

United States Senate

WASHINGTON, DC 20510

October 26, 2016

The Honorable Loretta Lynch
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 200530

Dear Attorney General Lynch:

We write to bring your attention to recent reports in the *Washington Post* regarding the Justice Department's regulation of pharmaceutical distributors.¹

We are concerned that the number of enforcement actions initiated by the Drug Enforcement Administration's Office of Diversion Control decreased significantly over the past five years. According to the *Post*, the judge who reviewed the diversion office's administrative caseload noted that civil case filings against distributors, manufacturers, pharmacies, and doctors plummeted from 131 in fiscal year 2011 to 40 in fiscal year 2014. The number of immediate suspension orders (ISOs) during the same period dropped from 65 to nine. The *Post* also reported a troubling allegation that wholesale drug distributors were going around the Office of Diversion Control and pressing higher level officials within the Justice Department in an effort to reach favorable resolutions to pending investigations.

This startling decrease in enforcement activity occurred just as our nation began to confront the scope of the opioid epidemic—and just as the over-prescription of powerful opioid painkillers was recognized as a major driver of the crisis. According to the Centers for Disease Control and Prevention, sales of opioid painkillers nearly quadrupled between 1999 and 2014, despite Americans not reporting an overall increase in their amount of pain.² Nearly 250 million prescriptions are now written for opioid painkillers each year, more than one for every adult in the country.³ The National Institute on Drug Abuse reports that nearly 80 percent of heroin users reported using prescription painkillers before they began using heroin.⁴

¹ Lenny Bernstein and Scott Higham, "Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control," *Washington Post*, October 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aca2bf8c-7f71-11e6-8d13-d7c704ef9fd9_story.html?hpid=hp_rhp-top-table-main_no-name%3Ahomepage%2Fstory; Lenny Bernstein, David S. Fallis and Scott Higham, "How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'" *Washington Post*, October 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8f7-7b6c1998b7a0_story.html?tid=a_inl.

² Centers for Disease Control and Prevention, "Prescribing Data," last modified March 16, 2016, <http://www.cdc.gov/drugoverdose/data/prescribing.html>.

³ See, e.g., Centers for Disease Control and Prevention, "Opioid Painkiller Prescribing," last modified July 1, 2014, <http://www.cdc.gov/vitalsigns/opioid-prescribing/>.

⁴ National Institute on Drug Abuse, "Prescription Opioids and Heroin," last modified December 2015, <https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use>.

We appreciate and commend the Justice Department for working together with drug manufacturers, distributors, pharmacies, and others, where feasible, to safeguard the supply chain for prescription opioids. But well-intentioned cooperation must not come at the expense of rigorous oversight of such entities. Diversion control is a powerful tool to combat opioid misuse. Rigorous enforcement, timely-brought cases, and meaningful penalties are also essential to ensure every part of the pharmaceutical supply chain adheres to the law. It is imperative that the DEA closely monitors opioid distribution and prescribing practices, while vigorously pursuing enforcement actions where systemic abuses endanger the public health or safety of Americans.

This issue is of great importance to the Committees on Judiciary and Finance. The Judiciary Committee has jurisdiction over criminal justice and drug enforcement policy, and is the authorizing committee for the Department of Justice and the Drug Enforcement Administration. The Finance Committee has jurisdiction over Centers for Medicaid and Medicare Services (CMS). By 2020, public and private spending on substance abuse disorder treatment is expected to reach \$42.1 billion, compared to \$24.3 billion in 2009.⁵ Medicare and Medicaid are expected to account for a third of this spending.⁶ In addition, wholesale pharmaceutical distributors are subject to CMS regulations.

Given these concerns, we would request that you respond to the following questions by November 28, 2016:

1. According to the *Post*, the Justice Department stated that diversion investigators are increasingly using criminal authorities to compel registrants to surrender licenses. For each year since 2011, please provide information on the number of:
 - a. Criminal enforcement actions that resulted in a registrant surrendering a license;
 - b. Orders to show cause that resulted in the revocation or suspension or a registration;
 - c. ISOs that resulted in the suspension of a registration; and
 - d. Investigations opened and closed by the Office of Diversion Control.
2. What factors have led to the decline in the use of orders to show cause and ISOs? Please describe any changes in policy or guidance that may have affected the use of these authorities.
3. Has the Ensuring Patient Access and Effective Drug Enforcement Act (Pub. L. No. 114-145) impacted the ability of the DEA to obtain ISOs? Please describe any current or expected impacts this law may have.
4. What standard does the DEA apply when reviewing administrative cases sought by the Office of Diversion Control—a “preponderance of the evidence” or “beyond a reasonable doubt,” as was reported by the *Post*? If the latter, why does the DEA believe that the

⁵ Substance Abuse and Mental Health Administration, *Projections of National Expenditures for Treatment of Mental and Substance Use Disorders, 2010-2020*, SMA-14-4883, 2014, <http://store.samhsa.gov/shin/content/SMA14-4883/SMA14-4883.pdf>, p. 30-31

⁶ *Supra*

standard it has chosen is appropriate for determining whether to bring an administrative case?

5. The *Post* reported that Cardinal Health reached a settlement in 2012 with the Justice Department related to sales of controlled substances to Gulf Coast Medical Pharmacy. Four years later, no fine has been levied and negotiations are ongoing, according to the *Post*'s reporting.
 - a. Please provide the settlement agreement between the U.S. Government and Cardinal Health.
 - b. What is the status of settlement negotiations, and why has the Department decided not to levy a fine in this case?
 - c. How does the time gap between a settlement agreement and fine – and the ongoing negotiations—in this case compare to other similar cases?
 - d. How is the Department enforcing the terms of this agreement?
 - e. Has Cardinal Health violated any of the terms of this agreement?

6. The *Post* cites a \$150 million settlement that the Justice Department reached with McKesson Corporation. According to securities filings the company made in 2015, the agreement settles “all potential administrative and civil claims relating to investigations about the Company’s suspicious order reporting practices for controlled substances.”⁷ The filing went on to say that the company agreed to “implement certain remedial measures” and suspend the DEA registrations of four distribution centers in Colorado, Michigan, Ohio and Florida, for between one and three years.⁸ According to previous securities filings, the U.S. Attorney for the Northern District of West Virginia brought similar claims that were being investigated subject to the Comprehensive Drug Abuse and Control Act.⁹
 - a. Please provide the settlement agreement between the U.S. Government and McKesson.
 - b. Please describe the circumstances that led to the investigation of the distribution centers whose licenses were suspended, including but not limited to:
 - i. The types and volumes of controlled substances involved in this case;
 - ii. The U.S. Attorney’s offices involved in the cases; and
 - iii. The provisions of law that the government believed had been violated.
 - c. How is the Department enforcing the terms of this agreement?
 - d. Has McKesson violated any of the terms of this agreement?

7. The *Post*'s reporting suggests that the pharmaceutical distributors have more work to do in order to stem prescription opioid diversion in addition to the settlements outlined above in questions 5 and 6, what other steps has the DEA undertaken to work with the largest drug distributors—namely, McKesson, Amerisource-Bergen, and Cardinal Health—to safeguard the supply chain for prescription opioids and identify diversion? If so, what has been the result of those efforts?

⁷ McKesson Corporation, *Form 8-K*, April 30, 2015, <https://www.sec.gov/Archives/edgar/data/927653/000119312515161747/d919028d8k.htm>.

⁸ *Supra*

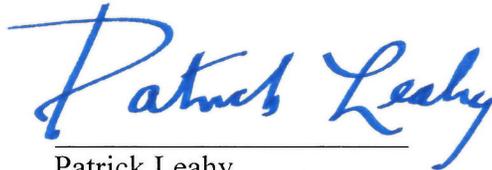
⁹ McKesson Corporation, *Form 10-Q for the quarterly period ended December 31, 2014*, February 15, 2015, p. 21, https://www.sec.gov/Archives/edgar/data/927653/000162828015000491/mck_10qx12312014.htm.

8. The *Post* reported multiple instances in which companies appeared to ignore or downplay concerns raised by employees or internal investigators. These actions appear to have led to the continued distribution of opioids to problematic pharmacies until regulatory or other outside enforcement forced distributors to take action.
 - a. What, if any, DEA regulations govern how companies should respond to these kinds of internal reports?
 - b. If no such regulations exist, does the DEA plan to develop guidance or regulations that would do so?

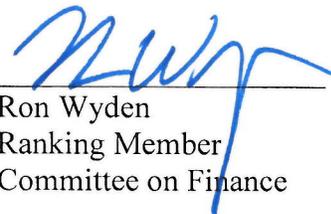
An opioid overdose claims a life every 20 minutes in the United States, which is equivalent to 78 people every day—a fourfold increase since 1999.¹⁰ We have heard countless stories of people affected by the scourge of opioid addiction, and are sure you have as well. We also know that you and your Department take this public health crisis incredibly seriously, and we look forward to continuing to work with you to ensure that the Department and DEA have sufficient resources to fight it.

If you or your staff has questions on this matter, please direct them to Senator Leahy’s Judiciary Committee staff at (202) 224-7703 or Senator Wyden’s Finance Committee staff at (202) 224-4515. Thank you for your attention to this important issue.

Sincerely,



Patrick Leahy
Ranking Member
Committee on the Judiciary



Ron Wyden
Ranking Member
Committee on Finance

cc:

The Honorable Charles P. Rosenberg
Acting Administrator
Drug Enforcement Administration

The Honorable Chuck Grassley
Chairman
Committee on the Judiciary

The Honorable Orrin Hatch
Chairman
Committee on Finance

¹⁰ Centers for Disease Control and Prevention, “Injury Prevention and Control: Opioid Overdose,” last modified June 21, 2016, <http://www.cdc.gov/drugoverdose/epidemic/>.