

117TH CONGRESS  
1ST SESSION

# H. R. 4811

To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate prices of drugs furnished under the Medicare program, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 29, 2021

Mr. DOGGETT (for himself, Mr. BEYER, Mr. BLUMENAUER, Mr. BOWMAN, Ms. BUSH, Mr. CARTWRIGHT, Mr. CASTRO of Texas, Mr. CICILLINE, Mr. CLEAVER, Mr. COHEN, Mr. DEFazio, Ms. DELAURO, Mrs. DINGELL, Ms. ESCOBAR, Mr. ESPAILLAT, Mr. GARAMENDI, Mr. GARCÍA of Illinois, Mr. GREEN of Texas, Mr. GRIJALVA, Ms. JACKSON LEE, Ms. JAYAPAL, Mr. KAHELE, Ms. KAPTUR, Mr. KHANNA, Mr. KIM of New Jersey, Mr. KRISHNAMOORTHY, Mr. LANGEVIN, Ms. LEE of California, Mr. LEVIN of Michigan, Mr. LOWENTHAL, Mr. MCNERNEY, Mr. MFUME, Mr. NADLER, Mr. NEGUSE, Ms. NORTON, Ms. OCASIO-CORTEZ, Ms. OMAR, Mr. PERLMUTTER, Ms. PINGREE, Mr. POCAN, Ms. PORTER, Ms. PRESSLEY, Mr. RASKIN, Ms. SCHAKOWSKY, Mr. SHERMAN, Mr. TAKANO, Mr. THOMPSON of Mississippi, Ms. TITUS, Ms. TLAIB, Mr. TORRES of New York, Mr. VELA, Mr. YARMUTH, Ms. LEGER FERNANDEZ, Ms. MOORE of Wisconsin, Ms. WATERS, Ms. CHU, Ms. NEWMAN, and Ms. VELÁZQUEZ) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Oversight and Reform, Veterans' Affairs, and Armed Services, 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

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## A BILL

To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate

prices of drugs furnished under the Medicare program,  
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 “Medicare Negotiation  
5 and Competitive Licensing Act of 2021”.

6 **SEC. 2. REQUIRING THE SECRETARY OF HEALTH AND**  
7 **HUMAN SERVICES TO NEGOTIATE PRICES OF**  
8 **DRUGS FURNISHED UNDER THE MEDICARE**  
9 **PROGRAM.**

10 (a) PART D.—Section 1860D–11 of the Social Secu-  
11 rity Act (42 U.S.C. 1395w–111) is amended by striking  
12 subsection (i) and inserting the following new subsection:

13 “(i) NEGOTIATION OF LOWER DRUG PRICES.—

14 “(1) IN GENERAL.—Notwithstanding any other  
15 provision of law, the Secretary shall, for plan years  
16 beginning on or after the date of the enactment of  
17 this subsection, negotiate with pharmaceutical man-  
18 ufacturers the negotiated prices (including discounts,  
19 rebates, and other price concessions) that may be  
20 charged to PDP sponsors and MA organizations  
21 during a negotiated price period (as specified by the  
22 Secretary) for specified covered part D drugs for  
23 such plan year for part D eligible individuals who

1 are enrolled under a prescription drug plan or under  
2 an MA–PD plan.

3 “(2) NEGOTIATION CONSIDERATIONS.—

4 “(A) FACTORS.—In negotiating such  
5 prices under paragraph (1), the Secretary shall  
6 take into account the following factors:

7 “(i) The comparative clinical effective-  
8 ness and cost effectiveness, when available  
9 from an impartial source, of such drug.

10 “(ii) The budgetary impact of pro-  
11 viding coverage of such drug.

12 “(iii) The number of similarly effec-  
13 tive drugs or alternative treatment regi-  
14 mens for each approved use of such drug.

15 “(iv) The associated financial burden  
16 on patients that utilize such drug.

17 “(v) The associated unmet patient  
18 need for such drug.

19 “(vi) The total revenues from global  
20 sales obtained by the manufacturer for  
21 such drug and the associated investment in  
22 research and development of such drug by  
23 the manufacturer.

24 “(B) ASSESSMENT OF FACTORS.—For pur-  
25 poses of assessing the factors described in sub-

1 paragraph (A) with respect to a covered part D  
2 drug, the Secretary shall, as soon as prac-  
3 ticable, establish a value assessment process  
4 consisting of standardized measures for such  
5 factors. With respect to a negotiation that oc-  
6 curs before the Secretary establishes such a  
7 process, the Secretary may use such other as-  
8 sessments as the Secretary determines appro-  
9 priate (such as assessments used with respect  
10 to ascertaining the value of drugs by the Sec-  
11 retary of Veterans Affairs, the Patient-Centered  
12 Outcomes Research Institute, the Institute for  
13 Clinical and Economic Review, and other coun-  
14 tries).

15 “(3) SPECIFIED COVERED PART D DRUGS.—In  
16 this subsection, the term ‘specified covered part D  
17 drug’ means, with respect to a negotiated price pe-  
18 riod beginning during—

19 “(A) the first plan year beginning on or  
20 after the date of the enactment of this sub-  
21 section, a covered part D drug that is a sole  
22 source drug (as defined in section  
23 1833(t)(14)(F)(i))—

1 “(i) with respect to which gross reve-  
2 nues for the preceding plan year were  
3 \$100,000,000 or greater; or

4 “(ii) that contains an active ingredient  
5 that was first approved by the Adminis-  
6 trator for Food and Drugs not later than  
7 10 years prior to the beginning of such  
8 first plan year;

9 “(B) the second plan year beginning on or  
10 after the date of the enactment of this sub-  
11 section, a covered part D drug that is a sole  
12 source drug (as so defined) or a biosimilar bio-  
13 logical product;

14 “(C) the third plan year beginning on or  
15 after the date of the enactment of this sub-  
16 section, a covered part D drug—

17 “(i) that is described in subparagraph  
18 (B); or

19 “(ii) with respect to which, during the  
20 preceding plan year, fewer than 3 manu-  
21 facturers (other than the manufacturer of  
22 such drug) marketed a generic version of  
23 such drug; and

24 “(D) the fourth plan year beginning on or  
25 after the date of the enactment of this sub-

1 section or a subsequent plan year, a covered  
2 part D drug.

3 “(4) NEGOTIATED PRICE LIMITATIONS AND FI-  
4 NALIZATION.—The negotiated price of each specified  
5 covered part D drug for a negotiated price period—

6 “(A) may not be less than an amount nec-  
7 essary to allow such manufacturer to recoup  
8 such manufacturer’s research and development  
9 costs associated with such drug;

10 “(B) subject to subparagraph (A), may not  
11 exceed 110 percent of the median price of such  
12 drug for the preceding plan year in the 10  
13 countries of the Organisation for Economic Co-  
14 operation and Development with the highest  
15 gross domestic product and with a per capita  
16 income that is not less than half the per capita  
17 income of the United States for such preceding  
18 plan year; and

19 “(C) shall be finalized not later than 30  
20 days before a PDP sponsor is required to sub-  
21 mit information described in subsection (b)(2)  
22 for the first plan year in such negotiated price  
23 period.

24 “(5) COMPETITIVE LICENSING AUTHORITY.—

1           “(A) IN GENERAL.—Notwithstanding any  
2           exclusivity under clause (iii) or (iv) of section  
3           505(j)(5)(F) of the Federal Food, Drug, and  
4           Cosmetic Act, clause (iii) or (iv) of section  
5           505(c)(3)(E) of such Act, section 351(k)(7)(A)  
6           of the Public Health Service Act, or section  
7           527(a) of the Federal Food, Drug, and Cos-  
8           metic Act, or by an extension of such exclusivity  
9           under section 505A of such Act or section 505E  
10          of such Act, and any other provision of law that  
11          provides for market exclusivity (or extension of  
12          market exclusivity) with respect to a drug, in  
13          the case that the Secretary is unable to success-  
14          fully negotiate an appropriate price for a speci-  
15          fied covered part D drug for a negotiated price  
16          period, the Secretary shall authorize the use of  
17          any patent, clinical trial data, or other exclu-  
18          sivity granted by the Federal government with  
19          respect to such drug as the Secretary deter-  
20          mines appropriate for purposes of manufac-  
21          turing such drug for sale under a Federal  
22          health care program, the insurance program  
23          under chapter 89 of title 5, United States Code,  
24          or a group health plan or health insurance cov-  
25          erage offered by a health insurance issuer. Any

1           entity making use of a competitive license to  
2           use patent, clinical trial data, or other exclu-  
3           sivity under this section shall provide to the  
4           manufacturer holding such exclusivity reason-  
5           able compensation, as determined by the Sec-  
6           retary based on the following factors:

7                   “(i) The risk-adjusted value of any  
8                   Federal government subsidies and invest-  
9                   ments in research and development used to  
10                  support the development of such drug.

11                  “(ii) The risk-adjusted value of any  
12                  investment made by such manufacturer in  
13                  the research and development of such  
14                  drug.

15                  “(iii) The impact of the price, includ-  
16                  ing license compensation payments, on  
17                  meeting the medical need of all patients.

18                  “(iv) The relationship between the  
19                  price of such drug, including compensation  
20                  payments, and the health benefits of such  
21                  drug.

22                  “(v) Other relevant factors determined  
23                  appropriate by the Secretary to provide  
24                  reasonable compensation.

25                  “(B) REASONABLE COMPENSATION.—



1 “(i) LIMITATIONS.—Reasonable com-  
2 pensation described in subparagraph (A)  
3 with respect to a specified covered out-  
4 patient drug and a plan year may not be  
5 made in an amount—

6 “(I) less than an amount nec-  
7 essary to allow such manufacturer to  
8 recoup such manufacturer’s research  
9 and development costs associated with  
10 such drug; and

11 “(II) subject to subclause (I),  
12 greater than 12 percent of the nego-  
13 tiated price set by the Secretary for  
14 such drug and such plan year.

15 “(ii) RECOVERY.—The manufacturer  
16 described in subparagraph (A) may seek  
17 recovery against the United States in the  
18 United States Court of Federal Claims.

19 “(C) INTERIM PERIOD.—Until 1 year after  
20 a drug described in subparagraph (A) is ap-  
21 proved under section 505(j) of the Federal  
22 Food, Drug, and Cosmetic Act or section  
23 351(k) of the Public Health Service Act and is  
24 provided under license issued by the Secretary  
25 under such subparagraph, PDP plans and MA—

1 PD plans shall not pay more for such drug  
2 than 110 percent of the median of the prices  
3 available, during the most recent 12-month pe-  
4 riod for which data is available prior to the be-  
5 ginning of such negotiated price period, from  
6 the manufacturer to any wholesaler, retailer,  
7 provider, health maintenance organization, non-  
8 profit entity, or governmental entity in the ten  
9 Organisation for Economic Cooperation and  
10 Development countries that have the largest  
11 gross domestic product with a per capita in-  
12 come that is not less than half the per capita  
13 income of the United States.

14 “(D) AUTHORIZATION FOR SECRETARY TO  
15 PROCURE DRUGS DIRECTLY.—

16 “(i) IN GENERAL.—The Secretary  
17 may procure a drug manufactured pursu-  
18 ant to a competitive license under subpara-  
19 graph (A) for purposes of this part or pur-  
20 suant to a Federal program license under  
21 subparagraph (C)(ii) for purposes of a  
22 Federal program directly from the entity  
23 manufacturing the drug pursuant to such  
24 a license.

1                   “(ii) CLARIFICATION REGARDING AP-  
2                   PLICATION OF BUY AMERICAN ACT.—In  
3                   the case where the Secretary procures a  
4                   drug under this subparagraph, the provi-  
5                   sions of chapter 83 of title 41, United  
6                   States Code (commonly referred to as the  
7                   ‘Buy American Act’) shall apply.

8                   “(E) PRIORITY FOR U.S. MANUFACTURERS  
9                   IN AUTHORIZING COMPETITIVE LICENSES.—In  
10                  authorizing a competitive license under this  
11                  paragraph, the Secretary—

12                  “(i) shall give preference to entities  
13                  that the Secretary determines have the  
14                  highest safety and security standards; and

15                  “(ii) may give priority to entities that  
16                  will manufacture such drug in the United  
17                  States.

18                  “(6) FDA REVIEW OF LICENSED DRUG APPLI-  
19                  CATIONS.—The Secretary shall prioritize review of  
20                  applications under section 505(j) of the Federal  
21                  Food, Drug, and Cosmetic Act for drugs licensed  
22                  under paragraph (3)(A).

23                  “(7) PROHIBITION OF ANTICOMPETITIVE BE-  
24                  HAVIOR.—No drug manufacturer may engage in  
25                  anticompetitive behavior with another manufacturer

1 that may interfere with the issuance and implemen-  
2 tation of a competitive license or run contrary to  
3 public policy.

4 “(8) REQUIRED REPORTING.—The Secretary  
5 may require pharmaceutical manufacturers or any  
6 other entity to disclose to the Secretary such infor-  
7 mation that the Secretary determines necessary for  
8 purposes of carrying out this subsection.

9 “(9) CLARIFICATION.—Nothing in this sub-  
10 section shall be construed as preventing the sponsor  
11 of a prescription drug plan or an organization offer-  
12 ing an MA-PD plan from obtaining a discount or  
13 reduction of the price for a covered part D drug  
14 below the price negotiated by the Secretary.

15 “(10) PUBLICATION OF NEGOTIATED PRICES  
16 AND CONTRACT TERMS.—The Secretary shall make  
17 available on a public website the price negotiated  
18 under this subsection, and any contract terms asso-  
19 ciated with such price, with respect to each specified  
20 covered part D drug.”.

21 (b) PART B.—

22 (1) IN GENERAL.—Section 1842(o) of the So-  
23 cial Security Act (42 U.S.C. 1395u(o)) is amended  
24 by adding at the end the following new paragraph:

1       “(8)(A) Notwithstanding any preceding provision of  
 2 this subsection, in the case of a drug or biological de-  
 3 scribed in paragraph (1) furnished during a negotiated  
 4 price period beginning on or after January 1 of the first  
 5 year beginning on or after the date of the enactment of  
 6 this paragraph, the amount payable under this part for  
 7 such drug or biological shall be equal to the negotiated  
 8 price for such drug or biological and period, as established  
 9 pursuant to subparagraph (B).

10       “(B) The provisions of section 1860D–11(i) shall be  
 11 applied to the negotiation of a negotiated price for a drug  
 12 or biological described in subparagraph (A) and a nego-  
 13 tiated price period in a similar manner (as determined by  
 14 the Secretary) as such provisions apply with respect to the  
 15 negotiation of a negotiated price for a specified part D  
 16 drug for a negotiated price period under such section.”.

17               (2) APPLICATION TO MA.—Section 1852 of the  
 18 Social Security Act (42 U.S.C. 1395w–22) is amend-  
 19 ed by adding at the end the following new sub-  
 20 section:

21       “(o) LIMITATION ON REIMBURSEMENT FOR CERTAIN  
 22 DRUGS.—In the case of a drug or biological furnished dur-  
 23 ing a negotiated price period (as defined for purposes of  
 24 section 1842(o)(8)) for which payment may be made  
 25 under such section, the total reimbursement for such drug

1 or biological made by an Medicare Advantage plan may  
 2 not exceed the negotiated price for such drug or biological  
 3 and period established pursuant to such section.”.

4 **SEC. 3. IDENTIFICATION OF PRESCRIPTION DRUG PRICE**  
 5 **SPIKES.**

6 (a) DEFINITIONS.—In this section:

7 (1) APPLICABLE ENTITY.—The term “applica-  
 8 ble entity” means the holder of an application ap-  
 9 proved under subsection (c) or (j) of section 505 of  
 10 the Federal Food, Drug, and Cosmetic Act (21  
 11 U.S.C. 355) or of a license issued under subsection  
 12 (a) or (k) of section 351 of the Public Health Serv-  
 13 ice Act (42 U.S.C. 262) for a drug described in  
 14 paragraph (5)(A).

15 (2) AVERAGE MANUFACTURER PRICE.—The  
 16 term “average manufacturer price”—

17 (A) has the same meaning given such term  
 18 under section 1927(k)(1) of the Social Security  
 19 Act (42 U.S.C. 1396r–8(k)(1)); or

20 (B) with respect to a drug for which there  
 21 is no average manufacturer price as so defined,  
 22 such term shall mean the wholesale acquisition  
 23 cost of the drug.

1           (3) COMMERCE.—The term “commerce” has  
2           the meaning given such term in section 4 of the  
3           Federal Trade Commission Act (15 U.S.C. 44).

4           (4) INSPECTOR GENERAL.—The term “Inspec-  
5           tor General” means the Inspector General of the De-  
6           partment of Health and Human Services.

7           (5) PRESCRIPTION DRUG.—

8                   (A) IN GENERAL.—The term “prescription  
9                   drug” means any drug (as defined in section  
10                  201(g) of the Federal Food, Drug, and Cos-  
11                  metic Act (21 U.S.C. 321(g))), including a com-  
12                  bination product whose primary mode of action  
13                  is determined under section 503(g) of such Act  
14                  (21 U.S.C. 353(g)) to be that of a drug, and  
15                  that—

16                           (i) is subject to section 503(b)(1) of  
17                           the Federal Food, Drug, and Cosmetic Act  
18                           (21 U.S.C. 353(b)(1)); and

19                           (ii) is covered by a Federal health  
20                           care program (as defined in section  
21                           1128B(f) of the Social Security Act (42  
22                           U.S.C. 1320a–7b(f))).

23           (B) TREATMENT OF REFORMULATED  
24           DRUGS.—For purposes of this section, a pre-  
25           scription drug with respect to which the Sec-

retary of Health and Human Services has approved any minor reformulation that does not produce a meaningful therapeutic benefit, the drug that was approved prior to any such reformulation and the drug with any such reformulation shall be considered one prescription drug.

(6) PRICE SPIKE.—

(A) IN GENERAL.—The term “price spike” means an increase in the average manufacturer price in commerce of a prescription drug for which the price spike percentage is equal to or greater than applicable price increase allowance.

(B) PRICE SPIKE PERCENTAGE.—The price spike percentage is the percentage (if any) by which—

(i) the average manufacturer price of a prescription drug in commerce for the calendar year; exceeds

(ii) the average manufacturer price of such prescription drug in commerce for the calendar year preceding such year.

(C) APPLICABLE PRICE INCREASE ALLOWANCE.—The applicable price increase allowance for any calendar year is the percentage (rounded to the nearest one-tenth of 1 percent) by



1 which the C-CPI-U (as defined in section  
2 1(f)(6) of the Internal Revenue Code of 1986)  
3 for that year exceeds the C-CPI-U for the pre-  
4 ceding calendar year.

5 (7) PRICE SPIKE REVENUE.—

6 (A) IN GENERAL.—The price spike revenue  
7 for any calendar year is an amount equal to—

8 (i) the gross price spike revenue,  
9 minus

10 (ii) the adjustment amount.

11 (B) GROSS PRICE SPIKE REVENUE.—The  
12 gross price spike revenue for any calendar year  
13 is an amount equal to the product of—

14 (i) an amount equal to the difference  
15 between clause (i) of paragraph (6)(B) and  
16 clause (ii) of such paragraph; and

17 (ii) the total number of units of the  
18 prescription drug which were sold in com-  
19 merce in such calendar year.

20 (C) ADJUSTMENT AMOUNT.—The adjust-  
21 ment amount is the amount, if any, of the gross  
22 price spike revenue which the Inspector General  
23 has determined is due solely to an increase in  
24 the cost of the inputs necessary to manufacture  
25 the prescription drug subject to the price spike.

1 (b) SUBMISSION BY PHARMACEUTICAL COMPANIES  
2 OF INFORMATION TO INSPECTOR GENERAL.—

3 (1) IN GENERAL.—For each prescription drug,  
4 the applicable entity shall submit to the Inspector  
5 General a quarterly report that includes the fol-  
6 lowing:

7 (A) For each prescription drug of the ap-  
8 plicable entity—

9 (i) the total number of units of the  
10 prescription drug which were sold in com-  
11 merce in the preceding calendar quarter;

12 (ii) the average and median price per  
13 unit of such prescription drug in commerce  
14 in the preceding calendar quarter, disag-  
15 gregated by month; and

16 (iii) the gross revenues from sales of  
17 such prescription drug in commerce in the  
18 preceding calendar quarter.

19 (B) Such information related to increased  
20 input costs or public health considerations as  
21 the applicable entity may wish the Inspector  
22 General to consider in making a determination  
23 under clause (ii) of subsection (c)(2)(B) or an  
24 assessment in clause (iii) of such subsection for  
25 the preceding calendar quarter.

1 (C) Such information related to any antici-  
2 pated increased input costs for the subsequent  
3 calendar quarter as the applicable entity may  
4 wish the Inspector General to consider in mak-  
5 ing a determination under clause (ii) of sub-  
6 section (c)(2)(B) or an assessment in clause  
7 (iii) of such subsection for such calendar quar-  
8 ter.

9 (2) PENALTY FOR FAILURE TO SUBMIT.—

10 (A) IN GENERAL.—An applicable entity de-  
11 scribed in paragraph (1) that fails to submit in-  
12 formation to the Inspector General regarding a  
13 prescription drug, as required by such para-  
14 graph, before the date specified in paragraph  
15 (3) shall be liable for a civil penalty, as deter-  
16 mined under subparagraph (B).

17 (B) AMOUNT OF PENALTY.—The amount  
18 of the civil penalty shall be equal to the product  
19 of—

20 (i) an amount, as determined appro-  
21 priate by the Inspector General, which is—

22 (I) not less than 0.5 percent of  
23 the gross revenues from sales of the  
24 prescription drug described in sub-

1 paragraph (A) for the preceding cal-  
2 endar year, and

3 (II) not greater than 1 percent of  
4 the gross revenues from sales of such  
5 prescription drug for the preceding  
6 calendar year, and

7 (ii) the number of days in the period  
8 between—

9 (I) the applicable date specified  
10 in paragraph (3), and

11 (II) the date on which the In-  
12 spector General receives the informa-  
13 tion described in paragraph (1) from  
14 the applicable entity.

15 (3) SUBMISSION DEADLINE.—An applicable en-  
16 tity shall submit each quarterly report described in  
17 paragraph (1) not later than January 17, April 18,  
18 June 15, and September 15 of each calendar year.

19 (c) ASSESSMENT BY INSPECTOR GENERAL.—

20 (1) IN GENERAL.—Not later than the last day  
21 in February of each year, the Inspector General, in  
22 consultation with other relevant Federal agencies  
23 (including the Federal Trade Commission), shall—

24 (A) complete an assessment of the infor-  
25 mation the Inspector General received pursuant

1 to subsection (b)(1) with respect to sales of pre-  
2 scription drugs in the preceding calendar year;  
3 and

4 (B) in the case of any prescription drug  
5 which satisfies the conditions described in para-  
6 graph (1) or (2) of subsection (d), submit a rec-  
7 ommendation to the Secretary of Health and  
8 Human Services that such drug be exempted  
9 from application of the tax imposed under sec-  
10 tion 4192 of the Internal Revenue Code of 1986  
11 (as added by section 3 of this Act) for such  
12 year.

13 (2) ELEMENTS.—The assessment required by  
14 paragraph (1)(A) shall include the following:

15 (A) Identification of each price spike relat-  
16 ing to a prescription drug in the preceding cal-  
17 endar year.

18 (B) For each price spike identified under  
19 subparagraph (A)—

20 (i) a determination of the price spike  
21 revenue;

22 (ii) a determination regarding the ac-  
23 curacy of the information submitted by the  
24 applicable entity regarding increased input  
25 costs; and

1 (iii) an assessment of the rationale of  
2 the applicable entity for the price spike.

3 (d) EXEMPTION OF CERTAIN DRUGS.—

4 (1) IN GENERAL.—The Secretary of Health and  
5 Human Services, upon recommendation of the In-  
6 spector General pursuant to subsection (c)(1)(B),  
7 may exempt any prescription drug which has been  
8 subject to a price spike during the preceding cal-  
9 endar year from application of the tax imposed  
10 under section 4192 of the Internal Revenue Code of  
11 1986 for such year, if the Secretary determines  
12 that—

13 (A) based on information submitted pursu-  
14 ant to subsection (b)(1)(B), a for-cause price  
15 increase exemption should apply; or

16 (B)(i) the prescription drug which has  
17 been subject to a price spike has an average  
18 manufacturer price of not greater than \$10 for  
19 a 30 day supply; and

20 (ii) such drug is marketed by not less than  
21 3 other holders of applications approved under  
22 subsection (c) or (j) of section 505 of the Fed-  
23 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
24 355), where such applications approved under

1           such subsection (j) use as a reference drug the  
2           drug so approved under such subsection (c).

3           (2) CLARIFICATION.—In considering, under  
4           paragraph (1)(A), information submitted pursuant  
5           to subsection (b)(1)(B), the Secretary—

6                   (A) has the discretion to determine that  
7                   such information does not warrant a for-cause  
8                   price increase exemption; and

9                   (B) shall exclude from such consideration  
10                  any information submitted by the applicable en-  
11                  tity threatening to curtail or limit production of  
12                  the prescription drug if the Secretary does not  
13                  grant an exemption from the application of the  
14                  tax under section 4192 of the Internal Revenue  
15                  Code of 1986.

16          (e) INSPECTOR GENERAL REPORT TO INTERNAL  
17 REVENUE SERVICE.—

18           (1) IN GENERAL.—Subject to paragraph (3),  
19           not later than the last day in February of each year,  
20           the Inspector General shall transmit to the Internal  
21           Revenue Service a report on the findings of the In-  
22           spector General with respect to the information the  
23           Inspector General received under subsection (b)(1)  
24           with respect to the preceding calendar year and the  
25           assessment carried out by the Inspector General

1 under subsection (c)(1)(A) with respect to such in-  
2 formation.

3 (2) CONTENTS.—The report transmitted under  
4 paragraph (1) shall include the following:

5 (A) The information received under sub-  
6 section (b)(1) with respect to the preceding cal-  
7 endar year.

8 (B) The price spikes identified under sub-  
9 paragraph (A) of subsection (c)(2).

10 (C) The price spike revenue determinations  
11 made under subparagraph (B)(i) of such sub-  
12 section.

13 (D) The determinations and assessments  
14 made under clauses (ii) and (iii) of subpara-  
15 graph (B) of such subsection.

16 (3) NOTICE AND OPPORTUNITY FOR HEAR-  
17 ING.—

18 (A) IN GENERAL.—No report shall be  
19 transmitted to the Internal Revenue Service  
20 under paragraph (1) in regards to a prescrip-  
21 tion drug unless the Inspector General has pro-  
22 vided the applicable entity with—

23 (i) the assessment of such drug under  
24 subsection (c)(1)(A); and



1 (ii) notice of their right to a hearing  
2 in regards to such assessment.

3 (B) NOTICE.—The notice required under  
4 subparagraph (A) shall be provided to the ap-  
5 plicable entity not later than 30 days after com-  
6 pletion of the assessment under subsection  
7 (c)(1)(A).

8 (C) REQUEST FOR HEARING.—Subject to  
9 subparagraph (E), an applicable entity may re-  
10 quest a hearing before the Secretary of Health  
11 and Human Services not later than 30 days  
12 after the date on which the notice under sub-  
13 paragraph (B) is received.

14 (D) COMPLETION OF HEARING.—In the  
15 case of an applicable entity which requests a  
16 hearing pursuant to subparagraph (C), the Sec-  
17 retary of Health and Human Services shall, not  
18 later than 12 months after the date on which  
19 the assessment under subsection (c)(1)(A) was  
20 completed by the Inspector General—

21 (i) make a final determination in re-  
22 gards to the accuracy of such assessment;  
23 and

1 (ii) provide the report described in  
2 paragraph (2) to the Internal Revenue  
3 Service.

4 (E) LIMITATION.—An applicable entity  
5 may request a hearing under subparagraph (C)  
6 with respect to a particular prescription drug  
7 only once within a 5-year period.

8 (4) PUBLICATION.—

9 (A) IN GENERAL.—Not later than the last  
10 day in February of each year, subject to sub-  
11 paragraph (B), the Inspector General shall  
12 make the report transmitted under paragraph  
13 (1) available to the public, including on the  
14 Internet website of the Inspector General, sub-  
15 ject to subparagraph (B).

16 (B) PROPRIETARY INFORMATION.—The  
17 Inspector General shall ensure that any infor-  
18 mation made public in accordance with sub-  
19 paragraph (A) excludes trade secrets and con-  
20 fidential commercial information.

21 (f) NOTIFICATION.—The Secretary of the Treasury,  
22 in conjunction with the Inspector General, shall notify, at  
23 such time and in such manner as the Secretary of the  
24 Treasury shall provide, each applicable entity in regard  
25 to any prescription drug which has been determined to

1 have been subject to a price spike during the preceding  
 2 calendar year and the amount of the tax imposed on such  
 3 applicable entity pursuant to section 4192 of the Internal  
 4 Revenue Code of 1986.

5 **SEC. 4. EXCISE TAX ON PRESCRIPTION DRUGS SUBJECT TO**  
 6 **PRICE SPIKES.**

7 (a) IN GENERAL.—Subchapter E of chapter 32 of the  
 8 Internal Revenue Code of 1986 is amended by adding at  
 9 the end the following new section:

10 **“SEC. 4192. PRESCRIPTION DRUGS SUBJECT TO PRICE**  
 11 **SPIKES.**

12 “(a) IMPOSITION OF TAX.—

13 “(1) IN GENERAL.—Subject to paragraph (3),  
 14 for each taxable prescription drug sold by an appli-  
 15 cable entity during the calendar year, there is hereby  
 16 imposed on such entity a tax equal to the greater  
 17 of—

18 “(A) the annual price spike tax for such  
 19 prescription drug, or

20 “(B) subject to paragraph (2), the cumu-  
 21 lative price spike tax for such prescription drug.

22 “(2) LIMITATION.—In the case of a taxable  
 23 prescription drug for which the applicable period (as  
 24 determined under subsection (c)(2)(E)(i)) is less

1       than 2 calendar years, the cumulative price spike tax  
2       shall not apply.

3           “(3) EXEMPTION.—For any calendar year in  
4       which the Secretary of Health and Human Services  
5       has provided an exemption for a taxable prescription  
6       drug pursuant to section 3(d) of the Medicare Nego-  
7       tiation and Competitive Licensing Act of 2021, the  
8       amount of the tax determined under paragraph (1)  
9       for such drug or device for such calendar year shall  
10      be reduced to zero.

11      “(b) ANNUAL PRICE SPIKE TAX.—

12           “(1) IN GENERAL.—The amount of the annual  
13      price spike tax shall be equal to the applicable per-  
14      centage of the price spike revenue received by the  
15      applicable entity on the sale of the taxable prescrip-  
16      tion drug during the calendar year.

17           “(2) APPLICABLE PERCENTAGE.—For purposes  
18      of paragraph (1), the applicable percentage shall be  
19      equal to—

20           “(A) in the case of a taxable prescription  
21      drug which has been subject to a price spike  
22      percentage greater than the applicable price in-  
23      crease allowance (as defined in section  
24      3(a)(6)(C) of the Medicare Negotiation and

1 Competitive Licensing Act of 2021) but less  
2 than 15 percent, 50 percent,

3 “(B) in the case of a taxable prescription  
4 drug which has been subject to a price spike  
5 percentage equal to or greater than 15 percent  
6 but less than 20 percent, 75 percent, and

7 “(C) in the case of a taxable prescription  
8 drug which has been subject to a price spike  
9 percentage equal to or greater than 20 percent,  
10 100 percent.

11 “(c) CUMULATIVE PRICE SPIKE TAX.—

12 “(1) IN GENERAL.—The amount of the cumu-  
13 lative price spike tax shall be equal to the applicable  
14 percentage of the cumulative price spike revenue re-  
15 ceived by the applicable entity on the sale of the tax-  
16 able prescription drug during the calendar year.

17 “(2) APPLICABLE PERCENTAGE.—

18 “(A) IN GENERAL.—For purposes of para-  
19 graph (1), the applicable percentage shall be  
20 equal to—

21 “(i) in the case of a taxable prescrip-  
22 tion drug which has been subject to a cu-  
23 mulative price spike percentage greater  
24 than the cumulative price increase allow-

1           ance but less than the first multi-year per-  
2           centage, 50 percent,

3           “(ii) in the case of a taxable prescrip-  
4           tion drug which has been subject to a cu-  
5           mulative price spike percentage equal to or  
6           greater than the first multi-year percent-  
7           age but less than the second multi-year  
8           percentage, 75 percent, and

9           “(iii) in the case of a taxable prescrip-  
10          tion drug which has been subject to a cu-  
11          mulative price spike percentage equal to or  
12          greater than the second multi-year percent-  
13          age, 100 percent.

14          “(B) CUMULATIVE PRICE SPIKE PERCENT-  
15          AGE.—The cumulative price spike percentage is  
16          the percentage (if any) by which—

17               “(i) the average manufacturer price of  
18               the taxable prescription drug in commerce  
19               for the preceding calendar year, exceeds

20               “(ii) the average manufacturer price  
21               of such prescription drug in commerce for  
22               the base year.

23          “(C) CUMULATIVE PRICE INCREASE AL-  
24          LOWANCE.—For purposes of clause (i) of sub-  
25          paragraph (A), the cumulative price increase al-

1 lowance for any calendar year is the percentage  
 2 (rounded to the nearest one-tenth of 1 percent)  
 3 by which the C–CPI–U (as defined in section  
 4 1(f)(6)) for that year exceeds the C–CPI–U for  
 5 the base year.

6 “(D) MULTI-YEAR PERCENTAGES.—For  
 7 purposes of subparagraph (A), the first multi-  
 8 year percentage and second multi-year percent-  
 9 age shall be determined in accordance with the  
 10 following table:

“Number of years in applicable period	First multi-year percentage	Second multi-year percentage
2 years .....	17.5	22.5
3 years .....	20	25
4 years .....	22.5	27.5
5 years .....	25	30.

11 “(E) APPLICABLE PERIOD AND BASE  
 12 YEAR.—

13 “(i) APPLICABLE PERIOD.—The appli-  
 14 cable period shall be the lesser of—

15 “(I) the 5 preceding calendar  
 16 years,

17 “(II) all calendar years beginning  
 18 after the date of enactment of this  
 19 section, or

1 “(III) all calendar years in which  
2 the taxable prescription drug was sold  
3 in commerce.

4 “(ii) BASE YEAR.—The base year  
5 shall be the calendar year immediately pre-  
6 ceding the applicable period.

7 “(3) CUMULATIVE PRICE SPIKE REVENUE.—  
8 For purposes of paragraph (1), the cumulative price  
9 spike revenue for any taxable prescription drug shall  
10 be an amount equal to—

11 “(A) an amount equal to the product of—

12 “(i) an amount (not less than zero)  
13 equal to—

14 “(I) the average manufacturer  
15 price of such prescription drug in  
16 commerce for the preceding calendar  
17 year, minus

18 “(II) the average manufacturer  
19 price of such prescription drug in  
20 commerce for the base year, and

21 “(ii) the total number of units of such  
22 prescription drug which were sold in com-  
23 merce in the preceding calendar year,  
24 minus



1           “(B) an amount equal to the sum of the  
 2           adjustment amounts, if any, determined under  
 3           section 3(a)(7)(C) of the Medicare Negotiation  
 4           and Competitive Licensing Act of 2021 for each  
 5           calendar year during the applicable period.

6           “(d) DEFINITIONS.—For purposes of this section—

7           “(1) TAXABLE PRESCRIPTION DRUG.—The  
 8           term ‘taxable prescription drug’ means a prescrip-  
 9           tion drug which has been identified by the Inspector  
 10          General of the Department of Health and Human  
 11          Services as being subject to a price spike.

12          “(2) OTHER TERMS.—The terms ‘applicable en-  
 13          tity’, ‘average manufacturer price’, ‘price spike’,  
 14          ‘price spike percentage’, and ‘price spike revenue’  
 15          have the same meaning given such terms under sec-  
 16          tion 3(a) of the Medicare Negotiation and Competi-  
 17          tive Licensing Act of 2021.”.

18          (b) CLERICAL AMENDMENTS.—

19               (1) The heading of subchapter E of chapter 32  
 20               of the Internal Revenue Code of 1986 is amended by  
 21               striking “**Medical Devices**” and inserting “**Cer-**  
 22               **tain Medical Devices and Prescription**  
 23               **Drugs**”.

24               (2) The table of subchapters for chapter 32 of  
 25               such Code is amended by striking the item relating

1 to subchapter E and inserting the following new  
 2 item:

“SUBCHAPTER E. CERTAIN MEDICAL DEVICES AND PRESCRIPTION DRUGS”.

3 (3) The table of sections for subchapter E of  
 4 chapter 32 of such Code is amended by adding at  
 5 the end the following new item:

“Sec. 4192. Prescription drugs subject to price spikes.”.

6 (c) EFFECTIVE DATE.—The amendments made by  
 7 this section shall apply to sales after the date of the enact-  
 8 ment of this Act.

9 **SEC. 5. APPLICATION OF MEDICARE PRICES TO OTHER IN-**  
 10 **SURERS AND THE UNINSURED.**

11 (a) FEDERAL HEALTH CARE PROGRAMS.—Part A of  
 12 title XI of the Social Security Act (42 U.S.C. 1301 et seq.)  
 13 is amended by adding at the end the following new section:

14 **“SEC. 1150C. APPLICATION OF MEDICARE NEGOTIATED**  
 15 **PRICES.**

16 “(a) IN GENERAL.—Notwithstanding any other pro-  
 17 vision of law, the price recognized under a Federal health  
 18 care program (as defined in section 1128B) or the insur-  
 19 ance program established under chapter 89 of title 5,  
 20 United States Code, for a specified covered part D drug  
 21 (as defined in section 1860D–11(i)), or a drug or biologi-  
 22 cal for which payment may be made under section  
 23 1842(o), with respect to a year for which coverage is pro-  
 24 vided under such Federal health care program or such in-

1 insurance program may not exceed the price for such drug  
2 established under such section 1860D–11(i) or 1842(o),  
3 as applicable.

4 “(b) APPLICATION OF OTHER PROVISIONS.—The  
5 provisions of section 1860D–11(i) shall apply with respect  
6 to a Federal health care program and the insurance pro-  
7 gram established under chapter 89 of title 5, United  
8 States Code, in the same manner as such provisions apply  
9 with respect to a prescription drug plan or an MA–PD  
10 plan under part D or C, respectively, of title XVIII.”.

11 (b) PRIVATE INSURER.—Subpart II of part A of title  
12 XXVII of the Public Health Service Act (42 U.S.C.  
13 300gg–11 et seq.) is amended by adding at the end the  
14 following new section:

15 **“SEC. 2730. APPLICATION OF MEDICARE NEGOTIATED**  
16 **PRICES.**

17 “(a) IN GENERAL.—Notwithstanding any other pro-  
18 vision of law, the price recognized under a group health  
19 plan, or under individual or group health insurance cov-  
20 erage offered by a health insurance issuer, for a specified  
21 covered part D drug (as defined in section 1860D–11(i)),  
22 or a drug or biological for which payment may be made  
23 under section 1842(o), with respect to a year for which  
24 coverage is provided under such plan or such coverage may

1 not exceed the price for such drug established under such  
2 section 1860D–11(i) or 1842(o), as applicable.

3 “(b) APPLICATION OF OTHER PROVISIONS.—The  
4 provisions of section 1860D–11(i) shall apply with respect  
5 to a group health plan, or individual or group health insur-  
6 ance coverage offered by a health insurance issuer, in the  
7 same manner as such provisions apply with respect to a  
8 prescription drug plan or an MA–PD plan under part D  
9 or C, respectively, of title XVIII.”.

10 (c) UNINSURED.—

11 (1) IN GENERAL.—Notwithstanding any other  
12 provision of law, the amount that a pharmacy fur-  
13 nishing a drug to a specified individual (as defined  
14 in paragraph (2)) may require as payment for such  
15 drug from such individual shall not exceed the price  
16 for such drug established under section 1860D–11(i)  
17 of the Social Security Act (42 U.S.C. 1395w–111(i))  
18 (or, if applicable, under section 1842(o)(8) of such  
19 Act).

20 (2) DEFINITION.—For purposes of paragraph  
21 (1), the term “specified individual” means, with re-  
22 spect to a drug, an individual who is not covered, or  
23 who has no coverage with respect to such drug,  
24 under a group health plan or group or individual  
25 health insurance coverage (as such terms are defined

1 in section 2791 of the Public Health Service Act (42  
 2 U.S.C. 300gg-91)) or under a Federal health care  
 3 program (as defined in section 1128B of the Social  
 4 Security Act, but including the insurance program  
 5 established under chapter 89 of title 5, United  
 6 States Code).

7 (3) ENFORCEMENT.—The Secretary of Health  
 8 and Human Services may impose a civil monetary  
 9 penalty of not more than \$10,000 per day on a  
 10 pharmacy for a violation of paragraph (1).

11 **SEC. 6. MANUFACTURER PROVISION OF INFORMATION.**

12 (a) IN GENERAL.—In the case of a manufacturer of  
 13 a drug or biological subject to a competitive licensing  
 14 agreement under section 1860D-11(i)(5) of the Social Se-  
 15 curity Act, as added by this Act, such manufacturer shall,  
 16 upon request from an entity electing to manufacture such  
 17 drug or biological, provide to such entity materials, data,  
 18 and information relating to the manufacture or supply of  
 19 such drug or biological, including—

- 20 (1) cellular clones and hybridoma stocks;
- 21 (2) plasmids, plasmid maps, and sequences of
- 22 antibody complementarity determining regions;
- 23 (3) physicochemical and biophysical character-
- 24 ization;
- 25 (4) growth conditions and protocols;

- 1 (5) attenuation or inactivation protocols;
- 2 (6) extraction and purification protocols;
- 3 (7) synthetic work-up and schemes;
- 4 (8) sufficient quantities of the drug or biological
- 5 cal for testing;
- 6 (9) the protocols and methods used for testing
- 7 the drug or biological; and
- 8 (10) the expected outcomes from those protocols.
- 9

10 (b) ENFORCEMENT.—The Secretary of Health and  
 11 Human Services may impose a civil monetary penalty on  
 12 a manufacturer of not more than \$10,000 per day for a  
 13 violation of subsection (a).

14 **SEC. 7. APPLICABILITY OF NEGOTIATED PRICE TO PRE-**  
 15 **SCRIPTION DRUGS FURNISHED BY THE DE-**  
 16 **PARTMENT OF DEFENSE AND THE DEPART-**  
 17 **MENT OF VETERANS AFFAIRS.**

18 (a) IN GENERAL.—Section 8126(a) of title 38,  
 19 United States Code, is amended—

- 20 (1) in paragraph (2), by inserting “, but may
- 21 not exceed the amount of the price negotiated by the
- 22 Secretary of Health and Human Services under sec-
- 23 tion 1860D–11(i) of the Social Security Act (42
- 24 U.S.C. 1395w–111(i)) (as amended by the Medicare
- 25 Negotiation and Competitive Licensing Act of 2019)

1 for a specified covered part D drug (as defined in  
2 such section) (or, if applicable, may not exceed the  
3 amount of the price negotiated by the Secretary of  
4 Health and Human Services under section  
5 1842(o)(8) of such Act for a drug or biological pay-  
6 able under such section) that is a covered drug of  
7 a manufacturer” after “best interests of the Depart-  
8 ment or such Federal agencies”; and

9 (2) in paragraph (3), by inserting “or, for a  
10 covered drug of a manufacturer that is a specified  
11 covered part D drug (as defined in section 1860D–  
12 11(i) of the Social Security Act (42 U.S.C. 1395w–  
13 111(i)) (as amended by the Medicare Negotiation  
14 and Competitive Licensing Act of 2019)) or a drug  
15 or biological for which payment may be made under  
16 section 1842(o)(8) of such Act, the price negotiated  
17 by the Secretary of Health and Human Services  
18 under such section 1806D–11(i) or 1842(o)(8) (as  
19 applicable) for the specified covered part D drug or  
20 the drug or biological” after “the price charged  
21 under the Federal Supply Schedule at the time the  
22 drug is procured”.

23 (b) DEPARTMENT OF DEFENSE ELEMENTS FOR  
24 PURPOSES OF PRICING STANDARDS.—Section 1074g(f) of  
25 title 10, United States Code, is amended—

1 (1) in the header, by inserting “AND NATIONAL  
2 MAIL-ORDER PHARMACY PROGRAM” after “PHAR-  
3 MACY PROGRAM”;

4 (2) by striking “the TRICARE retail pharmacy  
5 program shall be treated as an element of the De-  
6 partment of Defense” and inserting “the TRICARE  
7 retail pharmacy program and the national mail-order  
8 pharmacy program shall be treated as elements of  
9 the Department of Defense”; and

10 (3) by striking “provided by pharmacies under  
11 the program” and inserting “provided under such  
12 programs”.

13 **SEC. 8. SPECIFIED COVERED PART D DRUGS EXCISE TAX.**

14 (a) IN GENERAL.—Subchapter E of chapter 32 of the  
15 Internal Revenue Code of 1986 is amended by adding at  
16 the end the following new section:

17 **“SEC. 4193. SPECIFIED COVERED PART D DRUGS.**

18 “(a) IN GENERAL.—There is hereby imposed on the  
19 sale by the manufacturer, producer, or importer of any  
20 specified covered part D drug for a price in excess of the  
21 negotiated price in violation of section 1860D–11(i)(5)(C)  
22 of the Social Security Act during any period described in  
23 such section a tax equal to 100 percent of the price for  
24 which so sold.



1       “(b) DEFINITIONS.—The terms ‘specified covered  
2 part D drug’ and ‘negotiated price’ have the meaning such  
3 terms have under section 1860D–11 of the Social Security  
4 Act.”.

5       (b) CLERICAL AMENDMENTS.—

6           (1) The heading of subchapter E of chapter 32  
7 of the Internal Revenue Code of 1986 is amended by  
8 striking “**Medical Devices**” and inserting  
9 “**Other Medical Products**”.

10          (2) The table of subchapters for chapter 32 of  
11 such Code is amended by striking the item relating  
12 to subchapter E and inserting the following new  
13 item:

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

14          (3) The table of sections for subchapter E of  
15 chapter 32 of such Code is amended by adding at  
16 the end the following new item:

“Sec. 4193. Specified covered part D drugs.”.

17       (c) EFFECTIVE DATE.—The amendments made by  
18 this section shall apply to sales on or after the date that  
19 is 1 year after the date of the enactment of this Act.

20 **SEC. 9. DRUG MANUFACTURER REPORTING.**

21       Part P of title III of the Public Health Service Act  
22 (42 U.S.C. 280g et seq.) is amended by adding at the end  
23 the following:

1 **“SEC. 399V-7. DRUG MANUFACTURER REPORTING.**

2 “(a) MANDATORY REPORTING.—A drug manufac-  
3 turer shall submit to the Secretary and to Congress an  
4 annual report specifying with respect to the previous cal-  
5 endar year (except as provided in subsection (d)(2))—

6 “(1) the total expenditures of the manufacturer  
7 on—

8 “(A) domestic and foreign drug research  
9 and development, including an itemized descrip-  
10 tion of—

11 “(i) basic and preclinical research;

12 “(ii) clinical research, reported sepa-  
13 rately for each clinical trial;

14 “(iii) development of alternative dos-  
15 age forms and strengths for the drug mol-  
16 ecule or combinations, including the mol-  
17 ecule;

18 “(iv) other drug development activi-  
19 ties, such as nonclinical laboratory studies  
20 and record and report maintenance;

21 “(v) pursuing new or expanded indica-  
22 tions for such drug through supplemental  
23 applications under section 505 of the Fed-  
24 eral Food, Drug, and Cosmetic Act;

1 “(vi) carrying out postmarket require-  
2 ments related to such drug, including  
3 under section 505(o)(3) of such Act;

4 “(vii) carrying out risk evaluation and  
5 mitigation strategies in accordance with  
6 section 505–1 of such Act; and

7 “(viii) marketing research;

8 “(B) the acquisition of drug components  
9 and packaging, in total and per unit sold, bro-  
10 ken out by source and cost and identifying spe-  
11 cific costs that reflect internal transfers within  
12 the manufacturer’s company;

13 “(C) other acquisitions relating to drugs,  
14 including for the purchase of patents and li-  
15 censing or the acquisition of any corporate enti-  
16 ty owning any rights to a drug during or after  
17 development of the drug; and

18 “(D) marketing, advertising, and educating  
19 for the promotion of a drug, including a break-  
20 down of amounts aimed at consumers, pre-  
21 scribers, managed care organizations, and oth-  
22 ers, irrespective of whether a particular drug is  
23 mentioned in the marketing, advertising, or  
24 educating;

1           “(2) the gross revenue, net revenue, gross prof-  
2           it, and net profit of the manufacturer with respect  
3           to drugs;

4           “(3) the total number of units of each type of  
5           drug that were sold in interstate commerce;

6           “(4) pricing information with respect to the sale  
7           of drugs, including—

8                 “(A) wholesale acquisition cost;

9                 “(B) net average price realized by pre-  
10           scription drug benefit managers for drugs pro-  
11           vided to individuals in the United States, after  
12           accounting for any rebates or other payments  
13           from the manufacturer to the pharmacy benefit  
14           manager and from the pharmacy benefit man-  
15           ager to the manufacturer; and

16                 “(C) the net price of each drug, after ac-  
17           counting for discounts, rebates, or other finan-  
18           cial considerations, charged to purchasers in  
19           each applicable country of the Organisation for  
20           Economic Co-operation and Development;

21           “(5) any Federal benefits received by the manu-  
22           facturer with respect to a drug, including the  
23           amounts and periods of impact for each such ben-  
24           efit, including tax credits; Federal grants, including  
25           from the National Institutes of Health, the Depart-

1       ment of Defense, the Department of Energy, the  
2       Centers for Disease Control and Prevention, or other  
3       Federal departments or agencies; patent applications  
4       that benefitted from such grants; patent extensions;  
5       exclusivity periods; and waivers of fees;

6           “(6) the percentage of research and develop-  
7       ment expenditures described in clauses (i) through  
8       (v) of paragraph (1)(A) that were derived from Fed-  
9       eral funds;

10          “(7) executive compensation for the chief execu-  
11       tive officer, chief financial officer, and the 3 other  
12       most highly compensated executive officers, includ-  
13       ing bonuses, paid by such manufacturer, and stock  
14       options affiliated with the manufacturer that were  
15       offered to or accrued by such officers; and

16          “(8) any other information as the Secretary  
17       may require.

18       “(b) VOLUNTARY SUPPLEMENTAL REPORTING.—A  
19       drug manufacturer may supplement a report under sub-  
20       section (a) with any additional information the manufac-  
21       turer chooses to provide related to drug pricing decisions,  
22       such as—

23           “(1) total expenditures on drug research, drug  
24       development, and clinical trials on drugs that failed

1 to receive approval by the Food and Drug Adminis-  
2 tration; and

3 “(2) a list of drugs and drug prices of other  
4 manufacturers for purposes of comparison with the  
5 manufacturer’s own drugs and drug prices.

6 “(c) SPECIAL RULE.—A drug manufacturer shall—

7 “(1) to the extent possible, disaggregate the in-  
8 formation required to be reported by this section by  
9 the particular drug involved; and

10 “(2) submit all information required to be re-  
11 ported by this section with respect to each applicable  
12 drug in a single annual report.

13 “(d) SUBMISSION OF REPORTS.—

14 “(1) IN GENERAL.—

15 “(A) SUBMISSION BY DRUG MANUFACTUR-  
16 ERS.—Drug manufacturers shall submit the an-  
17 nual reports required under this section to the  
18 Secretary in a usable format, as the Secretary  
19 may require.

20 “(B) COLLATION BY THE SECRETARY.—

21 The Secretary shall collate the reports received  
22 as described in subparagraph (A) and submit  
23 such collated reports to Congress, together with  
24 an analysis of the reports by the Secretary that  
25 includes—

1 “(i) a summary of data from the re-  
2 ports;

3 “(ii) consideration of factors such as  
4 trends on research and development costs,  
5 Federal benefits, and manufacturer patient  
6 assistance programs; and

7 “(iii) the relationship between the fac-  
8 tors described in clause (ii) and prescrip-  
9 tion drug prices.

10 “(C) PUBLIC AVAILABILITY.—The Sec-  
11 retary shall make the reports submitted by  
12 manufacturers as described in subparagraph  
13 (A) and the collated reports together with the  
14 analysis of the Secretary described in subpara-  
15 graph (B) publicly available, including by post-  
16 ing such reports to the internet website of the  
17 Department of Health and Human Services, in  
18 a searchable format.

19 “(2) INITIAL REPORT.—

20 “(A) IN GENERAL.—A drug manufacturer  
21 shall submit an initial report pursuant to this  
22 section not later than one year after the date of  
23 enactment of this subparagraph (except as pro-  
24 vided in subparagraph (B)).

1           “(B)     REPORTING     PERIOD.—Notwith-  
2           standing the requirement in subsection (a) that  
3           each report under such subsection be for the  
4           previous calendar year, the initial report of a  
5           drug manufacturer under subsection (a) shall  
6           include, for each drug marketed by the manu-  
7           facturer, the information described in para-  
8           graphs (1) through (6) of subsection (a) for the  
9           calendar year period beginning with the later  
10          of—

11                 “(i) the calendar year in which the  
12                 drug was approved under section 505 of  
13                 the Federal Food, Drug, and Cosmetic  
14                 Act, was licensed under section 351 of this  
15                 Act, or received an exemption under sec-  
16                 tion 505(i) of the Federal Food, Drug, and  
17                 Cosmetic Act or section 351(a)(3) of this  
18                 Act; and

19                 “(ii) the calendar year in which the  
20                 manufacturer acquired the drug so ap-  
21                 proved, licensed, or exempted.

22           “(C)     SMALL BUSINESSES.—In the case of  
23           a drug manufacturer that has fewer than 500  
24           employees, the initial report required by in sub-



1 paragraph (A) shall be submitted by a date de-  
2 termined by the Secretary, which shall be—

3 “(i) not earlier than the deadline de-  
4 scribed in subparagraph (A); and

5 “(ii) not later than the date that is 3  
6 years after the date of enactment of this  
7 clause.

8 “(e) AUDIT BY THIRD PARTY.—The Secretary shall  
9 select a percentage (to be determined by the Secretary)  
10 of the reports submitted under subsection (a) for a fiscal  
11 year to be audited by an accredited third-party auditor  
12 (to be selected by the Secretary).

13 “(f) PENALTY FOR NONCOMPLIANCE.—The Sec-  
14 retary shall report to the Office of the Inspector General  
15 any manufacturer’s failure to submit a complete report as  
16 required under this section. Any manufacturer that fails  
17 to submit a complete report required under this section  
18 shall be subject to a civil penalty of up to \$200,000 for  
19 each day on which the violation continues. The Secretary  
20 shall collect the civil penalties under this subsection and,  
21 without further appropriation, shall use such funds to sup-  
22 port research of the National Institutes of Health.

23 “(g) DEFINITION.—In this section, the term ‘drug  
24 manufacturer’ means the manufacturer of an approved  
25 drug (including a drug approved under subsection (c) or

1 (j) of section 505 of the Federal Food, Drug, and Cos-  
2 metic Act and a biological product licensed under sub-  
3 section (a) or (k) of section 351 of this Act).”.

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