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1ST SESSION

S. 1584

To hold pharmaceutical companies accountable for dubious 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

MAY 21, 2019

Mr. SANDERS (for himself, Mr. BENNET, Ms. HARRIS, and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To hold pharmaceutical companies accountable for dubious 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 2019”.

1 **SEC. 2. PROHIBITION OF DUBIOUS MARKETING AND MEDI-**
2 **CALLY UNREASONABLE DISTRIBUTION PRAC-**
3 **TICES WITH RESPECT TO OPIOIDS.**

4 (a) DUBIOUS MARKETING OR DISTRIBUTION PRAC-
5 TICE WITH RESPECT TO AN OPIOID.—

6 (1) IN GENERAL.—In this section, the term
7 “dubious marketing or distribution practice with re-
8 spect to an opioid”, subject to paragraph (2),
9 means—

10 (A) including in any advertisement, pro-
11 motion, direct-to-consumer marketing materials,
12 or other marketing material a representation
13 that an opioid has no addiction-forming or ad-
14 diction-sustaining liability or has less of an ad-
15 diction-forming or addiction-sustaining liability
16 than one or more other opioids, knowing the
17 representation to be false, as determined by the
18 Secretary of Health and Human Services (re-
19 ferred to in this section as the “Secretary”), in
20 consultation with the Commissioner of Food
21 and Drugs (referred to in this section as the
22 “Commissioner”), based on research, testimoni-
23 als, and other evidence;

24 (B) knowingly supplying States or commu-
25 nities with a quantity of opioids that the person
26 knows is not medically reasonable; or

1 (C) failing to report to the Secretary any
2 order or pattern of orders for the distribution
3 of opioids in a State or community that the per-
4 son knows are not being dispensed in a medi-
5 cally reasonable manner.

6 (2) LIMITATION.—An act does not constitute a
7 “dubious marketing or distribution practice with re-
8 spect to an opioid”, with respect to a natural per-
9 son—

10 (A) within the meaning of paragraph
11 (1)(B), if such natural person was not involved
12 in the decision making regarding the quantity
13 of opioids to supply; or

14 (B) within the meaning of paragraph
15 (1)(C) if such natural person knows that the
16 Secretary should reasonably be aware of the rel-
17 evant order or pattern of orders for the dis-
18 tribution of opioids.

19 (b) PROHIBITION.—It shall be unlawful for any per-
20 son involved in the manufacture or distribution of an
21 opioid to engage in an dubious marketing or distribution
22 practice with respect to an opioid.

23 (c) PENALTIES.—

24 (1) IN GENERAL.—Any person who violates
25 subsection (b)—

1 (A) if a natural person employed by an
2 opioid manufacturer or distributor, shall be—

3 (i) subject to a civil penalty in an
4 amount equal to the sum of—

5 (I) such person's full amount of
6 salary for each year during which
7 such person engaged in dubious mar-
8 keting or distribution practices with
9 respect to an opioid product; and

10 (II) the amount by which the
11 stock or other certificates of owner-
12 ship interest of the person that is
13 owned by the individual has increased
14 in value during the period during
15 which such person engaged in dubious
16 marketing or distribution practices of
17 an opioid product, without regard to
18 whether the individual has sold any of
19 the stock or certificates from such
20 opioid manufacturer or distributor;
21 and

22 (ii) subject to a term of imprison-
23 ment—

24 (I) with respect to a violation in-
25 volving a drug in schedule II of sec-

1 tion 202 of the Controlled Substances
2 Act (21 U.S.C. 812), of not more
3 than 10 years; or

4 (II) with respect to a violation in-
5 volving a drug in schedule III of sec-
6 tion 202 of the Controlled Substances
7 Act (21 U.S.C. 812), of not more
8 than 5 years; or

9 (B) if a corporate entity, shall be subject
10 to a civil penalty in the amount equal to 75 per-
11 cent of the total profit such corporate entity
12 made on lawful sales of opioids in the United
13 States during the period in which the corporate
14 entity engaged in dubious marketing or dis-
15 tribution practices.

16 (2) OTHER PENALTIES APPLICABLE IN THE
17 CASE OF A VIOLATION BY A CORPORATE ENTITY.—

18 If a person that is a corporate entity violates sub-
19 section (b), the court, without regard to the partici-
20 pation of such individuals in, or knowledge of such
21 individuals of, the violation, shall—

22 (A) impose on the chief executive officer
23 (or equivalent) of the corporate entity a civil
24 penalty in an amount equal to the sum of—

1 (i) the salary of the individual during
2 the period in which the corporate entity
3 engaged in dubious marketing or distribu-
4 tion practices and such individual served
5 as chief executive office; and

6 (ii) the amount by which the stock or
7 other certificates of ownership interest of
8 the corporate entity that is owned by the
9 individual has increased in value during
10 the period that the corporate entity en-
11 gaged in dubious marketing or distribution
12 practices and such individual served as
13 chief executive officer, without regard to
14 whether the individual has sold any of the
15 stock or certificates;

16 (B) impose on any executive other than the
17 chief executive officer (or equivalent) who led
18 the finance, research, marketing, or sales de-
19 partment of the corporate entity a civil penalty
20 in the amount equal to the sum of—

21 (i) 25 percent of the salary of the in-
22 dividual during the period that the cor-
23 porate entity engaged in dubious mar-
24 keting or distribution practices and such
25 individual served as such an executive; and

1 (ii) 25 percent of the amount by
2 which the stock or other certificates of
3 ownership interest of the corporate entity
4 that is owned by the individual has in-
5 creased in value during the period that the
6 corporate entity engaged in dubious mar-
7 keting or distribution practices and such
8 individual served as such an executive,
9 without regard to whether the individual
10 has sold any of the stock or certificates;
11 and

12 (C) impose on any executive, including the
13 chief executive officer (or equivalent) who led
14 the finance, research, marketing, or sales de-
15 partment of the corporate entity during the cal-
16 endar year in which a court enters a judgment
17 that the corporate entity violated subsection (b)
18 and who is not subject to a civil penalty under
19 subparagraph (A) or (B), a civil penalty in the
20 amount equal to the sum of—

21 (i) 25 percent of the salary of the in-
22 dividual from the corporate entity during
23 the calendar year in which a court enters
24 such judgment; and

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

7 (d) RULES FOR APPLICATION.—

8 (1) QUANTITY OF OPIOIDS COVERED.—

9 (A) FORMULA.—For purposes of subpara-
 10 graphs (B) and (C) of subsection (a)(1), the
 11 Secretary, in consultation with the Attorney
 12 General and, as appropriate, provider groups
 13 and patient advocacy groups, using, if applica-
 14 ble, data from the Automated Reports and Con-
 15 solidated Ordering System of the Department
 16 of Justice, shall establish a formula for deter-
 17 mining the quantity of opioids that is not medi-
 18 cally reasonable with respect to a community or
 19 State.

20 (B) REBUTTABLE PRESUMPTION.—There
 21 shall be a rebuttable presumption that a person
 22 who supplies a State or community with a
 23 quantity of opioids that is not medically reason-
 24 able, as determined using the formula estab-
 25 lished under paragraph (1), knowingly supplied

1 such quantity in violation of subsection
 2 (a)(1)(B).

3 (2) MEDICALLY REASONABLE QUANTITIES IN
 4 AN ORDER.—

5 (A) GUIDANCE.—For purposes of sub-
 6 section (a)(1)(C), the Secretary shall issue
 7 guidance setting forth a procedure that opioid
 8 manufacturers and distributors shall follow to
 9 recognize orders or patterns of orders for the
 10 distribution of opioids that are not medically
 11 reasonable.

12 (B) REBUTTABLE PRESUMPTION.—There
 13 shall be a rebuttable presumption that a person
 14 who—

15 (i) receives an order that the Sec-
 16 retary determines to be not medically rea-
 17 sonable and does not report such order;
 18 and

19 (ii) did not follow the procedure set
 20 forth in the guidance described in subpara-
 21 graph (A) with respect to such order,
 22 knowingly failed to report as described in sub-
 23 section (a)(1)(C).

24 (e) FEES APPLICABLE TO ALL OPIOID MANUFAC-
 25 TURERS AND DISTRIBUTORS.—

1 (1) IN GENERAL.—The Secretary shall assess a
2 fee against each corporate entity that, during the pe-
3 riod beginning on January 1, 1993, and ending on
4 the day before the date of enactment of this Act,
5 manufactured or distributed any opioid drug that
6 was covered by a Federal health program at least
7 once during such period, in amounts, for each such
8 manufacturer or distributor, determined by the Sec-
9 retary through rulemaking.

10 (2) TOTAL AMOUNT.—The Secretary shall en-
11 sure that the total amount assessed under para-
12 graph (1) equals \$20,000,000,000.

13 (3) DUE DATES.—With respect to a fee as-
14 sessed under this subsection—

15 (A) not less than 50 percent of the amount
16 of the fee shall be paid within 1 year of the
17 date of enactment of this Act; and

18 (B) 100 percent of such amount shall be
19 paid not later than 2 years after the date of en-
20 actment of this Act.

21 (4) WITHDRAWAL OF APPROVAL IN THE CASE
22 OF NONPAYMENT BY MANUFACTURER.—If a manu-
23 facturer assessed a fee under this subsection fails to
24 pay the full fee as required under paragraph (3), the
25 Secretary shall withdraw approval of the application

1 under section 505 of the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 355) for the drug until the
3 fee is paid in full.

4 (5) INVESTIGATION.—Immediately after the
5 date of enactment of this Act, the Secretary, acting
6 through the Commissioner and in consultation with
7 the Attorney General, acting through the Adminis-
8 trator of the Drug Enforcement Administration,
9 shall begin an assessment to set fees under this sub-
10 section.

11 (f) REIMBURSEMENT OF ECONOMIC IMPACT.—

12 (1) ESTABLISHMENT OF FUND.—There is es-
13 tablished in the Treasury of the United States a
14 fund, to be known as the “Opioids Reimbursement
15 Fund” (referred to in this subsection as the
16 “Fund”), to be administered by the Secretary, in
17 consultation with the Commissioner.

18 (2) APPROPRIATIONS; TRANSFERS TO THE
19 FUND.—

20 (A) APPROPRIATION.—There is appro-
21 priated, out of any monies in the Treasury not
22 otherwise appropriated, \$20,000,000,000 to the
23 Fund.

24 (B) TRANSFERS.—In a manner consistent
25 with section 3302(b) of title 31, United States

1 Code, there shall be transferred to the Fund
2 from the General Fund of the Treasury an
3 amount equal to—

4 (i) the amount of the civil penalties
5 collected under subsection (c); plus

6 (ii) the amount of fees collected under
7 subsection (e).

8 (C) AVAILABILITY.—Funds appropriated
9 under paragraph (1) and transferred under
10 subparagraph (B) shall remain available until
11 expended.

12 (3) USE OF FUNDS.—

13 (A) IN GENERAL.—The Secretary, in con-
14 sultation with the Commissioner, may, without
15 further appropriation, use amounts in the Fund
16 to combat the misuse and abuse of opioids in
17 the United States, which may include transfer-
18 ring amounts from the Fund to other agencies
19 to carry out programs, projects, and activities
20 of the agencies to combat the misuse and abuse
21 of opioids in the United States.

22 (B) PRIORITY.—In using amounts in the
23 Fund, the Secretary shall give priority to pro-
24 viding funds for—

1 (i) programs, projects, and activities
2 of the Substance Abuse and Mental Health
3 Services Administration, the Department
4 of Labor, the Centers for Disease Control
5 and Prevention, and the Health Resources
6 and Services Administration;

7 (ii) programs, projects, and activities
8 that provide services to individuals directly
9 affected by the misuse and abuse of opioids
10 (including family members of such individ-
11 uals);

12 (iii) programs, projects, and activities
13 of the Department of Education related to
14 national activities for school safety, includ-
15 ing such activities authorized under section
16 4631 of the Elementary and Secondary
17 Education Act of 1965 (20 U.S.C. 7281)
18 to help State and local educational agen-
19 cies implement evidence-based opioid mis-
20 use and abuse prevention strategies for
21 schools in communities impacted by the
22 opioid crisis, and particularly for any ap-
23 plicant who describes how such applicant
24 would use the funds to prevent opioid mis-
25 use and abuse by students and address the

1 mental health needs of students affected by
 2 opioid misuse and abuse with their families
 3 or communities; and

4 (iv) Head Start programs, including
 5 Early Head Start programs, under the
 6 Head Start Act (42 U.S.C. 9831 et seq.)
 7 and the Healthy Start program of the
 8 Health Resources and Services Administra-
 9 tion to provide additional qualified child
 10 care providers trained in trauma-informed
 11 care in States with the largest number of
 12 children and families affected by the opioid
 13 crisis in their communities.

14 (C) AVAILABILITY.—Amounts transferred
 15 to an agency under subparagraph (A) shall re-
 16 main available until expended.

17 (D) SUPPLEMENT NOT SUPPLANT.—
 18 Amounts transferred to an agency under sub-
 19 paragraph (A) to carry out programs, projects,
 20 and activities of the agency shall supplement,
 21 and not supplant, amounts otherwise available
 22 for such purpose.

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

24 (a) IN GENERAL.—If a drug manufacturer violates
 25 section 2(b) with respect to a covered opioid, effective on

1 the date on which such manufacturer is found to have so
 2 violated such section—

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

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

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

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

21 (1) COVERED OPIOID.—A “covered opioid” is a
 22 prescription opioid drug, the sales of which in the
 23 United States, beginning on the date on which the
 24 drug was first eligible to be marketed in the United
 25 States and ending on the date on which the manu-

1 facturer was found to be in violation of section 2(b),
2 has generated at least \$1.

3 (2) PERIOD OF MARKET EXCLUSIVITY.—The
4 term “period of market exclusivity” with respect to
5 a drug means the total period of market exclusivity
6 granted under clause (ii), (iii), or (iv) of section
7 505(c)(3)(E) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 355(c)(3)(E)), section
9 505(j)(5)(B)(iv) of such Act, clause (ii), (iii), or (iv)
10 of section 505(j)(5)(F) of such Act, section 527 of
11 such Act (21 U.S.C. 360cc), or paragraph (6) or (7)
12 of section 351(k) of the Public Health Service Act
13 (42 U.S.C. 262(k)), and any extension of such a pe-
14 riod granted under section 505A or 505E of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 355a, 355f).

17 (3) PRODUCT HOPPING.—The term “product
18 hopping” means a reformulation of an approved
19 drug or biological product that allows a manufac-
20 turer to submit a new drug application under section
21 505(b) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 355(b)) or new application for a license
23 under section 351(a) of the Public Health Service
24 Act (42 U.S.C. 262(a)) and that—

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

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

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