

115TH CONGRESS  
2D SESSION

# S. 2440

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

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 15, 2018

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

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## 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)”;

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.

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