

United States Senate

WASHINGTON, DC 20510

July 30, 2020

The Honorable Timothy J. Shea
Acting Administrator
United States Drug Enforcement Administration
8701 Morrissette Dr.
Springfield, VA 22152

Dear Acting Administrator Shea:

The unprecedented strains from the COVID-19 pandemic have compounded our nation's ongoing opioid epidemic, with a recent surge in overdoses and deaths due in part to economic hardship and isolation. On July 12, the Secretary of Health and Human Services (HHS) renewed the determination that the opioid crisis is a public health emergency, and the Centers for Disease Control and Prevention (CDC) last week reported an increase in fatal drug overdoses in 2019 to the highest ever level. We write to urge the Drug Enforcement Administration (DEA) to continue tackling the opioid crisis by utilizing authorities provided by Congress to establish sensible opioid production quotas for 2021. In doing so, we urge you to carefully review the opioid production quota increases effectuated in April 2020 in response to the COVID-19 pandemic and assess whether those levels strike an appropriate balance between preventing oversupply/diversion and ensuring the availability of certain medications used for ventilator patients.

We have previously 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. Recent reporting from the *Washington Post* revealed that the pharmaceutical industry flooded every corner of the country with 76 billion oxycodone and hydrocodone pills between 2006 and 2012—outsized and unjustifiable volumes 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." While we appreciate the initial steps taken in recent years to reduce the aggregate production quotas for schedule II opioids, we remain concerned that they are still higher than necessary to meet legitimate medical needs.

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 use this authority to rein in the pharmaceutical industry's incessant demand for excessive levels of opioid production. However, we are concerned that DEA is not properly following this law's requirements to consult with the 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.

We remain troubled by DEA's explanation in its 2019 proposed rule that its estimate of diversion—for the purpose of setting the aggregate production quotas—was based upon reported theft loss and seizures, and that DEA could not use Medicaid sales data or drug overdose and death data from the CDC. To be clear, theft loss and seizures are not the basis for our nation's opioid epidemic and public health emergency. DEA's estimate that less than one percent of oxycodone and hydrocodone was diverted is simply not credible.

While we appreciate the challenges in directly linking patient overdoses to a specific controlled substance, DEA cannot merely ignore or discard this essential information from the quota-setting process. DEA should, for example, consult with states, HHS, and other public health agencies to estimate dispensing rates, addiction and abuse rates, surveys of access to prescription opioids through informal channels, and other public health data tools in order to assess how our nation's oversupply of prescription painkillers contributes to misuse, as is required by the law.

Further, in the 2019 proposed rule, DEA stated that, "illicit manufacturing cannot be tempered by adjusting the aggregate production quotas". This fails to acknowledge the potential impact that such adjustments may have on illicit *demand*. Approximately eleven billion opioid doses were put on the market in 2018—enough for every adult American to have a nearly 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. For example, four out of five new heroin users first began their addiction with prescription painkillers. We fear that the explanation provided by DEA ignores the clear connection between the staggering volumes of painkillers approved for production and the current overdose epidemic. 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.

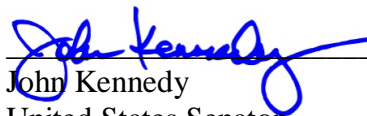
Therefore, we request a written explanation and staff briefing by September 15, 2020, of the data sources and strategic plan that DEA will utilize in order to better comply with the SUPPORT Act's requirements in setting the 2021 quotas.

As DEA proposes and finalizes the schedule II opioid production quotas for 2021, 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 even amidst the challenges of the COVID-19 pandemic. We look forward to continuing to work with you on this issue.

Sincerely,



Richard J. Durbin
United States Senator



John Kennedy
United States Senator