November 28, 2017

The Honorable Claire McCaskill
Ranking Member
U.S. Senate Committee on Homeland Security & Governmental Affairs
340 Dirksen Senate Office Building
Washington, DC, 20510

Dear Ranking Member McCaskill:

As Americans across the country struggle with the burden of opioid addiction every day, we appreciate the opportunity to submit this statement for the record related to your roundtable: Restoring DEA Enforcement Power Over Distributors. The Healthcare Distribution Alliance (HDA) believes that greater discussion and understanding of the regulation of the pharmaceutical supply chain would benefit all Americans and enhance our ability as a nation to bring an end to the opioid epidemic.

As the logistics experts in healthcare, pharmaceutical distributors deliver medicines — including specialty prescriptions, chronic disease treatments, cancer medicines and more — to licensed healthcare professionals for the patients they serve. Distributors work closely with a range of regulators, supply chain partners and law enforcement entities, most notably the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA). While distributors do not make medicines, market medicines, prescribe medicines or dispense them to patients, we do recognize our role — as well as those across the supply chain — in advancing meaningful initiatives to address the serious, complex issues raised by the opioid crisis.

In your exploration of this issue, we ask that you examine several issues related to the root causes of the crisis, as well as potential solutions. To reiterate, our industry’s commitment is full compliance with DEA regulations in order to protect public health and the integrity of the supply chain. For many years, however, a lack of communication and information sharing from DEA to its registrants — pharmacies, healthcare providers, manufacturers and distributors — exacerbated the challenges and weakened any system-wide efforts to counter the opioid crisis. Despite numerous requests for regulatory clarity, DEA too often did not help registrants understand exactly how the agency wanted them to operate and what information to report.

Prior to Congressional action in 2016, there was a recognition, notably among community pharmacists, that there were an increasing number of challenges in “procuring controlled substances which is of great concern for patients who need these medications.”1 Further, in June 2015, the Government Accountability Office (GAO)

issued a report that concluded: "Therefore, 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 [Controlled Substances Act (CSA)] roles and responsibilities."\(^2\)

Historically, the Office of Diversion Control expressed informal and evolving interpretations of its regulatory reporting requirements without taking any official agency action to redefine what is "suspicious" and what actions distributors must take.\(^3\) Despite the lack of formal guidance, distributors continued to meet their statutory obligations and have reported thousands of suspicious orders to DEA.

**Questions:** How has DEA used the thousands of suspicious order reports submitted by wholesale distributors? How many pharmacies and practitioners has DEA investigated in response to suspicious order reports? Has DEA shared suspicious order information with state Boards of Pharmacy, so that they also can be DEA's partners in preventing diversion and inappropriate usage of opioids?

Further, distributors repeatedly asked DEA to share data showing the amount of controlled substances that individual pharmacies receive from all of their suppliers. As required by law, each manufacturer and distributor reports its sales of certain controlled substances, including all controlled opioids, to DEA.\(^4\) The Agency captures those transaction reports in the Automation of Reports and Consolidation Orders Systems (ARCOS) database. Distributors are only aware of the amount that their company has shipped. Only DEA, through its ARCOS database, has the complete picture of the totality of distributors serving an individual customer. To date, distributors still do not have access to this critical data.

**Questions:** How has DEA used the ARCOS data — data submitted by manufacturers and distributors that allows DEA to see the full movement of the most addictive substances through the supply chain to the pharmacy, hospital and dentist level — over the years to identify and prevent bad actors from diverting opioids? Has DEA shared that data with state Boards of Pharmacy, to empower them to take action?

Moreover, the Office of Diversion Control for many years was approving dramatic increases in annual opioid production quotas. Because DEA has the authority to establish the total amount of each opioid manufactured and sold in the U.S., DEA could have reduced those numbers. For instance, DEA significantly reduced the quotas for ephedrine and pseudoephedrine in 2009 to prevent them from being diverted and used in manufacturing methamphetamine. Yet, DEA continued to increase opioid quotas even as other agencies were taking steps to address the opioid crisis. For example, in

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2012, DEA’s Office of Diversion Control increased the oxycodone quota by more than 79 percent over the previous year’s amount, increased the quota for hydromorphone by 21 percent, and increased the quota for hydrocodone by 35 percent. Under new leadership, DEA significantly reduced the manufacturing quotas for opioid medicines in 2016 and 2017 and has announced another reduction for 2018.

**Question:** Given DEA’s concerns about diversion and misuse, why did DEA not reduce quotas prior to 2016 for key opioid drugs like oxycodone, oxymorphone and hydrocodone?

In 2016, recognizing the broad implications to patients and the health system, Congress took a critical step to address one of the barriers to effective enforcement and coordination between DEA and registrants in regulating controlled substances and opioids. The *Ensuring Patient Access and Effective Drug Enforcement Act* (S. 483/Public Law 114-145) passed without dissent and with bipartisan support from Congress. The law, which was negotiated transparently with the Department of Justice (DOJ), DEA and Congress, provides 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. No previous public standard had existed before enactment of Public Law 114-145. Under the law, 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.”

**Questions:** Did DEA have a definition of “imminent danger” before the bill passed? What was that definition? When was it established? Why did DEA never publish or make public that definition? If DEA did not have a definition, how was a standard set?

Despite the improvements made to the Controlled Substances Act made by P.L. 114-145, notable mischaracterizations about the intent of the law have prompted efforts to repeal the law. However, simply repealing P.L. 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). 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 DEA’s ability to enforce the law and take legitimate actions to prevent prescription drug abuse, DEA and the Department of Justice should bring forward suggested changes to Congress.

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As an industry, we have always advocated for and welcome a more open dialogue with DEA. The more the Agency can work proactively with and provide clarity for the registrant community, the more effective we will be in our collective efforts to address opioid abuse and misuse.

As policymakers look to address the epidemic moving forward, it is vitally important for Congress to balance two key considerations — how to reduce the prevalence of opioid abuse and misuse, and preserve patient access for those undergoing treatments who would needlessly suffer without pain medicines. We acknowledge and appreciate this balanced approach reflected in the President's Commission on Combatting Drug Addiction and the Opioid Crisis Final Report\(^7\) 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.”\(^8\)

HDA members endorse a comprehensive set of policies\(^9\) designed 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. 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 the epidemic.

Sincerely,

[Signature]

John M. Gray
President and CEO

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