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115TH CONGRESS
2D SESSION

H. R. 5782

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 HOUSE OF REPRESENTATIVES

MAY 11, 2018

Ms. GABBARD (for herself and Mr. KHANNA) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and the Workforce, Ways and Means, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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.

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 2018''.

SEC. 2. PROHIBITION OF ILLEGAL MARKETING AND DISTRIBUTION PRACTICES WITH RESPECT TO OPIOIDS.

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

''(h)(1) In this subsection, the term 'illegal marketing or distribution practice with respect to an opioid' 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 1 or more other opioids, knowing the representation to be false, as determined by the Secretary, in consultation with the Commissioner, based on research, testimonials, and other evidence;

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

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

opioids that would cause a reasonable person to believe the opioids were not being dispensed in a medically reasonable manner.

''(2) It shall be unlawful for any person who manufactures or distributes an opioid to engage in an illegal marketing or distribution practice with respect to an opioid.

''(3)(A) Any person who violates paragraph (2)—

''(i) 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—

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

''(bb) 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 illegal 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) with respect to a violation that occurs on or after the date of enactment of the Opioid Crisis Accountability Act of 2018, subject to the period of imprisonment specified under section 401 of the Controlled Substances Act that would be applicable for a violation of subsection (a) of such section that involved the quantity of opioids that were involved in the illegal marketing or distribution practices with respect to an opioid;

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

''(I) $7,800,000,000; plus

''(II) 25 percent of the total profit such person made on lawful sales of opioids in the United States during the period in which the person engaged in illegal marketing or distribution practices.

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

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

''(I) the salary of the individual during the period in which the person engaged in illegal marketing or distribution practices and such individual served as chief executive officer; 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 that the person engaged in illegal 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;

''(ii) impose on any executive other than the chief executive officer (or equivalent) who led the finance, research, marketing, or sales department of the person 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 person

engaged in illegal 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 person that is owned by the individual has increased in value during the period that the person engaged in illegal 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

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

''(I) 25 percent of the salary of the individual 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 person that is owned by the individual has increased in value during the calendar year in which a court enters such judgment.

"(C) Any person described in clause (i) or (ii) of subparagraph (A) shall be required to issue a public statement apologizing for their role in creating, sustaining, and exacerbating the opioid epidemic in the United States.".

(b) INVESTIGATION; RETROACTIVE EFFECT.—

(1) INVESTIGATION.—Immediately after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs and in consultation with the Attorney General, acting through the Administrator of the Drug Enforcement Administration, shall begin investigating all opioid manufacturers and all executives employed by such manufacturers to determine whether any such manufacturers or executives, at any time before or after such date of enactment, violated subsection (h)(2) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) (as added by subsection (a)).

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

(c) 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 of Health and Human Services (referred to in this subsection as the ''Secretary''), in consultation with the Commissioner of Food and Drugs.

(2) TRANSFERS TO THE FUND.—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 the amount of the civil penalties collected under subsection (h)(3) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) (as added by subsection (a)), which shall remain available until expended.

(3) USE OF FUNDS.—

(A) IN GENERAL.—The Secretary, in consultation with the Commissioner of Food and Drugs, may, without further appropriation, use amounts in the Fund to combat the 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 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, and the Department of Justice;

(ii) programs, projects, and activities that provide services to individuals directly affected by the 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-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 abuse by students and address the mental health needs of students affected by opioid 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.), 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.

SEC. 3. REDUCED EXCLUSIVITY.

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

Drug, and Cosmetic Act (21 U.S.C. 333) (as added by section 2) 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 manufacturer was found to be in violation of subsection (h)(2) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), 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, or section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)), 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.

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

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

(1) such Federal funding, regardless of whether the Federal funding was received by the manufacturer or distributor or another entity; plus

(2) 25 percent of the total profit such manufacturer or distributor received in connection with manufacturing or distributing such opioid.

SEC. 5. TREATMENT OF CERTAIN TAX CREDITS FOR VIOLATORS OF ILLEGAL MARKETING AND DISTRIBUTION PRACTICES WITH RESPECT TO OPIOIDS.

(a) IN GENERAL.—Section 41 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

''(i) TREATMENT OF CERTAIN TAXPAYERS VIOLATING ILLEGAL MARKETING AND DISTRIBUTION PRACTICES WITH RESPECT TO OPIOIDS.—

''(1) IN GENERAL.—In the case of any taxpayer who has engaged in an illegal marketing or distribution practice with respect to an opioid (within the meaning of section 303(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333))—

''(A) no credit shall be allowed under subsection (a), section 45C(a), or section 3111(f) for any taxable year in the applicable period, and

''(B) the taxpayer's tax under this chapter for the taxable year described in paragraph (2)(A) shall be increased by an amount equal to the amount of credits allowed to such taxpayer by reason of subsection (a), section 45C(a), and section 3111(f) for the period described in paragraph (2)(B).

''(2) APPLICABLE PERIOD.—For purposes of this subsection, the term 'applicable period' means the period of taxable years which—

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

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

''(i) the illegal marketing or distribution practice with respect to the opioid permanently ceased, or

''(ii) the date on which the civil penalty described in subparagraph (A) is imposed.

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

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

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