United States Senate
WASHINGTON, DC 20510

December 14, 2022

The Honorable Anne Milgram
Administrator
United States Drug Enforcement Administration
8701 Morrissette Dr.
Springfield, VA 22152

Dear Administrator Milgram:

The nation's opioid epidemic continues to rage, as 2021 saw the highest recorded level of drug overdose deaths in history. As the Drug Enforcement Administration (DEA) utilizes all of its tools to confront this crisis, we write to commend the agency for its final rule on opioid production quotas for 2023. We urge DEA to continue applying the authorities provided by Congress to establish sensible quotas that prevent the downstream public health harm of the pharmaceutical industry's opioid over-production.

We previously have shared our deep concern 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. Reporting from *The Washington Post* revealed that the pharmaceutical industry flooded every corner of the country with more than 100 billion oxycodone and hydrocodone pills between 2006 and 2014—an outsized and unjustifiable volume of painkiller production that was undertaken with DEA's approval. An October 2019 report from the Department of Justice's Inspector General highlighted that, while the opioid epidemic surged, "DEA was authorizing manufacturers to produce substantially larger amounts of opioids."

Section 3282 of the *SUPPORT for Patients and Communities Act* (P.L. 115-271) strengthened DEA's statutory quota-setting authority by enhancing transparency and requiring opioid quotas to be adjusted to reflect diversion, overdose deaths, and public health. As the bipartisan authors of that section, we strongly encourage you to continue using this authority to rein in the pharmaceutical industry's incessant demand for excessive levels of opioid production.

We previously have expressed our concerns that DEA was not properly following this law's requirements to consult with the Department of Health and Human Services (HHS) Secretary and to consider reliable information on overdose rates, abuse, and overall public health impact in order to estimate the amount of diversion and make appropriate quota reductions. While we remain troubled by DEA's stunningly low estimate that less than one percent of oxycodone and hydrocodone was diverted, we do recognize and appreciate the new efforts undertaken by DEA to implement the law. For example, we applaud DEA's engagement with 30 states and territories to assess prescription drug monitoring program (PDMP) data for red flag indicators of diversion.

Given that one of the most common sources of prescription drug misuse is through access from friends and family, according to the National Survey on Drug Use and Health, we believe DEA must refine its methodologies for approximating diversion through legitimate channels. As stated in the proposed rule, "while PDMP data is useful in estimating diversion, it is not conclusive." While we appreciate the challenges in directly linking patient misuse and overdose to a specific controlled substance, DEA should consult with states, HHS, and other public health experts to estimate or create proxies—based upon survey and research data—on the volume of dispensed opioids contributing to addiction and abuse.

In prior years, we have been deeply troubled by DEA statements that fail to acknowledge how the sheer volume of available opioids heightens the risk for illicit diversion and abuse. Indeed, part of the intent of the *SUPPORT Act's* provision was to appropriately recognize the potential impact that quota adjustments may have on illicit demand. As powerful painkillers are marketed aggressively and prescribed at high rates, there is a need for DEA 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.

As DEA implements the schedule II opioid production quotas for 2023 and beyond, we urge you to apply DEA's statutory authorities to prevent and limit opioid diversion due to excessively high production levels. Thank you for your commitment to addressing the opioid epidemic. We look forward to continuing to work with you on this issue.

Sincerely,

Richard J. Durbin
United States Senator

John Kennedy
United States Senator