### 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

## 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 1 or more other opioids,
15	knowing the representation to be false, as deter-
16	mined by the Secretary, in consultation with the
17	Commissioner, based on research, testimonials, and
18	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 officer; 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.

"(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)).

- 1 (2) RETROACTIVE EFFECT.—Subsection (h)(2)
  2 of section 303 of the Federal Food, Drug, and Cos3 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.
  - (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.
- 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

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 prevention strategies for schools in communities 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 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.
- 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,

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- 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
  - (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.
- 22 (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

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- 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,
- 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 U.S.C. (21)355(c)(3)(E), metic Act 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).
  - (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

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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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