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COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
COMMITTEE ON APPROPRIATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEE ON RULES AND ADMINISTRATION

October 17, 2019

The Honorable Uttam Dhillon
Acting Administrator
United States Drug Enforcement Administration
8701 Morrissette Dr.
Springfield, VA 22152

Dear Acting Administrator Dhillon:

Facing the worst drug epidemic in our nation's history, I urge you to read this communication carefully and respond in a timely manner.

The October 1 report from the Department of Justice's Inspector General (IG) paints a damning picture of past missteps by the Drug Enforcement Administration (DEA) that have contributed to the nation's opioid epidemic. Since 2016, I have sounded the alarm about DEA's lax oversight of the pharmaceutical industry, and this IG report corroborates my concerns. I write today to seek information and outline additional steps DEA must take to regain public trust in the agency's ability to prevent and respond to the opioid crisis.

Aggregate Production Quotas

Through hearings, meetings, and letters, I have shared my deep concern with your predecessors that, between 1993 and 2015, DEA allowed aggregate production quotas for oxycodone to increase 39-fold, hydrocodone to increase 12-fold, hydromorphone to increase 23-fold, and fentanyl to increase 25-fold. The IG report highlighted that, while the opioid epidemic surged, "DEA was authorizing manufacturers to product substantially larger amounts of opioids." As a result, the pharmaceutical industry flooded every corner of the country with 76 billion oxycodone and hydrocodone pills between 2006 and 2012—outsized and unjustifiable numbers of painkillers shipped with DEA approval and awareness.

For years, my calls to rein in the pharmaceutical industry's insatiable demand for excessive opioid quota increases were met with passivity from DEA, which cited limitations from the Controlled Substances Act (CSA). So last year, Senator John Kennedy and I passed the bipartisan Opioid Quota Reform Act, which was signed into law as Section 3282 of the SUPPORT for Patients and Communities Act (P.L. 115-271), to strengthen DEA's statutory quota-setting authority by enhancing transparency and requiring opioid quotas to be adjusted to reflect diversion, overdose deaths, and public health. I am hopeful that our new law will address DEA's flagrant quota issues over the past two decades.

However, I was discouraged by DEA's explanation in its 2020 proposed quota rule that its estimate of diversion—for the purpose of setting aggregate production quotas—was based upon reported theft loss and seizures, not data on drug sales, overdoses, or deaths. While I appreciate the challenges in directly linking patient overdoses to a specific controlled substance, it defies logic that DEA would simply ignore or discard this information. DEA stated that,

"illicit manufacturing cannot be tempered by adjusting the aggregate production quotas", but this fails to acknowledge the potential impact that such adjustments may have on illicit *demand*.

I fear that ignoring the connection between the staggering volumes of painkillers approved for production and the overdose epidemic signals that DEA is reverting to the same one-eye-closed approach that precipitated this opioid crisis. The statute is clear that DEA must exercise its quota authority to serve as a gatekeeper and weigh the public health impact of how many opioids it allows to be sold each year in the United States.

If DEA requires any Congressional assistance to improve data sharing with states or the Department of Health and Human Services (HHS) to implement requirements under Section 3282, please outline such assistance that may be useful. Further, please provide a copy of the reports to Congress required under Section 3282 regarding transparency in individual manufacturing quotas, and strengthening DEA's processes for fixing and adjusting production quotas for opioids.

Registrant Licensure

The IG report found that "DEA's preregistration process did not adequately vet all new applicants before granting DEA registration" and that "DEA policy allowed, and still allows, registrants that have had their registration revoked, or that have surrendered it, to reapply for registration the day after a revocation is enforced or a surrender occurs." Further, the IG report found that, "DEA did not conduct background checks on all new applicants and relied instead on the good faith of applicants to disclose relevant information, even in cases in which the applicant had previously engaged in criminal activity." This is simply shocking.

The opportunity and privilege to be registered with the DEA to prescribe or dispense controlled substances should be undertaken with the sober appreciation for the potential human consequences from the diversion of controlled substances. The second and fifth recommendations from the IG provide a roadmap for DEA to rectify its process for allowing practitioners to prescribe or dispense controlled substances for opioids. I have previously introduced legislation (S. 2729 in the 115th Congress) to further require potential registrants to undergo dedicated training on responsible opioid prescribing and dispensing practices. If DEA requires any additional statutory authority to strengthen its pre-registration process for physicians, dentists, and pharmacists seeking DEA licensure or improve the information-sharing process with appropriate state licensing boards, please outline such statutory changes.

Oversight of Distributors

Following reporting from the *Washington Post*, Senator Ed Markey and I sent letters to DEA in 2016 regarding our concerns that the agency scaled back its enforcement efforts against opioid distributors that were flooding the market with extreme volumes of painkillers and neglecting their responsibilities under the CSA. The IG report found that "DEA rarely used its strongest enforcement tool, the Immediate Suspension Order (ISO), to stop registrants from diverting prescription drugs," and affirmed the steep decline in the use of ISOs by 90 percent (59 to 6) between fiscal years 2011 and 2017.

The IG report identified several potential explanations for the decline, including insufficient evidentiary presentations by DEA in legal actions, a disproportionate surge in enforcement actions between fiscal years 2010 and 2012, a "toxic" relationship between DEA's field offices and prosecutors, the passage of the 2016 Ensuring Patient Access and Effective Drug Enforcement Act, insufficient reporting of "suspicious orders" by distributors, and inadequate monitoring and use of the Automated Reports and Consolidated Orders System (ARCOS) database. In particular, the IG report noted infrequent ARCOS reporting intervals (registrants submitting both monthly and quarterly), and an inadequate scope of data captured (registrants not submitting information regarding schedule III-V controlled substances).

In a December 2017 Senate Judiciary Committee hearing, DEA testified that the agency, "supports changing the Ensuring Patient Access and Effective Drug Enforcement Act to allow DEA to more effectively stop bad actors." Please outline what statutory changes DEA supports, including specific language to either repeal provisions of the Ensuring Patient Access and Effective Drug Enforcement Act or revise the statutory definition of "imminent danger" and process for corrective action plans.

As part of the SUPPORT Act, I authored a provision, along with Senators Feinstein, Grassley, and Capito, to clarify and standardize the definition of suspicious orders to improve reporting and compliance. I further included a provision requiring DEA to provide two ARCOS data reports per year to state Attorneys General, law enforcement, and regulatory and licensing agencies on the volume, outliers, and trends of opioids in order to enhance oversight. I request information on whether DEA has provided these mandatory ARCOS data reports to states.

Approximately thirteen billion opioid doses were put on the market in 2017—enough for every adult American to have at least a three-week prescription of painkillers. As powerful painkillers are aggressively marketed and prescribed at high rates, this sheer volume of available opioids heightens the risk for illicit diversion and abuse. This unconscionable level of pharmaceutical excess happened with DEA's approval and monitoring. To ensure DEA is heeding the recommendations from the scathing IG report and learning lessons from its failure to stem the tide of the opioid epidemic, I request a meeting with you within the next month to discuss these issues and questions.

Thank you for your attention to these matters, and I look forward to your response to these requests.

Sincerely,

Dick Durbin

Richard J. Durbin
United States Senator