



Department of Justice

STATEMENT OF

**JOSEPH T. RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION**

BEFORE THE

**SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES**

FOR A HEARING ENTITLED

**“IMPROVING PREDICTABILITY AND TRANSPARENCY IN DEA AND FDA
REGULATION”**

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Chairman Pitts, Ranking Member Pallone, and distinguished Members of the Committee, on behalf of the men and women of the Drug Enforcement Administration (DEA), I am honored to have the opportunity to appear before you today to provide testimony concerning the Drug Enforcement Administration's efforts to enforce the Controlled Substances Act (CSA) utilizing our administrative authorities.

The Closed System of Distribution and the Registration Requirement

The CSA was designed to halt "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1979 U.S.C.C.A.N. at 4572. Recognizing the need for great scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, Congress established an independent and distinct framework under the CSA that creates a closed system of distribution for all controlled substances. See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970) ("[I]t cannot be overemphasized that the ...[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."). As such, the CSA requires the DEA to establish and maintain a system that strictly controls and monitors the flow of controlled substances in the United States, from the point of importation and manufacture, to distribution, dispensing, and finally, disposal. This is the "closed system of distribution." This framework requires that all those who handle controlled substances (e.g., importers, exporters, manufacturers, distributors, healthcare professionals, pharmacies, and researchers) are registered to do so if their registration is consistent with the public interest, in order to ensure that all controlled substance transactions are legitimate and can be accounted for.

When the DEA was established in 1973, the DEA regulated 480,000 registrants. Today, the DEA regulates more than 1.5 million registrants. As participants in the closed system of distribution, every registrant plays an important part in maintaining the closed system by complying with the CSA and its implementing regulations. Requirements such as recordkeeping, reporting, and physical security are specifically designed to ensure that controlled substances are not diverted to illicit use, and instead are available to meet the legitimate needs of the United States. Other important requirements include the proviso that a practitioner may only dispense (i.e., prescribe or administer) a pharmaceutical controlled substance for a legitimate medical

purpose while acting in the usual course of professional practice. There is also a requirement that all registrants and applicants for registration must “provide effective controls and procedures to guard against theft and diversion of controlled substances.” 21 C.F.R. § 1301.71(a). In fact, failure to maintain effective controls against diversion is a factor that shall be considered when determining whether a manufacturer or distributor’s registration is in the public interest. 21 U.S.C. § 823(a), (b), (d), (e). Distributors must also “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” 21 CFR § 1301.74(b). Finally, certain transactions involving pharmaceutical controlled substances must be reported to the DEA, such as thefts and losses. 21 CFR §§ 1301.74(c), 1301.76(b).

Consequences of Breaching the Closed System of Distribution

Diversion can occur when registrants fail to adhere to their responsibilities under the CSA and its implementing regulations. For example, failing to follow appropriate physical security requirements can leave controlled substances susceptible to diversion. Distributors that blindly sell pharmaceutical controlled substances to rogue pharmacies, and practitioners who issue prescriptions without a legitimate medical purpose are diverting. Diversion fuels abuse.

The problem of prescription drug abuse has increased exponentially in the last 15 years due to a combination of excessive prescribing, drug availability through friends and family, Internet trafficking, rogue pain clinics, prescribers who prescribe pharmaceutical controlled substances without a legitimate medical purpose or outside the usual course of professional practice, pharmacies that dispense illegitimate prescriptions, and supply chain wholesalers and manufacturers that fail to provide effective controls and procedures to guard against diversion—all of which fueled illicit access at the expense of public health and safety. According to the 2012 National Survey on Drug Use and Health (NSDUH), 6.8 million people age 12 or older used psychotherapeutic drugs for non-medical reasons during the past month (psychotherapeutic drugs included in this estimate are pain relievers, tranquilizers, stimulants, or sedatives and does not include over-the-counter drugs). This was higher than the number of users reported in 2011 (6.1 million), but similar to the number of users reported between 2005 and 2010. Non-medical use of psychotherapeutic drugs is second only to marijuana use (18.9 million) in terms of popularity. There are more current users of psychotherapeutic drugs for non-medical reasons than current users of cocaine, heroin, or hallucinogens (or some combination thereof).

The consequences of abuse are devastating. Recently, the Centers for Disease Control and Prevention (CDC) reported its analysis revealing that 38,329 people died from a drug overdose in the United States in 2010.¹ Nearly 60 percent of those drug overdose deaths (22,134) involved pharmaceutical drugs. Opioid analgesics, such as oxycodone, hydrocodone, and methadone, were

¹ Drug Overdose in the United States: Fact Sheet. www.cdc.gov/homeandrecreationalafety/overdose/facts.html (accessed March 18, 2014).

involved in about three of every four pharmaceutical overdose deaths (16,651), confirming the predominant role opioid analgesics play in drug overdose deaths.

Also of concern is that, according to the most recent NSDUH, there were 335,000 current heroin users in 2012, more than double the number in 2007 (161,000). The DEA believes the increased heroin use is driven by many factors, including an increase in the misuse (e.g., using more than medically indicated or using in a manner not medically indicated) and abuse (i.e., using in order to feel the psychoactive effects of the drug) of prescription psychotherapeutic drugs, specifically opioids.

Non-medical prescription opioid use, particularly by teens and young adults, can lead to heroin use. Black-market sales for prescription controlled substances are typically five to ten times their retail value. DEA intelligence reveals the “street” cost of prescription opioids steadily increases with the relative strength of the drug. For example, generally, hydrocodone combination products (a schedule III prescription drug and also the most prescribed drug in the country)² can be purchased for as little as \$5 to \$7 per tablet. Stronger drugs like oxycodone combinations (e.g., Percocet, a schedule II drug) can be purchased for as little as \$7 to \$10 per tablet. Even stronger prescription drugs are sold for as much as \$80.00 per tablet or more in the case of the previous formulation of OxyContin 80 mg, and \$30.00 to \$40.00 per tablet for 30 mg oxycodone single entity immediate release or the 30 mg oxymorphone extended release. These increasing costs make it difficult, especially for teens and young adults, to purchase in order to support their addiction, particularly when many first obtain these drugs for free from the family medicine cabinet or friends. Some users of prescription opioids turn to heroin, a much cheaper opioid, generally \$10 per bag, which provides a similar “high.”

Maintaining the Closed System of Distribution

In order to prevent diversion and maintain the closed system of distribution, the DEA is a law enforcement agency with a regulatory function. Although the DEA’s investigative techniques and methods remain constant with respect to enforcing the CSA, this unique mission calls for an array of criminal, civil, and administrative authorities. In other words, to maintain the closed system of distribution, the DEA can select from a variety of tools to appropriately deter diversion, ensure compliance, and ensure that every registration is in the public interest, as defined by the CSA. Some of the proactive tools include administrative inspections, pre-

² On February 27, 2014, DEA published in the *Federal Register* a Notice of Proposed Rulemaking (NPRM) to move hydrocodone combination products from schedule III to schedule II, as recommended by the Assistant Secretary for Health of the U.S. Department of Health and Human Services and as supported by the DEA’s own evaluation of relevant data. This NPRM proposes to impose the regulatory controls and sanctions applicable to schedule II substances on those who handle or propose to handle hydrocodone combination products. The NPRM is available on the DEA’s website, www.dea.usdoj.gov. Members of the public are invited to submit comments. Electronic comments must be submitted, or written comments postmarked, by 11:59 p.m. Eastern Time on April 27, 2014.

registration inspections, required reporting, order form requirements, education, and the quota system.

The DEA Diversion Groups concentrate on the regulatory aspects of enforcing the Controlled Substances Act. The DEA has steadily increased the frequency of compliance inspections of specific registrant categories such as manufacturers (including bulk manufacturers); distributors; pharmacies; and practitioners. This focus on oversight enables the DEA to educate registrants and ensure that DEA registrants understand and comply with the CSA and its implementing regulations. The DEA conducts approximately 6,000 regulatory inspections every year to ensure compliance with the law. Each inspection entails close communication between the 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.

To complement the panoply of proactive authorities, the DEA focuses its pharmaceutical investigations where diversion occurs: at the distributor, pharmacy and practitioner level of the supply chain. This includes non-registrants and end users who are involved in large-scale distribution, prescription fraud (prescriptions that were written in the name of a practitioner who did not authorize the dispensing of a controlled substance), and doctor shopping (drug seekers who present various complaints to multiple physicians to procure controlled substances). Many of the investigations that DEA initiates are conducted pursuant to complaints received from other law enforcement agencies, regulatory boards, private citizens, former patients, and health practitioners. In some cases involving health professionals, state regulatory or licensing authorities have already initiated proceedings and have requested DEA's assistance in their investigations.

DEA Tactical Diversion Squads (TDSs) investigate suspected violations of the CSA and other Federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement officers. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., doctor shoppers, prescription forgery rings, and practitioners and pharmacists who knowingly divert controlled substance pharmaceuticals). Between March 2011 and March 2014, the DEA increased the number of operational TDS's from 37 to 66. With the expansion of TDS groups across the U.S., the number of diversion-related criminal cases has increased. These TDS groups have also been able to increase the number of diversion-related Priority Target Organization (PTO) investigations. PTO investigations focus on those criminal organizations or groups that significantly impact local, regional or national areas of the country.

Another important component to maintaining the closed system of distribution is educating registrants on their responsibilities under the CSA and the implementing regulations. The DEA educates the registrant population, including pharmacy personnel, as well as parents, community leaders and law enforcement personnel regarding diversion trends and how to best prevent prescription drug diversion. The DEA Office of Diversion Control routinely makes presentations to the public, educators, community-based organizations, registrants, and their professional organizations, industry organizations, and law enforcement agencies regarding the diversion and non-medical use of pharmaceutical controlled substances.

The 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; to date, 34 separate PDACs have been held in 16 different states. Each one-day conference is held on a Saturday or a Sunday for the convenience of the pharmacy community. The conference is designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. The conference addresses pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners. The objective of this conference is to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity.

The DEA also established the Distributor Initiative Program in 2005 to educate registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders. 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 to prevent diversion and cut off the source of supply to these and other schemes. Wholesale distributors are required to design and operate a system that will detect suspicious orders and report those suspicious orders to the DEA. Through the Distributor Initiative Program, the DEA educates distributors about their obligations under the CSA, as well as provides registrants with current trends and “red flags” that might indicate that an order is suspicious, such as the type of drug(s) ordered, orders of unusual size, orders that deviate from a normal pattern, frequency of orders, breadth and type of products ordered, and the location of the customer.

Administrative Enforcement Authority

Once violations of the CSA or its implementing regulations are revealed, the DEA must determine what course of action to take—administrative, civil, and/or criminal—depending on the nature and severity of the violations at hand. The facts and circumstances that support criminal charges related to violations of the CSA will always support an administrative action against a DEA registrant. However, the facts and circumstances that support an administrative action will not

necessarily support criminal action against a registrant. The decision to take administrative, civil, and/or criminal action against a DEA registrant rests with the DEA and the prosecuting U.S. Attorneys.

There are several administrative actions that may be taken against a registrant, including issuing a Letter of Admonition (LOA), holding an Informal Hearing (IH), or issuing an Order to Show Cause (OTSC) that could result in the suspension or revocation of a registration, or denial of an application for registration. The LOA or IH can be used to provide formal notice to a registrant who is not in compliance with the regulations or statutory provisions of the CSA. The LOA and IH provide registrants an opportunity to recognize and acknowledge their infractions, and immediately correct them. From 2007 to 2013, the DEA issued approximately 5,500 LOAs to registrants and held approximately 118 IHs.

Before taking action to deny an application for registration or to revoke a registration, the DEA must serve the applicant or registrant with an OTSC why the registration should not be denied or revoked. The DEA Deputy Assistant Administrator may initiate an OTSC on the basis of any five statutory factors, or a combination thereof: material falsification of an application; a controlled substance-related felony conviction; lack of state authority; commission of acts inconsistent with the public interest; or exclusion from Medicare/Medicaid. The DEA generally reserves OTSC for those situations where registrants fail to comply with the CSA and/or its implementing regulations and repeated or egregious violations occur.

OTSC proceedings are conducted pursuant to the Administrative Procedure Act (APA) before an independent fact finder, the administrative law judge, on a date noted in the OTSC. Registrants have the opportunity to evaluate and test the DEA's evidence, and show they have taken corrective action, and any other mitigating factors, at a formal hearing. Upon the conclusion of the formal hearing, the administrative law judge provides a recommended decision to the Deputy Administrator, who reviews the record of proceedings and subsequently issues a Final Agency Decision.

When the DEA issues an OTSC, the DEA is authorized to simultaneously suspend the registration (by issuing an Immediate Suspension Order (ISO)) in order to immediately stop the harm the registrant is causing, or may cause, during the pendency of the OTSC proceeding. Issuing an ISO is the most severe administrative action the DEA can take, and, by law, is reserved for those entities that the DEA can show are an imminent danger to the public health or safety. This OTSC and ISO authority is used sparingly, compared to the vast number of investigations and inspections the DEA conducts every year. In FY11, the DEA issued more than 65 OTSC and ISO each. For FY14, as of March 28, 2014, the DEA had issued less than 20 OTSC and ISO combined.

It must be emphasized that these administrative “*proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings*” under the CSA or any other law of the United States. 21 U.S.C. § 824(c). Accordingly, civil and/or criminal action may proceed simultaneously with administrative proceedings. It is not uncommon for the DEA’s enhanced regulatory oversight and expanded criminal investigative efforts to result in the identification of registrants who fail to adhere to their regulatory responsibilities and, in so doing, also commit acts that are appropriate for civil or criminal sanction. In these instances, the DEA would take administrative action against these registrants, and also refer them for civil or criminal action.

The DEA’s administrative enforcement authorities, particularly the administrative sanction of revocation or suspension of registration are important tools in the DEA’s arsenal to ensure compliance, deter and prevent diversion, and ensure that every registration is in the public interest. Without these administrative tools, civil and criminal sanctions would increase, and it would be tremendously more difficult to protect the public health and safety from the diversion of pharmaceutical controlled substances. For example, before the DEA could shut down a pill mill, civil or criminal investigation and subsequent action would be necessary. Doctors writing prescriptions for fake ailments at \$400 per prescription could continue to deal drugs until civil or criminal sanction could occur. Pending such action, the registrant would be able to continue to push pills out the door as fast as possible.

Administrative Scheduling Authority

Another aspect of the closed system of distribution is the DEA’s authority to administratively control substances with abuse potential through rulemaking. These actions impose the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle the substances administratively controlled.

Proceedings for the issuance of a rule may be initiated by the Administrator of the DEA (pursuant to a delegation of authority from the Attorney General) on her own motion, upon request of the Secretary of the Department of Health and Human Services (HHS), or on the petition of any interested party. The Administrator may add a drug or other substance to a schedule or transfer it between schedules if she finds the drug or other substance has a potential for abuse and makes the findings required by 21 U.S.C. § 812(b) for the schedule in which the drug is to be placed. She may also remove a drug from the schedules if she finds that it does not meet the criteria for placement in any schedule.

Before initiating a rulemaking, the DEA must request from the Secretary of HHS a scientific and medical evaluation, and recommendation as to whether the drug should be controlled

(21 U.S.C. § 811(b)). The CSA in 21 U.S.C. § 811(c) sets out the following eight factors that must be considered when making any findings to control a drug or other substance:

1. Actual or relative potential for abuse.
2. Scientific evidence of its pharmacological effects.
3. State of current scientific knowledge regarding the drug.
4. History and current pattern of abuse.
5. Scope, duration, and significance of abuse.
6. Risk to the public health.
7. Psychic or physiological dependence liability.
8. Whether the substance is an immediate precursor of a substance already controlled.

In making the required evaluation and recommendations, the Secretary must consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of § 811(c), and any scientific or medical considerations involved in paragraphs (1), (4), and (5). The recommendations of the Secretary are binding as to scientific and medical matters, and if HHS recommends that the drug not be controlled, then the DEA may not control it. On the other hand, if HHS recommends that a drug be controlled, or that a drug be controlled in a particular schedule, that recommendation is not determinative. The CSA vests responsibility in the DEA to determine whether the facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control, and to make the findings necessary to control a drug in a particular schedule. Accordingly, the DEA is responsible for the final determination as to whether a drug should be scheduled, and as to the schedule in which the drug should be placed.

To fulfill its statutory mandate, the DEA reviews the HHS evaluation in great detail before making the findings necessary to schedule a substance. When the DEA receives the scientific and medical evaluation and scheduling recommendation from HHS, the DEA evaluates the facts provided and all other relevant data to determine whether the evidence warrants control of the substance, and if so, in which schedule to place the substance. Throughout the rulemaking process, the DEA independently considers the eight factors of 21 U.S.C. § 811(c) in order to make the findings required by 21 U.S.C. §§ 811(a) and 812(b).

The DEA is entrusted to ensure that all factors determinative of control and all findings are fully supported and legally defensible. Among other things, this involves reviewing the scientific and medical data provided in the HHS recommendation, verifying the underlying facts, analyses, and scientific literature supporting the HHS recommendation, as well as gathering and reviewing any other related data and/or scientific studies or literature that may exist. The DEA conducts its own eight-factor analysis because the DEA must be prepared to defend the scheduling action in the event an interested person requests an administrative hearing or the rulemaking is otherwise

challenged. The DEA also conducts a survey of the available scientific literature and data to ensure, among things, that information from published sources is current and relevant. Furthermore, the DEA and HHS have access to different data sets—e.g., the DEA collects and maintains sensitive law enforcement data on drug seizures and drug analysis (e.g., databases such as the National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE)), while HHS has unique access to product-specific information contained in a manufacturer’s New Drug Application. Even when the DEA and HHS access the same raw data (e.g., poison control center data, hospital emergency room data, and data from the Drug Abuse Warning Network), each agency’s analysis may differ based upon the context of the data and/or each agency’s experience with the data.

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. 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 appropriate. Generally, the complexity and length of time for DEA and/or HHS 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. The length of the administrative process also depends on 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.

During the administrative rulemaking process, the DEA may ask HHS to clarify aspects of its evaluation and recommendation or reconsider its scheduling recommendation. For example, the DEA requested HHS to reconsider its scheduling recommendation with respect to hydrocodone, based on DEA’s review of the available data.

As noted above, under the CSA, the DEA is required to consider the actual or relative potential for abuse (“abuse liability”) of a substance when making a scheduling determination. There is no history of use in the United States of newly developed pharmaceutical drug substances. Accordingly, determining abuse liability is a difficult undertaking requiring comparison to other substances of similar structure and abuse liability.

The CSA specifies in 21 U.S.C. § 812(b) the findings necessary to place a substance in a particular schedule. The level of control that will be required of a substance varies depending on the schedule in which the substance is placed. Accordingly, placement in the appropriate schedule will ensure that necessary controls are in place to detect and prevent diversion of the substance to illicit channels, thereby protecting public health and safety.

The placement factors involve whether the substance has a currently accepted medical use in treatment in the United States, the potential for abuse of the substance relative to substances in other schedules, and the level of physical or psychological dependence (severe, moderate or low) that may result from abuse of the drug. See 21 U.S.C. § 812(b).

In addition to the scientific review and analysis required to administratively schedule a drug or other substance, the DEA also assesses whether a scheduling action will have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. § 601 et seq. If the DEA determines that a scheduling action will have a significant economic impact on a substantial number of small entities, the DEA prepares an initial regulatory flexibility analysis which generally includes elements such as: a description of the reasons why action by the agency is being considered; a succinct statement of the objectives of, and legal basis for, the proposed rule; a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply; and a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule. Even if the DEA certifies that a scheduling action will not have a significant impact on a significant number of small entities, such certifications would be accompanied by a statement providing the factual basis for the certification. Accordingly, the DEA estimates, reviews, and analyzes data on the potential number of small entities affected by the rule and the potential costs that would be incurred by such entities.

Each scheduling action is unique--each substance is evaluated based upon the available information, and there may be more scientific and abuse liability data available for some substances than for other substances. Nonetheless, in recent years, DEA's administrative scheduling actions have increased as the DEA responsibilities have expanded.

From 1997 to 2010, DEA routinely published NPRMs to control newly approved pharmaceutical substances within six months of receiving the HHS scheduling recommendation. During that time, the DEA temporarily scheduled two substances each in 2002 and 2003 in order to avoid imminent hazard to the public safety pursuant to 21 U.S.C. § 811(h).

In 2011, the DEA began to use its temporary scheduling authority to control numerous emerging "designer drugs" because there was a marked increase in the trafficking and abuse of illicit designer drugs such as synthetic cannabinoids and cathinones which resulted in serious injury and death. These substances have become a significant public safety threat requiring the

DEA to devote a large amount of its resources to compiling the necessary scientific data and information, initiate control actions and communicate the scientific and technical information with other offices within DEA and other Federal agencies. The growing public health threat is evidenced by the expanding need for educational efforts across the country. In 2010, DEA scientific staff provided four presentations on designer drugs; in 2011, they presented seven times; in 2012, they presented 11 times; and as of August 21, 2013, they had already given 10 presentations. This developed expertise has demanded scientific staff testimony in important criminal prosecutions of traffickers of these dangerous synthetic drugs. A relatively recent, growing responsibility, this has stretched the resources of the scientific staff as they conduct the scientific analysis required and provide expert testimony in numerous criminal prosecutions pursuant to the Controlled Substance Analogue Enforcement Act of 1986 (Analogue Act). For example, in 2011, the DEA temporarily scheduled eight synthetic substances and subsequently prepared to permanently control these substances. During this time, the DEA received two scheduling recommendations from HHS for newly approved pharmaceutical substances. Of these two substances, the DEA published one NPRM nine months after receiving the HHS recommendation.

In 2012, the DEA was working towards permanently controlling the eight temporarily controlled designer drugs, and published NPRMs for six of those substances. During that time, the DEA received two more scheduling recommendations from HHS for newly approved pharmaceutical substances and published the pertinent NPRMs within six and eight months of receiving the HHS recommendations. Also in 2012, scientific staff provided expert testimony in ten instances and provided technical support in 18 instances with respect to prosecutions pursuant to the Analogue Act. By the end of August 2013, the DEA had temporarily controlled three more synthetic designer drugs, and the scientific staff had already provided testimony in 32 instances, and were providing technical support (including providing written declarations) in approximately 135 instances, in support of Analogue Act criminal prosecutions.

Conclusion

The primary purpose of the CSA is to protect the health and safety of the public while also ensuring legitimate access to controlled substance pharmaceuticals. The DEA has a responsibility to maintain the closed system of distribution established by the CSA, and it does so through various administrative enforcement measures. While there may be a perception among some registrant categories that the DEA unfairly targets them, the facts belie that view. As demonstrated, of 1.5 million registrants, only a very small fraction are subjected to adverse action pursuant to the DEA's administrative authority.

In recent years, rogue pain clinics, pharmacies that fill illegitimate prescriptions for pain clinic "patients", and the wholesale distributors that supply these pharmacies have caused, and continue

to cause, millions of dosage units of highly addictive controlled substances to be diverted. Consequently, the registrants involved—practitioners, pharmacies, and wholesale distributors that do not comply with the CSA or its implementing regulations—are allowing millions of dosage units of controlled substances to pour into the illicit market, endangering the public health and safety. When warranted, the DEA will take appropriate administrative, civil, or criminal action to prevent the registrant from continuing to divert controlled substances.