (or more) in the 2017 APQs for many prescription opioids, including oxycodone, hydrocodone, fentanyl, hydromorphone, and morphine. Hydrocodone was reduced to 66 percent of the previous years' (2016) level. In late 2017, DEA announced a nearly 20 percent reduction in the 2018 APQs (from the 2017 levels) for controlled substances, and these reductions included the aforementioned opioids as well as oxymorphone, codeine, and meperidine. These decreases can be attributed to combined local, state, and federal activities and interventions, including creating new partnerships, enforcing current regulations, and dissemination of provider education and guidance documents, including the Centers for Disease Control (CDC) *Guideline for Prescribing Opioids for Chronic Pain* released in March 2016. In addition, we are encouraged that more states have enacted and enforced laws mandating the use of PDMPs by medical providers and pharmacists which provides prescribers with valuable information to guide their medical decisions.

3. **GAO reported in February 2015 that DEA "does not have protocols, policies, training materials, or other documentation to manage the quota process" and that "DEA officials told [GAO] that they ensure consistency in their decision-making by having the Deputy Assistant Administrator of the Office of Diversion Control review and authorize every quota decision that is made." Who was the Deputy Assistant Administrator over diversion control at the time of the GAO report? Am I correct to understand that this individual signed off on every quota DEA set until he or she left the agency?**

Response: Mr. Joseph T. Rannazzisi, and yes, either Mr. Rannazzisi or his acting designee signed off on every quota DEA set while serving as the Deputy Assistant Administrator of the Office of Diversion Control (now the Diversion Control Division).

4. **At the hearing, I asked whether DEA authorized DEA Chief Administrative Law Judge John Mulrooney to publish his forthcoming article on the *Ensuring Patient Access and Effective Drug Enforcement Act* and what DEA's reaction was when it saw the article. You did not have answers to these questions at hand. I'd like to ask these questions again in written form, now that you have the ability to conduct some more investigation. To repeat, the questions are:**

a. **Did DEA authorize Judge Mulrooney to publish his forthcoming law review article on the *Ensuring Patient Access and Effective Drug Enforcement Act*?**
b. **What was DEA's reaction when it saw Judge Mulrooney's article?**

Response: As noted in DEA's February 2, 2018 response to Chairman Grassley, DEA policy requires that any publication of written material by DEA personnel, which may reasonably be interpreted as relating to the responsibilities, program, or operations of DEA, and gained as a result of their position with DEA, must be submitted and cleared through DEA's Publication Review Board (PRB). A search of PRB databases has found no record that Administrative Law Judge Mulrooney sought PRB clearance for any law review article as required by DEA policy.

5. **The *Washington Post* has reported that DEA was "forced" to accept a deal with Congress on the *Ensuring Patient Access and Effective Drug Enforcement Act* and quoted an unnamed DEA official as saying that Congress "would have passed this [law] with or without us." Please identify any comments or statements of which you or the agency is aware in which Senator Hatch, Senator Whitehouse, or Senate staff indicated they did not care about DEA's views on the bill, intended to move the bill forward regardless of DEA's views on the bill, or intended to move the bill forward even if DEA opposed the bill.**

Response: DEA acknowledges that it engaged heavily with Congress and provided technical assistance on the legislative proposals in both the House and Senate. Following the passage of H.R. 4709, DEA and the Department began to proactively engage with Members of the Senate. In August 2014, DEA and Department staff briefed Senator Grassley, Senator Whitehouse, and Senator Leahy's staff on their concerns with the "ISO standard" that the House had passed the preceding month. During these meetings, DEA and the Department offered to provide technical assistance relating to the statutory definition for "imminent danger to the public health and safety." Throughout the 1.5 years of negotiations, DEA and the Department steadfastly stated their belief that changes to the manner in which DEA issues ISOs and OTSCs were unnecessary and sought to fix a problem that did not exist. However, DEA and the Department did not formally object to the bill.

6. **Did DEA have its own, internal definition of "imminent danger to the public health or safety" prior to the *Ensuring Patient Access and Effective Drug Enforcement Act*?**

    a. **If yes: What was that definition? How was it different from the definition in the *Ensuring Patient Access and Effective Drug Enforcement Act*? When did DEA establish that definition? Why didn't DEA publish that definition or make it public?**
    b. **If no: How did DEA determine whether conduct rose to the level of imminent danger to the public health or safety?**

Response: The facts and circumstances necessarily vary from case to case; therefore, it would have been inappropriate for DEA to have adopted a formulaic interpretation of imminent danger. Rather, and consistent with the legal standard Congress implemented in the CSA governing ISOs, DEA in every case evaluated the facts and circumstances and made a determination of

whether, taken together, the registrant's continued registration posed an imminent danger to public health or safety—and thus whether an ISO would be legally viable. Following Congress' enactment of EPAEDEA, DEA has pursued ISOs when the facts and circumstances, taken together, demonstrate an "imminent danger" as defined by Congress under EPAEDEA.

7. **Distributors and manufacturers are required to report their sales of opioids and certain other controlled substances to DEA through the Automation of Reports and Consolidated Orders System (ARCOS).**

    a. **Please describe how DEA uses ARCOS data.**
    b. **Does DEA share any ARCOS data with distributors?**
        i. **If yes: Describe the types of ARCOS data shared with distributors.**
        ii. **If no: Why doesn't DEA share even aggregated ARCOS data with distributors so that distributors can identify customers that may be receiving extraordinary volumes of drugs from other distributors? Describe any legal constraints DEA believes prohibit it from sharing ARCOS data with distributors.**

Response: ARCOS is a data collection system in which manufacturers and distributors report their controlled substances transactions to DEA. ARCOS provides an acquisition/distribution transactional records of applicable activities to DEA involving certain controlled substances, in accordance with 21 U.S.C. § 827(d)(1) and 21 C.F.R. § 1304.33. This information is collected and compiled by DEA in accordance with law for determining quota, distribution trends, internal audits, and other analyses.

DEA must protect the commercial information of innocent parties. It is the policy of the U.S. government—enforced by the threat of criminal sanction—to protect as confidential the business records commercial enterprises are compelled to give the government. *See* 18 U.S.C. § 1905 ("Whoever, being an officer or employee of the United States or of any department or agency thereof . . . publishes, divulges, discloses, or makes known in any manner . . . any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment."). For this reason, DEA does not generally disclose information to the public that it believes is either confidential or proprietary. An important exception to this rule is the manner in which DEA cooperates with and shares information with local, State, tribal, and Federal Agencies. *See* 21 U.S.C. § 873.

Nevertheless, DEA is exploring ways to expand the use of ARCOS information to combat diversion. For example, on February 15, 2018, DEA launched a new tool within its ARCOS Online Reporting System to assist drug manufacturers and distributors with their

regulatory obligations under the CSA. Specifically, the tool allows a distributor or manufacturer to enter the DEA registration number of a prospective purchaser (pharmacy, hospital, doctor, etc.) as well as the 4-digit drug code for the controlled substance the buyer wishes to purchase and the ARCOS application will return a count of the number of registrants who have sold that particular controlled substance to that prospective purchaser in the last 6-months. The goal of this tool is to provide information that will help distributors to identify red flags while also protecting the confidential nature of the business information that registrants expect us protect.

DEA shares ARCOS information with state and local law enforcement entities pursuant to 28 C.F.R. § 0.103, on a case-specific basis, to assist in their efforts to combat diversion. DEA is in the midst of negotiations with state attorneys general to develop a framework to make ARCOS information generally available to their investigators. The Department is participating as a "friend of the court" in the ongoing Federal multi-district Litigation against opioid manufacturers and distributors that has been brought by state and local governments (In Re: *National Prescription Opiate Litigation*, N.D. Ohio Case No. 1:17-MD-2804). As part of the Department's participation, DEA is providing the parties and the Court with access to ARCOS data and other DEA information subject to a protective order that appropriately safeguards sensitive commercial information and business records.

DEA, as part of its efforts to continue engagement with distributors, 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 sale 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 that particular field division's diversion investigators on policy changes, new systems and regulations, and other relevant information.

Questions from Senator John Kennedy

1. **Please list the top ten highest ranking officials at the DEA at the time the Ensuring Patient Access and Effective Drug Enforcement Act was passed who supported the bill.**

2. **Please list the top ten highest ranking officials at the DEA at the time the Ensuring Patient Access and Effective Drug Enforcement Act was passed who opposed the bill.**

Response: Former DEA Administrator Michelle Leonhart, coordinating directly with the Deputy Attorney General and the Department's Office of Legislative Affairs, met with House Judiciary Committee Chairman Goodlatte on July 23, 2014, to express DEA's very serious concerns with H.R. 4709, an earlier version of the EPAEDEA that would later pass the House under Suspension of the Rules on July 29, 2014. This bill had been considered by the House Energy & Commerce Committee a month earlier, in June 2014, and was under consideration by the House Judiciary Committee. The bill contained a significant standard for issuing ISOs by including a requirement that the Government establish that a registrant "intentionally" distributing or dispensing controlled substances in a manner that poses a present or foreseeable risk of serious adverse health consequences or death. Administrator Leonhart asserted that this definition would restrict DEA from taking action in instances of negligence, gross negligence, and reckless conduct and would completely disregard health consequences or death.

It is important to note that H.R. 4709, which was not considered in the Senate, was reintroduced in the 114th Congress on January 22, 2015, and was passed, without amendment on April 21, 2015. DEA and the Department continued their opposition to this version throughout the 114th Congress.

Following the passage of H.R. 4709, DEA and the Department began proactively engaging with Members of the Senate. In August 2014, DEA and Department staff briefed Senator Grassley, Senator Whitehouse, and Senator Leahy's staff on their concerns with the "ISO standard" that the House had passed the preceding month. During these meetings, DEA and the Department offered to provide technical assistance relating to the statutory definition for "imminent danger to the public health and safety." Throughout the 1.5 years of negotiations, DEA and the Department steadfastly stated their belief that changes to the manner in which DEA issues ISOs and OTSCs were unnecessary and sought to fix a problem that did not exist.

3. **Please give us a brief overview of the position the DEA took at the time the Ensuring Patient Access and Effective Drug Enforcement Act was passed and how that position has changed. What practical reasons can you point to for this change in position?**

4. **During the hearing, you mentioned that the DEA and DOJ both support a change to current law and promised to get me a letter with specific fixes and amendments you believe will help with over production and over prescription. I look forward to hearing from you within 30 days.**

Response: The Department and DEA's position has always been that EPAEDEA legislation tried to solve a problem that did not exist. In the midst of this opioid epidemic, the Department and DEA need maximum flexibility within each of its available tools to ensure compliance with the CSA.

DEA supports amending EPAEDEA and offered technical assistance on Senator Feinstein's draft legislation that was provided by the Department on February 28, 2018. In addition, DEA and Department staff have briefed Senate Judiciary staff twice in person regarding the Department's position with respect to amending EPAEDEA.