

United States Senate

WASHINGTON, DC 20510

January 17, 2017

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

Dear Acting Administrator Rosenberg:

Thank you for the December 20, 2016 letter to us from the Congressional Affairs Section of the Drug Enforcement Administration (DEA), replying to our October 28, 2016 letter regarding the *Washington Post's* recent reporting on enforcement efforts against wholesale pharmaceutical distributors by the Department of Justice (DOJ) and the DEA. We write again because the letter we received is unresponsive to many of the important public policy questions we raised in our initial correspondence. Since we wrote to you, the Centers for Disease Control and Prevention (CDC) has released new data showing that the U.S. opioid epidemic is growing and that prescription and illicit opioids remain a driving force. According to the CDC, in 2015, more than 52,000 people in the United States died from a drug overdose, and of those, more than 33,000 — approximately 63 percent — involved a prescription or illicit opioid.¹ Especially in light of this new data, Congress and the American people deserve an explanation of how the DEA is enforcing laws that could help address this public health crisis.

The questions in our letter sought information that would shed light on the *Post's* allegations that, in the midst of the opioid epidemic, enforcement efforts by the DEA's Office of Diversion Control decreased dramatically. We asked about the accuracy of specific allegations in the *Post*, and requested that you provide us with explanations, as well as data — unquestionably available to the DOJ and DEA — that would either confirm or controvert the *Post's* reporting. Instead, we received an insufficient response that ignored those questions almost entirely and recited boilerplate information about the DEA's mission. Although some of the questions we raised in our letter were discussed at the staff briefing the DEA provided on December 2, 2016, that briefing was not a substitute for complete written responses to our questions.

We set forth below the questions from our October 28, 2016 letter that remain unanswered. We reiterate our request for written responses to these questions, and ask that you provide them by January 31, 2017.

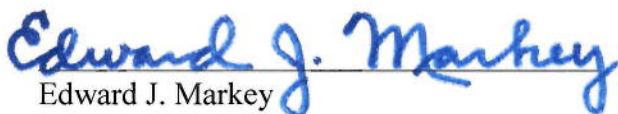
1. Did civil case filings against distributors, manufacturers, pharmacies, and doctors fall between fiscal years 2011 and 2014? Is the *Washington Post's* reporting that they fell from 131 to 40 correct? Why did this drop in civil case filings occur?

¹ <https://www.cdc.gov/media/releases/2016/p1216-continuing-opioid-epidemic.html>

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?
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 your prompt consideration. We look forward to your responses.

Sincerely,



Edward J. Markey
United States Senator




Richard J. Durbin
United States Senator


The Honorable Chuck Rosenberg

January 17, 2017

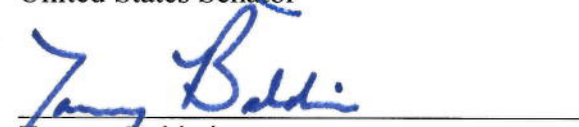
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Joe Manchin III
United States Senator



Amy Klobuchar
United States Senator



Tammy Baldwin
United States Senator



Bernard Sanders
United States Senator



Richard Blumenthal
United States Senator

cc: The Honorable Loretta Lynch