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United States Senate

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

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March 6, 2017

Michael E. Horowitz
Inspector General
Department of Justice
950 Pennsylvania Ave N.W.
Washington, D.C. 20530-0001

Dear Mr. Horowitz:

More than 183,000 people died in the United States from prescription opioid overdoses between 1999 and 2015, and more than 15,000 people died from prescription opioid overdoses in 2015 alone.¹ While opioid abuse has affected most communities across the United States, the epidemic has been particularly devastating in Missouri. From 2006 to 2010, heroin or opiate abuse diagnoses in Missouri emergency rooms rose 63.1%,² and the rate of prescription opioid-related inpatient hospitalizations and emergency room visits more than doubled from 187 per 100,000 to 424 per 100,000 between 2005 and 2014.³ Missouri also ranks first among Midwestern states in terms of the rate of prescription opioids sold.⁴

This epidemic has arisen, in part, from the failure of opioid distributors to monitor the flow of hundreds of millions of painkillers to pharmacies across the United States—and then to the black market. As the *Washington Post* has reported, at least 13 distributors, including three companies that control 85% of all U.S. pharmaceutical distribution, ignored warnings of opioid diversion “[e]ven when they were alerted to suspicious pain clinics or pharmacies by the [Drug Enforcement Agency] and their own employees.”⁵

¹ Centers for Disease Control, *Injury Prevention and Control: Opioid Overdose: Prescription Drug Overdose Data* (Dec. 16, 2016) (online at <https://www.cdc.gov/drugoverdose/data/overdose.html>).

² Kathleen Kane-Willis, et al., *A Multiple Indicator Analysis of Heroin and Opiate Use in Missouri: 2001 to 2011*, Missouri Recovery Network (March 2013).

³ Hospital Industry Data Institute, *Alarming Trends in Hospital Utilization for Opioid Overuse in Missouri* (Oct. 2015) (online at http://www.mhanet.com/mhaimages/HIDIHealthStats/Opioids_HealthStats_1015.pdf).

⁴ Kathleen Kane-Willis, et al., *A Multiple Indicator Analysis of Heroin and Opiate Use in Missouri: 2001 to 2011*, Missouri Recovery Network (March 2013).

⁵ *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Washington Post (Oct. 22, 2016).

In response, DEA has recently concluded significant settlements with major opioid distributors. Last month, McKesson Corporation agreed to pay a \$150 million penalty to resolve allegations that it “failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances distributed to its independent and small chain pharmacy customers.”⁶ In December 2016, Cardinal Health, Inc. resolved similar allegations, paying \$44 million after allegedly violating the Controlled Substances Act (CSA) in Maryland, Florida, and New York.⁷

Yet these settlements, coming years after similar allegations against distributors, raise the implication that DEA actions have been “too little, too late.”⁸ McKesson, for example, paid \$13.25 million to settle allegations regarding three of its warehouses—and “millions of doses of controlled substances...diverted from legitimate channels”—nine years before its January 2017 settlement.⁹ In 2008, Cardinal Health paid a \$34 million fine after its warehouses filled “thousands of suspicious orders from Internet pharmacies without reporting them,” but DEA investigators found evidence of widespread drug diversion at a Cardinal client in 2010, and Cardinal settled a related administrative case without paying a fine in 2012.¹⁰ Similarly, an AmerisourceBergen warehouse did not pay a fine to DEA “amid allegations that it was not controlling shipments of hydrocodone” back in 2007.¹¹

Recent actions against distributors have also occurred against a backdrop of significant enforcement challenges at DEA. The *Washington Post*, for example, has reported that “beginning in 2013, some officials at DEA headquarters began to block and delay enforcement actions against wholesale drug distributors and others, frustrating investigators in the field.”¹² Specifically, DEA leadership allegedly required a higher burden of proof—“beyond a reasonable doubt” instead of “a preponderance of evidence”—before allowing enforcement actions against distributors to proceed, and DOJ officials chastised Diversion Control Division employees for

⁶ U.S. Department of Justice, *McKesson Agrees to Pay Record \$150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* (Jan. 17, 2017) (online at <https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>).

⁷ U.S. Department of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016) (online at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act>).

⁸ *Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic*, ProPublica (Jan. 27, 2017).

⁹ *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Washington Post (Oct. 22, 2016).

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

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“going after industry.”¹³ The result, as Chief Administrative Law Judge John J. Mulrooney II noted in a 2014 report, was “an alarmingly low rate of Agency Diversion enforcement activity on a national level relative to historical data.”¹⁴ In fact, civil cases against private actors in the opioid pipeline and DEA immediate suspension orders both fell between 2011 and 2014.¹⁵

Troublingly, these developments parallel an effort by opioid manufacturers, distributors, and their law firms to hire dozens of former top DEA officials, including 31 officials directly involved in diversion control.¹⁶ These moves have prompted ethics experts to raise “serious questions about whether the ability of the diversion division to carry out its mission has been compromised by the pharmaceutical industry.”¹⁷

Given these serious concerns, I request that you investigate whether changes to legal standards for DEA enforcement actions and alleged interference from current and former senior DOJ and DEA officials have hampered efforts to hold distributors accountable for their lack of diversion oversight. If you have any questions related to this request, please contact Brandon Reavis of the Committee staff at Brandon_Reavis@hsgac.senate.gov or (202) 224-2627. Please send any official correspondence relating to this request to Amanda_Trosen@hsgac.senate.gov.

Sincerely,



Claire McCaskill
Ranking Member

cc: Ron Johnson
Chairman

¹³ *Id.*; *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Washington Post (Oct. 22, 2016).

¹⁴ *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Washington Post (Oct. 22, 2016).

¹⁵ *Id.*

¹⁶ *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Washington Post (Dec. 22, 2016).

¹⁷ *Id.*