



November 13, 2017

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Dear Congressional Leaders,

We, the undersigned Attorneys General, urge you to repeal Public Law 114-145, the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (“the Act”). The Act, which was signed into law on April 19, 2016, is a step backward in our collective effort to prevent the diversion and misuse of prescription drugs and address our worsening epidemic of opioid addiction and overdose deaths.

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In declaring the opioid epidemic a public health emergency, President Donald Trump stressed that “drug addiction and opioids are ravaging America” and underscored these grim statistics:

- In 2016, more than two million Americans had an addiction to prescription or illicit opioids.
- Since 2000, more than 300,000 Americans have died from overdoses involving opioids.
- Drug overdoses are now the leading cause of injury death in the United States, outnumbering both traffic crashes and gun-related deaths.
- The situation has only gotten worse, with drug overdose deaths in 2016 expected to exceed 64,000, more than the number of Americans killed during the Vietnam War.

In the midst of this deepening public health crisis – at a time when our nation needs every available weapon at its disposal to combat the opioid epidemic – the Act effectively strips the Drug Enforcement Administration (“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.

The Act added language to 21 U.S.C. § 824(d)(2) that redefined "imminent danger to the public health or safety" to mean a "substantial likelihood of an immediate threat of death, serious bodily harm, or abuse of a controlled substance." According to DEA Chief Administrative Law Judge John J. Mulrooney, II, the language has created an exceedingly high burden that is nearly impossible to meet.¹ As a result, the DEA’s ability to immediately suspend a registrant and institute simultaneous show cause proceedings against a manufacturer or distributor whose unlawful behavior endangers public health or safety is severely diminished.

In addition, the Act allows an applicant or registrant to file a "corrective action plan" prior to an appearance for a show cause proceeding. 21 U.S.C. § 824(c)(2)(C). This procedure, which requires review of a submitted plan and a determination of whether the proceedings should continue, hampers enforcement proceedings and puts the public at risk. As Judge Mulrooney and his co-author point out, the procedure “is akin to a state legislature 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 behavior in the future. Such mandates sound absurd because they would be absurd.”²

In sum, the Ensuring Patient Access and Effective Drug Enforcement Act neither safeguards patient access to medication nor allows for effective drug enforcement efforts. We urge you to

¹ See John J. Mulrooney, II & Katherine E. Legel, Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters, 101 MARQ. L. REV. 1, 113 (forthcoming Feb. 2018) [<https://law.marquette.edu/assets/news-and-events/pdf/marquette-law-review-mulrooney-legal.pdf>] (the new "definition . . . renders [the] utilization of an immediate suspension order against . . . registrants . . . all but impossible to defend in the federal courts").

² Mulrooney & Legel, 101 MARQ. L. REV. at 7-8.

repeal the Act so that the public is protected and drug manufacturers and distributors may be held accountable for their actions.

Sincerely,



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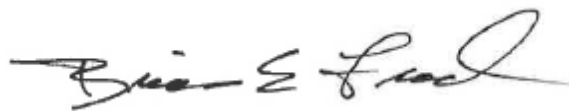
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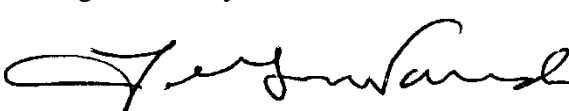
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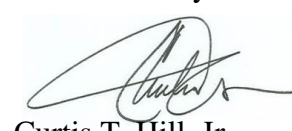
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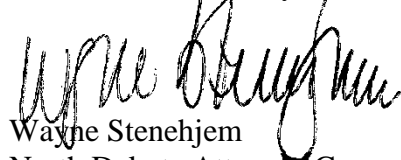
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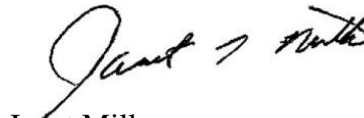
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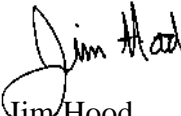
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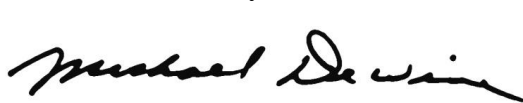
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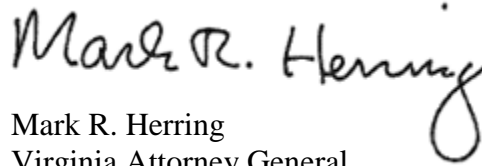
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