AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

S. 2535

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Mr. DURBIN (for himself, Mr. KENNEDY, Mr. GRASSLEY, and Mrs. FEINSTEIN)

Viz:

Strike all after the enacting clause and insert the following:

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 diver-

sion 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''.