

115TH CONGRESS
1ST SESSION

S. 1369

To amend the Internal Revenue Code of 1986 to establish an excise tax on certain prescription drugs which have been subject to a price spike, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 15, 2017

Mr. BROWN (for himself, Mrs. GILLIBRAND, Mr. FRANKEN, Mr. REED, Ms. HASSAN, and Mr. UDALL) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend the Internal Revenue Code of 1986 to establish an excise tax on certain prescription drugs which have been subject to a price spike, 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 “Stop Price Gouging
5 Act”.

6 **SEC. 2. IDENTIFICATION OF PRESCRIPTION DRUG PRICE**

7 **SPIKES.**

8 (a) DEFINITIONS.—In this section:

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

9 (2) AVERAGE MANUFACTURER PRICE.—The
10 term “average manufacturer price”—

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

14 (B) with respect to a drug for which there
15 is no average manufacturer price as so defined,
16 such term shall mean the wholesale acquisition
17 cost of the drug.

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

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

24 (5) PRESCRIPTION DRUG.—

1 (A) IN GENERAL.—The term “prescription
2 drug” means any drug (as defined in section
3 201(g) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 321(g))), including a com-
5 bination product whose primary mode of action
6 is determined under section 503(g) of such Act
7 (21 U.S.C. 353(g)) to be that of a drug, and
8 that—

9 (i) is subject to section 503(b)(1) of
10 the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 353(b)(1)); and

12 (ii) is covered by a Federal health
13 care program (as defined in section
14 1128B(f) of the Social Security Act (42
15 U.S.C. 1320a–7b(f))).

16 (B) TREATMENT OF REFORMULATED
17 DRUGS.—For purposes of this section, a pre-
18 scription drug with respect to which the Sec-
19 retary of Health and Human Services has ap-
20 proved any minor reformulation that does not
21 produce a meaningful therapeutic benefit, the
22 drug that was approved prior to any such refor-
23 mulation and the drug with any such reformu-
24 lation shall be considered one prescription drug.

25 (6) PRICE SPIKE.—

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

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

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

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

15 (C) APPLICABLE PRICE INCREASE ALLOW-
16 ANCE.—The applicable price increase allowance
17 for any calendar year is the percentage (round-
18 ed to the nearest one-tenth of 1 percent) by
19 which the medical care consumer price index
20 detailed expenditure category for all urban con-
21 sumers (United States city average) for that
22 year exceed such index for the preceding cal-
23 endar year.

24 (7) PRICE SPIKE REVENUE.—

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

3 (i) the gross price spike revenue,
4 minus

5 (ii) the adjustment amount.

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

9 (i) an amount equal to the difference
10 between clause (i) of paragraph (6)(B) and
11 clause (ii) of such paragraph; and

12 (ii) the total number of units of the
13 prescription drug which were sold in com-
14 merce in such calendar year.

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

21 (b) SUBMISSION BY PHARMACEUTICAL COMPANIES
22 OF INFORMATION TO INSPECTOR GENERAL.—

23 (1) IN GENERAL.—For each prescription drug,
24 the applicable entity shall submit to the Inspector

1 General a quarterly report that includes the fol-
2 lowing:

3 (A) For each prescription drug of the ap-
4 plicable entity—

5 (i) the total number of units of the
6 prescription drug which were sold in com-
7 merce in the preceding calendar quarter;

8 (ii) the average and median price per
9 unit of such prescription drug in commerce
10 in the preceding calendar quarter,
11 disaggregated by month; and

12 (iii) the gross revenues from sales of
13 such prescription drug in commerce in the
14 preceding calendar quarter.

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

22 (C) Such information related to any antici-
23 pated increased input costs for the subsequent
24 calendar quarter as the applicable entity may
25 wish the Inspector General to consider in mak-

1 ing a determination under clause (ii) of sub-
2 section (c)(2)(B) or an assessment in clause
3 (iii) of such subsection for such calendar quar-
4 ter.

5 (2) PENALTY FOR FAILURE TO SUBMIT.—

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

13 (B) AMOUNT OF PENALTY.—The amount
14 of the civil penalty shall be equal to the product
15 of—

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

18 (I) not less than 0.5 percent of
19 the gross revenues from sales of the
20 prescription drug described in sub-
21 paragraph (A) for the preceding cal-
22 endar year, and

23 (II) not greater than 1 percent of
24 the gross revenues from sales of such

1 prescription drug for the preceding
2 calendar year, and

3 (ii) the number of days in the period
4 between—

5 (I) the applicable date specified
6 in paragraph (3), and

7 (II) the date on which the In-
8 spector General receives the informa-
9 tion described in paragraph (1) from
10 the applicable entity.

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

15 (c) ASSESSMENT BY INSPECTOR GENERAL.—

16 (1) IN GENERAL.—Not later than the last day
17 in February of each year, the Inspector General, in
18 consultation with other relevant Federal agencies
19 (including the Federal Trade Commission), shall—

20 (A) complete an assessment of the infor-
21 mation the Inspector General received pursuant
22 to subsection (b)(1) with respect to sales of pre-
23 scription drugs in the preceding calendar year;
24 and

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

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

12 (A) Identification of each price spike relat-
13 ing to a prescription drug in the preceding cal-
14 endar year.

15 (B) For each price spike identified under
16 subparagraph (A)—

17 (i) a determination of the price spike
18 revenue;

19 (ii) a determination regarding the ac-
20 curacy of the information submitted by the
21 applicable entity regarding increased input
22 costs; and

23 (iii) an assessment of the rationale of
24 the applicable entity for the price spike.

25 (d) EXEMPTION OF CERTAIN DRUGS.—

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

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

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

17 (ii) such drug is marketed by not less than
18 3 other holders of applications approved under
19 subsection (c) or (j) of section 505 of the Fed-
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.
21 355), where such applications approved under
22 such subsection (j) use as a reference drug the
23 drug so approved under such subsection (c).

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

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

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

14 (e) INSPECTOR GENERAL REPORT TO INTERNAL
15 REVENUE SERVICE.—

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

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

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

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

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

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

14 (3) NOTICE AND OPPORTUNITY FOR HEAR-
15 ING.—

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

21 (i) the assessment of such drug under
22 subsection (c)(1)(A); and

23 (ii) notice of their right to a hearing
24 in regards to such assessment.

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

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

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

19 (i) make a final determination in re-
20 gards the accuracy of such assessment;
21 and

22 (ii) provide the report described in
23 paragraph (2) to the Internal Revenue
24 Service.

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

5 (4) PUBLICATION.—

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

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

18 (f) NOTIFICATION.—The Secretary of the Treasury,
19 in conjunction with the Inspector General, shall notify, at
20 such time and in such manner as the Secretary of the
21 Treasury shall provide, each applicable entity in regard
22 to any prescription drug which has been determined to
23 have been subject to a price spike during the preceding
24 calendar year and the amount of the tax imposed on such

1 applicable entity pursuant to section 4192 of the Internal
2 Revenue Code of 1986.

3 **SEC. 3. EXCISE TAX ON PRESCRIPTION DRUGS SUBJECT TO**
4 **PRICE SPIKES.**

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

8 **“SEC. 4192. PRESCRIPTION DRUGS SUBJECT TO PRICE**
9 **SPIKES.**

10 “(a) IMPOSITION OF TAX.—

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

16 “(A) the annual price spike tax for such
17 prescription drug, or

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

20 “(2) LIMITATION.—In the case of a taxable
21 prescription drug for which the applicable period (as
22 determined under subsection (c)(2)(E)(i)) is less
23 than 2 calendar years, the cumulative price spike tax
24 shall not apply.

1 “(3) EXEMPTION.—For any calendar year in
2 which the Secretary of Health and Human Services
3 has provided an exemption for a taxable prescription
4 drug pursuant to section 2(d) of the Stop Price
5 Gouging Act, the amount of the tax determined
6 under paragraph (1) for such drug or device for
7 such calendar year shall be reduced to zero.

8 “(b) ANNUAL PRICE SPIKE TAX.—

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

14 “(2) APPLICABLE PERCENTAGE.—For purposes
15 of paragraph (1), the applicable percentage shall be
16 equal to—

17 “(A) in the case of a taxable prescription
18 drug which has been subject to a price spike
19 percentage greater than the applicable price in-
20 crease allowance (as defined in section
21 2(a)(6)(C) of the Stop Price Gouging Act) but
22 less than 15 percent, 50 percent,

23 “(B) in the case of a taxable prescription
24 drug which has been subject to a price spike

1 percentage equal to or greater than 15 percent
2 but less than 20 percent, 75 percent, and

3 “(C) in the case of a taxable prescription
4 drug which has been subject to a price spike
5 percentage equal to or greater than 20 percent,
6 100 percent.

7 “(c) CUMULATIVE PRICE SPIKE TAX.—

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

13 “(2) APPLICABLE PERCENTAGE.—

14 “(A) IN GENERAL.—For purposes of para-
15 graph (1), the applicable percentage shall be
16 equal to—

17 “(i) in the case of a taxable prescrip-
18 tion drug which has been subject to a cu-
19 mulative price spike percentage greater
20 than the cumulative price increase allow-
21 ance but less than the first compounded
22 percentage, 50 percent,

23 “(ii) in the case of a taxable prescrip-
24 tion drug which has been subject to a cu-
25 mulative price spike percentage equal to or

1 greater than the first compounded percent-
2 age but less than the second compounded
3 percentage, 75 percent, and

4 “(iii) in the case of a taxable prescrip-
5 tion drug which has been subject to a cu-
6 mulative price spike percentage equal to or
7 greater than the second compounded per-
8 centage, 100 percent.

9 “(B) CUMULATIVE PRICE SPIKE PERCENT-
10 AGE.—The cumulative price spike percentage is
11 the percentage (if any) by which—

12 “(i) the average manufacturer price of
13 the taxable prescription drug in commerce
14 for the preceding calendar year, exceeds

15 “(ii) the average manufacturer price
16 of such prescription drug in commerce for
17 the base year.

18 “(C) CUMULATIVE PRICE INCREASE AL-
19 LOWANCE.—For purposes of clause (i) of sub-
20 paragraph (A), the cumulative price increase al-
21 lowance for any calendar year is the percentage
22 (rounded to the nearest one-tenth of 1 percent)
23 by which the medical care consumer price index
24 detailed expenditure category for all urban con-
25 sumers (United States city average) for that

1 year exceeds such index for the preceding cal-
 2 endar year.

3 “(D) COMPOUNDED PERCENTAGES.—For
 4 purposes of subparagraph (A), the first com-
 5 pounded percentage and second compounded
 6 percentage shall be determined in accordance
 7 with the following table:

“Number of years in applicable period	First com- pounded percentage	Second com- pounded percentage
2 years	32.25	44.00
3 years	52.09	72.80
4 years	74.90	107.36
5 years	101.14	148.83.

8 “(E) APPLICABLE PERIOD AND BASE
 9 YEAR.—

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

12 “(I) the 5 preceding calendar
 13 years,

14 “(II) all calendar years beginning
 15 after the date of enactment of this
 16 section, or

17 “(III) all calendar years in which
 18 the taxable prescription drug was sold
 19 in commerce.

1 “(ii) BASE YEAR.—The base year
2 shall be the calendar year immediately pre-
3 ceding the applicable period.

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

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

9 “(i) an amount (not less than zero)
10 equal to—

11 “(I) the average manufacturer
12 price of such prescription drug in
13 commerce for the preceding calendar
14 year, minus

15 “(II) the average manufacturer
16 price of such prescription drug in
17 commerce for the base year, and

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

22 “(B) an amount equal to the sum of the
23 adjustment amounts, if any, determined under
24 section 2(a)(7)(C) of the Stop Price Gouging

1 Act for each calendar year during the applicable
2 period.

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

4 “(1) TAXABLE PRESCRIPTION DRUG.—The
5 term ‘taxable prescription drug’ means a prescrip-
6 tion drug (as defined in section 2(a)(5) of the Stop
7 Price Gouging Act) which has been identified by the
8 Inspector General of the Department of Health and
9 Human Services, under section 2(c)(2)(A) of such
10 Act, as being subject to a price spike.

11 “(2) OTHER TERMS.—The terms ‘applicable en-
12 tity’, ‘average manufacturer price’, ‘price spike’,
13 ‘price spike percentage’, and ‘price spike revenue’
14 have the same meaning given such terms under sec-
15 tion 2(a) of the Stop Price Gouging Act.”.

16 (b) CLERICAL AMENDMENTS.—

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

22 (2) The table of subchapters for chapter 32 of
23 such Code is amended by striking the item relating
24 to subchapter E and inserting the following new
25 item:

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

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

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

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

7 **SEC. 4. STUDY ON MONOPOLY MEDICAL PRODUCTS.**

8 (a) IN GENERAL.—The Comptroller General of the
9 United States shall conduct a study that examines—

10 (1) how drug manufacturers and health plans
11 (including private insurers, the Medicare program,
12 and State Medicaid programs) establish initial
13 launch prices for newly approved drugs; and

14 (2) alternative methods that have been pro-
15 posed for setting the price of new drugs.

16 (b) STUDY OF SPECIFIC DRUGS.—As part of the
17 study described in subsection (a), the Comptroller General
18 shall examine drug pricing with respect to several drugs
19 approved within the 5-year period immediately preceding
20 the date of enactment of this Act and explore potential
21 alternative approaches to establish new drug prices that
22 could help make new drugs more affordable, better reflect
23 the clinical value of such drugs in treating patients, and
24 maintain incentives for innovation.

1 (c) FACTORS.—In conducting the study described in
2 subsection (a), the Comptroller General shall consider—

3 (1) what factors drug manufacturers and health
4 plans consider in establishing initial launch prices;

5 (2) how initial pricing decisions by drug manu-
6 facturers and health plans affect costs and use of
7 services for patients and public programs such as
8 the Medicare and Medicaid programs;

9 (3) efforts by health plans to limit costs, includ-
10 ing through benefit design or coverage limitations;

11 (4) how prices change in the first few years fol-
12 lowing a new drug's launch; and

13 (5) recommendations manufacturers, health
14 plans, and other experts have for alternative ap-
15 proaches to establishing new drug prices and the
16 benefits and challenges associated with such alter-
17 native approaches.

18 **SEC. 5. REVENUES COLLECTED.**

19 There are authorized to be appropriated to the Sec-
20 retary of Health and Human Services such sums as are
21 equal to any increase in revenue to the Treasury by reason
22 of the provisions of this Act or the amendments made by
23 this Act for the purposes of increasing amounts available

- 1 to the National Institutes of Health for research and de-
- 2 velopment of drugs.

