Bill passed to address flow of opioids

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WASHINGTON – In the midst of a prescription opioid, heroin, and fentanyl crisis that is devastating communities of all sizes in every state, the Senate Judiciary Committee today passed narrow, bipartisan legislation that will enhance the Drug Enforcement Administration's (DEA) existing opioid quota-setting authority by improving transparency and enabling DEA to adjust quotas to prevent opioid diversion and abuse. The *Opioid Quota Reform Act of 2018* was introduced by U.S. Senators Dick Durbin (D-IL), John Kennedy (R-LA), Dianne Feinstein (D-CA) and Chuck Grassley (R-IA) in March 2018. The bill now moves to the full Senate for consideration.

"The premise of our bill is simple. 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 abuse crisis. We are losing 115 Americans each day from opioid overdoses – more than 42,000 a year," said Durbin. "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 this bipartisan legislation will allow DEA to do just that. I look forward to working with my colleagues on both sides of the aisle to get this to the finish line."

"I'm pleased that our legislation, the Opioid Quota Reform Act, is now one step closer towards making a real, impactful change," said Kennedy. "We need to address addiction before it starts, and we must begin with readjusting the allowed number of opioid pills being produced each year in the United States."

"Too many opioids that are abused are diverted from clinics, prescriptions and other legitimate sources. 42,000 Americans lost their lives to the opioid epidemic in 2016 alone, more than the number of Americans killed in car accidents. If we're going to prevent addiction, we must reduce the excess number of opioids available to be diverted each year. This bill will increase transparency in setting quotas without blocking access for the legitimate and responsible use of opioids in medicine," said Feinstein.

“By moving this bill through committee, we’ve taken one important step toward beating back the opioid crisis that affects families and communities across our country every day,” Grassley said. “As Chairman of Judiciary Committee and the Narcotics Control Caucus, I care deeply about finding a solution to the opioid epidemic, and I’ve been glad to work with Senators Durbin, Kennedy and Feinstein toward that goal. With our legislation the DEA will have better information to set opioid production quotas, which is critical to curbing abuse while preserving access for those who need opioids to treat illnesses and manage pain.”

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. DEA approved significant increases in aggregate opioid production quotas between 1993 and 2015, including a 39-fold increase for oxycodone and a 12-fold increase for hydrocodone. Such increases occurred largely because current law directs DEA to only consider certain factors when setting quotas—like past sales and estimated demand—but not other factors such as the impact of such opioid production on diversion, abuse rates, or overdose deaths. As a result, 14 billion opioid doses are put on the market each year—far more than necessary under current medical guidelines and enough for every adult American to have nearly a one month’s prescription of addictive painkillers.

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.