

Testimony of

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Before the U.S. Senate  
Committee on the Judiciary

*“Tackling the Opioid Crisis: A Whole-of-Government Approach”*

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Good morning Chairman Graham, Ranking Member Feinstein and members of the Judiciary Committee. My name is Patrick Kelly and I am Executive Vice President, Government Affairs, of the Healthcare Distribution Alliance (HDA). Thank you for the opportunity to discuss a holistic approach to addressing the opioid crisis.

Since 1876, HDA has helped its members navigate regulation and innovation to ensure the right patients receive the right medicines at the right time, safely and efficiently. HDA's members include 36 national, regional and specialty primary distribution companies who are not only distributors, but also are technology innovators, information management experts, security specialists and logistics professionals.

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 our industry, most notably the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), and regulators in every state. In order to handle controlled substances, every legitimate entity in the pharmaceutical supply chain must have a valid DEA registration. This requirement applies to everyone—researchers, manufacturers, wholesale distributors, pharmacies and hospitals that dispense or administer controlled substances, as well as doctors, dentists, veterinarians, and other authorized practitioners that prescribe or administer these medications.

HDA's members work around the clock to help more than 180,000 healthcare facilities across the country keep their shelves adequately stocked with the legal, FDA-approved medications and products in order to meet the needs of their patients 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 regulate every step of this closed system.

HDA's distributor members have invested heavily in sophisticated information technology systems to help flag potentially suspicious orders for controlled substances and have enhanced due diligence efforts to try to prevent diversion of controlled substances from the legitimate supply chain.

Most recently, HDA has been working on implementation efforts for important new provisions of the SUPPORT (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities) Act. HDA encourages Congress to build upon provisions in the SUPPORT Act, specifically related to data sharing. With efforts underway, HDA believes this is a time to move forward as our members continue to enhance the safety and security of the supply chain and, in turn, the safety and well-being of the patients and communities they serve.

### **SUPPORT Act**

In the 115<sup>th</sup> Congress, HDA strongly supported the significant legislative action taken to protect Americans by advancing meaningful solutions to address the opioid epidemic through the passage of the SUPPORT Act. This new law offers a comprehensive response to the complex public health crisis that our country faces, including two key provisions to improve the monitoring of controlled substances. Specifically, the law enhances data sharing and coordination among pharmaceutical distributors, state and federal regulators and law enforcement, something HDA has been seeking for many years.

The DEA collects data that reflects the end-to-end movement of certain controlled substances through the pharmaceutical supply chain. The Automation of Reports and Consolidated Orders System (referred to as "ARCOS") is a comprehensive reporting system that captures the flow of certain DEA controlled substances from their point of manufacture through distribution to the

dispensing level. Every order of Schedule I and II products, along with Schedule III opioid-based medications is sent to DEA by registrants through ARCOS.

Until recently, each individual distributor only had access to its own data regarding what orders it processed and shipped to a particular customer. Distributors did not have visibility into what other entities may have been shipping to the same customer. The SUPPORT Act broadened distributor access to a portion of this critical data contained in the DEA's ARCOS database. We are hopeful this new access, coupled with some enhancements that we have suggested, will enable consideration of customer orders in the context of overall shipments of ARCOS-reportable drugs to a particular entity. This level of visibility has the potential to help distributors consider additional information to make more informed decisions about individual customers.

Further, in accordance with the Act, DEA has taken the first steps to establish a centralized database for suspicious order reporting, which will facilitate the sharing of information with state enforcement agencies that traditionally was available only to the DEA. The goal of the SUPPORT Act mandate for this database is a streamlined and uniform reporting mechanism for submitting suspicious order reports to DEA headquarters. The law requires that the DEA prepare and make available to states information regarding suspicious orders in a state - including information in the centralized database - within a reasonable period after obtaining the information. Further, the law requires DEA to provide feedback to Congress on how it is managing the suspicious order reports. HDA members are in the process of updating their systems and processes to accommodate these new changes and we will continue to work with the DEA on implementation.

### **Building upon the SUPPORT Act**

HDA is pleased that Congress continues to address issues related to the opioid epidemic and we encourage Congress to build upon the provisions in the SUPPORT Act. Specifically, we are

supportive of efforts to promote the development of a more dynamic ARCOS system, including registrant reporting at more frequent intervals and expanding the scope of ARCOS-reportable drugs to all controlled substances. Further, we have asked the DEA to address some operational challenges that registrants have encountered with the current database, including enabling registrants to utilize the data in a format that can be incorporated into their existing monitoring systems and allowing more than one employee to access the database at any particular time. Both provisions will further enhance the capabilities of registrants and the DEA.

### **Opportunities Moving Forward**

As policymakers continue to look for ways to address opioid abuse and diversion, it is important for Congress to balance two key considerations: reducing the prevalence of opioid abuse while also preserving patient access to FDA-approved medications for legitimate patients and healthcare facilities. We acknowledge and appreciate that this balanced approach is reflected in the President's Commission on Combatting Drug Addiction and the Opioid Crisis Final Report<sup>1</sup> and the National Academies of Sciences, Engineering, and Medicine report on "Pain Management and the Opioid Epidemic."<sup>2</sup>

Over the past few years, the leadership of DEA, in its role as regulator, has significantly improved communication and collaboration with the registrant community, including distributors, by providing additional insight on a variety of issues. HDA appreciates the willingness of DEA to engage with its registrants in this way. It is our understanding that DEA is in the process of reviewing a proposed rule on suspicious orders. HDA and its members look forward to reviewing and commenting on the proposed rule and are hopeful it will provide additional information and clarity on

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<sup>1</sup> [https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-15-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf) (accessed 11/19/19).

<sup>2</sup> [http://nationalacademies.org/hmd/reports/2017/pain-management-and-the-opioid-epidemic.aspx?\\_ga=2.20254911.681758302.1511290384-1216471816.1511290384](http://nationalacademies.org/hmd/reports/2017/pain-management-and-the-opioid-epidemic.aspx?_ga=2.20254911.681758302.1511290384-1216471816.1511290384) (accessed 11/19/19).

how registrants can identify and report suspicious orders, in support of the shared goal of preventing diversion of controlled substances.

Additionally, HDA members endorse a comprehensive set of Practical Solutions to Address Opioid Abuse and Misuse<sup>3</sup> to promote clinically appropriate guidelines and recommendations and establish a path forward at the state and federal level for advancing these changes. We note however, that HDA distributor members have no access to patient or prescription information. Our members are not medical professionals and cannot substitute their judgment for the clinical judgments of the physicians who write the prescriptions or the pharmacists who fill them. When it comes to establishing the number and types of opioids necessary and available for the legitimate medical needs of the United States, that responsibility rests with DEA and FDA.

Finally, HDA will continue to educate and raise awareness around the safe use and disposal of opioids as well as patients' rights, risks and responsibilities associated with use of these medicines through Allied Against Opioid Abuse (AAOA). We are proud to collaborate with the National Community Pharmacists Association, and many other national organizations, on this important effort.

### **Conclusion**

HDA distributor members are committed to helping to develop solutions to ensure patient access to FDA-approved medications while continuing to work collaboratively with our supply chain partners and communities to prevent opioid diversion and abuse. Thank you for the opportunity to participate in today's hearing and I look forward to answering any questions.

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<sup>3</sup> <https://www.hda.org/~media/pdfs/government-affairs/hda-practical-solutions-final.ashx> (accessed 11/19/19).