

AMENDMENT NO. 2 Calendar No. _____

Purpose: 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 SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

S. 2680

To address the opioid crisis.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

1 At the appropriate place, insert the following:

2 **SEC. ____ . PROHIBITION OF ILLEGAL MARKETING AND**
3 **DISTRIBUTION PRACTICES WITH RESPECT TO**
4 **OPIOIDS.**

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

8 “(h)(1) In this subsection, the term ‘illegal marketing
9 or distribution practice with respect to an opioid’ means—

10 “(A) including in any advertisement, promotion,
11 direct-to-consumer marketing materials, or other

1 marketing material a representation that an opioid
2 has no addiction-forming or addiction-sustaining li-
3 ability or has less of an addiction-forming or addic-
4 tion-sustaining liability than 1 or more other opioids,
5 knowing the representation to be false, as deter-
6 mined by the Secretary, in consultation with the
7 Commissioner, based on research, testimonials, and
8 other evidence;

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

15 “(C) failing to report to the Secretary any
16 order or pattern of orders for the distribution of
17 opioids that would cause a reasonable person to be-
18 lieve the opioids were not being dispensed in a medi-
19 cally reasonable manner.

20 “(2) It shall be unlawful for any person who manu-
21 factures or distributes an opioid to engage in an illegal
22 marketing or distribution practice with respect to an
23 opioid.

24 “(3)(A) Any person who violates paragraph (2)—

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

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

5 “(aa) such person’s full amount of
6 salary for each year during which such
7 person engaged in illegal marketing or dis-
8 tribution practices with respect to an
9 opioid product; and

10 “(bb) the amount by which the stock
11 or other certificates of ownership interest
12 of the person that is owned by the indi-
13 vidual has increased in value during the
14 period during which such person engaged
15 in illegal marketing or distribution prac-
16 tices of an opioid product, without regard
17 to whether the individual has sold any of
18 the stock or certificates from such opioid
19 manufacturer or distributor; and

20 “(II) with respect to a violation that occurs
21 on or after the date of enactment of the Opioid
22 Crisis Accountability Act of 2018, subject to
23 the period of imprisonment specified under sec-
24 tion 401 of the Controlled Substances Act that
25 would be applicable for a violation of subsection

1 (a) of such section that involved the quantity of
2 opioids that were involved in the illegal mar-
3 keting or distribution practices with respect to
4 an opioid;

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

7 “(I) \$7,800,000,000; plus

8 “(II) 25 percent of the total profit such
9 person made on lawful sales of opioids in the
10 United States during the period in which the
11 person engaged in illegal marketing or distribu-
12 tion practices.

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

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

20 “(I) the salary of the individual dur-
21 ing the period in which the person engaged
22 in illegal marketing or distribution prac-
23 tices and such individual served as chief
24 executive office; and

1 “(II) the amount by which the stock
2 or other certificates of ownership interest
3 of the person that is owned by the indi-
4 vidual has increased in value during the
5 period that the person engaged in illegal
6 marketing or distribution practices and
7 such individual served as chief executive
8 officer, without regard to whether the indi-
9 vidual has sold any of the stock or certifi-
10 cates;

11 “(ii) impose on any executive other than
12 the chief executive officer (or equivalent) who
13 led the finance, research, marketing, or sales
14 department of the person a civil penalty in the
15 amount equal to the sum of—

16 “(I) 25 percent of the salary of the in-
17 dividual during the period that the person
18 engaged in illegal marketing or distribution
19 practices and such individual served as
20 such an executive; and

21 “(II) 25 percent of the amount by
22 which the stock or other certificates of
23 ownership interest of the person that is
24 owned by the individual has increased in
25 value during the period that the person en-

1 gaged in illegal marketing or distribution
2 practices and such individual served as
3 such an executive, without regard to
4 whether the individual has sold any of the
5 stock or certificates; and

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

15 “(I) 25 percent of the salary of the in-
16 dividual during the calendar year in which
17 a court enters such judgment; and

18 “(II) 25 percent of the amount by
19 which the stock or other certificates of
20 ownership interest of the person that is
21 owned by the individual has increased in
22 value during the calendar year in which a
23 court enters such judgment.

24 “(C) Any person described in clause (i) or (ii)
25 of subparagraph (A) shall be required to issue a

1 public statement apologizing for their role in cre-
2 ating, sustaining, and exacerbating the opioid epi-
3 demic in the United States.”.

4 (b) INVESTIGATION; RETROACTIVE EFFECT.—

5 (1) INVESTIGATION.—Immediately after the
6 date of enactment of this Act, the Secretary of
7 Health and Human Services, acting through the
8 Commissioner of Food and Drugs and in consulta-
9 tion with the Attorney General, acting through the
10 Administrator of the Drug Enforcement Administra-
11 tion, shall begin investigating all opioid manufactur-
12 ers and all executives employed by such manufactur-
13 ers to determine whether any such manufacturers or
14 executives, at any time before or after such date of
15 enactment, violated subsection (h)(2) of section 303
16 of the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 333) (as added by subsection (a)).

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

23 (c) REIMBURSEMENT OF ECONOMIC IMPACT.—

24 (1) ESTABLISHMENT OF FUND.—There is es-
25 tablished in the Treasury of the United States a

1 fund, to be known as the “Opioids Reimbursement
2 Fund” (referred to in this subsection as the
3 “Fund”), to be administered by the Secretary of
4 Health and Human Services (referred to in this sub-
5 section as the “Secretary”), in consultation with the
6 Commissioner of Food and Drugs.

7 (2) TRANSFERS TO THE FUND.—In a manner
8 consistent with section 3302(b) of title 31, United
9 States Code, there shall be transferred to the Fund
10 from the General Fund of the Treasury an amount
11 equal to the amount of the civil penalties collected
12 under subsection (h)(3) of section 303 of the Fed-
13 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333)
14 (as added by subsection (a)), which shall remain
15 available until expended.

16 (3) USE OF FUNDS.—

17 (A) IN GENERAL.—The Secretary, in con-
18 sultation with the Commissioner of Food and
19 Drugs, may, without further appropriation, use
20 amounts in the Fund to combat the abuse of
21 opioids in the United States, which may include
22 transferring amounts from the Fund to other
23 agencies to carry out programs, projects, and
24 activities of the agencies to combat the abuse of
25 opioids in the United States.

1 (B) PRIORITY.—In using amounts in the
2 Fund, the Secretary shall give priority to pro-
3 viding funds for—

4 (i) programs, projects, and activities
5 of the Substance Abuse and Mental Health
6 Services Administration, the Department
7 of Labor, and the Department of Justice;

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

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-abuse
20 prevention strategies for schools in commu-
21 nities impacted by the opioid crisis, and
22 particularly for any applicant who de-
23 scribes how such applicant would use the
24 funds to prevent opioid abuse by students
25 and address the mental health needs of

1 students affected by opioid abuse with
2 their families or communities; and

3 (iv) Head Start programs, including
4 Early Head Start programs, under the
5 Head Start Act (42 U.S.C. 9831 et seq.),
6 to provide additional qualified child care
7 providers trained in trauma-informed care
8 in States with the largest number of chil-
9 dren and families affected by the opioid
10 crisis in their communities.

11 (C) AVAILABILITY.—Amounts transferred
12 to an agency under subparagraph (A) shall re-
13 main available until expended.