## <sup>115TH CONGRESS</sup> 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".

# SEC. 2. PROHIBITION OF ILLEGAL MARKETING AND DIS TRIBUTION PRACTICES WITH RESPECT TO 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 marketing8 or distribution practice with respect to an opioid' means—

9 "(A) including in any advertisement, promotion, direct-to-consumer marketing materials, or other 10 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;

"(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

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

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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	

24 "(I) 25 percent of the salary of the in-25 dividual 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 4 which the stock or other certificates of 5 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 practices and such individual served as 10 11 such an executive, without regard to 12 whether the individual has sold any of the 13 stock or certificates; and

"(iii) impose on any executive, including 14 15 the chief executive officer (or equivalent) who led the finance, research, marketing, or sales 16 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 in24 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)).

(2) RETROACTIVE EFFECT.—Subsection (h)(2)
 of section 303 of the Federal Food, Drug, and Cos metic Act (21 U.S.C. 333) (as added by subsection
 (a)) shall take effect on January 1, 1985, and shall
 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 Fund" (referred to in this subsection as the 10 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) (as added by subsection (a)), which shall remain 22 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 of the Department of Education related to 22 23 national activities for school safety, includ-24 ing such activities authorized under section

4631 of the Elementary and Secondary

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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.

(a) IN GENERAL.—If a drug manufacturer violatessubsection (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—

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

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 subsection
 (h)(2) of section 303 of the Federal Food, Drug,
 and Cosmetic Act (21 U.S.C. 333), has generated at
 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

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 support of Federal funding, in addition to the applicable 16 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 manufac22 turer 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.

#### 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 Rev6 enue Code of 1986 is amended by adding at the end the
7 following new subsection:

8 "(i) TREATMENT OF CERTAIN TAXPAYERS VIO9 LATING ILLEGAL MARKETING AND DISTRIBUTION PRAC10 TICES 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).

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.".

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