

Durbin, Kennedy applaud DEA for lowering opioid quotas for third year in a row

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WASHINGTON – U.S. Senators Dick Durbin (D-IL) and John Kennedy (R-LA) today praised the Drug Enforcement Administration's (DEA) proposal to reduce production quotas for nearly all Schedule II prescription opioids by an average of 10 percent for next year. The DEA is responsible for establishing annual quotas determining the exact amount of each opioid drug that is permitted to be produced in the U.S. each year. After two decades of dramatic increases to the volume of opioids allowed to come to the market, the DEA has heeded Durbin's call over the past three years to help prevent opioid addiction by responsibly reducing nearly all opioid quotas. After today's announcement, three powerful, addictive painkillers are set to see a significant reduction from what was allowed on the market just three years prior: a 38 percent cut to oxycodone production over three years; and a 48 percent cut to fentanyl production over three years.

In May, the Senate Judiciary Committee passed targeted, bipartisan <u>legislation</u> that will enhance DEA's existing opioid quota-setting authority by improving transparency and enabling DEA to adjust quotas to prevent opioid diversion and abuse while ensuring an adequate supply for legitimate medical needs. The *Opioid Quota Reform Act of 2018* was introduced in March by Durbin and Kennedy, along with Senators Dianne Feinstein (D-CA) and Chuck Grassley (R-IA). The legislation will complement and strengthen recent DEA regulations on opioid quota-setting. The bill is now under consideration by the full Senate.

"In 2016, the pharmaceutical industry produced 14 billion opioid doses—enough for every adult in America to have a three week supply of opioids. Now we are in the midst of an opioid addiction crisis. We are losing 115 Americans each day from opioid overdoses – more than 42,000 a year," said Durbin. "There is a growing recognition that we need to take a serious look at how many of these pills are

allowed to flood our markets and streets. That is why I commend the DEA for taking steps—three years in a row—to reduce the number of opioids allowed to be produced in the U.S. But our work is not done. Opioid quota reform is needed so DEA can take important factors like diversion and abuse into account when setting quotas, rather than chasing the downstream consequences of this crisis. And my bipartisan legislation with Senator Kennedy will allow DEA to do just that. I look forward to working with my colleagues on both sides of the aisle to get our legislation across the finish line."

"This is a huge first step in fighting the battle against our country's opioid epidemic," said Kennedy. "In Louisiana, overdose deaths increased by more than 14% from 2015-2016. By reducing the amount of certain Schedule II prescription opioids, we can begin to stop the abuse before it starts. However, there is still work to be done to stop the addiction cycle. That's why my bill with Sen. Durbin is so important; we need an across the board cut to the number of manufactured opioids."

Between 1993 and 2015, the DEA allowed production of oxycodone to increase 39-fold, hydrocodone to increase 12-fold, hydromorphone to increase 23-fold, and fentanyl to increase 25-fold. As a result, the number of opioid pain relievers dispensed in the United States has skyrocketed over the last two decades – from 76 million prescriptions in 1991 to more than 245 million prescriptions in 2014. The increase in opioid-related overdose deaths has mirrored the dramatic rise in opioid prescribing, with more than 42,000 deaths in 2016.

The bipartisan Durbin-Kennedy--Grassley-Feinstein*Opioid Quota Reform Act of 2018* enhances DEA's existing quota-setting authority by improving transparency and expanding DEA's ability to focus on preventing opioid diversion and abuse. The bill would:

- Provide that when DEA establishes annual production quotas for opioids, in addition to considering existing statutory factors such as prior-year sales and research needs, DEA must also estimate how much diversion occurs of that opioid and make appropriate reductions to opioid quotas based on that estimate. In making its estimates of opioid diversion, DEA must consider information on rates of opioid overdose deaths, abuse, and public health impact;
- Require DEA, if it approves any annual increase in opioid quotas, to explain publicly why the public health benefits of the increase clearly outweigh the potential harmful consequences;

- Highlight trends in manufacturer-level quota increases by having DEA report anonymized data to Congress on the number of manufacturers that DEA authorizes to produce opioids each year and how many of those manufacturers' quotas have increased from the previous year;
- Give DEA discretion to set more granular quotas that account for variations in dosage forms, helping to avoid situations where some dosage forms face shortages even though aggregate quotas are sufficient to meet legitimate needs; and
- Direct DEA to issue a report on how changes in accepted medical use and opioids returned through drug takeback events will be factored into the opioid quota-setting process.

The *Opioid Quota Reform Act of 2018* is supported by groups including the National Association of County and City Health Officials, National Safety Council, National Association of Counties, Trust for America's Health, and Safe States Alliance.

The DEA's opioid quota proposal for 2019 was published today in the Federal Register. It will be open for comment before finalization later this year.