



**U.S. Department of Justice**

Office of Legislative Affairs

---

Office of the Assistant Attorney General

*Washington, D.C. 20530*

**MAY 01 2015**

The Honorable Fred Upton  
Chairman  
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 Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the Committee on April 7, 2014, at a hearing entitled "Improving Predictability and Transparency in DEA and FDA Regulation." We hope that this information is of assistance to the Committee.

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,

A handwritten signature in blue ink, appearing to read "Peter J. Kadzik".

Peter J. Kadzik  
Assistant Attorney General

Enclosure

cc: The Honorable Frank Pallone, Jr.  
Ranking Member

**Questions for the Record**  
**Deputy Assistant Administrator Joseph T. Rannazzisi**  
**Drug Enforcement Administration**  
**Committee on Energy and Commerce**  
**U.S. House of Representatives**  
**“Improving Predictability and Transparency in DEA and FDA Regulation.”**  
**April 7, 2014**

**Questions Posed by the Honorable Joseph R. Pitts**

- 1. We have been hearing from pharmacies that their wholesalers are cutting them off for ordering above the “normal” amount. Will you describe your expectations of wholesalers and what guidance has been provided to wholesalers in the last year to help them conduct due diligence on their customers?**

**Response:**

The U.S. Department of Justice Drug Enforcement Administration (DEA) regulations require non-practitioners such as wholesale distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” (21 C.F.R. § 1301.74(b).) Further, all DEA registrants “shall provide effective controls and procedures to guard against theft and diversion of controlled substances.” (21 C.F.R. § 1301.71(a).) One factor relevant to compliance with the security requirements is the “adequacy of the registrant’s . . . system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.” (21 C.F.R. § 1301.71(b)(14).)

In recent years, DEA has steadily increased the frequency of compliance inspections of specific categories of registrants, such as manufacturers (including bulk manufacturers), distributors, pharmacies, and certain practitioners. This renewed focus on oversight has enabled DEA to take a more proactive approach to educating registrants and ensuring that they understand and comply with the Controlled Substances Act (CSA) and its implementing regulations. DEA conducts approximately 6,000 regulatory inspections every year to ensure compliance with Federal laws and regulations. Each inspection entails close communication between DEA and the registrant to educate the registrant about proper procedures and to ensure corrective action is taken to comply with the law. These inspections typically result in remediation or continued compliance, and no further action is taken. DEA conducts compliance inspections of registered distributors every two years.

DEA’s Distributor Initiative Program was implemented in late 2005 and was designed to educate wholesale distributors that were supplying diversion schemes such as rogue Internet pharmacies and more recently rogue pain clinics and rogue pharmacies. The goal of the

program is to cut off the source of supply to these or other schemes through effective due diligence and monitoring for suspicious orders.

As stated above, wholesale distributors are required to design and operate a system that would disclose suspicious orders to the registrant and report those suspicious orders to DEA. Through the Distributor Initiative Program, DEA provides registrants with information such as “red flags,” trending information, and data analysis that they should be aware of prior to distributing controlled substances. Factors that should generally be considered include, but are not limited to: the type of drug(s) ordered (e.g., the breadth and schedule of controlled substances ordered); orders of unusual size; orders that deviate from a normal pattern; frequency of orders, and the percent of controlled and non-controlled substances ordered.

In June 2013, DEA held a two-day Manufacturers/Importers/Exporters Conference, which provided a forum to present Federal laws and regulations that affect the pharmaceutical and chemical manufacturing, importing, and exporting industry and to discuss practices designed to detect and prevent diversion. In addition, topics such as quotas, year-end reporting, Automation of Reports and Consolidated Ordering System (ARCOS) reporting, import/export permits, and import/export declarations were discussed. Approximately 370 people attended, representing over 200 registrants. Currently, there is a Manufacturers/Importers/Exporters Conference tentatively scheduled for September 22-24, 2015.

DEA has also held two Distributor Conferences, most recently on April 15-16, 2015, and previously on October 22, 2013. These conferences provided an overview of federal laws and regulations that affect pharmaceutical and chemical distributors, such as recordkeeping, ARCOS, and suspicious order monitoring.

**2. Does DEA conduct an investigation on pharmacy registrants when wholesalers have reported suspicious orders for a particular pharmacy? Can other wholesalers continue to serve that pharmacy?**

**Response:**

Reported suspicious orders are just one factor that is considered amongst many when determining a course of action with respect to registered pharmacies.

Each registered distributor must determine, based on all of the circumstances, whether the fact that one distributor has reported suspicious orders from a particular pharmacy bears on subsequent ordering activity of the particular pharmacy.

**3. Does DEA conduct due diligence on an initial application for DEA registration (pharmacy, wholesaler, physician, etc.)? What does that involve?**

**Response:**

DEA's responsibilities with respect to registering entities are outlined in the CSA 21 U.S.C. § 823. Generally, there are five or six factors depending on the type of registration, for example: maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels; compliance with applicable state and local law; prior conviction record of applicant under Federal or state laws relating to the manufacture, distribution, or dispensing of such substances; past experience in the distribution of controlled substances. DEA must consider these factors when determining whether to register a manufacturer, distributor, or practitioner (e.g., a pharmacy or physician). DEA carefully reviews each applicable factor. Before denying an application for registration, DEA is required to provide the applicant with notice and an opportunity to appear before an independent fact-finder to show cause as to why the registration should not be denied.

**Questions Posed by the Honorable Michael C. Burgess**

4. **I am hearing that DEA actions are causing great difficulties for legitimate patients that are not able to access the medications they need to manage chronic pain. According to DEA's website, "the mission of DEA's Office of Diversion Control is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate supply for legitimate medical, commercial, and scientific needs."**
- A. **How does DEA ensure that it's regulatory and enforcement actions are not having the unintended consequences of causing harm to legitimate patients?**

**Response:**

The CSA and its implementing regulations have established a closed system of distribution so that a controlled substance is at all times under the legal authority of an entity registered with DEA, or specifically exempted from registration, until the controlled substance reaches the ultimate user (e.g., patient), or is destroyed. This closed system helps DEA detect and prevent diversion of controlled substances by controlling and monitoring the movement of these substances along the supply chain. DEA routinely works with manufacturers to ensure that an adequate and uninterrupted supply of pharmaceutical controlled substances and listed chemicals is available to meet the legitimate medical, commercial, and scientific needs of the United States. DEA has no authority to direct what a company must manufacture, how much to manufacture, when to introduce such products into the supply chain, or what pharmaceutical controlled substances a pharmacy may legitimately dispense to its patients.

Although DEA is the agency responsible for enforcing the CSA, DEA does not act as the federal equivalent of a state medical board overseeing or regulating the general practice of medicine. DEA has consistently emphasized and supported the prescriptive authority of an individual practitioner under the CSA to administer, dispense, and prescribe controlled substances for the legitimate treatment of pain within acceptable medical standards as outlined in the DEA Statement of Policy published in the Federal Register on September 6, 2006, titled, *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52716, and DEA Clarification published on August 26, 2005, titled, *Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances*, 70 Fed. Reg. 50408.

- B. **Does DEA meet with chronic pain patient groups and others to ensure that the agency understands the needs and concerns of patients?**

**Response:**

DEA routinely responds in writing to inquiries from patients and patient advocacy groups. In the last two years, DEA has adopted a more proactive approach to educating registrants through

holding Pharmacy Diversion Awareness Conferences (PDACs) throughout the country, as discussed later in these responses. DEA has directed resources to these PDACs in order to reach as many registrants as possible. During this timeframe, no chronic pain patient groups or other related groups have requested meetings; however, if such a meeting were to be requested, DEA would consider meeting with the group in order to listen to their concerns.

5. **The Federal Controlled Substances Act (CSA) has been federal law since the early 1970's. Despite decades of DEA enforcement actions, it seems that the drug abuse problem continues unabated, whether the problem is heroin, cocaine, morphine, oxycodone, hydrocodone, etc. Do you not think it is long past due to take a step back and bring together a wide variety of stakeholders to agree upon new solutions to combat drug abuse, as has been proposed by H. R. 4069?**

**Response:**

DEA conducts a number of outreach initiatives intended to educate registrants on their responsibilities, discuss suspicious order monitoring, and respond to other registrant inquiries. This includes hosting regular conferences with manufacturers, distributors, and pharmacists to discuss their ongoing registrant obligations. DEA also educates parents, community leaders, and law enforcement personnel regarding diversion trends, the scope of the prescription drug diversion problem, and how to best address prescription drug diversion in communities throughout the United States.

Further, the Office of National Drug Control Policy's (ONDCP) Prescription Drug Abuse Prevention Plan expands upon the Administration's *National Drug Control Strategy* and includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement. DEA plays an important role in all four of these areas. These outreach initiatives are discussed in greater detail below.

**Education**

The Department of Justice (the Department) focuses on education as a crucial first step in preventing prescription drug abuse. Through its Demand Reduction Program, DEA delivers educational content via its websites [www.GetSmartAboutDrugs.com](http://www.GetSmartAboutDrugs.com) and [www.JustThinkTwice.com](http://www.JustThinkTwice.com). These websites serve as a resource to parents, caregivers, educators, professionals, and teens. DEA also focuses on reducing the demand for illicit drugs, including the abuse of prescription drugs, through its Red Ribbon Week programming, partnerships with other Federal, state, local and non-profit organizations, and numerous publications made available to the general public.

DEA also provides education and guidance to industry professionals such as pharmacists, distributors, and manufacturers by delivering information to registrants, professional associations, and industry organizations on current diversion and abuse trends of pharmaceutical drugs and listed chemicals. DEA also provides information and guidance concerning new and existing programs, policies, legislation, and regulations. DEA's Diversion

Control Program establishes and maintains liaison and working relationships with other Federal agencies, state and local governments, regulated industries, industry organizations, professionals, professional associations, and regulatory boards that interface with DEA regarding diversion matters. In Fiscal Year (FY) 2014, DEA conducted more than 75 public education and outreach events regarding prescription drug abuse. Because of the importance of these activities in addressing prescription drug abuse, the Department has included an Education and Outreach component to DEA's performance measures.

The following reflect the kinds of outreach initiatives undertaken by DEA's Diversion Control Program:

- DEA, along with state regulatory and law enforcement officials, and in conjunction with the National Association of Boards of Pharmacy, hosts Pharmacy Diversion Awareness Conferences (PDACs) throughout the country. Each one-day PDAC is held on Saturday or Sunday for the convenience of the pharmacy community. The conferences are developed and designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. Topics addressed include pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners, with the objective of educating pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity.
- During FY 2013, DEA hosted 18 PDACs in eight states. Further, DEA hosted 16 PDACs in eight states during FY 2014. As of March 18, 2015, DEA hosted two PDACs in one state in FY 2015. Since DEA began hosting PDACs in 2011, through February 8, 2015, more than 7,841 pharmacy professionals have attended these educational conferences. There are 14 additional proposed PDACs in seven states for FY 2015.
- The Manufacturers/Importers/Exporters Conference held on June 18-19, 2013, provided a forum to present federal laws and regulations that affect the pharmaceutical and chemical manufacturing, importing, and exporting industry and to discuss practices to prevent diversion while minimizing the impact on legitimate commerce. In addition, topics such as quotas, year-end reporting, ARCOS reporting, import/export permits and import/export declarations were discussed. Approximately 370 people attended, representing more than 200 registrants. There is a Manufacturers/Importers/Exporters Conference tentatively scheduled for September 22-24, 2015.
- The Distributor Conference was held on October 22, 2013. This conference provided an overview of federal laws and regulations governing issues that affect pharmaceutical and chemical distributors, such as recordkeeping, ARCOS, and suspicious order reporting. A Distributor Conference was held on April 15-16, 2015.
- The National Conference on Pharmaceutical and Chemical Diversion was held on September 30 through October 1, 2014. This national conference was held to facilitate the exchange of information between DEA and their state and local counterparts who focus on combating the diversion of pharmaceutical controlled substances and regulated

chemicals. Attendees included individuals from state and local agencies who are responsible for regulatory drug or chemical control as well as operational personnel whose investigations target the diversion of licitly manufactured controlled substances and regulated chemicals. Approximately 70 people attended.

- To better assist DEA registrants with their understanding of the CSA and implementing regulations, manuals are drafted and made available to the public. The manuals are not considered legal documents. Readers are instructed to refer to the most current copy of the CSA, the Narcotic Addict Treatment Act of 1974, the Drug Addiction Treatment Act of 2000, the Code of Federal Regulations (C.F.R.), and Federal Register Notices to obtain complete and accurate information. The following manuals are available via DEA website:
  - Chemical Handler's Manual
  - Pharmacist's Manual
  - Practitioner's Manual

Additionally, DEA established the Distributor Initiative Program in August 2005 to educate and inform distributors of their responsibilities under the CSA and its implementing regulations by discussing suspicious order monitoring systems, reviewing sales and purchase data, and discussing national trends involving the abuse and diversion of controlled substances. This program was initially designed to educate wholesale distributors who were supplying controlled substances to rogue Internet pharmacies and, more recently, to diverting pain clinics and pharmacies. The goal of this educational program is to increase distributor awareness and vigilance so that they cut off the source of supply to these and other schemes.

### Monitoring

One of the best ways to combat the rising tide of prescription drug abuse is the implementation and use of Prescription Drug Monitoring Programs (PDMPs). PDMPs are typically state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement. These programs are established through state legislation and are tailored to the specific needs of a particular state. PDMPs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists.<sup>1</sup> However, in many states with operational PDMPs, participation by prescribers and dispensers is voluntary, with utilization rates well below 50%.<sup>2</sup> The Brandeis University Center of Excellence developed a PDMP Management Tool, which recommends calculating the number of in-state prescribers with PDMP accounts as a percentage of the number of in-state prescribers who issued controlled substance prescriptions during the prior year. Based on this calculation, for example, in Florida just 18% of the in-state prescribers who issued more than one controlled substance prescription have registered to use the database (11,408 in-state prescribers signed up for PDMP accounts out of the 62,238 in-

---

<sup>1</sup> This statement applies to all schedules. However, while many prescription monitoring programs cover all schedules, some programs apply only to controlled substances in Schedule II.

<sup>2</sup> The Brandeis University PDMP Center of Excellence, retrieved 12/18/14  
<http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps>.

state prescribers who issued controlled substance prescriptions during the prior year).<sup>3</sup> While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent prescription drug abuse and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, the use of PDMPs is limited across state lines because interconnectivity remains a challenge; at the same time, many drug traffickers and other drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous prescribers and dispensers. Also, not everyone who is using/misusing/abusing is being captured by PDMPs, because PDMPs only capture prescriptions for individuals for whom the drug is intended. According to data from the 2013 National Survey on Drug Use and Health, among persons aged 12 or older in 2012-2013 who used pain relievers nonmedically in the past 12 months, 53.0 percent got the drug they used most recently from a friend or relative for free, and 10.6 percent bought the drug from a friend or relative.

The Department continues to support and encourage the development and maintenance of Prescription Drug Monitoring Programs at the state level. Currently, 49 states have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users). The District of Columbia has enacted legislation enabling the establishment of a PDMP; Missouri has no PDMP. As of June 2014, only 20 states had laws mandating that prescribers and in some cases dispensers enroll with their state's PDMP, and 22 states had laws mandating that prescribers in some cases dispensers use the PDMP in certain circumstances.

The Department has also supported the development of PDMPs through the Harold Rogers Prescription Drug Monitoring grant program, distributing a total of over \$87 million from FY 2002 to FY 2014, including \$7 million in FY 2014. The purpose of this grant program is to plan, implement, and enhance PDMPs. It focuses on providing help for states that want to establish a PDMP or expand an existing PDMP. In 2012, the Department provided further policy guidance on data sharing efforts among state PDMPs, a critical aspect of the program.

#### Proper Medication Disposal

Prior to the passage of the Secure and Responsible Drug Disposal Act of 2010, enacted in October 2010 (Pub. L. 111-273) (Disposal Act), the CSA provided no legal means for ultimate users to transfer possession of controlled substance medications to other individuals for disposal. The Disposal Act amends the CSA to authorize ultimate users and Long Term Care Facilities (LTCFs) to deliver controlled substances to another authorized person for the purpose of disposal in accordance with regulations promulgated by DEA.

On September 9, 2014, DEA published in the Federal Register the final rule on the Disposal of Controlled Substances. The final rule became effective on October 9, 2014, and it implements the Disposal Act by establishing requirements that allow authorized registrants to develop secure, ongoing, and responsible methods for ultimate users and LTCFs to dispose of pharmaceutical controlled substances. The final rule expands the options available to collect controlled substances from ultimate users for the purpose of disposal, including: (1) take-back

---

<sup>3</sup> Electronic-Florida Online Reporting of Controlled Substances Evaluation, 2013-2014 Prescription Drug Monitoring Program Annual Report, published December 1, 2014.

events; (2) mail-back programs; and (3) collection receptacle locations. These regulations contain specific provisions that:

- Recognize the continuing authority of law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles;
- Allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles; and
- Allow authorized retail pharmacies and hospitals/clinics with an on-site pharmacy to voluntarily maintain collection receptacles at long term care facilities.

In addition, DEA conducted nine Prescription Drug Take-Back Days from September 2010 to September 2014. Each take-back day provided the public with thousands of sites nationwide to turn in their unwanted or expired prescription drugs safely and securely. On September 26, 2014, the most recent National Prescription Drug Take-Back Day, 617,150 pounds (309 tons) of prescription medications were collected from members of the public. As a result of all nine National Prescription Drug Take-Back Days, DEA, in conjunction with its state, local and tribal law enforcement partners, removed a total of just under 4.9 million pounds (2,411 tons) of medications from circulation. Although law enforcement continues to have discretion with respect to take-back events, DEA discontinued this nationwide program because the new final rule on the Disposal of Controlled Substances provides the public with expanded options to safely and responsibly dispose of their unused and unwanted, lawfully-possessed pharmaceutical controlled substances through collection receptacles and mail-back packages. This rule allows for ongoing medication disposal, thereby ridding the home of unused or unwanted drugs that pose a poisoning hazard or can be diverted.

### Enforcement

The Department, via DEA's Diversion Control Program, is using all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit manufacture and distribution of pharmaceutical controlled substances in violation of the CSA. The deployment of Tactical Diversion Squads (TDSs) is DEA's primary method of criminal law enforcement in the Diversion Control Program. The recent expansion of the TDS program has resulted in 66 operational TDSs throughout the United States, covering 41 states, Puerto Rico, and the District of Columbia. These TDSs incorporate the enforcement, investigative, and regulatory skill sets of DEA Special Agents, Diversion Investigators, other Federal law enforcement, and state and local Task Force Officers. The expansion of the TDS groups has enabled the Diversion Groups to concentrate on the regulatory aspects of the Diversion Control Program.

Several DEA investigations of rogue pain clinics in Southern Florida have resulted in charges against 172 individuals, including 51 doctors and 24 clinic/pharmacy owners, the seizure of approximately 2.5 million dosage units of controlled substances, and approximately \$16.6 million in currency, real property, and exotic cars. In addition, approximately 42 doctors and 11 pharmacies lost their DEA registrations. Approximately 192 doctors and 68 pharmacies

voluntarily surrendered their DEA registrations.

In addition to the focus on criminal law enforcement, the Department of Justice also dedicates resources to civil and regulatory matters. DEA is pursuing additional actions when registrants and other entities violate the law. For example, in March 2013, United Parcel Service (UPS) agreed to a \$40 million settlement with the Department for payments it received from illicit online pharmacies. This settlement is part of a non-prosecution agreement with the United States Attorney's Office for the Northern District of California (San Francisco) and is the result of a five-year investigation of 12 rogue internet pharmacies. This investigation resulted in 43 convictions, \$34 million in seized assets, and forfeiture orders totaling \$51 million.

During 2013, DEA, together with the United States Attorneys' Office for the Western District of Oklahoma and the Southern District of Florida, pursued significant regulatory and civil actions in two cases where registrants violated provisions of the CSA. In April 2013, CVS Pharmacy, Inc. executed an \$11 million settlement agreement in which it agreed to pay a civil penalty for CSA violations and failure to keep proper records of pharmacy sales. In June 2013, Walgreens Corporation agreed to pay \$80 million in civil penalties for actions by their distribution center and six pharmacies in Florida that resulted in the diversion of millions of dosage units of oxycodone, a powerful schedule II painkiller. Their actions helped fuel a prescription drug epidemic in the State of Florida over several years.

While some issues related to prescription drug abuse have worsened in recent years, particularly along the heroin-prescription opiate vector, the Department's continued focus on prescription drug abuse has yielded significant improvements in many areas. For example, the substantial civil penalties and settlements with CVS, Walgreens, and UPS, described above have signaled the serious potential consequences for companies and registrants that fail to recognize the dangers of prescription drug abuse and follow the law regarding controlled substances. Further, the Department and DEA have observed significant changes in Florida, where rogue pain clinics have long been known to operate and have helped fuel the prescription drug abuse epidemic in several other states. According to the Florida Department of Health, the number of pain management clinics in Florida as of December 31, 2013, is 360, down from 635 at the end of 2010. In 2010, 90 of the top 100 oxycodone-purchasing physicians in the country were in Florida, but that number dropped to 13 in 2011. The Department will continue to direct efforts towards the issue of prescription drug abuse, with DEA leading as the Nation's principal enforcer of Federal drug laws and regulations.

6. **How do you response to comments that DEA's actions to stop prescription drug abuse are merely causing an increase in the heroin abuse problem? Why does the DEA not adopt more holistic approaches to drug abuse so that shutting off one source of abuse does not simply lead to another substance being abused? Do you not think this leads to perceptions that all DEA cares about are the numbers of enforcement actions and not about real solutions to stop drug abuse?**

**Response:**

DEA is dedicated to protecting the public health and safety by enforcing the CSA, regardless of "the numbers of enforcement actions." Enforcing the CSA necessarily entails taking action against persons or corporations that violate the CSA. Enforcement activity is a measure of effectiveness in maintaining the closed system of distribution. As explained in DEA's written statement for the record, the rise in heroin use is due only in part to the rise in prescription drug abuse. As discussed above, ONDCP has established a comprehensive, four-part plan to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement.

7. **Will you explain DEA's efforts to education physicians about the corresponding responsibility of pharmacists under the CSA? If I understand correctly, the CSA requires a pharmacist, prior to dispensing any controlled substance, to determine if the prescription complies with all legal and regulatory requirements, and whether the prescription has been issued for a "legitimate medical purpose" by a prescriber acting in the usual course of his or her practice. Simply put, this means that pharmacists are required to perform due diligence on each controlled substance prescription before dispensing the medication-this may mean calling back the physician to obtain and confirm certain information before the prescription can legally be dispensed. Yet, it seems that some physicians are unaware of this federal requirement-so written guidance and education seems appropriate. Would you agree more agency education can be done?**

**Response:**

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. (21 C.F.R. § 1306.04(a).) An order purporting to be a prescription issued not in the usual course of professional treatment is not a prescription within the meaning and intent of the CSA and the person knowingly filling such a purported prescription shall be subject to the penalties provided for violations of the law relating to controlled substances. Please see the response to question 2 for further information regarding DEA's education of registrants.

DEA provides education and guidance to registrants, professional associations, and industry organizations on current diversion and abuse trends of pharmaceutical drugs and listed chemicals, new and existing programs, policies, legislation, and regulations. DEA's Diversion Control Program establishes and maintains liaison and working relationships with other federal agencies, state and local governments, regulated industries, industry organizations,

professionals, professional associations, and regulatory boards that interface with DEA regarding diversion matters. In FY 2013, DEA conducted more than 114 public education and outreach events regarding prescription drug abuse.

8. **The Drug Quality and Security Act of 2013 provides for the registration with the Food and Drug Administration of “outsourcing facilities.” These entities are engaged in compounding and distribution of sterile medications in interstate commerce. Sterile medications may contain controlled substances. What plans does the DEA have to require registration of these outsourcing facilities? How will these outsourcing facilities be inspected and reviewed? When will the registration and inspections be conducted? What conversations have been held to date with the FDA to coordinate interagency accountability for appropriate oversight of these outsourcing facilities?**

**Response:**

Depending on the circumstances, compounding by an “outsourcing facility” under section 503B of the Federal Food, Drug and Cosmetic Act (as added by the Drug Quality and Security Act) may be a “manufacturing” activity under the CSA if the medication contains a controlled substance.<sup>4</sup> If so, the CSA requires that these “outsourcing facilities” be registered with DEA as manufacturers. DEA does not differentiate whether a company is applying because it is an “outsourcing facility” or a traditional manufacturer of controlled substances. If the entity’s business activity is manufacturing as defined in the CSA, whether in bulk or dosage units, repackaging/relabeling, or as an “outsourcing facility” under the Drug Quality and Security Act, the entity must apply for a controlled substances registration with DEA as a manufacturer. All manufacturers are subject to the same pre-registration investigation standards.

DEA strives to perform a thorough pre-registration investigation prior to issuing any DEA registration in order to ensure that all registrations are consistent with the applicable standards of the CSA. All applicants applying for a controlled substances registration as a manufacturer with DEA are subject to an onsite inspection by DEA, in which investigators review physical security, recordkeeping, and other operational plans to ensure that issuing a registration would be consistent with the requirements of the CSA. Further, DEA verifies with appropriate state and federal authorities that the entities/individuals have been granted the appropriate authority for their type of business. The timeline for this process varies, as it is dependent upon the complexity of the manufacturer’s business operations.

---

<sup>4</sup> Section 503B(d)(4)(B) of the Drug Quality and Security Act mentions in the definition of outsourcing facility that “an outsourcing facility is not required to be a licensed pharmacy.” Retrieved 4/28/15  
<https://www.congress.gov/113/bills/hr3204/BILLS-113hr3204enr.pdfD>.

- 9. If questions arise during the inspection process, is there a transparent and formal procedure to provide written agency feedback?**

**Response:**

During the pre-registration inspection process, there is an open line of communication between DEA investigators and the applicant. Applicants are given opportunities to provide the investigators with any relevant information pertaining to the statutory factors to be considered when registering a manufacturer. (See 21 U.S.C. § 823(a), (d).) In addition, before DEA could deny a registration as a manufacturer, DEA would be required to provide the applicant with notice and an opportunity to show cause as to why the registration should not be denied, before an independent fact-finder, pursuant to the Administrative Procedure Act. (See 21 U.S.C. § 824(c).)

- 10. Amidst all of the efforts to curb prescription drug abuse, what are you doing to help ensure that legitimate patients can continue to access their prescription pain medications?**

**Response:**

Please see response to question 4.A, above.

- 11. DEA has no mandated timeline for approval. Do you believe it is medically ethical to deny access to a drug for over a year after FDA has determined that the product is safe and effective?**

**Response:**

The process of evaluating and determining the abuse and dependence liability of a substance, and evaluating that liability in light of other already scheduled substances, is complex and drug-specific. Accordingly, the level of analysis required to control each drug is unique and a direct comparison to the timing of the scheduling of other substances is not feasible. Generally, the complexity and length of time it takes for DEA to conduct an analysis depends on many variable factors, including, but not limited, to: the availability of scientific data and literature; the depth and breadth of the available scientific data and literature; the quality of the available data; the reliability of scientific data and conclusions; whether scientific studies must be conducted to determine abuse liability; whether the drug or substance is a new molecular entity or a drug that is already used in medical treatment; whether an interested person requests an administrative hearing; how many public comments are received in response to the scheduling action; the nature and content of any public comments received; and the extent of any regulatory analysis that may be conducted in support of the administrative action, which depends on many factors including how widely the substance or drug is used throughout the United States, who will be affected by the scheduling action, the financial impact on the affected entities, and the impact on the economy and state, local, and tribal governments.

Upon receiving from U.S. Department of Health and Human Services (HHS) a scientific and medical evaluation and a scheduling recommendation for a FDA-approved pharmaceutical product, and pursuant to 21 U.S.C. § 811(b) of the CSA, DEA reviews HHS's scientific and medical evaluation and all other relevant data to determine whether the drug meets the criteria to be controlled under the CSA. DEA must prepare its own review via a scheduling review document, and make the findings necessary for control of the drug. These findings determine the most appropriate schedule for the drug involved. In making findings, DEA must ensure that all factors determinative of control and all findings are supported by scientifically and legally defensible positions.

Upon determining that the drug meets the criteria for control under the CSA, DEA drafts a Notice of Proposed Rulemaking (NPRM) for publication in the Federal Register. Following publication of the NPRM in the Federal Register, there will be a comment period during which the public can make comments to the proposed scheduling of the drug. Once the comment period closes, DEA is required to take each comment under consideration when drafting the Final Rule to schedule the drug.

As described above, a comprehensive and thorough review of each proposed scheduling action is required to control the FDA-approved pharmaceutical. Thus, it is very difficult to estimate the typical amount of time required for each step in the process to be completed. However, DEA utilizes all of its available resources fully so that FDA-approved pharmaceuticals with abuse potential are appropriately controlled and thus are available to the U.S. public in an efficient and timely manner.

**12. When the FDA approves a product that means the drug has been found to be safe and effective for patients suffering for a particular disease, correct?**

**Response:**

DEA defers to the Department of Health and Human Services regarding the approval of substances for human use.

**13. Will 503b OFs be required to be distributors or manufacturers at DEA?**

**Response:**

Where the compounding as contemplated by the Drug Quality and Security Act is a "manufacturing" activity under the CSA, the outsourcing facilities must be registered with DEA as manufacturers. Registered manufacturers may distribute those substances that they manufacture without being separately registered as distributors. Please see the response to question 5 for additional information.

### **Questions Posed by the Honorable Gus Bilirakis**

- 14. FDA has developed a comprehensive inspection program for each sector it regulates-such as drugs, devices, food, cosmetics. In so doing, FDA has established program inspectional manuals, field guidelines, and industry guidelines.**
- A. Does DEA have similar public materials to address the inspection process and compliance issues for DEA registrants within the legitimate manufacturing, distribution and dispensing of controlled substances? If not, why not?**

#### **Response:**

As discussed in Question 5, DEA assists registrants with their understanding of the CSA and implementing regulations by providing manuals. The manuals are not considered legal documents. Readers are instructed to refer to the most current copy of the CSA, the Narcotic Addict Treatment Act of 1974, the Drug Addiction Treatment Act of 2000, the C.F.R., and Federal Register Notices to obtain complete and accurate information. The following manuals are available via the DEA Diversion website ([www.DEADiversion.usdoj.gov](http://www.DEADiversion.usdoj.gov)): Chemical Handler's Manual, Pharmacist's Manual, and Practitioner's Manual.

Aside from the public materials described above, a large majority of manufacturers and distributors are provided the opportunity to learn of their regulatory obligations during conferences. For example, 20 out of the top 25 manufacturers attended DEA's last Manufacturer/Importer/Exporter Conference and they represent 74.4% of the controlled substances in the market. Furthermore, 16 out of the top 25 distributors attended the last Distributors Conference and they represent 76.72% of controlled substances in the market.

- B. How does DEA ensure that its policies across the nation-from region to region and from inspector to inspector-are consistent?**

#### **Response:**

As a law enforcement agency, DEA conducts its inspections and investigations as determined by many factors, including diversion trends and analysis. While the CSA and implementing regulations apply to all registrants equally, DEA may utilize different methods of investigation, or more frequent inspections, depending on the diversion schemes in certain regions of the country, and the individual circumstances of a particular registrant's suspected diversion activities.

**C. Is there a DEA internal quality assurance program?**

**Response:**

DEA provides its investigators with a Diversion Investigator Manual. This manual assists investigators in performing their regulatory duties and ensures uniformity across cyclic investigations. Although this manual provides a general template for regulatory inspections, each inspection may differ based upon the unique circumstances of the registrant, such as the classes of controlled substances handled, volume of business, and other factors. Immediate supervisors and upper management within each DEA Field Office review the investigative reports of all investigators, concurring or not concurring on results as necessary. All investigators must successfully pass the twelve-week Basic Diversion Investigator School prior to entry on duty. Additionally, DEA provides ongoing training for all investigators, including, but not limited to: Regulatory Refresher Courses; Advanced Diversion Investigator Training; Basic and Advanced Interview and Interrogation Training; Diversion Conspiracy and Complex Investigations; Diversion Investigative Training Course; Diversion Financial Techniques; and Prosecuting Diversion Cases. These courses provide investigators with the tools necessary to successfully conduct thorough, uniform, and fair investigations.

**D. Has DEA had its inspection process audited by a third party or OIG?**

**Response:**

No.