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 CHARLES E. GRASSLEY

RESPONSE FROM BRIAN E. FROSH, ATTORNEY GENERAL OF MARYLAND (JANUARY 24, 2018)

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1. **According to your testimony, the Attorney General's Office of Maryland has not been impeded by the law since it does not have the authority to stop distribution, but rather "catch it on the back end."**

    a. **In your experience as the Attorney General for Maryland, how did the enforcement actions against distribution companies and manufacturers function prior to the passage of the Ensuring Patient Access and Effective Drug Enforcement Act ("EPAEDEA")?**

    Prior to EPAEDEA, the DEA used enforcement actions to suspend and then revoke the registrations of, or require corrective action by, drug distributors who shipped excessive quantities of pills to pharmacies that were diverting those pills or who otherwise failed to maintain adequate diversion controls. When, for example, a distributor began to ship hundreds of thousands or millions of opioid pills to individual pharmacies, in amounts that could not possibly have been justified by legitimate medical need, the DEA could suspend the distributor's registration on the ground that such shipments were an "imminent danger to the public health and safety" – without the unnecessary statutory burden that it also demonstrate immediate death, bodily injury, or abuse in the absence of an immediate suspension order. After initiating an administrative enforcement

action, the DEA could then determine whether to revoke a registration or to reinstate it in light of appropriate corrective and remedial measures that it could require of the registrant.

b. Have there been any noticeable changes since the Act's passage?

Yes. As of the December 12, 2017 hearing, the DEA had issued no immediate suspension orders against distributors or manufactures since the enactment of EPAEDEA. Instead, the DEA has acknowledged that EPAEDEA constrains its ability to do so. Andrea Noble, Justice Department to Review Law that Limited DEA Amid Opioid Crisis, The Washington Times (Oct. 17, 2017). The DEA has urged Congress to correct this problem, and Congress should do so immediately by repealing EPAEDEA. As Ms. Ashley testified, "DEA needs every tool it can get to combat the opioid crisis."

c. Have any investigations initiated by your office been negatively impacted because of the enactment of EPAEDEA?

Yes. While it would not be appropriate for me to comment on pending investigations, to the extent that DEA would have taken action that EPAEDEA has prevented it from taking, EPAEDEA has, at a minimum, closed off a source of information upon which our investigators would rely.

d. How did the law affect the "back end" from your vantage point?

EPAEDEA drastically reduces – if not eliminates – the DEA's ability to stop diversionary orders before distribution takes place. To the extent that such orders are fulfilled, the harm that the DEA would prevent takes place and drugs are diverted. This inherently burdens public resources aimed at controlling the problem; if the DEA does not stop shipments, it is up to others to police diversion after-the-fact, when it is more difficult to do so and when it is necessary to clean up problems that could have been prevented.

Additionally, DEA action provides information that informs subsequent enforcement activities by states. The DEA and the states

are partners in law enforcement efforts to abate the opioid crisis, and reducing the DEA's ability to do its part makes the task of protecting the public more difficult for all of us engaged in the effort.

2. **What data did you rely on in formulating your position before signing the November 13, 2017 letter advocating for repeal of EPAEDEA?**

I relied extensively upon the Centers for Disease Control's comprehensive analysis of prescribing levels and patterns in various localities throughout the United States. The CDC, examining prescribing patterns at the county level through commercial data used by the pharmaceutical industry, has determined that the high rate of opioid prescribing in certain counties across the United States "cannot be explained by the underlying health status of the population." Centers for Disease Control & Prevention, Prescription Opioids, https://www.cdc.gov/drugoverdose/opioids/prescribed.html (last visited Jan. 19, 2018). The CDC's conclusion, coupled with raw data that shows that the number of opioid prescriptions annually is enough in many counties to provide each resident with a bottle of pills and more, convincingly demonstrate the staggering levels of over-distribution of these drugs. When the statistics show enough prescriptions for every adult in places like Kent County and Washington County, Maryland, or in Appanoose, Cass Clay, Lee, Lucas, Page, Union, and Wapello Counties in Iowa, it should be clear that the DEA needs additional – not fewer – tools. Centers for Disease Control & Prevention, U.S. County Prescribing Rates, 2016, https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html (last visited Jan. 19, 2018).

I also relied upon overdose death and addiction statistics generated by the CDC and by various state agencies, and the correlation that the CDC finds between overconsumption of opioids and the risk of addiction and death. Centers for Disease Control & Prevention, Opioid Prescribing, https://www.cdc.gov/vitalsigns/opioids/index.htmlhttps: //www.cdc.gov/vitalsigns/opioids/index.html (last visited Jan. 19, 2018).

Additionally, I examined statistics demonstrating the DEA's level of enforcement activity, and statements of the DEA's chief administrative law judge, leadership, and DEA field personnel about the impact of EPAEDEA, which are consistent with my own experience and that of my staff. Law enforcement agencies must operate under governing legal standards.

Partnerships with regulated entities – such as drug distributors – are shaped by those standards. When these standards are made inappropriately restrictive, agencies are rendered less able to enforce the law as it should be enforced. In my judgment and experience, in the judgment of 43 of my colleagues from both parties, and in the judgment of the DEA and its field employees, EPAEDEA clearly impedes efforts to combat the opioid crisis. Congress should never have enacted EPAEDEA, and should repeal it immediately.

3. **From a prosecutorial standpoint, why is the presence of a standard of review for DEA's use of Immediate Suspension Orders (ISOs) a bad thing?**

   The issue is not the "presence of a standard of review," but, as stated in question four, below, "the *change* in the standard of review." EPAEDEA changed the standard of review that had existed for decades from "imminent danger to the public health and safety" to "immediate threat that death, serious bodily harm, or abuse . . . will occur in the absence of an immediate suspension." The previous standard of an "imminent danger" was already more than adequate to guide the DEA's enforcement authority, which Members of this Committee indicated was clearly not excessive in scope. There was simply no need, in the midst of a nationwide opioid crisis, to fundamentally change the standard of review and curtail the DEA's ability to suspend orders that are imminently dangerous to public health and safety.

4. **How has the change in the standard of review directly impacted your office's investigations?**

   I have outlined EPAEDEA's implications for our investigations in my answers to questions 1(c) and 1(d), above.