U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Springfield, Virginia 22152

DEC 2 0 2016

The Honorable Edward J. Markey
United States Senate
Washington, DC 20510

Dear Senator Markey:

Thank you for your letter dated October 28, 2016, to Attorney General Loretta Lynch and the Drug Enforcement Administration's (DEA) Acting Administrator Chuck Rosenberg regarding reports in the *Washington Post* pertaining to the DEA's regulation of pharmaceutical distributors. This letter supplements the briefing we provided to your staff on December 2, 2016.

Scope of the Problem:

At no time in DEA's nearly 45 year history has a robust regulatory program been more important in fulfilling its mission to prevent pharmaceutical drug diversion. This diversion has contributed to our Nation's epidemic of opioid misuse and today, drug overdoses are the leading cause of injury-related death in the United States, eclipsing deaths from motor vehicle crashes or firearms.[1] More than 52,000 overdose deaths took place in 2015, or approximately 143 per day, more than half (63 percent) of which involved either a prescription opioid or heroin. The latest National Survey on Drug Use and Health released on September 8, 2016, shows that 6.4 million persons aged 12 or older reported current misuse of prescription-type psychotherapeutic drugs. Of that, 3.8 million reported current misuse of pain relievers.[2]

Administrative Actions Against Registrants, Including Distributors:

DEA regulates more than 1.6 million registrants who handle, dispense, or prescribe controlled substances or listed chemicals, including manufacturers, distributors, practitioners, researchers, importers, and exporters, the vast majority of whom operate within the law. When DEA determines that a registrant is not in compliance with the Controlled Substances Act (CSA) and/or the Code of Federal Regulations (CFR), DEA may deploy a full array of administrative actions, ranging in

1 Centers for Disease Control and Prevention, Web-based Injury Statistics Query and Reporting System (WISQARS) [online], (2014), available at: http://www.cdc.gov/injury/wisqars/fatal.html.
2 Center for Behavioral Health Statistics and Quality. (2016). Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Retrieved from http://www.samhsa.gov/data/

seriousness from Letters of Admonition, Administrative Hearings, Memoranda of Agreement, surrenders of a DEA registration "for cause," an Order to Show Cause (OTSC), or an Immediate Suspension Order (ISO). The *Washington Post* article focused on two of these administrative tools – OTSC and ISO. During the time period reviewed by the *Washington Post* (FY 2011 – FY 2015), DEA conducted 90 Administrative Hearings, issued more than 6,500 Letters of Admonition, and entered into more than 1,300 Memoranda of Agreement with registrants, including distributors. These administrative actions are designed to change registrant behavior and ensure compliance with the CSA.

The nature of pharmaceutical drug diversion changed in the mid-to-late 2000s, when the state of Florida was widely regarded as the epicenter of the prescription drug crisis. Beginning in approximately 2007, pain clinics proliferated in Florida. These clinics were responsible for prescribing large quantities of drugs for pain without medical justification.[3] By 2010, Florida was home to 98 of the top 100 physicians prescribing and dispensing oxycodone directly from their offices.[4] DEA regards these "pill mills" as a primary cause of the ensuing prescription drug epidemic.

During this period, DEA focused significant enforcement resources on these Florida prescribers. In 2011 and 2012, DEA, and its law enforcement partners in Florida, conducted large-scale enforcement operations, which exposed these pill mills. DEA's efforts resulted in numerous ISOs and OTSCs against several individual practitioners – one contributing reason for the higher than average number of OTSCs and ISOs in FY 2011 compared to prior and subsequent years.

In addition, since FY 2011, DEA's tactical diversion squads (TDS) have assumed a greater role in diversion enforcement. DEA now has 77 operational TDS groups across the United States, a significant increase (67 percent) over the 46 groups DEA had in FY 2012. TDS groups focus primarily on criminal enforcement and the results of their work often lead DEA registrants to surrender their DEA registration for cause. In these instances, DEA would not be required to initiate an administrative action to revoke the DEA registration. For example, between FY 2011 and FY 2015, a total of 4,756 registrations were voluntarily surrendered.

DEA continues to proactively pursue criminal and/or civil cases with United States Attorneys' Offices across the country. In August 2016, DEA's Diversion Control Division hosted training on pharmaceutical drug investigations and prosecutions for 89 United States Attorney's Offices. The three-day training conference was attended by approximately 500 Assistant United States Attorneys and covered numerous topics including: an overview and history of diversion prosecution; charging and investigative strategies; prosecuting death or serious bodily injury cases; and, a roadmap to the successful prosecution of diversion cases. DEA continues to seek opportunities to increase the civil and criminal prosecution of registrants operating outside the law.

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3 *Decline in Drug Overdose Deaths After State Policy Changes – Florida, 2010-2012,* Centers for Disease Control and Prevention, 63(26); 569-74 (July 4, 2014).
4 *Ibid.*

DEA's Legal Standard Has Not Changed:

In administrative cases the ultimate legal question to be decided is, and remains, whether, by a preponderance of the evidence, the DEA registrant's continued registration is "in the public interest." The *Washington Post* article incorrectly stated that the burden of proof for administrative cases changed from a "preponderance of the evidence" to "beyond a reasonable doubt." DEA utilizes the preponderance standard noted above.

Cooperation with Those DEA Regulates – Education and Outreach:

Nearly 80 percent of current heroin users report having misused prescription opioids before initiating heroin use. As such, DEA manages a robust oversight program that deploys a full spectrum of administrative, civil and criminal tools against those whose continued registration is no longer consistent with the public interest.[5] However, DEA believes that just as important is the recognition that DEA cannot solve this problem through regulatory oversight or enforcement alone. DEA will continue to partner with its 1.6 million registrants, including the approximately 900 distributors, to leverage their abilities to minimize the risk of opioids, or other controlled prescription drugs, finding their way to those who may go on to misuse them.

DEA maintains a proactive program of outreach to its registrant population, including distributors. In fact, the DEA's Distributor Initiative is designed to educate and inform them and other registrants of their statutory responsibilities to prevent the diversion of controlled substances. Additionally, DEA Diversion Investigators meet with distributors and discuss national trends, due diligence and Automation of Reports and Consolidated Order System (ARCOS) data for sales and purchases of Schedule II and III controlled substances. During FY 2016, the Diversion Control Division conducted 14 distributor's initiative briefings.

DEA continues to work with distributors to safeguard the prescription opioids supply chain and to identify diversion. Distributors registered with DEA are subject to an unannounced regulatory investigation every two years. In part, these inspections allow for an accountability audit of selected controlled substances, a comparison of ARCOS records with source documents, and thorough review of all records required to be maintained by the CFR. During FY 2016, DEA conducted 352 regulatory investigations of distributors throughout the United States.

Finally, DEA regulations require registrants to provide effective controls and procedures to guard against theft and diversion of controlled substances; however, DEA regulations do not specifically address how registrants should respond to internal concerns raised or reported by their employees. DEA has met with industry on several occasions and considered their concerns regarding the identification and reporting of suspicious orders. DEA is currently working to provide specific guidance and will publish policy guidance and/or new regulations to address this issue.

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5 Pursuant to 21 U.S.C. 823

Moving Forward:

DEA continues to combat the opioid crisis in many ways: criminally, civilly, administratively, and through robust demand reduction efforts. DEA believes that we can do better. We have implemented new case intake procedures for our administrative cases, and we continue to expand the TDS groups to focus on criminal and civil investigations. We are also working on developing a pilot program to hire and assign Special Assistant United States Attorneys to districts that are prescription drug diversion hotspots. These initiatives, combined with our commitment to continued education and outreach efforts with our registrants, are essential to combatting the prescription opioid epidemic.

We hope this information is helpful. Please do not hesitate to contact this office again if we may provide additional assistance regarding this or any other matter.

Sincerely,

Matthew J. Strait
Section Chief
Congressional Affairs Section