

Statement from
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Committee on the Judiciary

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Good morning Chairman Grassley, Ranking Member Feinstein and Members of the Judiciary Committee. My name is John Gray and I am President and CEO of the Healthcare Distribution Alliance (HDA). Thank you for the opportunity to discuss with the Committee the industry's efforts to address opioid misuse, abuse, and diversion as well as the broader state of enforcement following the 2016 enactment of The Ensuring Patient Access and Effective Drug Enforcement Act (Public Law 114-145).

Since 1876, HDA has helped its members navigate regulations and innovations to ensure the right medicines arrive to the right patients at the right time, safely and efficiently. HDA's members include 35 national, regional and specialty primary distribution companies who are not only distributors, but also are technology innovators, information management experts, security specialists and efficiency professionals.

HDA's members work around the clock to help more than 200,000 healthcare facilities across the country keep their shelves stocked with the legal, FDA-approved medications and products that patients need every day. The medications that HDA members deliver are prescribed by physicians, dentists, veterinarians, and other authorized practitioners; administered in hospitals, clinics, and long-term care facilities; and dispensed by pharmacies. Federal and state requirements impact every step of this process.

Distributors do not manufacture, prescribe, dispense, or drive demand for medicines. Instead, our industry's primary mission is to operate the safest and most secure and efficient supply chain in the world. In this effort, pharmaceutical distributors work closely with supply chain partners and with the entities that regulate us, most notably the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), and regulators in every state. Primary pharmaceutical distributors have invested heavily in information technology systems to help better flag suspicious ordering patterns,

and have enhanced overall “know your customer” due diligence efforts to further prevent the abuse, misuse and potential diversion of controlled substances.

HDA and its members recognize our role and responsibility to advance meaningful initiatives to address the serious, complex issues raised by the opioid abuse crisis. We agree with the recent recommendations made by the President’s Commission on Combating Drug Addiction and the Opioid Crisis, as well as the National Academies of Science, Engineering, and Medicine that the challenges presented by prescription drug abuse and diversion call for a collaborative effort by insurers, healthcare providers, pharmacists, distributors, manufacturers and state and federal authorities. HDA also applauds Congress’s commitment to finding and implementing solutions to the opioid abuse epidemic.

Today, I will focus on HDA’s efforts to seek greater clarity from DEA regarding regulatory obligations under the Controlled Substances Act (CSA); our support for DEA’s enforcement power, including the Agency’s power to suspend a DEA registration to protect public health and safety; the importance of a clear definition of “imminent danger;” and finally, the urgent need to move forward with practical solutions.

Industry Communications with DEA

HDA members are committed to full compliance with the CSA and with DEA regulations. Let me be clear: HDA does not wish to undermine DEA's enforcement authority or deprive DEA of the enforcement tools it needs. Distributors seek a consistent and reliable partnership with DEA to tackle the opioid abuse epidemic.

For many years, however, a lack of communication and information sharing from DEA to the entities it regulates, including pharmacies, healthcare providers, manufacturers and distributors, alongside significant changes in DEA’s expectations, created complications. Specifically, over the

past 11 years, DEA has repeatedly evolved and refined its interpretation of a regulation requiring manufacturers and distributors to monitor for and report to DEA suspicious orders of controlled substances. While the text of the regulation in 21 C.F.R. § 1301.74(b) – the official requirement – is unchanged since 1973, DEA has interpreted that language¹ in letters to industry in 2006² and 2007,³ and in adjudicatory orders, including one in 2007⁴ and another in 2015.⁵ Throughout this evolution, HDA members have worked to understand and to comply with the varying information from DEA. Distributors have reported hundreds of thousands of suspicious orders to DEA over the years and have not received feedback from DEA regarding the efficacy or appropriateness of the reporting, or whether in fact the reporting has been utilized by DEA in any meaningful way.

Over the same period, DEA also revised its views about what constitutes “effective controls against diversion of particular controlled substances,” which the CSA requires of manufacturers and distributors. Notably, in a 2006 letter, DEA added a requirement that distributors conduct “due diligence” on their customers. DEA’s brief thoughts about the scope of “due diligence” focused primarily on identifying Internet pharmacies, a key concern at the time, and evolved through the years. Through that evolution, DEA assigned to distributors some responsibilities that appear more law enforcement in their nature than ever before, saying, for example, “It is ... incumbent upon you to identify illicit or suspicious activities which may result in the diversion of controlled substances.”⁶

¹ We further note that discussion of the related but different requirement, applicable only to listed chemicals, to report regulated transactions in extraordinary quantities or with uncommon payment or delivery methods, was discussed in a 1998 report. DEA Report to the U.S. Attorney General by the Suspicious Orders Task Force (Comprehensive Methamphetamine Control Act of 1996) (October 1998).

² Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Sept. 27, 2006).

³ Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to Registrant (Dec. 27, 2007).

⁴ Southwood Pharmaceuticals, Inc.; Revocation of Registration, 72 Fed. Reg. 36487 (July 3, 2007).

⁵ Masters Pharmaceuticals, Inc.; Decision and Order, 80 Fed. Reg. 55418 (Sept. 15, 2015).

⁶ https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf (dated April 12, 2011, accessed 12/1/17).

Despite HDA's repeated requests, DEA has not published guidance or regulations to reflect these expanding requirements. While DEA may have clarified its expectations individually to certain wholesale distributors, such clarity must be shared with the entire industry to be effective. Had DEA articulated its changing interpretations through proper guidance development or notice and comment rulemaking in an open and transparent process, DEA could have incorporated input from distributors relating to their capabilities and the changing practices of all entities within the supply chain.

This is not a matter of willful ignorance by HDA members, and DEA's lack of communication is not specific to distributors. The agency itself has acknowledged its weaknesses. As then-Acting Administrator Chuck Rosenberg testified to this committee in June 2016 about DEA's relationship with its registrants, "I think we've been slow. I think we've been opaque. I think we haven't responded to them. We're trying to issue guidelines for them more quickly. We're trying to answer their questions."⁷

The Government Accountability Office (GAO) also recognized the detrimental impacts of the DEA's opaqueness. In June 2015, the GAO found that a lack of communication between DEA and registrants, including distributors, pharmacies, and physicians, was hampering efforts to effectively combat prescription drug diversion.⁸ The GAO stated that, "The lack of awareness among registrants of DEA resources and conferences suggests that DEA may not have an adequate means of communicating with its registrant populations," and it concluded that, "Without more registrant awareness of DEA resources and adequate guidance and communication from DEA, registrants may not fully understand or meet their CSA roles and responsibilities." Yet the GAO reported that "Despite the lack of awareness we found that existed among registrants, DEA officials have indicated

⁷ Senate Judiciary Committee hearing "Oversight of the Drug Enforcement Administration" (June 22, 2016).

⁸ GAO, Prescription Drugs: More DEA Information About Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access (June 2015), *available at* <http://www.gao.gov/assets/680/671032.pdf> (accessed 11/21/17).

that they do not believe they need to take any additional steps to improve communication or raise registrants' awareness of the agency's conferences and resources."

Distributors and other registrants have only sought meaningful compliance information from DEA. HDA members, along with nearly all of the more than 1.7 million DEA registrants nationwide,⁹ are working to comply with the laws that allow these powerful medications to be made safely available to the patients that need them, while also protecting the public from inappropriate access. While we appreciate that DEA does not want to inadvertently share its law enforcement approaches with bad actors, HDA members are regulated by and registered with DEA, and seek only appropriate regulatory information.

DEA's Use of Immediate Suspension Orders

In addition to DEA's changing interpretations of legal requirements, DEA's use of its Immediate Suspension Order (ISO) authority raised concern among DEA registrants, including HDA members, and with federal judges.¹⁰

Every legitimate entity in the pharmaceutical supply chain must have a DEA registration before they handle controlled substances. This requirement applies to everyone—researchers, manufacturers, wholesale distributors, pharmacies and hospitals that dispense or administer controlled substances, and doctors, dentists, veterinarians, and other authorized practitioners that prescribe or administer these powerful drugs.

With DEA's responsibility to register and oversee entities that handle controlled substances, comes the authority to revoke the registrations that DEA has previously granted. This authority comes

⁹ A "very small percentage of registrants exploit the system." Robert Patterson, Remarks at Press Conference (Nov. 29, 2017). "Logically and holistically the overwhelming majority, 99 plus percent, are our allies in this thing." Chuck Rosenberg, Testimony to Senate Judiciary Committee (June 22, 2016).

¹⁰ See, e.g., *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, and analogous cases overturning the issuance of ISOs. See also oral argument transcript, *Walgreens v. Holder* (D.C. Cir. 2013) ("Normally those [factors for revocation] would be determined in a due process hearing, and you seem to be establishing a line that says any time we charge a major violation we get an ISO, and I don't see any other line you're going for." J. Tatel.)

in two forms. The standard process is the Order to Show Cause, in which a registrant is entitled to full due process, including a hearing before DEA's Administrative Law Judge (ALJ), before DEA can revoke the registration. The second is the Immediate Suspension Order (ISO).

ISOs are an extraordinary remedy, as they summarily eliminate the registrant's ability to handle controlled substances before any due process hearing. DEA can issue an ISO upon the agency's own finding that there is an "imminent danger to the public health or safety," under the CSA. No Administrative Law Judge reviews the ISO before issuance—it is initiated by DEA staff and issued by DEA leadership. And the ALJ has no authority to review the ISO after it is issued.¹¹ The ISO stops the registrant from receiving, storing, manufacturing, distributing, prescribing and/or dispensing controlled substances from the moment DEA serves the order. The registrant is not entitled to a hearing on the ISO itself, but only on any Order to Show Cause that DEA issues concurrently, meaning that the process for regaining the ability to handle controlled substances could take an extended amount of time. This action, while targeted at registrants, also can limit access to needed medications by legitimate patients.

The single guardrail in the issuance of an ISO is the requirement that DEA find an "imminent danger to the public health or safety." Yet neither Congress nor DEA had published or stated any definition of "imminent danger"—it remained a completely subjective determination made solely by DEA.

In the ISOs issued over more than 40 years, the vast majority of which were directed at physicians and pharmacies, DEA never published any standard for what might constitute "imminent danger." This left the agency free to adapt its own requirements, with no notice, to suit the circumstances before it.

¹¹ JJ Mulrooney *et al.*, Drug Diversion Administrative Revocation and Application Hearings for Medical and Pharmacy Practitioner, 78 Albany L. Rev. 365 (2015).

Over the years, many DEA registrants challenged in federal court the basis for DEA's issuance of an ISO. The challenges included numerous occasions when DEA issued an ISO for conduct that DEA knew had ceased at the time it issued the ISO. In other words, even though companies already had taken the specific remedial action that DEA sought, the companies had to argue their appeals in federal court, and their ability to handle any controlled substances was negated in the meantime.

The Need for Congressional Action

The shifting expectations, lack of guidance, and DEA enforcement actions had consequences for registrants and patients. Community pharmacists in particular noted increasing challenges in “procur[ing] controlled substances which is a great concern for patients who need these medications.”¹² Communication challenges with DEA persisted. The June 2015 GAO report concluded that “adequate DEA communication with and guidance for its registrants are essential to help ensure that registrants take actions that prevent abuse and diversion but do not unnecessarily diminish patients' access to controlled substances for legitimate use because of their uncertainty about how to appropriately meet their CSA roles and responsibilities.”

In 2016, recognizing the broad implications to patients and the health system, Congress passed Public Law 114-145, providing for the first time a statutory definition for the term “imminent danger” for purposes of DEA's extraordinary power to immediately suspend a registrant's authorization to handle controlled substances. Under the law, which Congress negotiated transparently with the Department of Justice (DOJ) and DEA, and which garnered bipartisan support and passed without

¹² National Community Pharmacists Association, NCPA Controlled Substances Access Survey Results (Jan. 2014) available at <http://www.ncpanet.org/pdf/survey/2014/controlled-substances-access-survey.pdf> (accessed 12/10/2017).

dissent,¹³ DEA remains fully empowered to take immediate action against a registrant if there is “a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.” This definition clarifies that “public health or safety” expressly includes “abuse of a controlled substance.” The definition appropriately requires DEA to link the actions of the specific manufacturer, distributor, prescriber or pharmacy to an identifiable public health threat related to the registrant’s actions.

HDA’s members do not want the medications they distribute to be misused or abused. If physicians and pharmacies, prescribe or dispense controlled substance medications without a legitimate medical purpose, the standard for DEA issuing an ISO should not be unduly burdensome. Likewise, if a manufacturer or distributor poses an imminent danger to public health or safety, DEA should not have an unduly burdensome standard for issuing an ISO. Although the standard should not be unduly burdensome, there must be a defined standard. That is why HDA and its members have supported the articulation of a clear standard for ISOs in the statute since 2014. And HDA’s position remains unchanged.

Including a definition in the statute merely establishes and clarifies, for registrants and for DEA, a known standard. For businesses such as wholesale distributors, definitional clarity fosters compliance. Clarity also improves and enhances communication. We have great respect for the men and women of the DEA, and we believe that greater clarity and definition in our collective compliance obligations can significantly improve registrants’ abilities to prevent diversion and work collaboratively with each other and with DEA.

Without a definition, the executive and judicial branches were likely to continue their decades-long, case-by-case determination of whether a suspension of a registration is appropriate. DEA

¹³ <https://www.hatch.senate.gov/public/index.cfm/2017/10/hatch-office-responds-to-seriously-flawed-washington-post-opioid-report> (accessed 11/21/17).

Deputy Assistant Administrator Neil Doherty recently agreed with Representative Costello (R-Pa.) that we need a definition to avoid the prior vagueness problem.¹⁴ In a country governed by the rule of law, which is defined in part by the idea that laws and requirements should be readily understood, stable, and evenly enforced, with adequate notice to potentially responsible persons, omitting the definition would seem to be a step backward.

A second important provision of Public Law 114-145 is the opportunity for registrants to submit a corrective action plan to address compliance issues in their handling of controlled substances. The corrective action plan option does not apply where DEA needs to take urgent, extraordinary action due to “imminent danger,” as discussed above. A registrant may submit a corrective action plan only in the more standard Order to Show Cause proceeding, and DEA is not required to accept the plans that registrants submit. Nevertheless, this language is important to DEA’s regulated community.

In the past, when a DEA registrant asked the agency for feedback and guidance—how the company should change its procedures or activities to meet DEA’s expectations for compliance with the law and the regulations—DEA provided only limited information, and would not confirm whether a registrant’s changes would, in DEA’s view, satisfy the CSA’s requirements and correct the problems DEA had identified. For companies committed to full compliance with the law, corrective action plans provide a meaningful step forward. This provision was also necessary because some DEA Administrative Law Judges prohibited registrants from presenting their corrective action unless the registrant first accepted responsibility for all of the conduct that DEA had alleged. In some circumstances, then, a registrant would have to accept responsibility for conduct that was alleged but not committed before the registrant could present evidence of corrective actions for other conduct.

¹⁴ Neil Doherty, Testimony before U.S. House Committee on Energy and Commerce (Oct. 25, 2017).

The corrective action plan procedures in the law are modeled on and generally analogous to procedures FDA has long used with regulated industry to bring a company into compliance with the Federal Food, Drug, and Cosmetic Act (FDCA). At the conclusion of an FDA inspection of a regulated company such as a pharmaceutical manufacturer, an investigator may issue an FDA Form 483 if the investigator has observed any conditions that may constitute violations of the FDCA. FDA encourages companies “to respond to the FDA Form 483 in writing with their correction action plan and then implement that correction plan expeditiously.”¹⁵ FDA will inform the company whether it accepts the correction plan as adequate to address the violation and prevent its reoccurrence.

Finally, Public Law 114-145 requires DEA to submit a report to Congress. The intent of the report, which was due in April of this year, was to seek feedback from numerous federal agencies, in consultation with a wide range of stakeholders, on the broader issue of prescription drug abuse. We appreciate Congress’s continued request for the completion of this report.

After Enactment of Public Law 114-145

Public Law 114-145 clarifies and explains DEA’s existing authorities and does not detract from them. DEA retains a wide range of regulatory and law enforcement tools that it can use to affect the behavior of people in the supply chain. DEA has continued vigorously to use these tools since Public Law 114-145’s passage. The tools include:

- The responsibility to establish the total amount of each Schedule I and Schedule II controlled substance—including every controlled opioid—that may be sold in the U.S. in each calendar year (known as Aggregate Production Quota);
- The responsibility to issue, deny, renew, and revoke DEA registrations for individuals and companies that manufacture, handle, dispense, or prescribe controlled substances;

¹⁵ <https://www.fda.gov/ICECI/Inspections/ucm256377.htm> (accessed 12/4/17).

- Complete knowledge of the amount of each Schedule II controlled substance sent to every pharmacy, hospital, and doctor's office in the country, as reported by manufacturers and distributors through ARCOS;
- The right to inspect every DEA-regulated location;
- Subpoena authority to request records and information relevant to compliance;
- The ability to shape behavior through Letters of Admonition and Memoranda of Agreement, as well as meetings with registrants;
- The use of pressure to encourage a registrant to voluntarily surrender its registration without any formal hearing process;
- Immediate suspension of a DEA-regulated entity's right to handle controlled substances without a hearing;
- Revocation of a registrant's authority to handle controlled substances after a hearing;
- Criminal charges and penalties against bad actors that violate the CSA;
- Civil charges and penalties, including multi-million dollar civil settlements for failure to comply with a recordkeeping, reporting, or other requirements; and
- Forfeiture of any controlled substance obtained in violation of the law.

Tools such as letters of admonition, memoranda of agreement, and the new corrective action plan provision are perfectly suited for encouraging compliance.

Despite the improvements that Public Law 114-145 made to the CSA, notable mischaracterizations about the intent of the law have prompted efforts to repeal the law. However, simply repealing Public Law 114-145 fails to take into account the perspective and interest of patients and providers, as dozens of patient and local pharmacy organizations, including the National Community Pharmacists Association, the National Fibromyalgia & Chronic Pain Association and the

U.S. Pain Foundation, recently indicated. As described, DEA continues to maintain substantial civil, administrative and criminal enforcement authorities over registrants. If it is determined that there have been any unintended consequences that undermine the DEA's ability to enforce the law and take legitimate actions to prevent prescription drug abuse, DEA and DOJ should explain in detail those consequences and bring forward suggested changes to Congress. We will gladly work with Congress and the Administration to address any identified concerns.

Opportunities Moving Forward

As policymakers look to address the epidemic moving forward, it is vitally important for Congress to balance two key considerations: reducing the prevalence of opioid abuse and misuse while also preserving patient access for those who would needlessly suffer without pain medicines. We acknowledge and appreciate that this balanced approach is reflected in the President's Commission on Combatting Drug Addiction and the Opioid Crisis Final Report¹⁶ and the National Academies of Sciences, Engineering, and Medicine report on "Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use."¹⁷

HDA members endorse a comprehensive set of policies¹⁸ to prevent opioid abuse and misuse, promote clinically appropriate guidelines and recommendations, and establish a path forward at the state and federal level for advancing these changes.

One challenge that has hampered the medical community is the lack of complete data to effectively identify patients who may be "doctor-shopping" for additional pain medicines for themselves or family members. Even while improvements in electronic health records and greater use

¹⁶ https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf (accessed 11/21/17).

¹⁷ http://nationalacademies.org/hmd/reports/2017/pain-management-and-the-opioid-epidemic.aspx?_ga=2.20254911.681758302.1511290384-1216471816.1511290384 (accessed 11/21/17).

¹⁸ <https://hda.org/~media/pdfs/government-affairs/hda-practical-solutions-final.ashx> (accessed 11/21/17).

of prescription drug monitoring programs (PDMPs) at the state level have provided some support for early intervention efforts, there is still a long way to go in making these programs accessible and usable for those prescribing and dispensing medicines. HDA believes more widespread adoption of PDMPs should be encouraged.

Secondly, as distributors, HDA members have no access to patient or prescription information. Our members are not medical professionals and cannot substitute their judgment for that of the physicians who write the prescriptions or the pharmacists who fill them. When it comes to establishing the number of opioids available for the legitimate medical needs of the United States, that responsibility rests with the DEA.

The DEA has a window into the entire movement of the most addictive prescription drugs in the U.S., from manufacturer down to pharmacy and hospital. Each manufacturer and distributor reports its sales of certain controlled substances, including all controlled opioids, to the DEA. The Agency captures these transactions in the Automation of Reports and Consolidated Orders System (ARCOS) database.

DEA is the only entity with this complete view. Each individual distributor only knows what it ships to a particular customer — not what other entities are shipping to the same customer. HDA has repeatedly asked DEA to share aggregated, blinded ARCOS data, so that HDA member distributors can use this same data to identify potentially problematic customers. ARCOS disposition data, if provided by DEA in aggregate form without identifying competitor distributors, could allow wholesale distributors to consider a customer's orders in the context of that entity's overall ordering. This would provide additional data points in determining whether an order is suspicious. In previously asking DEA to share ARCOS data, HDA also has explained to DEA that such data could:

- Help indicate the drugs that distributor registrants should watch most carefully;

- Help in the increasingly difficult effort to detect trends and patterns solely by evaluating each company's data individually;
- Help in identifying individual practitioners' orders of interest, which are much less frequent than retail pharmacies or large health care entities (*e.g.*, hospitals) and therefore more difficult to analyze for trends.

Conclusion

For distributors, opioids are a small fraction of the medicines we distribute, but we are committed to helping to develop solutions to ensure patients have access to safe, effective treatments while also working toward ending their abuse and diversion. Thank you for the opportunity to participate in today's hearing and I look forward to answering any questions.