UNITED STATES SENATE COMMITTEE ON THE JUDICIARY

HEARING ON
"TACKLING THE OPIOID CRISIS: A WHOLE-OF-GOVERNMENT APPROACH."

DECEMBER 17, 2019

QUESTIONS FOR THE RECORD FROM

SENATOR DIANNE FEINSTEIN

Questions for Patrick Kelly, Executive Vice President, Government Affairs, Healthcare Distribution Alliance (HDA)

1. Distribution Reporting Systems

Between 2006 and 2012, over 8 billion pain pills were dispensed in my home state of California; enough to give each Californian 40 pills per year. This resulted in 9,800 prescription drug-related overdose deaths. The overabundance of pills in California and other parts of the country demonstrate that opioid manufacturers and distributors must strengthen their internal controls.

In 2018, the Using Data to Prevent Opioid Diversion Act of 2018, which I authored, was enacted as part of the SUPPORT Act. It requires the DEA to work more closely with manufacturers and distributors to ensure adequate distribution of opioids. If manufacturers and distributors fail to work closely and carefully to identify suspicious orders, they can be held civilly and criminally responsible.

a) *In addition to the ARCOS system, what other internal controls do distributors and manufacturers have in place to identify and report suspicious orders of opioids?*

Distributors use a variety of different criteria and utilize sophisticated monitoring systems and algorithms for determining whether an order placed by one of their customers for a controlled substance meets the criteria for being a "suspicious order," as defined by the regulation. We look forward to DEA's proposed rule on suspicious orders and hope it will bring further clarity to the suspicious order reporting process and enhance the DEA and registrant community's efforts to prevent diversion of controlled substance.

b) With this in mind, what changes have drug manufacturers and distributors implemented to ensure that cities, towns, and states are not flooded with excessive amounts of opioids?

HDA strongly supported passage of the SUPPORT Act. Among many provisions, it broadened distributor access to a portion of critical data contained in the DEA's ARCOS database. For the first time since enactment of the Controlled Substances Act, distributors have visibility into a particular customer's orders from other distributors. This has the potential to help distributors consider additional information to make more informed decisions about individual orders for controlled substances.

As our members implement the provisions in the SUPPORT Act, they have encountered some operational challenges to using the data as it has been made available to them in the ARCOS database. Most importantly, our members would like the data to be available in bulk format so that it can be downloaded into existing systems. Right now, it is a very labor-intensive process. Our members like the ability to more easily integrate that ARCOS data into their monitoring systems so that the data can be used to its full potential. This is an important priority and we are working with DEA to try and address this issue.

In addition, the system currently allows only one employee of a distributor to access the database at a given time. DEA should expand the tool to allow for more than one employee to use the database in real-time.

We appreciate your leadership in introducing legislation that would address some of these operational challenges, as well as increase the frequency of ARCOS reporting and expand the types of controlled substances that are reported to the DEA.

2. Communication with the Drug Enforcement Administration

Communication between the Drug Enforcement Administration (DEA) and opioid manufacturers and distributors can play a critical role in identifying, reporting, and preventing suspicious orders of opioids. This point has been underscored in several reports issued by the GAO, and most recently, by the Department of Justice's Inspector General.

a) In your view, has the communication between your members and the DEA improved in recent years?

Over the past few years, the leadership of DEA, in its role as regulator, has started to improve 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 more actively and openly engage with its registrants in this way and we look forward to continued and further increased collaboration.

b) What additional steps can be taken to increase communication among all of the players in the supply chain?

Addressing the opioid crisis requires collaboration across the entire supply chain in concert with state and federal authorities. HDA has engaged in discussions with CMS, FDA and DEA to help identify solutions relating to opioid abuse. We are committed to continuing to work closely and openly with state and federal authorities to prevent diversion.

HDA members are also working with a number of groups to improve understanding about the dangers of opioid abuse, how to properly dispose of unwanted medicines and better utilization of data to prevent diversion and identify at-risk individuals. In February 2018, HDA launched Allied Against Opioid Abuse (AAOA), a national education and prevention effort focused on raising awareness around the safe use and disposal of opioids, as well as patients' rights, risks and responsibilities associated with the use of these medicines.

Ongoing communication and collaboration with registrants and the DEA will remain critical to addressing the opioid abuse crisis.

Questions for the Record from Senator Charles E. Grassley
U.S. Senate Committee on the Judiciary
"Tackling the Opioid Crisis: A Whole-of-Government Approach"
Submitted on January 7, 2020

Mr. Patrick Kelly

1. **How is Healthcare Distribution Alliance (HDA) working with DEA to ensure that the recommendations from the September 2019 Department of Justice Office of Inspector General Report are fulfilled and effective?**
   The OIG Report identified ways that the DEA can enhance their abilities to address the opioid abuse crisis. The report made several recommendations, which DEA has indicated are being implemented. For example, one of the recommendations was that all suspicious order reports be sent to DEA headquarters (as opposed to local DEA field offices), which was required under the SUPPORT Act. Some HDA members were already reporting all suspicious orders to headquarters, and others are in the process of updating their systems and processes to accommodate this and other new changes. HDA and its members look forward to continuing to work with DEA as they implement additional recommendations included in the report.

2. **What impact has the SUPPORT Act had on drug distribution companies, and has it been helpful in ensuring distributor compliance with DEA regulations?**
   HDA strongly supported passage of the SUPPORT Act. Among many provisions, it broadened distributor access to a portion of critical data contained in the DEA's ARCOS database. For the first time since enactment of the Controlled Substances Act, distributors have visibility into a particular customer's orders from other distributors. This has the potential to help distributors consider additional information to make more informed decisions about individual customers.

   As our members implement the provisions in the SUPPORT Act, they have encountered some operational challenges to using the data as it has been available to them in the ARCOS database. Most importantly, our members would like the data to be available in bulk format so that it can be downloaded into existing systems. Right now, it is a very labor-intensive process. Our members would like the ability to more easily integrate ARCOS data into their monitoring systems so that the data can be used to its full potential. This is an important priority and we are working with DEA to try and address this issue.

   In addition, the system currently allows only one employee of a distributor to access the database at a given time. DEA should expand the tool to allow for more than one employee to use the database in real-time.

   We appreciate your leadership in introducing legislation that would address some of these operational challenges, as well as increase the frequency of reporting and expand the types of controlled substances that are reported to the DEA.

3. **Transparency among manufacturers, distributors, and the DEA is critical to limit drug diversion. I've supported measures to require monthly updates on the sale and delivery of controlled substances, and also penalize the inaction or criminal behavior of manufacturers, distributors, and pharmacies.**
    a. **Can you explain why consistent reporting of sales and delivery of opioids are important to limit drug diversion?**
    Distributors report inventories, acquisitions, and dispositions of all substances in Schedules I and II, and narcotic and Gamma-Hydroxybutyric Acid (GHB) substances in Schedule III to ARCOS. Additionally, distributors use a variety of different criteria and utilize sophisticated monitoring systems and algorithms for determining whether an order placed by one of their customers for a controlled substance is suspicious. Consistent reporting is important and we look forward to DEA's proposed rule on suspicious orders, which we hope will bring greater clarity and consistency to the suspicious order reporting process and enhance the DEA and registrant community's efforts to prevent diversion of controlled substance.

    b. How can the relationship between each of your groups and the DEA improve in this area to prevent drug diversion?
    Over the past few years, the leadership of DEA, in its role as regulator, has started to improve 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 more actively and openly engage with its registrants in this way and we look forward to continued and further increased collaboration.

Questions for Patrick M. Kelly
From Senator Mazie K. Hirono

1. In your opening statement, you seemed to suggest that drug distributors don't have any responsibility for the opioid epidemic. You said "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." In other words, it's everyone's fault but distributors.

   But, in fact, distributors have significant responsibility for the crisis we are in. McKesson has twice had to pay civil penalties for failing to report suspicious opioid orders. In October, AmerisourceBergen, Cardinal Health, and McKesson were forced to settle with two Ohio counties who alleged that these distributors allowed high volumes of pills to flood into communities and be diverted for improper use. These are just a few examples.

   a. **Do drug distributors accept responsibility for contributing to the opioid crisis?**
   HDA members provide a safe and secure supply of all FDA-approved medications, when ordered by a registered and regulated pharmacy or other legitimate customer. We maintain effective controls to prevent diversion of all controlled substances when they are within our control, and report our shipments as required by DEA.

   Because we are part of the healthcare supply chain, we should be part of the solution, and we are doing that, through our involvement with FDA and CMS initiatives, and through our continued efforts to help DEA identify problematic pharmacies. HDA members endorse a comprehensive set of Practical Solutions to Address Opioid Abuse and Misuse[1] and, in 2018, launched leadership with Allied Against Opioid Abuse, a national education and prevention effort focused on raising awareness around the safe use and disposal of opioids as well as patients' rights, risks and responsibilities associated with the use of these medicines.

   b. **What steps has the drug distribution industry taken to ensure that suspicious opioid orders are reported to the authorities?**
   Pharmaceutical distributors are required to design and operate a system to disclose "suspicious orders," and to report those orders to DEA. Under the Controlled Substances Act, suspicious orders are defined as "including, but not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." Distributors use a variety of different criteria and utilize sophisticated monitoring systems and algorithms for determining whether an order placed by one of their customers for a controlled substance is suspicious. We look forward to DEA's

[1] https://www.hda.org/~/media/pdfs/government-affairs/hda-practical-solutions-final.ashx (accessed 1/8/2020).

proposed rule on suspicious orders and hope it will bring further clarity to the suspicious order reporting process and enhance the DEA and registrant community's efforts to prevent diversion of controlled substance.