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Attorney General Balderas Urges Congress to Repeal Law that Supports Opioid Oversupply & Handcuffs the DEA

DEA should be able to issue immediate suspension orders

Balderas sued opioid manufacturers & distributors in September

Albuquerque, NM – **Attorney General Hector Balderas** sent a letter late yesterday to congressional leaders, urging them to repeal a 2016 federal law so registered drug manufacturers and distributors who have willfully contributed to the nation's oversupply of pain killers (opioids), can be held accountable. The "Ensuring Patient Access and Effective Drug Enforcement Act of 2016" (P.L. 114-145) has severely limited the Drug Enforcement Administration's (DEA) response to the opioid crisis. On average, over 500 New Mexicans die annually of a drug overdose, and approximately 70% of those deaths resulted from either opioid pain relievers or heroin. In more than a third of NM counties, over 80% of every 100 citizens has a prescription for opioids.

"New Mexico is in a state of emergency due to the opioid crisis that is ravaging our families, law enforcement agencies, healthcare system and economy," said **Attorney General Hector Balderas**. "I'm urging Congress to join our fight in New Mexico by repealing this absurd law that handcuffs the DEA and allows opioid manufacturers and distributors to fuel their addiction to profits as they flood the market with an oversupply of opioids. Earlier this year, I filed lawsuits against the opioid manufacturers and distributors, and launched Project OPEN: Opioid Prevention & Education Network as part of a multipronged attack on the opioid crisis in New Mexico."

"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 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 immediate danger to public health or safety," reads the **National Association of Attorneys General letter** sent late yesterday to U.S. Senate and House of Representative leaders and signed by 44 attorneys general in the states, District of Columbia and Virgin Islands. "We urge you to repeal the Act so that the public is protected and drug manufacturers and distributors may be held accountable for their actions."

While deaths in New Mexico due to illicit drugs have remained steady during the past 10 years, deaths due to prescription drugs – particularly opioid pain relievers – have increased dramatically, nearly doubling between 2000 and 2014. New Mexico's death rate from drug overdose grew in lockstep with the increasing sale and distribution of opioid drugs by the manufacturers and wholesale distributors. The New Mexico Department of Health estimates that in 2007 alone prescription opioid abuse and misuse cost the State of New Mexico \$890 million for items such as excess medical and prescription costs, lost earnings from premature deaths and costs associated with correctional facilities and police services.

In Rio Arriba County and Mora County, overdose death rates were more than five times the national rate. Also in Rio Arriba County, 64 out of every 1000 babies born are addicted to opioids which is 10 times the national average.

Please see attached for a copy of the letter.

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November 13, 2017

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Hon. John Cornyn Majority Whip 517 Hart Bldg. Washington, DC 20510

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Hon. Frank Pallone Jr. Ranking Member Energy and Commerce Committee 2322A Rayburn House Office Bldg. Washington, DC 20515

Hon. Dianne Feinstein Ranking Member Senate Judiciary Committee 331 Hart Bldg. Washington, DC 20510

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.

1850 M Street, NW Twelfth Floor Washington, DC 20036 Phone: (202) 326-6000 http://www.naag.org/ 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. 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 coauthor 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 inkstained 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."

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-legel.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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