

United States Senate

WASHINGTON, DC 20510

July 11, 2017

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

Dear Acting Administrator Rosenberg:

As our nation continues to confront the worsening prescription opioid, heroin, and fentanyl epidemic, we write to urge the Drug Enforcement Administration (DEA) to build upon last year's progress in reducing aggregate production quotas for schedule II opioids and further lower those levels for 2018.

In order to effectively combat this raging crisis, stakeholders—especially our federal oversight agencies—must use every tool available to prevent the flood of addictive narcotic painkillers onto the market that can result in misuse, abuse, and diversion. We have shared our deep concern that, for the past two decades, DEA has approved significant increases in the aggregate volume of opioids allowed to be produced for sale in the United States. 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.

As the gatekeeper for how many opioids are allowed to be sold legally every year in the United States, we commend DEA on taking initial steps last year to lower production quotas for the first time in a generation. We were pleased that DEA followed our calls to lower nearly all opioid production quotas by 25 percent or more, including reducing the quota for hydrocodone by 34 percent. However, the 2017 production quota levels for numerous schedule II opioids remain dramatically higher than they were a decade ago. Further reductions, through DEA's existing quota-setting authority, are necessary to rein in this epidemic.

We have, and will continue to, engage with the U.S. Food and Drug Administration (FDA) on ensuring they are providing your agency with the appropriate information—which takes into account the downstream public health impact of the volume of opioids authorized to come to market—to help inform DEA's quota-setting process. In addition, as we have stated to you in the past, we believe that DEA should use existing authorities under the Controlled Substances Act to consider the recent Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain and proactively adjust opioid production quotas, given this “change in the currently accepted medical use” of opioids.

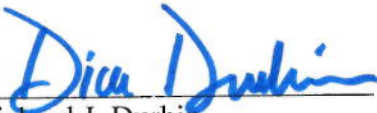
Finally, as DEA issues its draft order for the 2018 production quotas, we urge the agency to foster enhanced transparency and accountability by taking the following actions:

- Provide an analysis of the approved 2016 opioid production quotas relative to the amount that was ultimately used;

- Provide an explanation for the draft 2018 order of the considerations DEA took into account in establishing the opioid production quotas; and if there is a proposed increase to any opioid production quota, provide a justification of why the public health benefits of increasing the quotas outweigh the consequences of having an increased volume of such substance available for sale and potential diversion in the United States; and
- Make public the approved individual procurement quota for each manufacturer of schedule II opioids, including oxycodone, hydrocodone, oxymorphone, hydromorphone, and fentanyl.

We appreciate DEA's commitment to tackling the opioid epidemic through changes to aggregate production quotas. By continuing to use its quota-setting authority in a proactive and robust way to combat the opioid crisis, while preserving access for legitimate medical use, DEA has the opportunity to make a real and immediate difference that will benefit American communities and save lives.

Sincerely,



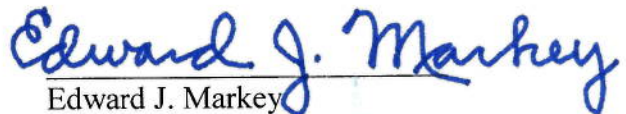
Richard J. Durbin
United States Senator



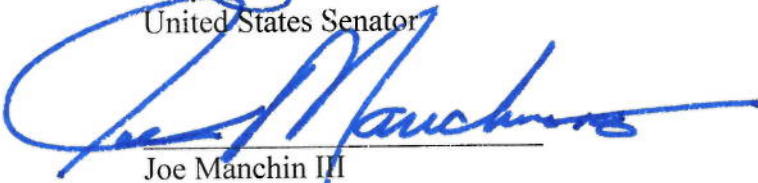
Sherrod Brown
United States Senator



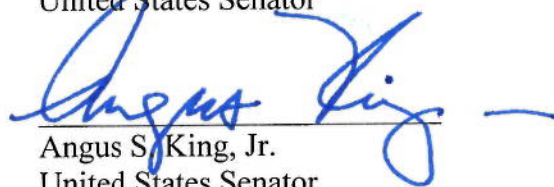
Amy Klobuchar
United States Senator



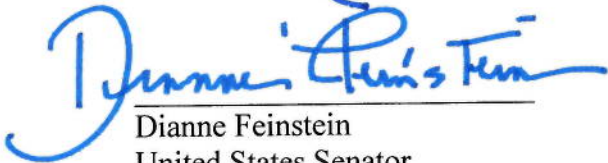
Edward J. Markey
United States Senator



Joe Manchin III
United States Senator



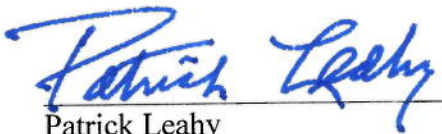
Angus S. King, Jr.
United States Senator



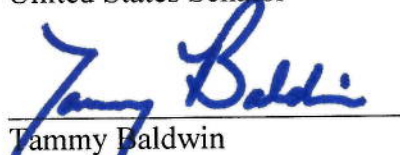
Dianne Feinstein
United States Senator



Claire McCaskill
United States Senator



Patrick Leahy
United States Senator



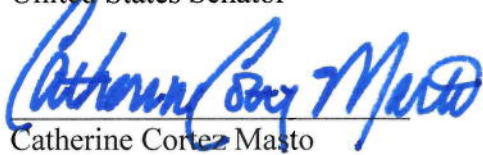
Tammy Baldwin
United States Senator



Jeanne Shaheen
United States Senator



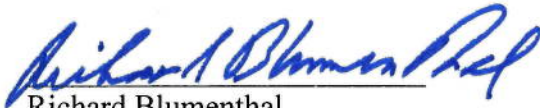
Kirsten Gillibrand
United States Senator



Catherine Cortez Masto
United States Senator



Margaret Wood Hassan
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Al Franken
United States Senator