Questions for the Record from Senator Charles E. Grassley
To President and CEO of Healthcare Distribution Alliance, John Gray
U.S. Senate Committee on the Judiciary
"Oversight on the Ensuring Patient Access and Drug Enforcement Act."
Submitted on December 20, 2017

Answers provided by John M. Gray on January 3, 2018

1. **Opioid distributors are required to report their sales of opioids to DEA through the ARCOS system. The distributors are also required to self-report suspicious orders. They have internal compliance functions to help them sort through what orders may be suspicious and what orders are legitimate. DEA keeps a database, ARCOS, for opioid sales data, and DEA has knowledge and data on suspicious reporting activity.**

    a. **Does anyone within the supply chain – drug manufacturers, distributors, and pharmacies – have access to ARCOS?**

    No one within the supply chain has access to ARCOS. Only DEA has access to the ARCOS system.

    b. **How would access to ARCOS change the way in which HDA handles its business?**

    HDA is not a DEA registrant and does not report to the ARCOS database. HDA does not have access to the data of our individual member companies nor does it in any way direct the activities of HDA member companies. We believe ARCOS data is most appropriate for DEA registrants who have reporting responsibilities under the Controlled Substances Act.

    c. **How would access to ARCOS change the way in which drug distribution companies handle their business?**

    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.

d. Without ARCOS data available to other actors within the supply chain, how is information or data pertaining to suspicious orders communicated?

Information and data pertaining to suspicious orders flows only one way: from manufacturers and distributors to regulators. HDA members do not receive information from DEA or from state regulators relating to suspicious orders. HDA members also do not receive from DEA information about pharmacies, prescribers, or other entities about which DEA may have concerns. HDA members must make decisions based on only the information their individual company has access to.

2. How would the repeal of the Ensuring Patient Access and Effective Drug Enforcement Act affect drug distribution companies?

If Congress were to repeal the EPAEDEA from the Controlled Substances Act, it would return registrants to the prior level of uncertainty about the scope of DEA's enforcement authority. Specifically, including a definition of "imminent danger" in the statute 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 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.

Further, the corrective action plan language adds an important new communication tool. In revocation proceedings following orders to show cause, DEA's Administrative Law Judges had previously been willing to consider a registrant's corrective actions, but the judges would first require the registrant to accept responsibility for all of the conduct that DEA had alleged. In effect, a registrant may have had to accept responsibility for conduct that was alleged but not committed before the registrant could present evidence of corrective actions for other conduct.

3. Does the change in the language as a result of the Ensuring Patient Access and Effective Drug Enforcement Act impact way that drug distribution companies conduct themselves?

Yes, the changes to the law have been one element of several that have positively impacted the way that HDA members conduct themselves and interact with DEA. The addition of a definition to the Controlled Substances Act, in conjunction with improving communication with the DEA, have begun to provide some of the regulatory clarity that HDA members have been seeking for many years. While we believe that there is still significant room for improvement in information-sharing between DEA and its registrants, these steps toward added clarity improve distributors' ability to work collaboratively with DEA to prevent diversion.

a. If so, please provide some examples.

HDA has asked its member companies for examples and hopes to be able to provide such examples in follow-up communication.

b. If not, describe why you think the change in language has not made an impact.

4. Why can't distributors work within the previous framework prior to enactment of EPAEDEA?

With regard to the immediate suspension order (ISO) language, HDA believes that the longstanding statutory provision allowing a DEA registration to be revoked where there is "an imminent danger to the public health or safety" is appropriate. This language, which Congress retained, appropriately limits the usage of ISOs to those extraordinary circumstances in which due process should not be granted prior to DEA's unilateral decision to suspend a registration.

The challenge, under the prior framework, was the lack of a publicly known definition of "imminent danger." Without a publicly known definition, DEA was free to adapt its own requirements, with no notice, to suit the circumstances before it. In the EPAEDEA, Congress created an appropriate, known standard against which both regulators and regulated can assess conduct, to which DEA and the Department of Justice did not object.

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Outside of the enforcement context, when a DEA registrant in the past would ask the agency for feedback and guidance as a part of its ongoing communications with its regulator—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. DEA would not confirm whether a registrant's changes would, in DEA's view, satisfy the CSA's requirements.

The new provision—allowing registrants to submit a corrective action plan to address compliance issues in handling controlled substances—is a step forward in allowing registrants to fully understand and address their compliance responsibilities.

SENATE JUDICIARY COMMITTEE

HEARING ON
"OVERSIGHT OF THE ENSURING PATIENT ACCESS AND EFFECTIVE DRUG ENFORCEMENT ACT"

DECEMBER 12, 2017

QUESTIONS FOR THE RECORD FROM

SENATOR DIANNE FEINSTEIN

RESPONSE FROM JOHN M. GRAY, PRESIDENT AND CEO OF THE HEALTHCARE DISTRIBUTION ALLIANCE (JANUARY 3, 2018)

Questions for President and Chief Executive Officer John Gray, Healthcare Distribution Alliance

1. Reporting Suspicious Orders

Between 2007 and 2012, opioid distributors delivered 780 million oxycodone and hydrocodone pills to pharmacies throughout West Virginia. This resulted in 1,728 fatal overdoses over six years.

a. Please explain how your members identify suspicious orders of prescription opioids, how they report these to DEA, and in what timeframe. What additional safeguards can your members put into place to better protect against diversion?

HDA members have invested heavily in information technology systems to help better flag suspicious orders, and consider many relevant data points and factors in the process, which also assists in efforts to better protect against diversion. Each registrant has developed its own proprietary method for identifying suspicious orders. The DEA regulation in 21 C.F.R. 1301.74(b) defines suspicious orders as including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." When DEA has identified additional factors that registrants should consider—beyond those identified in the regulation—DEA has shared these with registrants in letters to industry, in adjudicatory decisions, and in presentations at conferences.

DEA's regulations require that suspicious orders be reported to the local DEA Field Office "when discovered." 21 C.F.R. 1301.74(b). DEA does not require a specific format for that report, and different registrants may report in different ways.

2. Communication with DEA

A 2015 Government Accountability Office report made three recommendations to DEA about how to improve communication with its registrants to ensure better compliance with the Controlled Substances Act. One of the recommendations indicated that DEA should provide additional guidance to registrants about what constitutes a suspicious order.

a. Have your members received additional guidance on what constitutes a suspicious order?

DEA has not yet issued a guidance document or proposed rule about what constitutes a suspicious order.

b. In your opinion, has the communication between DEA and its registrants changed since this report was issued and since the Ensuring Patient Access and Effective Drug Enforcement Act was enacted?

Yes, it has. DEA has resumed public meetings with registrants and has reopened lines of communication. We are encouraged by the progress thus far.

3. Using Data to Prevent Diversion

The Automation of Reports and Consolidated Orders System, commonly known as ARCOS, is a data collection system maintained by DEA in which drug manufacturers and distributors report their controlled substance transactions. These reports can help identify the diversion of controlled substances in to illicit channels.

a. Would sharing de-identified data with registrants that only includes information such as the total number and type of opioids going to specific pharmacies and the total number of distributors serving specific pharmacies help prevent diversion?

Yes. 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:

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4. Opioid Quotas

The Attorney General, acting through DEA, is responsible for limiting the amount of a controlled substance that can be produced, distributed, and purchased by drug manufacturers. This is mandated by the Controlled Substances Act. Based on a number of factors, DEA gives each manufacturer a quota for the amount of a controlled substances it can produce, distribute, or buy to make prescription drugs. Importantly, these factors do not include abuse and overdose rates for particular substances or classes of substances, like opioids.

a. Would legislation amending the Controlled Substances Act to explicitly authorize DEA to consider abuse and overdose rates when setting quotas be helpful?

Because HDA does not have insight into the complex issue of quota setting, and because wholesale distributors do not drive demand for products, we defer to those with appropriate expertise.