Calendar No. 473

115TH CONGRESS
2D SESSION

S. 2535

To amend the Controlled Substances Act to strengthen Drug Enforcement Administration discretion in setting opioid quotas.

IN THE SENATE OF THE UNITED STATES

MARCH 12, 2018

Mr. DURBIN (for himself, Mr. KENNEDY, Mr. GRASSLEY, and Mrs. FEINSTEIN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

JUNE 19, 2018

Reported by Mr. GRASSLEY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Controlled Substances Act to strengthen Drug Enforcement Administration discretion in setting opioid quotas.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

~~**SECTION 1. SHORT TITLE.**~~

~~This Act may be cited as the "Opioid Quota Reform Act".~~

SEC. 2. STRENGTHENING CONSIDERATIONS FOR DEA OPIOID QUOTAS.

Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended—

(1) in the last sentence of subsection (a), by striking " and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance"; and

(2) by adding at the end the following:

"(i)(1) In fixing and adjusting production and manufacturing quotas under this section for fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone, the Attorney General shall consider the impact of the production and manufacturing quotas on overall public health and rates of diversion, abuse, and overdose deaths related to these controlled substances in the United States. Any of the considerations in this subsection or in subsection (a) may be used to determine changes to levels of such production and manufacturing quotas in a given year.

"(2)(A) For any year in which the approved production quota for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone is higher than the approved production quota for the substance in the previous year, the Attorney General shall include in its final order an explanation of why the public health benefits of increasing such quota outweigh the consequences of having an increased

volume of such substance available for sale, and potential diversion, in the United States.

''(B) Not later than 1 year after the date of enactment of this subsection and every year thereafter, the Attorney General shall provide to the Caucus on International Narcotics Control, Committee on the Judiciary, Committee on Health, Education, Labor, and Pensions, and Committee on Appropriations of the Senate and the Committee on the Judiciary, Committee on Energy and Commerce, and Committee on Appropriations of the House of Representatives, the following information with regard to each of the substances described in subparagraph (A):

''(i) An anonymized count of the total number of manufacturers issued individual manufacturing quotas that year for that substance.

''(ii) A count of how many such manufacturers were issued an approved manufacturing quota that was higher than the quota issued to that manufacturer for that substance in the previous year.

''(3) Not later than 180 days after the date of enactment of this subsection, the Attorney General shall submit to Congress a report on how the Attorney General will ensure that the annual process of fixing and adjusting pro-

~~duction and manufacturing quotas under this section takes into consideration—~~

~~"(A) efforts to reduce the costs, injuries, and deaths associated with the diversion and abuse of prescription opioids and heroin, including changes in the accepted medical use of certain controlled substances; and~~

~~"(B) data collection and evaluation of the volume of controlled substances that are diverted and collected from approved drug collection receptacles, mail-back programs, and take-back events.".~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Opioid Quota Reform Act".

SEC. 2. STRENGTHENING CONSIDERATIONS FOR DEA OPIOID QUOTAS.

(a) IN GENERAL.—Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended—

(1) in subsection (a)—

(A) by inserting "(1)" after "(a)";

(B) in the second sentence, by striking "Production" and inserting "Except as provided in paragraph (2), production"; and

(C) by adding at the end the following:

"(2) The Attorney General may, if the Attorney General determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance, establish an aggregate or individual production quota under this subsection, or a procurement quota established by the Attorney General by regulation, in terms of pharmaceutical dosage forms prepared from or containing the controlled substance.";

(2) in subsection (b), in the first sentence, by striking "production" and inserting "manufacturing";

(3) in subsection (c), by striking "October" and inserting "December"; and

(4) by adding at the end the following:

"(i)(1)(A) In establishing any quota under this section, or any procurement quota established by the Attorney General by regulation, for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone (in this subsection referred to as a 'covered controlled substance'), the Attorney General shall estimate the amount of diversion of the covered controlled substance that occurs in the United States.

"(B) In estimating diversion under this paragraph, the Attorney General—

"(i) shall consider information the Attorney General, in consultation with the Secretary of Health and Human Services, determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and

"(ii) may take into consideration whatever other sources of information the Attorney General determines reliable.

"(C) After estimating the amount of diversion of a covered controlled substance, the Attorney General shall make appropriate quota reductions, as determined by the Attorney General, from the quota the Attorney General would have otherwise established had such diversion not been considered.

"(2)(A) For any year for which the approved aggregate production quota for a covered controlled substance is higher than the approved aggregate production quota for the covered controlled substance for the previous year, the Attorney General shall include in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

"(B) Not later than 1 year after the date of enactment of this subsection, and every year thereafter, the Attorney General shall submit to the Caucus on International Narcotics Control, the Committee on the Judiciary, the Committee on Health, Education, Labor, and Pensions, and the Committee on Appropriations of the Senate and the Committee on the Judiciary, the Committee on Energy and Commerce, and the Committee on Appropriations of the House of Representatives the following information with regard to each covered controlled substance:

"(i) An anonymized count of the total number of manufacturers issued individual manufacturing quotas that year for the covered controlled substance.

"(ii) An anonymized count of how many such manufacturers were issued an approved manufacturing quota that was higher than the quota issued to that manufacturer for the covered controlled substance in the previous year.

"(3) Not later than 1 year after the date of enactment of this subsection, the Attorney General shall submit to Congress a report on how the Attorney General, when fixing and adjusting production and manufacturing quotas under this section for covered controlled substances, will—

"(A) take into consideration changes in the accepted medical use of the covered controlled substances; and

"(B) work with the Secretary of Health and Human Services on methods to appropriately and anonymously survey opioid patients in order to estimate and evaluate the type and amount of covered controlled substances that patients are submitting for collection from approved drug collection receptacles, mail-back programs, and take-back events.".

(b) CONFORMING CHANGE.—The Law Revision Counsel is directed to amend the heading for subsection (b) of section 826 of title 21, United States Code, by striking "PRODUCTION" and inserting "MANUFACTURING".

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