United States Senate
WASHINGTON, DC 20510

October 28, 2016

The Honorable Loretta Lynch
Attorney General
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

The Honorable Chuck Rosenberg
Acting Administrator
United States Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Attorney General Lynch and Acting Administrator Rosenberg:

We write to express our serious concern about last week's *Washington Post* report, which found that, over the last few years, the U.S. Drug Enforcement Administration (DEA) has scaled back its enforcement efforts against wholesale opioid distributors that are violating DEA's rules intended to prevent legal controlled substances from entering into the illicit market.[1]

The allegations in the *Washington Post* article are especially troubling given the opioid-abuse epidemic that is claiming nearly 30,000 lives in the United States annually. While much of the national attention has focused rightly on opioid painkiller manufacturers like Purdue Pharma, wholesale distributors also play a significant role in the crisis when they place prescription drugs in the hands of corrupt drugstores, pill mills, and crooked physicians. DEA's Diversion Control Division is charged with disrupting and preventing this flow of pharmaceuticals for illicit purposes while maintaining an adequate supply for legitimate needs. However, the *Washington Post's* report suggests that the Diversion Control Division has been hampered in its efforts to fully and forcefully carry out its important mission.

Specifically, the *Washington Post* reported that, among other things, when the Diversion Control Division ramped up enforcement actions in response to the burgeoning opioid-abuse epidemic, the distribution industry fought back — with apparent success. According to the report, DEA lawyers were instructed to begin using a higher standard of proof before enforcement cases could proceed; wholesale opioid distributors subject to enforcement actions by the DEA circumvented the agency's oversight by seeking relief from the Office of the Deputy Attorney General; and other roadblocks were placed in the way of DEA investigators as they attempted to take action against unlawful distributors.

As a consequence, according to the *Washington Post*, while civil case filings against distributors, manufacturers, pharmacies, and doctors reached 131 in fiscal year (FY) 2011, they

[1] http://wapo.st/2eEh4ZS

fell to 40 in FY 2014. During that same 2011-2014 period, the number of orders immediately suspending a distributor's DEA registration — the most powerful tool in the Diversion Division's arsenal — dropped from 65 to nine.

This occurred as prescription opioid overdose deaths increased by 12 percent between 2011-2014, and heroin overdose deaths increased by 140 percent in that time.[2] In 2014 alone, U.S. retail pharmacies dispensed 245 million opioid painkiller prescriptions[3] and there were 28,647 opioid overdose deaths.[4] Today, at least half of all opioid overdose deaths involve a prescription opioid.[5] DEA's 2014 National Drug Threat Assessment Summary noted that 21.5 percent of responding law enforcement agencies reported controlled prescription drugs as the greatest drug threat, a 119% increase since 2009.[6] Yet the *Washington Post* reported that the Chief Administrative Law Judge who reviews DEA Diversion Control Division cases had such a low caseload in 2014 that he permitted judges to hear cases from other federal agencies.

In light of the serious allegations in the *Washington Post's* reporting, we write to request that, by November 11, 2016, you answer the following questions about the DEA's anti-diversion enforcement efforts:

1. Did civil case filings against distributors, manufacturers, pharmacies, and doctors fall between fiscal years 2011 and 2014? Is the *Washington Post's* reporting that they fell from 131 to 40 correct? Why did this drop in civil case filings occur?

2. If the drop in diversion cases is attributable in part to shifting focus away from pill mills and onto physicians (among others), what impact has that shift in focus had on the surrender of physician licenses? Has the number of license surrenders increased? How many were tied to DEA enforcement actions? Please describe whether this shift has been effective in its aims relative to the prior focus on pill mills.

3. Did immediate suspension orders fall between fiscal years 2011 and 2014? Is the *Washington Post's* reporting that they fell from 65 to nine correct? Why did this drop in immediate suspension orders occur?

4. Was DEA policy changed so that DEA lawyers were required to satisfy a higher "beyond a reasonable doubt" standard — as opposed to a "preponderance of the evidence" standard — before civil cases could proceed?

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[2] https://wonder.cdc.gov/mcd.html
[3] http://www.nejm.org/doi/full/10.1056/NEJMra1507771#t=article
[4] http://www.cdc.gov/drugoverdose/data/statedeaths.html
[5] http://www.cdc.gov/drugoverdose/data/overdose.html
[6] https://www.dea.gov/resource-center/dir-ndta-unclass.pdf

Who imposed that requirement and why? Are there other scenarios under which DEA has imposed this higher requirement?

5. Please explain what role, if any, the Office of the Deputy Attorney General has had in any policy changes affecting the Diversion Control Division's ability to bring civil cases, enforcement actions, issue show cause orders or immediate suspension orders, or take any other steps to fulfill its mandate.

6. What is the status of current enforcement actions against distributors? For the past five years, please provide figures for the number of administrative, civil, and criminal actions initiated by DEA, as well as show cause orders and immediate suspension orders issued.

7. Please identify all fines levied against wholesale opioid distributors during the past five years.

8. What steps are you taking to ensure that DOJ and DEA can proactively and promptly take action against distributors that are violating anti-diversion rules?

9. The *Washington Post* reported that in one instance in 2010, the volume of OxyContin orders from an Ohio pain clinic drew the attention of the manufacturer, which subsequently reduced the distributor's supply by 20 percent. What are the requirements on pharmaceutical manufacturers and distributors for monitoring internal reports, trends, and outliers within its supply chain and reporting this information to the DEA? For the past five years, please provide figures on the number of reports to DEA from both pharmaceutical manufacturers and distributors on suspected cases of unlawful diversion.

Thank you for our time and consideration. We look forward to your prompt responses.

Sincerely,

Edward J. Markey
United States Senator

Richard J. Durbin
United States Senator

Joe Manchin III
United States Senator

Amy Klobuchar
United States Senator

Tammy Baldwin
United States Senator

Bernard Sanders
United States Senator

Richard Blumenthal
United States Senator