

115TH CONGRESS  
2D SESSION

**S.** \_\_\_\_\_

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.

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IN THE SENATE OF THE UNITED STATES

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Mr. SANDERS introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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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.

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 office; 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.

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)).

1           (2) RETROACTIVE EFFECT.—Subsection (h)(2)  
2 of section 303 of the Federal Food, Drug, and Cos-  
3 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.

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  
10 Fund” (referred to in this subsection as the  
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)  
22 (as added by subsection (a)), which shall remain  
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  
22               of the Department of Education related to  
23               national activities for school safety, includ-  
24               ing such activities authorized under section  
25               4631 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  
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.**

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

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

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

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

23 (1) COVERED OPIOID.—A “covered opioid” is a  
24 prescription opioid drug, the sales of which in the  
25 United States, beginning on the date on which the

1 drug was first eligible to be marketed in the United  
2 States and ending on the date on which the manu-  
3 facturer was found to be in violation of subsection  
4 (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 metic Act (21 U.S.C. 355(c)(3)(E)), 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).

20 (3) PRODUCT HOPPING.—The term “product  
21 hopping” means a reformulation of an approved  
22 drug or biological product that allows a manufac-  
23 turer to submit a new drug application under section  
24 505(b) of the Federal Food, Drug, and Cosmetic Act  
25 (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  
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.