

## 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.

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### IN THE SENATE OF THE UNITED STATES

MARCH 12, 2018

Mr. DURBIN (for himself, Mr. KENNEDY, Mr. GRASSLEY, and Mrs. FEIN-  
STEIN) 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*]

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## A BILL

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

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Opioid Quota Reform  
5 Act”.

1 **SEC. 2. STRENGTHENING CONSIDERATIONS FOR DEA**  
2 **OPIOID QUOTAS.**

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

5 (1) in the last sentence of subsection (a), by  
6 striking “ and not in terms of individual pharma-  
7 ceutical dosage forms prepared from or containing  
8 such a controlled substance”; and

9 (2) by adding at the end the following:

10 “(i)(1) In fixing and adjusting production and manu-  
11 facturing quotas under this section for fentanyl, oxycodone,  
12 hydrocodone, oxymorphone, and hydromorphone, the  
13 Attorney General shall consider the impact of the produc-  
14 tion and manufacturing quotas on overall public health  
15 and rates of diversion, abuse, and overdose deaths related  
16 to these controlled substances in the United States. Any  
17 of the considerations in this subsection or in subsection  
18 (a) may be used to determine changes to levels of such  
19 production and manufacturing quotas in a given year.

20 “(2)(A) For any year in which the approved produc-  
21 tion quota for fentanyl, oxycodone, hydrocodone, oxymor-  
22 phone, or hydromorphone is higher than the approved pro-  
23 duction quota for the substance in the previous year, the  
24 Attorney General shall include in its final order an expla-  
25 nation of why the public health benefits of increasing such  
26 quota outweigh the consequences of having an increased

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

3       ~~“(B) Not later than 1 year after the date of enact-~~  
4 ~~ment of this subsection and every year thereafter, the At-~~  
5 ~~torney General shall provide to the Caucus on Inter-~~  
6 ~~national Narcotics Control, Committee on the Judiciary,~~  
7 ~~Committee on Health, Education, Labor, and Pensions,~~  
8 ~~and Committee on Appropriations of the Senate and the~~  
9 ~~Committee on the Judiciary, Committee on Energy and~~  
10 ~~Commerce, and Committee on Appropriations of the~~  
11 ~~House of Representatives, the following information with~~  
12 ~~regard to each of the substances described in subpara-~~  
13 ~~graph (A):~~

14           ~~“(i) An anonymized count of the total number~~  
15 ~~of manufacturers issued individual manufacturing~~  
16 ~~quotas that year for that substance.~~

17           ~~“(ii) A count of how many such manufacturers~~  
18 ~~were issued an approved manufacturing quota that~~  
19 ~~was higher than the quota issued to that manufac-~~  
20 ~~turer for that substance in the previous year.~~

21       ~~“(3) Not later than 180 days after the date of enact-~~  
22 ~~ment of this subsection, the Attorney General shall submit~~  
23 ~~to Congress a report on how the Attorney General will~~  
24 ~~ensure that the annual process of fixing and adjusting pro-~~

1 duction and manufacturing quotas under this section  
 2 takes into consideration—

3       ~~“(A) efforts to reduce the costs, injuries, and~~  
 4       ~~deaths associated with the diversion and abuse of~~  
 5       ~~prescription opioids and heroin, including changes in~~  
 6       ~~the accepted medical use of certain controlled sub-~~  
 7       ~~stances; and~~

8       ~~“(B) data collection and evaluation of the vol-~~  
 9       ~~ume of controlled substances that are diverted and~~  
 10       ~~collected from approved drug collection receptacles,~~  
 11       ~~mail-back programs, and take-back events.”.~~

12 **SECTION 1. SHORT TITLE.**

13       *This Act may be cited as the “Opioid Quota Reform*  
 14 *Act”.*

15 **SEC. 2. STRENGTHENING CONSIDERATIONS FOR DEA**  
 16 **OPIOID QUOTAS.**

17       *(a) IN GENERAL.—Section 306 of the Controlled Sub-*  
 18 *stances Act (21 U.S.C. 826) is amended—*

19               *(1) in subsection (a)—*

20                       *(A) by inserting “(1)” after “(a)”;*

21                       *(B) in the second sentence, by striking*  
 22               *“Production” and inserting “Except as provided*  
 23               *in paragraph (2), production”;* and

24                       *(C) by adding at the end the following:*

1       “(2) *The Attorney General may, if the Attorney Gen-*  
 2 *eral determines it will assist in avoiding the overproduc-*  
 3 *tion, shortages, or diversion of a controlled substance, estab-*  
 4 *lish an aggregate or individual production quota under this*  
 5 *subsection, or a procurement quota established by the Attor-*  
 6 *ney General by regulation, in terms of pharmaceutical dos-*  
 7 *age forms prepared from or containing the controlled sub-*  
 8 *stance.*”;

9               (2) *in subsection (b), in the first sentence, by*  
 10 *striking “production” and inserting “manufac-*  
 11 *turing”;*

12               (3) *in subsection (c), by striking “October” and*  
 13 *inserting “December”;* and

14               (4) *by adding at the end the following:*

15       “(i)(1)(A) *In establishing any quota under this sec-*  
 16 *tion, or any procurement quota established by the Attorney*  
 17 *General by regulation, for fentanyl, oxycodone,*  
 18 *hydrocodone, oxymorphone, or hydromorphone (in this sub-*  
 19 *section referred to as a ‘covered controlled substance’), the*  
 20 *Attorney General shall estimate the amount of diversion of*  
 21 *the covered controlled substance that occurs in the United*  
 22 *States.*

23       “(B) *In estimating diversion under this paragraph,*  
 24 *the Attorney General—*

1           “(i) shall consider information the Attorney Gen-  
2           eral, in consultation with the Secretary of Health and  
3           Human Services, determines reliable on rates of over-  
4           dose deaths and abuse and overall public health im-  
5           pact related to the covered controlled substance in the  
6           United States; and

7           “(ii) may take into consideration whatever other  
8           sources of information the Attorney General deter-  
9           mines reliable.

10          “(C) After estimating the amount of diversion of a cov-  
11          ered controlled substance, the Attorney General shall make  
12          appropriate quota reductions, as determined by the Attor-  
13          ney General, from the quota the Attorney General would  
14          have otherwise established had such diversion not been con-  
15          sidered.

16          “(2)(A) For any year for which the approved aggregate  
17          production quota for a covered controlled substance is high-  
18          er than the approved aggregate production quota for the  
19          covered controlled substance for the previous year, the Attor-  
20          ney General shall include in the final order an explanation  
21          of why the public health benefits of increasing the quota  
22          clearly outweigh the consequences of having an increased  
23          volume of the covered controlled substance available for sale,  
24          and potential diversion, in the United States.

1       “(B) Not later than 1 year after the date of enactment  
 2 of this subsection, and every year thereafter, the Attorney  
 3 General shall submit to the Caucus on International Nar-  
 4 cotics Control, the Committee on the Judiciary, the Com-  
 5 mittee on Health, Education, Labor, and Pensions, and the  
 6 Committee on Appropriations of the Senate and the Com-  
 7 mittee on the Judiciary, the Committee on Energy and  
 8 Commerce, and the Committee on Appropriations of the  
 9 House of Representatives the following information with re-  
 10 gard to each covered controlled substance:

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

14               “(ii) An anonymized count of how many such  
 15 manufacturers were issued an approved manufac-  
 16 turing quota that was higher than the quota issued to  
 17 that manufacturer for the covered controlled substance  
 18 in the previous year.

19       “(3) Not later than 1 year after the date of enactment  
 20 of this subsection, the Attorney General shall submit to Con-  
 21 gress a report on how the Attorney General, when fixing  
 22 and adjusting production and manufacturing quotas under  
 23 this section for covered controlled substances, will—

1           “(A) take into consideration changes in the ac-  
2       cepted medical use of the covered controlled sub-  
3       stances; and

4           “(B) work with the Secretary of Health and  
5       Human Services on methods to appropriately and  
6       anonymously survey opioid patients in order to esti-  
7       mate and evaluate the type and amount of covered  
8       controlled substances that patients are submitting for  
9       collection from approved drug collection receptacles,  
10      mail-back programs, and take-back events.”.

11      (b) CONFORMING CHANGE.—The Law Revision Coun-  
12      sel is directed to amend the heading for subsection (b) of  
13      section 826 of title 21, United States Code, by striking  
14      “PRODUCTION” and inserting “MANUFACTURING”.



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