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

Questions for Executive Director Carmen Catizone, National Association of Boards of Pharmacy

1. Internal Policy Changes at DEA

I understand that you have served as an expert witness for DEA in cases against registrants who do not adequately protect against diversion.

a. *Have you noticed any changes in internal DEA policies, either prior to or since the enactment of the Ensuring Patient Access and Effective Drug Enforcement Act, in terms of the burden of proof that must be met in order to bring cases against bad actors? Please explain.*
In the cases that I have served as an expert witness for the DEA and US Attorneys' offices, I have noticed an inexplicable raising of the bar for the burden of proof. Typically, I am presented with data and evidence relative to an indictment, administrative action, or criminal hearing. Upon review of that data, an opinion is issued that supports further actions by the DEA or US Attorney's offices and/or serve as the basis for my testimony at a hearing or trial. I have been serving in this capacity for almost 10 years. In the past two years, the opinions that I have been asked to submit have required multiple revisions, contrary to prior opinions, in order to include information that seemed above and beyond what was already contained in the opinion in order to move the case or action forward.

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?*
   Yes, the DEA assisted with the Controlled Substances Stakeholder Coalition organized by NABP that included all components of the drug distribution and patient care systems. The Coalition developed a guidance document and video to help practitioners and the industry identify "red flags" that would signal diversion or suspicious orders. The DEA was an active participant in that process and assisted with informing practitioners and registrants about the availability of the document and video. The DEA also engaged in a nation-wide educational effort to inform practicing pharmacists and state regulators about the pharmacist's corresponding responsibility, diversion, red flags, and suspicious orders. NABP worked with the DEA to create the meetings that occurred in the states and involved representatives of state regulatory boards at every session. NABP also served as the continuing education provider for the awarding of Continuing Pharmacy Education credit for pharmacists and pharmacy technicians attending the DEA sessions.

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?*
   NABP and the state boards of pharmacy have always had a close relationship with the DEA and communicated openly. In 2015, the DEA convened a meeting with industry representatives to further open lines of communication and continue the dialogue on diversion, corresponding responsibility, suspicious orders, and patient safety.

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?

The release of the ARCOS data may help prevent diversion in some, limited instances. In the cases that I have served as an expert witness for the DEA and US Attorneys' offices, the amount of controlled substances shipped by the egregious wholesale distributor was such that additional information from the ARCOS would have had no impact on the situation or case.

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?*

   If meaningful data can be collected on abuse and overdose rates, it probably would help to lower quotas. However, unless there is a determined effort to stop prescribers from illegally prescribing controlled substances, wholesale distributors from illegally distributing controlled substances, and pharmacists from illegally dispensing controlled substances, the reduction in quotas may result in a significant access problem for legitimate patients.