

# United States Senate

COMMITTEE ON  
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS  
WASHINGTON, DC 20510-6250

CHRISTOPHER R. HIXON, STAFF DIRECTOR  
MARGARET E. DAUM, MINORITY STAFF DIRECTOR

May 8, 2017

Mr. Charles P. Rosenberg  
Acting Administrator  
Drug Enforcement Administration  
700 Army Navy Drive  
Arlington, VA 22202

Dear Acting Administrator Rosenberg:

The Committee on Homeland Security and Governmental Affairs is continuing its work to help combat the ongoing opioid crisis that continues to destroy lives throughout the nation. As the chief federal law-enforcement agency responsible for enforcing the nation's drug laws, the Drug Enforcement Administration (DEA) has a duty to investigate violations of controlled substance laws. Accordingly, we write to request information about the DEA's practices with respect to enforcement actions in anti-diversion investigations.

The Committee has done extensive and collaborative work to address the opioid crisis. In the 114th Congress, the Committee held field hearings across the country to hear from doctors, law-enforcement officials, local government leaders, and families affected by the opioid epidemic in those states.<sup>1</sup> We found that America's insatiable demand for drugs has led to challenges in securing our border.<sup>2</sup> This work spurred Sen. Johnson's Promoting Responsible Opioid Prescribing Act of 2016 (Prop Act), which sought to end the financial incentive for doctors to prescribe opioids.<sup>3</sup> The Obama Administration subsequently implemented the policies prescribed by the Prop Act through regulation.<sup>4</sup>

The DEA is instrumental in preventing and investigating the diversion of controlled pharmaceuticals, from both government and private facilities. In 2015, when the Committee examined allegations of opioid abuse at a VA facility in Tomah, Wisconsin, we learned that the

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<sup>1</sup> See *Border Security and America's Heroin Epidemic: The Impact of the Trafficking and Abuse of Heroin and Prescription Opioids in Wisconsin: Field Hearing Before the S. Comm. on Homeland Sec. and Gov't Affairs, 114th Cong. (2016)*; *Examining the Impact of the Opioid Epidemic in Ohio: Field Hearing Before the S. Comm. on Homeland Sec. and Gov't Affairs, 114th Cong. (2016)*; *America's Heroin Epidemic at the Border: Local, State, and Federal Law Enforcement Efforts to Combat Illicit Narcotic Trafficking: Field Hearing Before the S. Comm. on Homeland Sec. and Gov't Affairs, 114th Cong. (2015)*; and *All Hands on Deck: Working Together to End the Trafficking and Abuse of Prescription Opioids, Heroin, and Fentanyl: Field Hearing Before the S. Comm. on Homeland Sec. and Gov't Affairs, 114th Cong. (2015)*.

<sup>2</sup> S. Comm. on Homeland Sec. and Gov't Affairs, *America's Insatiable Demand for Drugs: The Public Health and Safety Implications for Our Unsecure Border* (Sept. 1, 2016).

<sup>3</sup> Promoting Responsible Opioid Prescribing Act of 2016, S. 2758, 114th Cong. (2016).

<sup>4</sup> Centers for Medicare and Medicaid Services, *CMS Hospital Value-Based Purchasing Program Results for Fiscal Year 2017*, Nov. 11, 2016, available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-11-01.html>.

DEA had been investigating allegations of diversion relating to the facility since at least 2009.<sup>5</sup> Two years after news broke of the tragedies—and eight years since the DEA began its investigation—we are unaware of any administrative or criminal charges stemming from the tragedies at the Tomah VA facility.

According to news reports, the DEA has also been slow to target private pharmaceutical distributors. The *Washington Post* has reported, for example, that when DEA agents “began to target wholesale companies that distributed hundreds of millions of highly addictive pills to the corrupt pharmacies and pill mills that illegally sold the drugs for street use,” DEA officials at headquarters “began delaying and blocking enforcement actions.”<sup>6</sup> The DEA has also reportedly provided “conflicting guidance” to a pharmaceutical company about its responsibilities to report suspicious orders from retailers.<sup>7</sup> The conflicting guidance reportedly contributed to the government’s inability to obtain criminal convictions following its investigation.<sup>8</sup>

To assist the Committee in better understanding how the DEA has pursued anti-diversion investigations during the opioid epidemic, we respectfully request the following information and material:

1. For each year since FY 2011, please provide the following data relating to the DEA’s anti-diversion activities:
  - a. The number of civil case filings against distributors, manufacturers, pharmacies, and doctors;
  - b. The number of immediate licensure suspension orders or orders to show cause against distributors, manufacturers, pharmacies, and doctors;
  - c. The number of voluntary license surrenders by doctors, including the number of such surrenders related to DEA enforcement actions; and
  - d. The number of administrative enforcement actions brought against opioid distributors and manufacturers.

For each entry, please identify the entity, the date of the DEA’s action, the nature of the allegations, and the disposition of the matter.

2. For each year since FY 2011, please identify all fines the DEA has levied against distributors and manufacturers, including the amount, date, and recipient of each fine.

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<sup>5</sup> See Maj. Staff of S. Comm. on Homeland Security and Gov’t. Affairs, *The Systemic Failures and Preventable Tragedies at the Tomah VA Medical Center*, 114th Cong. (2016).

<sup>6</sup> Lenny Bernstein and Scott Higham, *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control*, WASHINGTON POST, Oct. 22, 2016, [https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9\\_story.html](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html). [herein after Bernstein and Higham Oct. 22, 2016 article].

<sup>7</sup> Lenny Bernstein and Scott Higham, *The government’s struggle to hold opioid manufacturers accountable*, WASHINGTON POST, April 2, 2017, [https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm\\_term=.dcac0011d733](https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.dcac0011d733). [herein after Bernstein and Higham April 2, 2017 article].

<sup>8</sup> *Id.*

3. For each year since FY 2011, please list the number of reports to the DEA from manufacturers and distributors concerning suspicious orders of pharmaceuticals, broken down by the individual manufacturer or distributor.
4. For each year since FY 2011, please provide the following data relating to the DEA's anti-diversion activities:
  - a. The number of anti-diversion investigations relating to a Department of Veterans Affairs (VA) facility or doctor;
  - b. The number of license suspensions or civil proceedings against a VA facility or doctor; and
  - c. The number of criminal proceedings brought against a VA provider.For each entry, please identify the relevant facility, date of the proceeding, the nature of the allegations, and the disposition of the matter.
5. According to a news report, beginning in 2013 DEA attorneys "started requiring a higher standard of proof" before civil cases could move forward.<sup>9</sup> According to former officials, DEA leadership changed the burden of proof that investigators needed to meet before proceeding with administrative cases from a "preponderance of evidence" to "beyond a reasonable doubt."<sup>10</sup>
  - a. Is this assertion accurate? If so, please explain the reasoning behind this change and provide supporting material.
  - b. If accurate, please explain whether the DEA received approval or guidance from the Department of Justice, including the Office of the Deputy Attorney General, before requiring a higher standard of proof before proceeding with administrative cases.
6. As mentioned above, DEA officials may have presented conflicting guidance to a pharmaceutical manufacturer concerning its obligation to know its "customers' customers."<sup>11</sup> Please describe any obligations manufacturers hold to monitor and report suspicious activity by pharmacies and doctors, the sources for these obligations under law or DEA regulations, and any related guidance the DEA has provided to manufacturers.
7. When investigating a VA facility or provider, please explain the process by which the DEA obtains investigative information from the VA. Has the DEA ever experienced difficulties obtaining information from the VA necessary to complete an investigation? Please explain.

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<sup>9</sup> Bernstein and Higham Oct. 22, 2016 article, *supra* note 6.

<sup>10</sup> *Id.*

<sup>11</sup> Bernstein and Higham April 2, 2017 article, *supra* note 7.

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Please provide these materials as soon as possible, but by no later than May 22, 2017. After reviewing this information, the Committee may seek a staff-level briefing at the appropriate time.

The Committee on Homeland Security and Governmental Affairs is authorized by Rule XXV of the Standing Rules of the Senate to investigate “the efficiency, economy, and effectiveness of all agencies and departments of the Government.”<sup>12</sup> Additionally, S. Res. 62 (115th Congress) authorizes the Committee to examine “the efficiency and economy of all branches and functions of Government with particular references to the operations and management of Federal regulatory policies and programs.”<sup>13</sup>

Thank you for your prompt attention to this matter. If you have any questions regarding this request, please ask your staff to contact Kyle Brosnan or Brian Downey with the majority staff at (202) 224-4751 or Brandon Reavis with the minority staff at (202) 224-2627.

Sincerely,



Ron Johnson  
Chairman

Enclosure



Claire McCaskill  
Ranking Member

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<sup>12</sup> S. Rule XXV(k); *see also* S. Res. 445, 108th Cong. (2004).

<sup>13</sup> S. Res. 62 § 12, 115th Cong. (2017).