

116TH CONGRESS  
1ST SESSION

# S. 2387

To establish a process by which reasonable drug prices may be determined,  
and for other purposes.

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IN THE SENATE OF THE UNITED STATES

JULY 31, 2019

Mr. VAN HOLLEN (for himself and Mr. SCOTT of Florida) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To establish a process by which reasonable drug prices may  
be determined, and for other purposes.

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 “We Protect American  
5 Investment in Drugs Act” or the “We PAID Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) In addition to spurring economic growth,  
9 the National Institutes of Health supports some of  
10 the most significant breakthroughs in biomedical in-

1       novation, including some that are commercialized  
2       into new pharmaceutical products.

3               (2) The National Institutes of Health funding  
4       contributed, either directly or indirectly, to the de-  
5       velopment of all 210 new molecular entities approved  
6       by the Food and Drug Administration between 2010  
7       and 2016, according to an analysis published in the  
8       Proceedings of the National Academy of Sciences.

9               (3) In fiscal year 2019, Congress provided  
10       \$39,100,000,000 in funding for the National Insti-  
11       tutes of Health.

12              (4) According to a Kaiser Family Foundation  
13       health tracking poll in February 2019—

14                   (A) nearly 80 percent of people in the  
15       United States say that the cost of prescription  
16       drugs is “unreasonable” and only 25 percent  
17       trust pharmaceutical companies to price their  
18       products fairly; and

19                   (B) one-fourth of people in the United  
20       States say it is difficult to afford their prescrip-  
21       tion drugs, and 3 in 10 say they have not taken  
22       their medications as prescribed due to costs.

23              (5) According to a September 2018 report from  
24       the AARP—

1 (A) between 2016 and 2017, retail prices  
2 for 267 widely used brand name prescription  
3 drugs increased by 8.4 percent after 5 straight  
4 years of double-digit average annual price in-  
5 creases;

6 (B) brand name drug prices increased 4  
7 times faster than general inflation in 2017; and

8 (C) retail prices increased in 2017 for 87  
9 percent (231 of 267) of the widely used brand  
10 name prescription drugs reviewed, and all but 5  
11 such increases exceeded the rate of inflation.

12 (6) In 2016, prescription drug spending in the  
13 United States was \$477,000,000,000, according to  
14 an estimate from the Assistant Secretary for Plan-  
15 ning and Evaluation of the Department of Health  
16 and Human Services.

17 (7) Prescription drugs account for nearly \$1  
18 out of every \$5 in overall spending under the Medi-  
19 care program, as well as 21 percent of Medicare  
20 beneficiaries' out-of-pocket health spending, not in-  
21 cluding premiums.

22 (8)(A) A drug's list price has a significant im-  
23 pact on what payors and patients pay to purchase  
24 prescription drugs.

1           (B) In prescription drug plans under Medicare  
2 part D, and a growing number of commercial health  
3 plans, seniors' and other beneficiaries' cost-sharing  
4 is based on a percentage of a drug's list price. As  
5 a result, higher drug list prices mean higher out-of-  
6 pocket costs for Medicare beneficiaries for their re-  
7 tail prescriptions.

8           (C) For prescription drugs covered under Medi-  
9 care part B, beneficiaries are responsible for paying  
10 20 percent of the Medicare-approved amount for the  
11 drug, and the part B deductible also applies. This  
12 can be a significant burden for high-cost part B  
13 drugs.

14           (D) A drug's list price is a factor in deter-  
15 mining the amount of the rebate paid to State Med-  
16 icaid plans by the drug's manufacturer under the  
17 Medicaid Drug Rebate Program, and an increase in  
18 the drug's list price may result in increased Med-  
19 icaid costs.

20           (E) In the private health insurance market,  
21 pharmacy benefit manager and wholesaler fees are  
22 based on a percentage of the list price. Higher list  
23 prices increase costs in this part of the distribution  
24 chain.

1 (F) From 2007 through 2017, enrollment in  
2 high-deductible health plans with a health savings  
3 account (4.2 percent to 18.9 percent) and without a  
4 health savings account (10.6 percent to 24.5 per-  
5 cent) increased among adults between ages 18 and  
6 64 with employment-based coverage, while enroll-  
7 ment in traditional plans decreased, according to the  
8 Centers for Disease Control and Prevention. Individ-  
9 uals with high-deductible health plans pay more out  
10 of pocket for medical expenses until their deductible  
11 is met, making high-cost drugs challenging to afford.

12 (G) A larger share of prescription drug plans  
13 under Medicare part D charged a deductible in 2019  
14 than in 2018 (71 percent in 2019, and 63 percent  
15 in 2018), according to the Kaiser Family Founda-  
16 tion. Fifty-two percent of prescription drug plans  
17 will require enrollees to satisfy the standard deduct-  
18 ible of \$415 in 2019.

19 **SEC. 3. DEFINITIONS.**

20 For purposes of this Act:

21 (1) **APPLICABLE DRUG.**—The term “applicable  
22 drug” means a drug (as defined in section 201 of  
23 the Federal Food, Drug, and Cosmetic Act (21  
24 U.S.C. 321)) that—

1 (A) is approved under section 505(c) of the  
2 Federal Food, Drug, and Cosmetic Act (21  
3 U.S.C. 355(c)) or section 351(a) of the Public  
4 Health Service Act (42 U.S.C. 262(a));

5 (B) is subject to section 503(b)(1) of such  
6 Act (21 U.S.C. 353(b)(1)); and

7 (C) is covered by a qualifying patent on  
8 the drug, on a method of using such drug, or  
9 on a method or machine used to manufacture  
10 or administer such drug with respect to which  
11 the drug sponsor retained the title to any sub-  
12 ject invention under section 202 of title 35,  
13 United States Code, or entered into a licensing  
14 agreement after the date of enactment of this  
15 Act.

16 (2) CONFLICT OF INTEREST.—The term “con-  
17 flict of interest” means an association, including a  
18 financial or personal association, or past employ-  
19 ment, that has the potential to bias or have the ap-  
20 pearance of biasing an individual’s decisions in mat-  
21 ters related to the Drug Affordability and Access  
22 Committee or the conduct of other activities under  
23 this Act.

24 (3) MANUFACTURER LIST PRICE.—The term  
25 “manufacturer list price” means the national price

1 for a prescription drug established by the manufac-  
2 turer or licensee found in a catalogue or other public  
3 source that is the price from which market discounts  
4 and price concessions are calculated.

5 (4) PERIOD OF MARKET EXCLUSIVITY.—The  
6 term “period of market exclusivity” means any pe-  
7 riod of market exclusivity granted with respect to a  
8 prescription drug under clause (ii), (iii), or (iv) of  
9 section 505(c)(3)(E) of the Federal Food, Drug, and  
10 Cosmetic Act (21 U.S.C. 355(c)(3)(E)), clause (ii),  
11 (iii), or (iv) of section 505(j)(5)(F) of such Act, sec-  
12 tion 527 of such Act (21 U.S.C. 360cc), or section  
13 351(k)(7) of the Public Health Service Act (42  
14 U.S.C. 262(k)(7)), and any extension of such period  
15 granted under section 505A or 505E of the Federal  
16 Food, Drug, and Cosmetic Act (21 U.S.C. 355a,  
17 355f).

18 (5) QUALIFYING PATENT.—The term “quali-  
19 fying patent” means any patent—

20 (A) held by the Federal Government; or

21 (B) which the applicant with respect to the  
22 patent was required to disclose under section  
23 202(c)(6) of title 35, United States Code, in the  
24 application for the patent.

1           (6) SECRETARY.—The term “Secretary” means  
2           the Secretary of Health and Human Services.

3 **SEC. 4. NATIONAL ACADEMY OF MEDICINE STUDY ON DE-**  
4 **TERMINING A REASONABLE DRUG PRICE.**

5           (a) IN GENERAL.—Not later than 60 days after the  
6 date of enactment of this Act, the Secretary shall seek  
7 to enter into a contract with the National Academy of  
8 Medicine (referred to in this section as the “Academy”)  
9 under which the Academy agrees to study—

10           (1) how best to determine the reasonableness of  
11 a drug’s manufacturer list price and retail price and  
12 develop at least 1 framework for determining the  
13 reasonableness of a drug’s manufacturer list price  
14 and retail price taking into consideration—

15           (A) affordability of the drug to payers,  
16 purchasers, and patients across wide market  
17 segments in a manner that ensures equitable  
18 access;

19           (B) investment by the National Institutes  
20 of Health or any other Federal Government en-  
21 tity in the development of the drug;

22           (C) inclusion of research funded by the  
23 National Institutes of Health or other Federal  
24 Government entity in the development of the  
25 drug;



1 (D) manufacturer research and develop-  
2 ment costs as shown on the manufacturer's  
3 Federal tax filing under sections 41 and 174 of  
4 the Internal Revenue Code of 1986;

5 (E) investment and the rate of return  
6 needs for the drug manufacturer;

7 (F) market for the drug;

8 (G) the cost of production and distribution  
9 of the drug;

10 (H) the price of the drug in other similar,  
11 industrialized countries;

12 (I) estimated global and domestic sales of  
13 the drug;

14 (J) gross and net expenditures by public  
15 payers for coverage of the drug under Federal  
16 health programs, to the extent available; and

17 (K) any additional information the Acad-  
18 emy determines appropriate;

19 (2) an appropriate timeline for the submission  
20 of information to the Drug Affordability and Access  
21 Committee required under section 6(a)(2) to deter-  
22 mine the reasonableness of a drug's manufacturer  
23 list price and retail price; and

24 (3) an appropriate timeline for the Drug Af-  
25 fordability and Access Committee to determine the

1       reasonableness of a drug’s manufacturer list price  
2       and retail price to be in effect the second year after  
3       coming to market.

4       (b) REPORT.—Any contract between the Secretary  
5       and the Academy under this section shall include a re-  
6       quirement that the Academy submit a report on the re-  
7       sults of the study described in subsection (a) to the Sec-  
8       retary, the Drug Affordability and Access Committee, and  
9       Congress.

10   **SEC. 5. DRUG AFFORDABILITY AND ACCESS COMMITTEE.**

11       (a) ESTABLISHMENT.—There is hereby authorized to  
12       be established a nonprofit corporation to be known as the  
13       Drug Affordability and Access Committee (referred to in  
14       this section as the “Committee”), which is neither an  
15       agency nor establishment of the United States Govern-  
16       ment. The Committee shall be headed by an Executive Di-  
17       rector.

18       (b) PURPOSE.—The purpose of the Committee is to  
19       determine a reasonable manufacturer list price and retail  
20       price for each applicable drug.

21       (c) BOARD OF DIRECTORS.—

22               (1) IN GENERAL.—The Committee shall have a  
23       Board of Directors, which shall be composed of ex  
24       officio and appointed members in accordance with

1 this subsection. All appointed members of the Board  
2 shall be voting members.

3 (2) EX OFFICIO MEMBERS.—The non-voting ex  
4 officio members of the Committee shall be the fol-  
5 lowing individuals or their designees:

6 (A) The Secretary of Health and Human  
7 Services.

8 (B) The Director of the National Institutes  
9 of Health.

10 (C) The Commissioner of Food and Drugs.

11 (D) The Director of the Agency for  
12 Healthcare Research and Quality.

13 (E) The Director of the Centers for Dis-  
14 ease Control and Prevention.

15 (F) The Administrator of the Centers for  
16 Medicare & Medicaid Services.

17 (G) The Assistant Secretary for Planning  
18 and Evaluation.

19 (3) APPOINTED MEMBERS.—

20 (A) IN GENERAL.—Ten additional mem-  
21 bers shall be appointed to the Committee by the  
22 Comptroller General of the United States not  
23 later than 180 days after the date of enactment  
24 of this Act. Such members shall include—

1 (i) 2 patient and consumer represent-  
2 atives not affiliated with any organization  
3 that receives funding from pharmaceutical  
4 manufacturers;

5 (ii) 3 provider representatives, includ-  
6 ing 1 hospital representative and 1 phar-  
7 macist representative;

8 (iii) 1 health services researcher;

9 (iv) 1 health care economist;

10 (v) 1 representative of a sponsor of a  
11 health plan or health insurance coverage;

12 (vi) 1 pharmacy benefit management  
13 services representative; and

14 (vii) 1 drug manufacturer representa-  
15 tive.

16 (B) DURATION OF TERMS.—Members ap-  
17 pointed to the Committee under subparagraph  
18 (A) shall be appointed to serve 5-year terms,  
19 which shall be staggered for the members first  
20 appointed.

21 (C) TERM LIMITS.—Members appointed to  
22 the Committee under subparagraph (A) may  
23 not be so appointed for more than 2 terms.

24 (D) CONFLICTS OF INTEREST.—

1 (i) IN GENERAL.—In appointing mem-  
2 bers under subparagraph (A), the Comp-  
3 troller General of the United States shall  
4 consider and disclose any potential con-  
5 flicts of interest. Members of the Board  
6 shall recuse themselves or be recused from  
7 relevant Committee activities in the case  
8 where the member (or an immediate family  
9 member of such member) has a conflict of  
10 interest.

11 (ii) DISCLOSURE OF CONFLICTS OF  
12 INTEREST.—

13 (I) IN GENERAL.—A conflict of  
14 interest or potential conflict of inter-  
15 est shall be disclosed, as applicable—

16 (aa) by the Committee, in  
17 appointing members to an advi-  
18 sory committee and for employ-  
19 ment as staff on the Committee;  
20 and

21 (bb) by the Comptroller  
22 General of the United States, in  
23 appointing members of the Com-  
24 mittee.

1 (II) MANNER OF DISCLOSURE.—  
2 Conflicts of interests shall be disclosed  
3 as soon as practicable on the internet  
4 websites of the Committee and of the  
5 Government Accountability Office.  
6 The information so disclosed shall in-  
7 clude the type, nature, and magnitude  
8 of the interests of the individual in-  
9 volved, except to the extent that the  
10 individual recuses himself or herself  
11 from participating in the consider-  
12 ation of activity in which the potential  
13 conflict exists.

14 (E) CONFIDENTIALITY.—The Committee  
15 shall maintain the confidentiality of any infor-  
16 mation provided to the Committee under this  
17 section that is a trade secret or confidential in-  
18 formation.

19 (F) VACANCIES.—Vacancies on the Board  
20 shall be filled in the same manner as the origi-  
21 nal appointment was made. Any vacancy in the  
22 membership of the Board shall not affect the  
23 power of the remaining members to execute the  
24 duties of the Board.

1           (G) COMPENSATION.—While serving on  
2           the business of the Committee (including travel  
3           time), a member of the Committee shall be enti-  
4           tled to compensation at the per diem equivalent  
5           of the rate provided for level IV of the Execu-  
6           tive Schedule under section 5315 of title 5,  
7           United States Code, and while so serving away  
8           from home and the member's regular place of  
9           business, a member may be allowed travel ex-  
10          penses, as authorized by the Chairman of the  
11          Committee.

12          (H) NO FEDERAL EMPLOYEES.—No em-  
13          ployee of the Federal Government shall be an  
14          appointed member of the Committee.

15          (d) EXECUTIVE DIRECTOR.—

16           (1) APPOINTMENT.—The Board shall appoint  
17           an Executive Director who shall serve at the pleas-  
18           ure of the Board. The Executive Director shall be  
19           responsible for the day-to-day operations of the  
20           Committee and shall have such specific duties and  
21           responsibilities as the Board shall prescribe, includ-  
22           ing to identify, recruit, and hire staff.

23           (2) COMPENSATION.—The compensation of the  
24           Executive Director shall be fixed by the Board.

1           (3) CONFLICTS OF INTEREST AND CONFIDEN-  
2           TIALITY.—The Executive Director and all staff of  
3           the Committee shall be subject to the same conflict  
4           of interest and confidentiality requirements as the  
5           Board members, as described in subparagraphs (D)  
6           and (E) of subsection (c)(3).

7           (e) INITIAL MEETING.—The initial meeting of the  
8           Committee shall take place within 60 days of all members  
9           being appointed. In the initial meeting, the Committee  
10          shall—

- 11           (1) incorporate the Committee;
- 12           (2) designate a Chair; and
- 13           (3) appoint the Executive Director.

14          (f) DUTIES AND AUTHORITIES.—The duties and au-  
15          thorities of the Committee are as follows:

16           (1) ADMINISTRATIVE DUTIES.—The Committee  
17           shall establish administrative guidelines for the  
18           Committee, including—

19                   (A) establishing bylaws for the Committee  
20                   that are published in the Federal Register and  
21                   made available for public comment;

22                   (B) establishing policies for the selection of  
23                   officers, employees, agents, and contractors of  
24                   the Committee;



1 (C) establishing policies that would subject  
2 all employees, fellows, and trainees of the Com-  
3 mittee to the conflict of interest standards  
4 under subsection (c)(3)(D);

5 (D) specifying a process for annual Board  
6 review of the operations of the Committee;

7 (E) establishing specific duties of the Ex-  
8 ecutive Director;

9 (F) evaluating the performance of the Ex-  
10 ecutive Director; and

11 (G) carrying out other necessary activities  
12 regarding the functioning of the Committee.

13 (2) PROCESS, METHODOLOGY, AND TIMELINE  
14 FOR DETERMINING REASONABLE PRICES.—

15 (A) IN GENERAL.—Not later than 2 years  
16 after receipt of the report of the National Acad-  
17 emy of Medicine under section 4, the Com-  
18 mittee shall—

19 (i) outline the process and method-  
20 ology by which the Committee will deter-  
21 mine, based on such report, whether the  
22 manufacturer list price and retail price is  
23 reasonable for each applicable drug;

24 (ii) outline the timeline under which  
25 the manufacturer, based on such report, is

1 required to submit the information re-  
2 quired under section 6(a)(2) to the Com-  
3 mittee;

4 (iii) outline the timeline under which  
5 the Committee is required to determine,  
6 based on such report, whether the manu-  
7 facturer list price and retail price is rea-  
8 sonable for each applicable drug; and

9 (iv) publish such proposed process,  
10 methodology, and timeline on the internet  
11 website of the Committee.

12 (B) PUBLIC INPUT.—Not later than 60  
13 days after publication of the proposed process,  
14 methodology, and timeline under subparagraph  
15 (A), the Committee shall hold a minimum of 2  
16 public stakeholder meetings to solicit feedback  
17 on such proposed process, methodology, and  
18 timeline.

19 (C) PUBLICATION OF FINAL PROCESS,  
20 METHODOLOGY, AND TIMELINE.—Not later  
21 than 30 months after receipt of the report  
22 under section 4, the Committee shall publish a  
23 final process, methodology, and timeline on the  
24 Committee's internet website.

1 (D) UPDATES TO PROCESS, METHOD-  
2 OLOGY, AND TIMELINE.—The Committee may  
3 make changes and updates to the final process,  
4 methodology, and timeline as necessary. Any  
5 such changes or updates shall be published on  
6 the internet website of the Committee.

7 (3) ISSUANCE OF REASONABLE PRICING DETER-  
8 MINATION.—

9 (A) DETERMINATIONS.—The Committee  
10 shall issue a reasonable pricing determination  
11 for each applicable drug that—

12 (i) is based on a review of the infor-  
13 mation submitted under section 6(a); and

14 (ii) uses the process, methodology,  
15 and timeline developed by the Committee  
16 under paragraph (2).

17 (B) TIMEFRAME.—The Committee shall  
18 issue a reasonable pricing determination under  
19 subparagraph (A) for a drug that, upon ap-  
20 proval of an application under section 505(b) of  
21 the Federal Food, Drug, and Cosmetic Act (21  
22 U.S.C. 355(b)) or section 351(a) of the Public  
23 Health Service Act (42 U.S.C. 262(a)), will be  
24 an applicable drug, taking into consideration

1 the recommended timeframe under section  
2 4(a)(2).

3 (C) REPORTS TO DRUG MANUFACTUR-  
4 ERS.—For each reasonable pricing determina-  
5 tion made under subparagraph (A), the Com-  
6 mittee shall submit a report in writing to the  
7 applicable drug manufacturer outlining such de-  
8 termination. Each such report shall be made  
9 public, excluding any proprietary information.

10 (4) APPOINTMENT OF ADVISORY COMMIT-  
11 TEES.—The Committee may appoint permanent or  
12 ad hoc advisory committees as determined appro-  
13 priate to assist in the work of the Committee. All  
14 members of any such advisory committee shall be  
15 subject to the same conflict of interest requirements  
16 as Committee members.

17 (g) ANNUAL REPORTS.—The Committee shall submit  
18 an annual report to Congress and to the Secretary, and  
19 shall make the annual report available to the public. Each  
20 such report shall include—

21 (1) a description of the activities conducted  
22 under this Act;

23 (2) the budget of the Committee for the fol-  
24 lowing year; and

1           (3) any other relevant information, including in-  
 2           formation on the membership of the Board, advisory  
 3           committees, and the executive staff of the Com-  
 4           mittee, any conflicts of interest with respect to such  
 5           individuals, and any bylaws adopted by the Board  
 6           during the preceding year.

7   **SEC. 6. REQUIREMENTS FOR ENTERING INTO A LICENSING**  
 8                                   **AGREEMENT.**

9           (a) IN GENERAL.—Upon retaining the title to any  
 10          subject invention under section 202 of title 35, United  
 11          States Code, or entering into a partial or exclusive licens-  
 12          ing agreement relating to an applicable drug, the drug  
 13          manufacturer shall agree to—

14                 (1) beginning one year after an applicable drug  
 15                 first comes to market, limit the annual price in-  
 16                 crease on such drug to the percentage by which the  
 17                 medical care consumer price index detailed expendi-  
 18                 ture category for all urban consumers for that year  
 19                 exceed such index for the preceding calendar year;

20                 (2) submit to the Drug Affordability and Access  
 21                 Committee, on a good faith timeline that is con-  
 22                 sistent with the recommendation under section  
 23                 5(f)(2)(A)(ii)—

24                         (A) the manufacturer list price for the  
 25                         drug;

1 (B) the retail price for the drug;

2 (C) information on expenditures, includ-  
3 ing—

4 (i) the total annual expenditures of  
5 the manufacturer on materials and manu-  
6 facturing for the drug;

7 (ii) the total expenditures of the man-  
8 ufacturer on acquiring patents and licens-  
9 ing for the drug, including expected royalty  
10 payments;

11 (iii) the total expenditures of the man-  
12 ufacturer on research and development as  
13 shown on the manufacturer's Federal tax  
14 returns under sections 41 and 174 of the  
15 Internal Revenue Code of 1986;

16 (iv) the amount of the manufacturer's  
17 total expenditures derived from any Fed-  
18 eral funding source, including tax deduc-  
19 tions or credits claimed; and

20 (v) total expected expenditures for  
21 marketing and advertising for the drug in  
22 the first 3 years that the drug is on the  
23 market;

24 (D) the anticipated number of patients  
25 who will be treated with the drug;

1 (E) a copy of the application submitted  
2 under section 505(b) of the Federal Food,  
3 Drug, and Cosmetic Act (21 U.S.C. 355(b)) or  
4 section 351(a) of the Public Health Service Act  
5 (42 U.S.C. 262(a)) and any subsequent infor-  
6 mation or data requested by, or submitted to,  
7 the Food and Drug Administration during the  
8 approval process;

9 (F) any additional information requested  
10 by the Drug Affordability and Access Com-  
11 mittee; and

12 (G) any additional information the manu-  
13 facturer chooses to provide related to drug pric-  
14 ing decisions;

15 (3) submit the manufacturer list price and re-  
16 tail price of an applicable drug to the Drug Afford-  
17 ability and Access Committee for a reasonable price  
18 determination; and

19 (4) beginning one year after an applicable drug  
20 first comes to market, not exceed the reasonable  
21 price, as determined by such Committee, for the  
22 drug's manufacturer list price.

23 (b) PENALTIES.—

24 (1) LOSS OF PERIOD OF MARKET EXCLU-  
25 SIVITY.—In the case of a drug manufacturer subject

1 to this section who increases the price of an applica-  
2 ble drug to an amount that exceeds the amount  
3 under subsection (a)(1) or exceeds the reasonable  
4 price as required under subsection (a)(4), any period  
5 of market exclusivity with respect to the applicable  
6 drug shall be deemed expired, effective on the date  
7 of such price increase or launch price.

8 (2) PROHIBITION ON ENTERING INTO FUTURE  
9 LICENSING AGREEMENTS.—If a drug manufacturer  
10 fails to adhere to the limit on annual price increases  
11 under subsection (a)(1), such drug manufacturer,  
12 and its president, chief executive officer, chief oper-  
13 ating officer, and general counsel employed at the  
14 time of the violation, shall be ineligible for future li-  
15 censing agreements for qualifying patented tech-  
16 nology.

17 (3) PROHIBITION ON ENTERING INTO FUTURE  
18 LICENSING AGREEMENTS.—If a drug manufacturer  
19 fails to adhere to the reasonable price as required  
20 under subsection (a)(4), the drug manufacturer, and  
21 its president, chief executive officer, chief operating  
22 officer, and general counsel, shall be ineligible for fu-  
23 ture licensing agreements for qualifying patented  
24 technology.



1           (4) FAILURE TO SUBMIT INFORMATION OR SUB-  
2           MITTING FALSE INFORMATION TO THE DRUG AF-  
3           FORDABILITY AND ACCESS COMMITTEE.—Any manu-  
4           facturer that fails to submit information required  
5           under subsection (a)(2) to be submitted to the Drug  
6           Affordability and Access Committee, or who submits  
7           false information to such Committee shall be subject  
8           to a civil monetary penalty of \$500,000 and if a vio-  
9           lation is not corrected within 30 days following noti-  
10          fication of such violation, \$1,000,000 for each day  
11          that the violation continues after such period until  
12          the violation is corrected.

13           (5) EXCESSIVE PRICE IN THE FIRST YEAR OF  
14          LAUNCH.—If a drug manufacturer’s launch price in  
15          the first year for an applicable drug is at least 50  
16          percent higher than the reasonable price as required  
17          under subsection (a)(4) to be in effect for the second  
18          year, the drug manufacturer shall be subject to a  
19          civil monetary penalty of the cost of the drug in ex-  
20          cess of 50 percent multiplied by the number of doses  
21          of the drug sold in the United States in the first  
22          year on the market.

23           (6) DISTRIBUTION OF PAYMENTS TO THE NA-  
24          TIONAL INSTITUTES OF HEALTH.—

1           (A) IN GENERAL.—Each fiscal year, there  
2 shall be transferred, out of funds in the Treas-  
3 ury not otherwise obligated, to the Director of  
4 the National Institutes of Health, an amount  
5 equal to the amount collected in civil penalties  
6 under this subsection during the previous fiscal  
7 year, unless the amount otherwise appropriated  
8 to the National Institutes of Health for the fis-  
9 cal year in which such transfer would occur is  
10 less than the amount so appropriated for the  
11 previous fiscal year.

12           (B) DELAYED DISTRIBUTION.—If, in ac-  
13 cordance with clause (i), the Secretary of the  
14 Treasury does not transfer amounts under such  
15 clause during any portion of a fiscal year, and,  
16 at a later date in such fiscal year, the appro-  
17 priations to the National Institutes of Health  
18 becomes equal to or greater than the amount of  
19 appropriations for the previous fiscal year, such  
20 Secretary shall transfer such amount at any  
21 time in such fiscal year.

22 **SEC. 7. PROPER DISCLOSURE OF GOVERNMENT SUPPORT.**

23           (a) DEFINITIONS.—In this section—

24               (1) the term “contractor”—

1 (A) has the meaning given the term in sec-  
2 tion 201 of title 35, United States Code; and

3 (B) includes an assignee of a contractor to  
4 the extent that the assignee is the entity that  
5 files an application described in section  
6 202(c)(6);

7 (2) the term “covered contractor” means a con-  
8 tractor that—

9 (A) is a party to a funding agreement that  
10 contains an appropriate provision to effectuate  
11 the requirement under section 202(c)(6); and

12 (B) files a United States patent applica-  
13 tion with respect to a subject invention that the  
14 contractor conceived or first actually reduced to  
15 practice in the performance of work under the  
16 funding agreement described in subparagraph  
17 (A);

18 (3) the term “covered patentee” means the pat-  
19 entee with respect to a patent issuing from an appli-  
20 cation described in paragraph (2)(B);

21 (4) the term “drug” has the meaning given that  
22 term in section 201 of the Federal Food, Drug, and  
23 Cosmetic Act;

1           (5) the terms “funding agreement” and “sub-  
2       ject invention” have the meanings given the terms in  
3       section 201 of title 35, United States Code;

4           (6) the term “patentee” has the meaning given  
5       the term in section 100 of title 35, United States  
6       Code; and

7           (7) the term “section 202(c)(6)” means section  
8       202(c)(6) of title 35, United States Code.

9       (b) ACTIONS FOR FAILURE TO DISCLOSE GOVERN-  
10     MENT SUPPORT.—

11           (1) PRIVATE RIGHT OF ACTION.—

12           (A) IN GENERAL.—A person (including a  
13       government entity) may bring a civil action in  
14       an appropriate district court of the United  
15       States against a covered patentee—

16           (i) on the ground that the application  
17       for the patent with respect to which the  
18       covered patentee holds title failed to com-  
19       ply with the requirement under section  
20       202(c)(6); and

21           (ii) if the person is injured by the fail-  
22       ure to comply described in clause (i).

23           (B) SCOPE.—In an action brought under  
24       subparagraph (A), if the court finds by a pre-  
25       ponderance of the evidence that the application

1 described in that subparagraph failed to comply  
2 with the requirement under section 202(c)(6),  
3 the court shall cancel as unpatentable any claim  
4 of the patent issuing from that application.

5 (2) INTER PARTES REVIEW.—Section 311 of  
6 title 35, United States Code, is amended by striking  
7 subsection (b) and inserting the following:

8 “(b) SCOPE.—A petitioner in an inter partes review  
9 may request to cancel as unpatentable 1 or more claims  
10 of a patent—

11 “(1)(A) on a ground that could be raised under  
12 section 102 or 103; and

13 “(B) on the basis of prior art consisting of pat-  
14 ents or printed publications; or

15 “(2) on the ground that the application with re-  
16 spect to the patent was subject to the requirement  
17 in section 202(c)(6) and failed to comply with that  
18 requirement.”.

19 (c) DISCLOSURE OF GRANTS.—Section 111(a)(2) of  
20 title 35, United States Code, is amended—

21 (1) in subparagraph (B), by striking “and” at  
22 the end;

23 (2) in subparagraph (C), by striking the period  
24 and inserting “; and”; and

25 (3) by adding at the end the following:

1           “(D) with respect to a drug (as defined in  
2           section 201 of the Federal Food, Drug, and  
3           Cosmetic Act) covered by a qualifying patent on  
4           the drug, on a method of using such drug, or  
5           on a method or machine used to manufacture  
6           or administer such drug, a disclosure of any  
7           Federal grant received in the 10-year period  
8           prior to submitting the application, in which the  
9           applicant is listed as the principal investigator  
10          or co-investigator with respect to the grant.”.

11          (d) GAO REPORT.—Not later than 5 years after the  
12          date of enactment of this Act, and once every 5 years  
13          thereafter, the Comptroller General of the United States  
14          shall—

15                 (1) conduct a study that reviews—

16                         (A) the compliance by covered contractors  
17                         with the requirement under section 202(c)(6);  
18                         and

19                         (B) the effectiveness of the National Insti-  
20                         tutes of Health in conducting oversight of the  
21                         extent to which covered contractors are com-  
22                         plying with the requirement under section  
23                         202(c)(6); and

24                 (2) submit to Congress the results of each  
25          study conducted under paragraph (1), which shall

1 include, in each case, recommendations for addi-  
2 tional practices and policies to improve the effective-  
3 ness of the requirement under section 202(c)(6), in-  
4 cluding any mechanism to better enforce that re-  
5 quirement.

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