

115TH CONGRESS
2D SESSION

S. 2691

To hold pharmaceutical companies accountable for illegal marketing and distribution of opioid products and for their role in creating and exacerbating the opioid epidemic in the United States.

IN THE SENATE OF THE UNITED STATES

APRIL 17, 2018

Mr. SANDERS (for himself and Ms. HARRIS) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To hold pharmaceutical companies accountable for illegal marketing and distribution of opioid products and for their role in creating and exacerbating the opioid epidemic in the United States.

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 Crisis Account-
5 ability Act of 2018”.

1 **SEC. 2. PROHIBITION OF ILLEGAL MARKETING AND DIS-**
2 **TRIBUTION PRACTICES WITH RESPECT TO**
3 **OPIOIDS.**

4 (a) IN GENERAL.—Section 303 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 333) is amended by
6 adding at the end the following:

7 “(h)(1) In this subsection, the term ‘illegal marketing
8 or distribution practice with respect to an opioid’ means—

9 “(A) including in any advertisement, promotion,
10 direct-to-consumer marketing materials, or other
11 marketing material a representation that an opioid
12 has no addiction-forming or addiction-sustaining li-
13 ability or has less of an addiction-forming or addic-
14 tion-sustaining liability than one or more other
15 opioids, knowing the representation to be false, as
16 determined by the Secretary, in consultation with
17 the Commissioner, based on research, testimonials,
18 and other evidence;

19 “(B) supplying States or communities with a
20 quantity of opioids that is not medically reasonable,
21 as determined by the Secretary, in consultation with
22 the Attorney General using, if applicable, data from
23 the Automated Reports and Consolidated Ordering
24 System of the Department of Justice; or

25 “(C) failing to report to the Secretary any
26 order or pattern of orders for the distribution of

1 opioids that would cause a reasonable person to be-
2 lieve the opioids were not being dispensed in a medi-
3 cally reasonable manner.

4 “(2) It shall be unlawful for any person who manu-
5 factures or distributes an opioid to engage in an illegal
6 marketing or distribution practice with respect to an
7 opioid.

8 “(3)(A) Any person who violates paragraph (2)—

9 “(i) if a natural person employed by an opioid
10 manufacturer or distributor, shall be—

11 “(I) subject to a civil penalty in an amount
12 equal to the sum of—

13 “(aa) such person’s full amount of
14 salary for each year during which such
15 person engaged in illegal marketing or dis-
16 tribution practices with respect to an
17 opioid product; and

18 “(bb) the amount by which the stock
19 or other certificates of ownership interest
20 of the person that is owned by the indi-
21 vidual has increased in value during the
22 period during which such person engaged
23 in illegal marketing or distribution prac-
24 tices of an opioid product, without regard
25 to whether the individual has sold any of

1 the stock or certificates from such opioid
2 manufacturer or distributor; and

3 “(II) with respect to a violation that occurs
4 on or after the date of enactment of the Opioid
5 Crisis Accountability Act of 2018, subject to
6 the period of imprisonment specified under sec-
7 tion 401 of the Controlled Substances Act that
8 would be applicable for a violation of subsection
9 (a) of such section that involved the quantity of
10 opioids that were involved in the illegal mar-
11 keting or distribution practices with respect to
12 an opioid;

13 “(ii) if not a natural person, shall be subject to
14 a civil penalty in the amount equal to the sum of—

15 “(I) \$7,800,000,000; plus

16 “(II) 25 percent of the total profit such
17 person made on lawful sales of opioids in the
18 United States during the period in which the
19 person engaged in illegal marketing or distribu-
20 tion practices.

21 “(B) If a person that is not a natural person
22 violates paragraph (2), the court, without regard to
23 the participation of such individuals in, or knowledge
24 of such individuals of, the violation, shall—

1 “(i) impose on the chief executive officer
2 (or equivalent) of the person a civil penalty in
3 an amount equal to the sum of—

4 “(I) the salary of the individual dur-
5 ing the period in which the person engaged
6 in illegal marketing or distribution prac-
7 tices and such individual served as chief
8 executive office; and

9 “(II) the amount by which the stock
10 or other certificates of ownership interest
11 of the person that is owned by the indi-
12 vidual has increased in value during the
13 period that the person engaged in illegal
14 marketing or distribution practices and
15 such individual served as chief executive
16 officer, without regard to whether the indi-
17 vidual has sold any of the stock or certifi-
18 cates;

19 “(ii) impose on any executive other than
20 the chief executive officer (or equivalent) who
21 led the finance, research, marketing, or sales
22 department of the person a civil penalty in the
23 amount equal to the sum of—

24 “(I) 25 percent of the salary of the in-
25 dividual during the period that the person

1 engaged in illegal marketing or distribution
2 practices and such individual served as
3 such an executive; and

4 “(II) 25 percent of the amount by
5 which the stock or other certificates of
6 ownership interest of the person that is
7 owned by the individual has increased in
8 value during the period that the person en-
9 gaged in illegal marketing or distribution
10 practices and such individual served as
11 such an executive, without regard to
12 whether the individual has sold any of the
13 stock or certificates; and

14 “(iii) impose on any executive, including
15 the chief executive officer (or equivalent) who
16 led the finance, research, marketing, or sales
17 department of the person during the calendar
18 year in which a court enters a judgment that
19 the person violated paragraph (2) and who is
20 not subject to a civil penalty under clause (i) or
21 (ii), a civil penalty in the amount equal to the
22 sum of—

23 “(I) 25 percent of the salary of the in-
24 dividual during the calendar year in which
25 a court enters such judgment; and

1 “(II) 25 percent of the amount by
2 which the stock or other certificates of
3 ownership interest of the person that is
4 owned by the individual has increased in
5 value during the calendar year in which a
6 court enters such judgment.

7 “(C) Any person described in clause (i) or (ii)
8 of subparagraph (A) shall be required to issue a
9 public statement apologizing for their role in cre-
10 ating, sustaining, and exacerbating the opioid epi-
11 demic in the United States.”.

12 (b) INVESTIGATION; RETROACTIVE EFFECT.—

13 (1) INVESTIGATION.—Immediately after the
14 date of enactment of this Act, the Secretary of
15 Health and Human Services, acting through the
16 Commissioner of Food and Drugs and in consulta-
17 tion with the Attorney General, acting through the
18 Administrator of the Drug Enforcement Administra-
19 tion, shall begin investigating all opioid manufactur-
20 ers and all executives employed by such manufactur-
21 ers to determine whether any such manufacturers or
22 executives, at any time before or after such date of
23 enactment, violated subsection (h)(2) of section 303
24 of the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 333) (as added by subsection (a)).

1 (2) RETROACTIVE EFFECT.—Subsection (h)(2)
 2 of section 303 of the Federal Food, Drug, and Cos-
 3 metic Act (21 U.S.C. 333) (as added by subsection
 4 (a)) shall take effect on January 1, 1985, and shall
 5 have retroactive effect.

6 (c) REIMBURSEMENT OF ECONOMIC IMPACT.—

7 (1) ESTABLISHMENT OF FUND.—There is es-
 8 tablished in the Treasury of the United States a
 9 fund, to be known as the “Opioids Reimbursement
 10 Fund” (referred to in this subsection as the
 11 “Fund”), to be administered by the Secretary of
 12 Health and Human Services (referred to in this sub-
 13 section as the “Secretary”), in consultation with the
 14 Commissioner of Food and Drugs.

15 (2) TRANSFERS TO THE FUND.—In a manner
 16 consistent with section 3302(b) of title 31, United
 17 States Code, there shall be transferred to the Fund
 18 from the General Fund of the Treasury an amount
 19 equal to the amount of the civil penalties collected
 20 under subsection (h)(3) of section 303 of the Fed-
 21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333)
 22 (as added by subsection (a)), which shall remain
 23 available until expended.

24 (3) USE OF FUNDS.—

1 (A) IN GENERAL.—The Secretary, in con-
2 sultation with the Commissioner of Food and
3 Drugs, may, without further appropriation, use
4 amounts in the Fund to combat the abuse of
5 opioids in the United States, which may include
6 transferring amounts from the Fund to other
7 agencies to carry out programs, projects, and
8 activities of the agencies to combat the abuse of
9 opioids in the United States.

10 (B) PRIORITY.—In using amounts in the
11 Fund, the Secretary shall give priority to pro-
12 viding funds for—

13 (i) programs, projects, and activities
14 of the Substance Abuse and Mental Health
15 Services Administration, the Department
16 of Labor, and the Department of Justice;

17 (ii) programs, projects, and activities
18 that provide services to individuals directly
19 affected by the abuse of opioids (including
20 family members of such individuals);

21 (iii) programs, projects, and activities
22 of the Department of Education related to
23 national activities for school safety, includ-
24 ing such activities authorized under section
25 4631 of the Elementary and Secondary

1 Education Act of 1965 (20 U.S.C. 7281)
 2 to help State and local educational agen-
 3 cies implement evidence-based opioid-abuse
 4 prevention strategies for schools in commu-
 5 nities impacted by the opioid crisis, and
 6 particularly for any applicant who de-
 7 scribes how such applicant would use the
 8 funds to prevent opioid abuse by students
 9 and address the mental health needs of
 10 students affected by opioid abuse with
 11 their families or communities; and

12 (iv) Head Start programs, including
 13 Early Head Start programs, under the
 14 Head Start Act (42 U.S.C. 9831 et seq.),
 15 to provide additional qualified child care
 16 providers trained in trauma-informed care
 17 in States with the largest number of chil-
 18 dren and families affected by the opioid
 19 crisis in their communities.

20 (C) AVAILABILITY.—Amounts transferred
 21 to an agency under subparagraph (A) shall re-
 22 main available until expended.

23 **SEC. 3. REDUCED EXCLUSIVITY.**

24 (a) IN GENERAL.—If a drug manufacturer violates
 25 subsection (h)(2) of section 303 of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 333) (as added by
 2 section 2) with respect to a covered opioid, effective on
 3 the date on which such manufacturer is found to have so
 4 violated such section—

5 (1) any remaining period of market exclusivity
 6 with respect to such covered opioid shall be revoked;

7 (2) the period of market exclusivity with respect
 8 to any other opioid for which such manufacturer is
 9 the holder of an approved application under section
 10 505 of the Federal Food, Drug, and Cosmetic Act
 11 (21 U.S.C. 355) or a license under section 351 of
 12 the Public Health Service Act (42 U.S.C. 262) shall
 13 be reduced to one-half of the remaining period of
 14 market exclusivity; and

15 (3) no new or additional exclusivity shall be
 16 awarded to any opioid for which an application is
 17 submitted by such manufacturer for approval under
 18 section 505 of the Federal Food, Drug, and Cos-
 19 metic Act (21 U.S.C. 355) or under section 351 of
 20 the Public Health Service Act (42 U.S.C. 262) or
 21 marketed as a result of product hopping.

22 (b) DEFINITIONS.—For purposes of this section:

23 (1) COVERED OPIOID.—A “covered opioid” is a
 24 prescription opioid drug, the sales of which in the
 25 United States, beginning on the date on which the

1 drug was first eligible to be marketed in the United
2 States and ending on the date on which the manu-
3 facturer was found to be in violation of subsection
4 (h)(2) of section 303 of the Federal Food, Drug,
5 and Cosmetic Act (21 U.S.C. 333), has generated at
6 least \$1.

7 (2) PERIOD OF MARKET EXCLUSIVITY.—The
8 term “period of market exclusivity” with respect to
9 a drug means the total period of market exclusivity
10 granted under clause (ii), (iii), or (iv) of section
11 505(c)(3)(E) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 355(c)(3)(E)), section
13 505(j)(5)(B)(iv) of such Act, clause (ii), (iii), or (iv)
14 of section 505(j)(5)(F) of such Act, section 527 of
15 such Act, or section 351(k)(7) of the Public Health
16 Service Act (42 U.S.C. 262(k)(7)), and any exten-
17 sion of such a period granted under section 505A or
18 505E of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 355a, 355f).

20 (3) PRODUCT HOPPING.—The term “product
21 hopping” means a reformulation of an approved
22 drug or biological product that allows a manufac-
23 turer to submit a new drug application under section
24 505(b) of the Federal Food, Drug, and Cosmetic Act
25 (21 U.S.C. 355(b)) or new application for a license

1 under section 351(a) of the Public Health Service
2 Act (42 U.S.C. 262(a)) and that—

3 (A) is intended for the treatment of the
4 same medical condition as the drug or biological
5 product that was originally so approved; and

6 (B) is undertaken in conjunction with the
7 sponsor's actions to reduce or eliminate demand
8 for the original formulation of the drug or bio-
9 logical product.

10 **SEC. 4. PENALTY WITH RESPECT TO OPIOIDS DEVELOPED**
11 **USING FEDERAL FUNDING.**

12 If a drug manufacturer or distributor violates sub-
13 section (h)(2) of section 303 of the Federal Food, Drug,
14 and Cosmetic Act (21 U.S.C. 333) (as added by section
15 2) with respect to an opioid that was developed with the
16 support of Federal funding, in addition to the applicable
17 penalties under such subsection (h), such manufacturer or
18 distributor shall be subject to a civil penalty in an amount
19 equal to the sum of—

20 (1) such Federal funding, regardless of whether
21 the Federal funding was received by the manufac-
22 turer or distributor or another entity; plus

23 (2) 25 percent of the total profit such manufac-
24 turer or distributor received in connection with man-
25 ufacturing or distributing such opioid.

1 **SEC. 5. TREATMENT OF CERTAIN TAX CREDITS FOR VIOLA-**
 2 **TORS OF ILLEGAL MARKETING AND DIS-**
 3 **TRIBUTION PRACTICES WITH RESPECT TO**
 4 **OPIOIDS.**

5 (a) IN GENERAL.—Section 41 of the Internal Rev-
 6 enue Code of 1986 is amended by adding at the end the
 7 following new subsection:

8 “(i) TREATMENT OF CERTAIN TAXPAYERS VIO-
 9 LATING ILLEGAL MARKETING AND DISTRIBUTION PRAC-
 10 TICES WITH RESPECT TO OPIOIDS.—

11 “(1) IN GENERAL.—In the case of any taxpayer
 12 who has engaged in an illegal marketing or distribu-
 13 tion practice with respect to an opioid (within the
 14 meaning of section 303(h) of the Federal Food,
 15 Drug, and Cosmetic Act (21 U.S.C. 333))—

16 “(A) no credit shall be allowed under sub-
 17 section (a), section 45C(a), or section 3111(f)
 18 for any taxable year in the applicable period,
 19 and

20 “(B) the taxpayer’s tax under this chapter
 21 for the taxable year described in paragraph
 22 (2)(A) shall be increased by an amount equal to
 23 the amount of credits allowed to such taxpayer
 24 by reason of subsection (a), section 45C(a), and
 25 section 3111(f) for the period described in para-
 26 graph (2)(B).

1 “(2) APPLICABLE PERIOD.—For purposes of
 2 this subsection, the term ‘applicable period’ means
 3 the period of taxable years which—

4 “(A) begins with the taxable year in which
 5 a civil penalty has been imposed for an illegal
 6 marketing or distribution practice with respect
 7 to an opioid under section 303(h)(3) of the
 8 Federal Food, Drug, and Cosmetic Act, and

9 “(B) has a duration equal to the number
 10 of taxable years in the period that begins with
 11 the first day on which the illegal marketing or
 12 distribution practice with respect to the opioid
 13 occurred and ends on the earlier of date on
 14 which—

15 “(i) the illegal marketing or distribu-
 16 tion practice with respect to the opioid per-
 17 manently ceased, or

18 “(ii) the date on which the civil pen-
 19 alty described in subparagraph (A) is im-
 20 posed.

21 For purposes of subparagraph (B), any portion of a
 22 taxable year that is less than a whole taxable year
 23 shall be treated as a whole taxable year.”.

1 (b) EFFECTIVE DATE.—The amendments made by
2 this section shall apply to taxable years ending after the
3 date of the enactment of this Act.

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