

115TH CONGRESS
2D SESSION

S. _____

To combat the opioid epidemic by reforming existing laws and providing for the public's safety, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Ms. CANTWELL (for herself and Ms. HARRIS) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To combat the opioid epidemic by reforming existing laws and providing for the public's safety, 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 "Comprehensive Addic-
5 tion Reform, Education, and Safety Act of 2018" or the
6 "CARES Act".

7 **SEC. 2. OPIOID ADVERTISING AND CONSUMER SAFETY.**

8 (a) **REQUIRING FDA REVIEW OF TELEVISION AD-**
9 **VERTISEMENTS FOR CONTROLLED SUBSTANCES.—Sec-**

1 tion 503C of the Federal, Food, Drug, and Cosmetic Act
2 (21 U.S.C. 353c) is amended—

3 (1) in subsection (a), by striking “The Sec-
4 retary” and inserting “Subject to subsection (f), the
5 Secretary”;

6 (2) in subsection (c), by inserting “or (f)” after
7 “subsection (e)”;

8 (3) by redesignating subsection (f) as sub-
9 section (g); and

10 (4) by inserting after subsection (e) the fol-
11 lowing:

12 “(f) ADVERTISEMENTS FOR CONTROLLED SUB-
13 STANCES.—

14 “(1) IN GENERAL.—In the case of a television
15 advertisement for a controlled substance (as defined
16 in section 102 of the Controlled Substances Act)—

17 “(A) the Secretary shall require the sub-
18 mission of such advertisement under subsection
19 (a); and

20 “(B) the sponsor of such advertisement
21 may not disseminate the advertisement until the
22 Secretary has conducted the review under this
23 section.

24 “(2) AUTHORIZATION OF APPROPRIATIONS.—

25 There is authorized to be appropriated \$5,000,000

1 for the period of fiscal years 2019 through 2023 to
2 increase the proficiency and speed of the Secretary
3 in conducting and reviewing television advertise-
4 ments for controlled substances (as so defined)
5 under this section.”.

6 (b) ENFORCEMENT.—Section 301 of the Federal,
7 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
8 ed by adding at the end the following:

9 “(eee) The failure to comply with the requirements
10 under section 503C(f).”.

11 (c) RULE OF CONSTRUCTION.—No amendment made
12 by this section shall preclude the enforcement, under any
13 relevant civil or other enforcement authority, of a State
14 consumer protection statute.

15 **SEC. 3. INCREASING CIVIL AND CRIMINAL PENALTIES.**

16 Section 402(c) of the Controlled Substances Act (21
17 U.S.C. 842(c)) is amended—

18 (1) in paragraph (1)(B), by striking “shall not
19 exceed \$10,000.” and inserting the following: “shall
20 not exceed—

21 “(i) except as provided in clause (ii),
22 \$10,000; and

23 “(ii) if the violation is committed by a
24 manufacturer of opioids and relates to the
25 reporting of suspicious orders for opioids

1 or failing to maintain effective controls
2 against diversion of opioids, \$100,000.”;
3 and

4 (2) in paragraph (2)—

5 (A) in subparagraph (A), by inserting “or
6 (D)” after “subparagraph (B)”; and

7 (B) by adding at the end the following:

8 “(D) In the case of a violation referred to in subpara-
9 graph (A) that was a violation of paragraph (5) or (10)
10 of subsection (a) committed by a manufacturer of opioids
11 that relates to the reporting of suspicious orders for
12 opioids or failing to maintain effective controls against di-
13 version of opioids, the criminal fine under title 18, United
14 States Code, shall not exceed \$500,000.”.

15 **SEC. 4. OPIOID MANUFACTURER ACCOUNTABILITY AND**
16 **COMBATING DIVERSION.**

17 (a) PUBLICATION OF CERTAIN RECORDS.—Not later
18 than 1 year after the date of enactment of this Act, and
19 every year thereafter, the Administrator of the Drug En-
20 forcement Administration shall publish in the Federal
21 Register and on the Internet website of the Drug Enforce-
22 ment Administration the prior conviction records under
23 Federal and State law of manufacturers of opioids, as de-
24 scribed in section 303(a)(4) of the Controlled Substances
25 Act (21 U.S.C. 823(a)(4)).

1 (b) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to the Administrator of
3 the Drug Enforcement Administration for diversion inves-
4 tigators and tactical diversion squads of the Drug En-
5 forcement Administration such sums as may be necessary
6 for each of fiscal years 2019 through 2023, which shall
7 be in addition to any amounts otherwise made available
8 to the Administrator.

9 **SEC. 5. HEROIN ENFORCEMENT GROUPS.**

10 (a) IN GENERAL.—The Attorney General shall estab-
11 lish heroin enforcement groups within the Drug Enforce-
12 ment Administration to target and dismantle illicit heroin
13 trafficking organizations.

14 (b) FUNDING.—There is authorized to be appro-
15 priated to carry out this section \$50,000,000 for fiscal
16 year 2019.