

**BRIAN E. FROSH**  
*Attorney General*



**ELIZABETH F. HARRIS**  
*Chief Deputy Attorney General*

**CAROLYN QUATTROCKI**  
*Deputy Attorney General*

**STATE OF MARYLAND**  
**OFFICE OF THE ATTORNEY GENERAL**

FACSIMILE NO. 410-576-7035

WRITER'S DIRECT DIAL NO. 410-576-6311

Written Testimony of

**Brian E. Frosh**  
**Attorney General of Maryland**

Before the  
**United States Senate**  
**Committee on the Judiciary**

Hearing on  
**Oversight of the Ensuring Patient Access and Effective Law Enforcement Act**

**December 12, 2017**

Mr. Chairman and Honorable Members of the Committee:

Thank you for the opportunity to testify today. I am Brian Frosh, the Attorney General of Maryland. As Maryland's chief law enforcement officer, I have been engaged since assuming office in the battle against our country's devastating opioid crisis. I come before you to urge the repeal of the Ensuring Patient Access and Effective Drug Enforcement Act (EPAEDEA or Act).

On November 13, 43 of my colleagues and I sent a bipartisan letter to Congressional leaders making this same request. EPAEDEA has been a step backward in our collective efforts to prevent the unlawful distribution and diversion of opioids that have contributed to this epidemic. The Drug Enforcement Administration (DEA), our vital federal partner, must have all the tools necessary to be as effective as it possibly can be in this struggle, and given the depth of the crisis, Congress should be enhancing its authority. EPAEDEA does the opposite. It handcuffs the DEA. It makes it more difficult to stop suspicious shipments of narcotics that will compound the harm already plaguing countless communities across the country. EPAEDEA also gives additional protection to those suspected of illegal activity by formally requiring the DEA to evaluate "corrective action plans" instead of proceeding as expeditiously as possible to suspend or revoke the registration of harmful actors. It thereby offers an unnecessary bargaining chip to those the DEA has found are harming the public.

## THE SCOPE OF THE CRISIS

First, the consequences of this epidemic include the following:

- In 2016, more than two million Americans were suffering from addiction to prescription or illicit opioids.<sup>1</sup>
- Since 2000, about 200,000 Americans have died from overdoses involving prescription opioids, and this number exceeds 300,000 if deaths from heroin and illicit fentanyl are included.<sup>2</sup>
- Drug overdoses are now the leading cause of injury death in the United States, outnumbering both traffic crashes and gun-related deaths.<sup>3</sup>
- And it keeps getting worse; drug overdose deaths in 2017 are expected to exceed 70,000, more than the number of Americans killed during the Vietnam War.<sup>4</sup>

Despite widespread public and private sector efforts, the country has not yet been able to reverse this epidemic's deadly trajectory. State attorneys general are deploying multiple strategies, including prosecuting violations of state laws in the marketing, sale, and distribution of prescription opioids. We also represent state public health authorities and other agencies working, through regulatory oversight, to rein in harmful activity. Yet, while these efforts have made a dent in the crisis, the epidemic rages on, with clear evidence that the prescribing, distribution, and manufacturing of opioids in excess of medical need is contributing to its severity.<sup>5</sup>

---

<sup>1</sup> Josh Katz, *Drug Deaths in America Are Rising Faster Than Ever*, New York Times (June 5, 2017), <https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html>; see also National Institute on Drug Abuse, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse> (last visited Dec. 10, 2017).

<sup>2</sup> U.S. Centers for Disease Control & Prevention, Prescription Opioid Overdose Data, <https://www.cdc.gov/drugoverdose/data/overdose.html> (last visited Dec. 10, 2017); U.S. Centers for Disease Control & Prevention, New Data Show Continuing Opioid Epidemic in the United States, <https://www.cdc.gov/media/releases/2016/p1216-continuing-opioid-epidemic.html> (Dec. 16, 2016).

<sup>3</sup> U.S. Centers for Disease Control & Prevention, All Injuries, <https://www.cdc.gov/nchs/fastats/injury.htm> (last visited Dec. 10, 2017).

<sup>4</sup> Steve Birr, *Heroin Use Spikes as Drug Deaths Are Expected to Top 70,000 This Year*, The Daily Caller (Sept. 11, 2017), <http://dailycaller.com/2017/09/11/heroin-use-spikes-as-drug-deaths-are-expected-to-top-70000-this-year/>; Nadia Kounang, *US Heroin Deaths Jump 533% Since 2002, Report Says*, CNN.com (Sept. 8, 2017), <http://www.cnn.com/2017/09/08/health/heroin-deaths-samhsa-report/index.html>.

<sup>5</sup> U.S. Centers for Disease Control & Prevention, *Prescription Opioid Overdose Data*, <https://www.cdc.gov/drugoverdose/data/overdose.html> (last visited Dec. 10, 2017); see also Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of*

Consider these facts:

- In 2016, opioid manufacturers and distributors put enough opioids in circulation in the United States for pharmacies to fill almost 215 million prescriptions,<sup>6</sup> enough to give nearly nine out of every ten adults a prescription.
- Staggering amounts of opioids were shipped to particular localities, in quantities that common sense dictates could not possibly be justified by medical necessity in the local population. For example:
  - In 2016, enough opioids were distributed in four of Maryland's 24 counties to provide an opioid prescription to every adult and child, and then some.
  - In Washington County, not 75 miles northwest of here, pharmacies dispensed enough opioids to fill almost 170,000 prescriptions for 150,000 adults and children.
  - In Kent County, 75 miles in the other direction, pharmacies dispensed almost 23,000 opioid prescriptions for 19,700 adults and children.
  - And in Allegany County, the prescription rate was almost 130%, or about 92,000 prescriptions for only 72,000 people.<sup>7</sup>
- Comparable statistics reveal similar incidents of breathtaking over-distribution in every state, with repeated reports of clearly excessive quantities of opioids delivered to pill mills filling prescriptions that serve no medical need.<sup>8</sup>
- According to the Centers for Disease Control, about a quarter of U.S. counties receive enough opioid prescriptions for every adult or more.<sup>9</sup>

No state, community, or family is immune. This extraordinary level of harm places on all levels of government the obligation to work aggressively to combat the practices that fuel the addiction and overdose deaths destroying our communities.

---

*Addiction*, 36 Annual Survey of Public Health 559-74 (2015).

<http://www.annualreviews.org/doi/abs/10.1146/annurev-publhealth-031914-122957>.

<sup>6</sup> U.S. Centers for Disease Control & Prevention, *U.S. Prescribing Rate Map*, <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Dec. 10, 2017); U.S. Department of Health & Human Services, *The Opioid Epidemic: By the Numbers*, <https://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf> (June 2016).

<sup>7</sup> U.S. Centers for Disease Control & Prevention, *U.S. County Prescribing Rates, 2016*, <https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html> (last visited Dec. 10, 2017); U.S. Census Bureau, *American Factfinder Data*, [https://factfinder.census.gov/faces/nav/jsf/pages/community\\_facts.xhtml](https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml) (last accessed Dec. 10, 2017).

<sup>8</sup> Leonard J. Paulozzi *et al.*, *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers & Benzodiazepines*, 63 *Morbidity & Mortality Weekly Rpt.* 563 (July 4, 2014), available at [https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s\\_cid=mm6326a2\\_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s_cid=mm6326a2_w) (last visited Dec. 10, 2017).

<sup>9</sup> U.S. Centers for Disease Control & Prevention, *U.S. Prescribing Rate Map*, <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Dec. 10, 2017)

## WHAT THE LAW DOES

As the bipartisan coalition of state attorneys general put it last month in its letter to Congress:

“In the midst of this deepening public health crisis – at a time when our nation needs every available weapon at its disposal – the Act effectively strips the DEA of a mission-critical tool, namely, the ability to issue an immediate suspension order against a drug manufacturer or distributor whose unlawful conduct poses an imminent danger to public health or safety.”

Under the Controlled Substances Act (CSA), the DEA has authority to issue an immediate suspension order where the DEA “finds that there is an imminent danger to the public health or safety.” 21 U.S.C. § 824. EPAEDEA altered this standard by defining “imminent danger” to require “a substantial likelihood of an immediate threat of death, serious bodily harm, or abuse of a controlled substance.” 21 U.S.C. § 824(d)(2). This language has effectively eviscerated the DEA’s ability to act, drawing “imminent danger to the public health or safety” so narrowly that, in the words of former DEA Administrative Law Judge John Mulrooney, it is now “all but logically impossible” for the DEA to suspend a distributor for failing to comply with the CSA.<sup>10</sup>

EPAEDEA further constrains the DEA’s effectiveness by giving distributors a new avenue to avoid sanctions for engaging in unlawful diversion. The CSA now allows a registrant to file a “corrective action plan” (CAP) prior to an appearance for a show cause proceeding, and it requires the DEA to consider that CAP in determining whether enforcement proceedings should continue. In effect, it affords lawbreakers who have helped create the opioid crisis leverage to obtain additional chances. Again, at a time when the DEA’s ability to use its enforcement tools effectively to combat unlawful diversion is so critical, giving new tools instead to noncompliant registrants makes no sense. As Judge Mulrooney points out, this new requirement is akin to “mandating that law enforcement authorities allow shoplifting suspects caught in the act to outline how they intend to replace purloined items on store shelves . . . or perhaps allow bank robbers to round up and return ink-stained money and agree not to rob any more banks – all before any of those wrongdoers actually admit fault and without any consequence that might deter such behaviors in the future. Such mandates sound absurd because they would be absurd.”<sup>11</sup>

I remain mindful of the imperative that, in fighting this crisis, we must be careful not to overcorrect. We must vigilantly protect against impeding patient access to prescription drugs that serve legitimate medical needs. Yet EPAEDEA does not advance this important goal. Instead, it simply diminishes the DEA’s ability to prevent unlawful opioid diversion at the very time we are in

---

<sup>10</sup> John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, Marquette Law Review Vol. 101, P. 15 (forthcoming, Feb. 2018). <https://www.documentcloud.org/documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html>.

<sup>11</sup> Mulrooney & Legel, 101 Marquette Law Review at 7-8.

desperate need of strong national enforcement efforts to help successfully defeat this nationwide crisis.

## **CONCLUSION**

In sum, as have 43 of my colleagues from both parties, I implore Congress to help us move forward, not backward. As one of the greatest public health emergencies of our time, the opioid crisis demands a strong and decisive response across all levels of government. State attorneys general and local law enforcement officials will continue to do everything within our authority to abate this crisis and hold accountable those who are contributing to the devastation it has wrought. Yet the country's success in defeating this threat depends upon all of us – state, local, and federal authorities – working together effectively. To protect the families we serve, I urge Congress to act swiftly to restore and strengthen the DEA's ability to be a fully successful partner by repealing EPAEDEA.