

115TH CONGRESS
2D SESSION

S. _____

To amend the Controlled Substances Act to require the Drug Enforcement Administration to report certain information on distribution of opioids, and for other purposes.

IN THE SENATE OF THE UNITED STATES

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

A BILL

To amend the Controlled Substances Act to require the Drug Enforcement Administration to report certain information on distribution of opioids, and for other purposes.

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 "Using Data to Prevent
5 Opioid Diversion Act of 2018".

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) In 2016, there were nearly 64,000 drug
2 overdose deaths in the United States. More than
3 42,000 of these deaths were opioid-related.

4 (2) The regulations promulgated under the
5 Controlled Substances Act (21 U.S.C. 801 et seq.)
6 require drug manufacturers and distributors to—

7 (A) provide effective controls against the
8 diversion of controlled substances;

9 (B) detect and disclose suspicious orders to
10 the Drug Enforcement Administration; and

11 (C) keep complete and accurate records re-
12 lating to the manufacture or distribution of
13 controlled substances.

14 (3) Despite the requirements described in para-
15 graph (2), it has been publicly reported that between
16 2006 and 2016, nearly 21,000,000 opioids were dis-
17 tributed to 2 pharmacies in Williamson, West Vir-
18 ginia, which has a population of approximately
19 3,000. It has been further reported that between
20 2007 and 2008, nearly 9,000,000 pills were distrib-
21 uted to a single pharmacy in Kermit, West Virginia,
22 which has a population of 392.

23 (4) Similarly, it has been publicly reported that
24 780,000,000 oxycodone and hydrocodone pills were
25 distributed to pharmacies throughout West Virginia

1 between 2007 and 2012. In the same period, more
2 than 1,700 people in the State died from overdoses
3 of these 2 substances.

4 (5) Drug manufacturers and distributors are
5 required to report the sale, delivery or other disposal
6 of narcotics to the Drug Enforcement Administra-
7 tion through the Automated Reports and Consoli-
8 dated Ordering System.

9 (6) Notwithstanding the reporting requirement
10 described in paragraph (5), the Drug Enforcement
11 Administration does not disclose the total quantity
12 and type of opioids distributed to a single pharmacy
13 or practitioner with those manufacturers and dis-
14 tributors who are required to input information into
15 the Automated Reports and Consolidated Ordering
16 System. This creates a barrier to identifying and
17 stopping potentially suspicious orders.

18 (7) Although manufacturers and distributors
19 are already required to provide effective controls
20 against the diversion of controlled substances, this
21 lack of data sharing may create a barrier to better
22 identifying and stopping potentially suspicious or-
23 ders.

24 (8) On an annual basis, the Attorney General
25 of the United States is statutorily required to share

1 the controlled substance or substances in schedule II
2 that have the highest rates of abuse and to prepare
3 and make available reports on the distribution pat-
4 terns of such substances, with State regulatory, li-
5 censing, and law enforcement agencies. The Attor-
6 ney General of the United States has entered into
7 data sharing agreements with the attorneys general
8 of the vast majority of States, Puerto Rico, and the
9 District of Colombia to share, pursuant to State law
10 and policy, data obtained from State prescription
11 drug monitoring programs and other sources.

12 (9) To further reduce barriers associated with
13 identifying suspicious patterns and stopping the di-
14 version of opioids, the remaining States and terri-
15 tories of the United States should enter into similar
16 agreements with, and to the greatest extent practical
17 share data obtained from State prescription drug
18 monitoring programs with, the Attorney General of
19 the United States.

20 **SEC. 3. PURPOSE.**

21 (a) IN GENERAL.—The purpose of this Act is to pro-
22 vide drug manufacturers and distributors with access to
23 anonymized information through the Automated Reports
24 and Consolidated Ordering System to help drug manufac-

1 turers and distributors identify, report, and stop sus-
2 picious orders of opioids and reduce diversion rates.

3 (b) **RULE OF CONSTRUCTION.**—Nothing in this Act
4 should be construed to absolve a drug manufacturer, drug
5 distributor, or other Drug Enforcement Administration
6 registrant from the responsibility of the manufacturer, dis-
7 tributor, or other registrant to—

8 (1) identify, report, and stop suspicious orders;

9 or

10 (2) use all available sources of information to
11 determine—

12 (A) the legitimacy of a customer's order;

13 and

14 (B) whether or not an order described in
15 subparagraph (A) is suspicious.

16 **SEC. 4. AMENDMENTS.**

17 (a) **RECORDS AND REPORTS OF REGISTRANTS.**—Sec-
18 tion 307 of the Controlled Substances Act (21 U.S.C. 827)
19 is amended—

20 (1) by redesignating subsections (f), (g), and
21 (h) as subsections (g), (h), and (i), respectively;

22 (2) by inserting after subsection (e) the fol-
23 lowing:

24 “(f)(1) The Attorney General shall, not less fre-
25 quently than quarterly, make the following information

1 available to manufacturer and distributor registrants
2 through the Automated Reports and Consolidated Order-
3 ing System, or any subsequent automated system devel-
4 oped by the Drug Enforcement Administration to monitor
5 selected controlled substances:

6 “(A) The total number of distributor reg-
7 istrants that distribute controlled substances to a
8 pharmacy or practitioner registrant, aggregated by
9 the name and address of each pharmacy and practi-
10 tioner registrant.

11 “(B) The total quantity and type of opioids dis-
12 tributed, listed by Administration Controlled Sub-
13 stances Code Number, to each pharmacy and practi-
14 tioner registrant described in subparagraph (A).

15 “(2) The information required to be made available
16 under paragraph (1) shall be made available not later than
17 the 15th day of the first month following the quarter to
18 which the information relates.

19 “(3)(A) All registered manufacturers and distributors
20 shall be responsible for reviewing the information made
21 available by the Attorney General under this subsection.

22 “(B) In determining whether to initiate proceedings
23 under this title against a registered manufacturer or dis-
24 tributor based on the failure of the registrant to maintain
25 effective controls against diversion or otherwise comply

1 with the requirements of this title or the regulations issued
2 thereunder, the Attorney General may take into account
3 that the information made available under this subsection
4 was available to the registrant.”; and

5 (3) by inserting after subsection (i), as so re-
6 designated, the following:

7 “(j) All of the reports required under this section
8 shall be provided in an electronic format.”.

9 (b) COOPERATIVE ARRANGEMENTS.—Section 503 of
10 the Controlled Substances Act (21 U.S.C. 873) is amend-
11 ed—

12 (1) by striking subsection (c) and inserting the
13 following:

14 “(c)(1) The Attorney General shall, once every 6
15 months, prepare and make available to regulatory, licens-
16 ing, attorneys general, and law enforcement agencies of
17 States a standardized report containing descriptive and
18 analytic information on the actual distribution patterns,
19 as gathered through the Automated Reports and Consoli-
20 dated Ordering System, or any subsequent automated sys-
21 tem, pursuant to section 307 and which include detailed
22 amounts, outliers, and trends of distributor and pharmacy
23 registrants, in such States for the controlled substances
24 contained in schedule II, which, in the discretion of the

1 Attorney General, are determined to have the highest
2 abuse.

3 “(2) If the Attorney General publishes the report de-
4 scribed in paragraph (1) once every 6 months as required
5 under paragraph (1), nothing in this subsection shall be
6 construed to bring an action in any court to challenge the
7 sufficiency of the information or to compel the Attorney
8 General to produce any documents or reports referred to
9 in this subsection.”.

10 (c) CIVIL AND CRIMINAL PENALTIES.—Section 402
11 of the Controlled Substances Act (21 U.S.C. 842) is
12 amended—

13 (1) in subsection (a)—

14 (A) in paragraph (15), by striking “or” at
15 the end;

16 (B) in paragraph (16), by striking the pe-
17 riod at the end and inserting “; or”; and

18 (C) by inserting after paragraph (16) the
19 following:

20 “(17) in the case of a registered manufacturer
21 or distributor of opioids, to fail to review the most
22 recent information made available by the Attorney
23 General in accordance with section 307(f) before
24 each distribution of a controlled substance referred
25 to in such information.”; and

1 (2) in subsection (c)—

2 (A) in paragraph (1), by striking subpara-
3 graph (B) and inserting the following:

4 “(B)(i) Except as provided in clause (ii), in the case
5 of a violation of paragraph (5), (10), or (17) of subsection
6 (a), the penalty shall not exceed \$10,000.

7 “(ii) In the case of a violation described in clause (i)
8 committed by a registered manufacturer or distributor of
9 opioids and related to the reporting of suspicious orders
10 for opioids, failing to maintain effective controls against
11 diversion of opioids, or failing to review the most recent
12 information made available by the Attorney General in ac-
13 cordance with section 307(f), the penalty shall not exceed
14 \$100,000.”; and

15 (B) in paragraph (2)—

16 (i) in subparagraph (A), by inserting
17 “or (D)” after “subparagraph (B)”; and

18 (ii) by adding at the end the fol-
19 lowing:

20 “(D) In the case of a violation described in subpara-
21 graph (A) that was a violation of paragraph (5), (10), or
22 (17) of subsection (a) committed by a registered manufac-
23 turer or distributor of opioids that relates to the reporting
24 of suspicious orders for opioids, failing to maintain effec-
25 tive controls against diversion of opioids, or failing to re-

1 view the most recent information made available by the
2 Attorney General in accordance with section 307(f), the
3 criminal fine under title 18, United States Code, shall not
4 exceed \$500,000.”.

5 **SEC. 5. REPORT.**

6 Not later than 1 year after the date of enactment
7 of this Act, the Attorney General shall submit to Congress
8 a report that provides information about how the Attorney
9 General is using data in the Automation of Reports and
10 Consolidated Orders System to identify and stop sus-
11 picious activity, including whether the Attorney General
12 is looking at aggregate orders from individual pharmacies
13 to multiple distributors that in total are suspicious, even
14 if no individual order rises to the level of a suspicious
15 order to a given distributor.