116TH CONGRESS
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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Opioid Crisis Accountability Act of 2019''.

SEC. 2. PROHIBITION OF DUBIOUS MARKETING AND MEDICALLY UNREASONABLE DISTRIBUTION PRACTICES WITH RESPECT TO OPIOIDS.

(a) DUBIOUS MARKETING OR DISTRIBUTION PRACTICE WITH RESPECT TO AN OPIOID.—

(1) IN GENERAL.—In this section, the term ''dubious marketing or distribution practice with respect to an opioid'', subject to paragraph (2), means—

(A) including in any advertisement, promotion, direct-to-consumer marketing materials, or other marketing material a representation that an opioid has no addiction-forming or addiction-sustaining liability or has less of an addiction-forming or addiction-sustaining liability than one or more other opioids, knowing the representation to be false, as determined by the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), in consultation with the Commissioner of Food and Drugs (referred to in this section as the ''Commissioner''), based on research, testimonials, and other evidence;

(B) knowingly supplying States or communities with a quantity of opioids that the person knows is not medically reasonable; or

(C) failing to report to the Secretary any order or pattern of orders for the distribution of opioids in a State or community that the person knows are not being dispensed in a medically reasonable manner.

(2) LIMITATION.—An act does not constitute a ''dubious marketing or distribution practice with respect to an opioid'', with respect to a natural person—

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

(B) within the meaning of paragraph (1)(C) if such natural person knows that the Secretary should reasonably be aware of the relevant order or pattern of orders for the distribution of opioids.

(b) PROHIBITION.—It shall be unlawful for any person involved in the manufacture or distribution of an opioid to engage in an dubious marketing or distribution practice with respect to an opioid.

(c) PENALTIES.—

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

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

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

(I) such person's full amount of salary for each year during which such person engaged in dubious marketing or distribution practices with respect to an opioid product; and

(II) the amount by which the stock or other certificates of ownership interest of the person that is owned by the individual has increased in value during the period during which such person engaged in dubious marketing or distribution practices of an opioid product, without regard to whether the individual has sold any of the stock or certificates from such opioid manufacturer or distributor; and

(ii) subject to a term of imprisonment—

(I) with respect to a violation involving a drug in schedule II of sec-

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

(II) with respect to a violation involving a drug in schedule III of section 202 of the Controlled Substances Act (21 U.S.C. 812), of not more than 5 years; or

(B) if a corporate entity, shall be subject to a civil penalty in the amount equal to 75 percent of the total profit such corporate entity made on lawful sales of opioids in the United States during the period in which the corporate entity engaged in dubious marketing or distribution practices.

(2) OTHER PENALTIES APPLICABLE IN THE CASE OF A VIOLATION BY A CORPORATE ENTITY.—If a person that is a corporate entity violates subsection (b), the court, without regard to the participation of such individuals in, or knowledge of such individuals of, the violation, shall—

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

(i) the salary of the individual during the period in which the corporate entity engaged in dubious marketing or distribution practices and such individual served as chief executive office; and

(ii) the amount by which the stock or other certificates of ownership interest of the corporate entity that is owned by the individual has increased in value during the period that the corporate entity engaged in dubious marketing or distribution practices and such individual served as chief executive officer, without regard to whether the individual has sold any of the stock or certificates;

(B) impose on any executive other than the chief executive officer (or equivalent) who led the finance, research, marketing, or sales department of the corporate entity a civil penalty in the amount equal to the sum of—

(i) 25 percent of the salary of the individual during the period that the corporate entity engaged in dubious marketing or distribution practices and such individual served as such an executive; and

(ii) 25 percent of the amount by which the stock or other certificates of ownership interest of the corporate entity that is owned by the individual has increased in value during the period that the corporate entity engaged in dubious marketing or distribution practices and such individual served as such an executive, without regard to whether the individual has sold any of the stock or certificates; and

(C) impose on any executive, including the chief executive officer (or equivalent) who led the finance, research, marketing, or sales department of the corporate entity during the calendar year in which a court enters a judgment that the corporate entity violated subsection (b) and who is not subject to a civil penalty under subparagraph (A) or (B), a civil penalty in the amount equal to the sum of—

(i) 25 percent of the salary of the individual from the corporate entity during the calendar year in which a court enters such judgment; and

(ii) 25 percent of the amount by which the stock or other certificates of ownership interest of the corporate entity that is owned by the individual has increased in value during the calendar year in which a court enters such judgment.

(d) RULES FOR APPLICATION.—

(1) QUANTITY OF OPIOIDS COVERED.—

(A) FORMULA.—For purposes of subparagraphs (B) and (C) of subsection (a)(1), the Secretary, in consultation with the Attorney General and, as appropriate, provider groups and patient advocacy groups, using, if applicable, data from the Automated Reports and Consolidated Ordering System of the Department of Justice, shall establish a formula for determining the quantity of opioids that is not medically reasonable with respect to a community or State.

(B) REBUTTABLE PRESUMPTION.—There shall be a rebuttable presumption that a person who supplies a State or community with a quantity of opioids that is not medically reasonable, as determined using the formula established under paragraph (1), knowingly supplied

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

(2) MEDICALLY REASONABLE QUANTITIES IN AN ORDER.—

(A) GUIDANCE.—For purposes of subsection (a)(1)(C), the Secretary shall issue guidance setting forth a procedure that opioid manufacturers and distributors shall follow to recognize orders or patterns of orders for the distribution of opioids that are not medically reasonable.

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

(i) receives an order that the Secretary determines to be not medically reasonable and does not report such order; and

(ii) did not follow the procedure set forth in the guidance described in subparagraph (A) with respect to such order,

knowingly failed to report as described in subsection (a)(1)(C).

(e) FEES APPLICABLE TO ALL OPIOID MANUFACTURERS AND DISTRIBUTORS.—

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

(2) TOTAL AMOUNT.—The Secretary shall ensure that the total amount assessed under paragraph (1) equals $20,000,000,000.

(3) DUE DATES.—With respect to a fee assessed under this subsection—

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

(B) 100 percent of such amount shall be paid not later than 2 years after the date of enactment of this Act.

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

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

(5) INVESTIGATION.—Immediately after the date of enactment of this Act, the Secretary, acting through the Commissioner and in consultation with the Attorney General, acting through the Administrator of the Drug Enforcement Administration, shall begin an assessment to set fees under this subsection.

(f) REIMBURSEMENT OF ECONOMIC IMPACT.—

(1) ESTABLISHMENT OF FUND.—There is established in the Treasury of the United States a fund, to be known as the ''Opioids Reimbursement Fund'' (referred to in this subsection as the ''Fund''), to be administered by the Secretary, in consultation with the Commissioner.

(2) APPROPRIATIONS; TRANSFERS TO THE FUND.—

(A) APPROPRIATION.—There is appropriated, out of any monies in the Treasury not otherwise appropriated, $20,000,000,000 to the Fund.

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

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

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

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

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

(3) USE OF FUNDS.—

(A) IN GENERAL.—The Secretary, in consultation with the Commissioner, may, without further appropriation, use amounts in the Fund to combat the misuse and abuse of opioids in the United States, which may include transferring amounts from the Fund to other agencies to carry out programs, projects, and activities of the agencies to combat the misuse and abuse of opioids in the United States.

(B) PRIORITY.—In using amounts in the Fund, the Secretary shall give priority to providing funds for—

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

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

(iii) programs, projects, and activities of the Department of Education related to national activities for school safety, including such activities authorized under section 4631 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7281) to help State and local educational agencies implement evidence-based opioid misuse and abuse prevention strategies for schools in communities impacted by the opioid crisis, and particularly for any applicant who describes how such applicant would use the funds to prevent opioid misuse and abuse by students and address the

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

(iv) Head Start programs, including Early Head Start programs, under the Head Start Act (42 U.S.C. 9831 et seq.) and the Healthy Start program of the Health Resources and Services Administration to provide additional qualified child care providers trained in trauma-informed care in States with the largest number of children and families affected by the opioid crisis in their communities.

(C) AVAILABILITY.—Amounts transferred to an agency under subparagraph (A) shall remain available until expended.

(D) SUPPLEMENT NOT SUPPLANT.—Amounts transferred to an agency under subparagraph (A) to carry out programs, projects, and activities of the agency shall supplement, and not supplant, amounts otherwise available for such purpose.

SEC. 3. REDUCED EXCLUSIVITY.

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

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

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

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

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

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

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

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

(2) PERIOD OF MARKET EXCLUSIVITY.—The term ''period of market exclusivity'' with respect to a drug means the total period of market exclusivity granted under clause (ii), (iii), or (iv) of section 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E)), section 505(j)(5)(B)(iv) of such Act, clause (ii), (iii), or (iv) of section 505(j)(5)(F) of such Act, section 527 of such Act (21 U.S.C. 360cc), or paragraph (6) or (7) of section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), and any extension of such a period granted under section 505A or 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355f).

(3) PRODUCT HOPPING.—The term ''product hopping'' means a reformulation of an approved drug or biological product that allows a manufacturer to submit a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or new application for a license under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) and that—

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

(B) is undertaken in conjunction with the sponsor's actions to reduce or eliminate demand for the original formulation of the drug or biological product.

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