Durbin helps introduce legislation to ensure transparency and accountability in DEA quotas for prescription opioid painkillers

September 29 2017 9:45 AM

WASHINGTON – As the nation suffers from a national public health emergency in the form of an opioid epidemic that took the lives of nearly 50,000 Americans last year, U. S. Senator Dick Durbin (D-IL) joined Senator Edward J. Markey (D-MA) today to introduce legislation, the *Opioid Quota Openness, Transparency, and Awareness Act*

(Opioid QuOTA Act), to shed light on the secretive process by which the pharmaceutical companies gain approval to produce the deadly opioid painkillers.

The Drug Enforcement Administration (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. Until recently, the DEA has consistently approved

significant increases in the number of opioids coming to the U.S. market. Between 1993 and 2015, the DEA allowed production quotas for oxycodone to increase 39-fold; hydrocodone to increase 23-fold; and fentanyl to increase 25-fold.

However, in 2016—after years of dramatic increases to the volume of opioids allowed to come to the market—the DEA heeded Durbin's call to help address America's opioid epidemic by reducing nearly all opioid quotas by 25 percent or more. This was the first reduction of its kind in over twenty years. And just this August, following Durbin's request, the DEA proposed to once again reduce production quotas for nearly all Schedule II prescription opioids next year. After DEA's recent announcement regarding quotas for 2018, three powerful, addictive painkillers will see a significant reduction from what was allowed on the market just two years prior: a 31 percent cut to oxycodone over two years; a 43 percent cut to hydrocodone over two years; and a 42 percent cut to fentanyl over two years.

Despite this improvement, for 2018, the equivalent of nine billion 10-milligram pills of OxyContin is still proposed to be manufactured in the United States. And despite this massive quantity of addictive opioid pain medication that the DEA would approve for production, there is little public information about which individual companies are manufacturing prescription opioid pills or how many.

"While the DEA has taken necessary steps over the past two years to reduce the amount of opioids that can be manufactured and sold in the United States, there is still much more that must be done to stop this national emergency that kills 91 Americans every day," said Durbin. "Quota levels for numerous opioids remain dramatically higher than they were a decade ago. The public deserves the right to know which drug companies are manufacturing these opioids, how many they are producing each year, and their justification for asking the DEA to approve their ever-increasing quota requests. But our work will not be done until these quotas continue to come down, doctors become more judicious in their prescribing, drug companies stop misleading the public about their products, and we do more to help those who are currently addicted get treatment."

Along with Durbin and Markey, the legislation is co-sponsored by Senators Joe Manchin (D-WV), Sherrod Brown (D-OH), Jeanne Shaheen (D-NH), and Maggie Hassan (D-NH).

Specifically, the legislation requires the U.S. Attorney General to make available through DEA's website the quotas for an opioid painkiller issued to a registered manufacturer, as well as that manufacturer's actual use of the quota. The bill also makes available the applications submitted to DEA by registered manufacturers requesting a particular quantity of active ingredient, and year-end reports on actual quota use, which DEA now treats as confidential.

A copy of the *Opioid QuOTA Act* can be found here.