United States Senate
WASHINGTON, DC 20510

November 1, 2019

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

Re: Docket No. DEA-508P - Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances for 2020

Dear Acting Administrator Dhillon:

We write to comment on the proposed 2020 aggregate production quotas for controlled substances that the Drug Enforcement Administration (DEA) published on September 12. As DEA finalizes the 2020 aggregate production quotas for schedule II opioids, we strongly urge the agency to consider the public health crisis caused by the opioid epidemic and meaningfully reduce opioids quotas from 2019 levels, as proposed in the Federal Register notice.

As our nation confronts the worst drug overdose epidemic in its history, we write to urge the Drug Enforcement Administration (DEA) to tackle the opioid crisis by utilizing new authorities that Congress provided to establish more sensible opioid production quotas for 2020. The Opioid Quota Reform Act, which was signed into law as 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 legislation, we strongly encourage you to use this new authority to rein in the pharmaceutical industry's incessant demand for excessive levels of opioid production.

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 undertaken with DEA approval and awareness.

The October 1 report from the Department of Justice's Inspector General specifically highlighted that, while the opioid epidemic surged, "DEA was authorizing manufacturers to product 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 far too high.

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. For example, four in five new heroin users first began their addiction with prescription painkillers.

DEA explained in its 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 Centers for Disease Control and Prevention (CDC). While we appreciate the challenges in directly linking patient overdoses to a specific controlled substance, DEA cannot ignore or discard this essential information from the quota-setting process. 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*.

We fear that the explanation provided by DEA for ignoring the clear connection between the staggering volumes of painkillers approved for production and the current overdose epidemic signals that DEA is reverting to the short-sighted 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.

As DEA finalizes the opioid production quotas for 2020, we urge you to apply DEA's new 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 our continued engagement on this issue.

Sincerely,

Richard J. Durbin
United States Senator

John Kennedy
United States Senator