

116TH CONGRESS
1ST SESSION

S. 378

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

FEBRUARY 7, 2019

Mr. BROWN (for himself, Mrs. GILLIBRAND, and Ms. HASSAN) 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.—

(A) IN GENERAL.—The term “prescription drug” means any drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))), including a combination product whose primary mode of action is determined under section 503(g) of such Act (21 U.S.C. 353(g)) to be that of a drug, and that—

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

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

(B) TREATMENT OF REFORMULATED DRUGS.—For purposes of this section, a prescription drug with respect to which the Secretary 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.—

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 C-CPI-U (as defined in section
 20 1(f)(6) of the Internal Revenue Code of 1986)
 21 for that year exceeds the C-CPI-U for the pre-
 22 ceding calendar year.

23 (7) PRICE SPIKE REVENUE.—

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

1 (i) the gross price spike revenue,
2 minus

3 (ii) the adjustment amount.

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

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

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

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

19 (b) SUBMISSION BY PHARMACEUTICAL COMPANIES
20 OF INFORMATION TO INSPECTOR GENERAL.—

21 (1) IN GENERAL.—For each prescription drug,
22 the applicable entity shall submit to the Inspector
23 General a quarterly report that includes the fol-
24 lowing:

1 (A) For each prescription drug of the ap-
2 plicable entity—

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

6 (ii) the average and median price per
7 unit of such prescription drug in commerce
8 in the preceding calendar quarter, disag-
9 gregated by month; and

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

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

20 (C) Such information related to any antici-
21 pated increased input costs for the subsequent
22 calendar quarter as the applicable entity may
23 wish the Inspector General to consider in mak-
24 ing a determination under clause (ii) of sub-
25 section (c)(2)(B) or an assessment in clause

1 (iii) of such subsection for such calendar quar-
 2 ter.

3 (2) PENALTY FOR FAILURE TO SUBMIT.—

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

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

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

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

21 (II) not greater than 1 percent of
 22 the gross revenues from sales of such
 23 prescription drug for the preceding
 24 calendar year, and

1 (ii) the number of days in the period
 2 between—

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

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

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

13 (c) ASSESSMENT BY INSPECTOR GENERAL.—

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

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

23 (B) in the case of any prescription drug
 24 which satisfies the conditions described in para-
 25 graph (1) or (2) of subsection (d), submit a rec-

ommendation to the Secretary of Health and Human Services that such drug be exempted from application of the tax imposed under section 4192 of the Internal Revenue Code of 1986 (as added by section 3 of this Act) for such year.

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

(A) Identification of each price spike relating to a prescription drug in the preceding calendar year.

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

(i) a determination of the price spike revenue;

(ii) a determination regarding the accuracy of the information submitted by the applicable entity regarding increased input costs; and

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

(d) EXEMPTION OF CERTAIN DRUGS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, upon recommendation of the Inspector General pursuant to subsection (c)(1)(B),

1 may exempt any prescription drug which has been
2 subject to a price spike during the preceding cal-
3 endar year from application of the tax imposed
4 under section 4192 of the Internal Revenue Code of
5 1986 for such year, if the Secretary determines
6 that—

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

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

14 (ii) such drug is marketed by not less than
15 3 other holders of applications approved under
16 subsection (c) or (j) of section 505 of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C.
18 355), where such applications approved under
19 such subsection (j) use as a reference drug the
20 drug so approved under such subsection (c).

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

1 (A) has the discretion to determine that
 2 such information does not warrant a for-cause
 3 price increase exemption; and

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

11 (e) INSPECTOR GENERAL REPORT TO INTERNAL
 12 REVENUE SERVICE.—

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

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

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

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

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

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

12 (3) NOTICE AND OPPORTUNITY FOR HEAR-
 13 ING.—

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

19 (i) the assessment of such drug under
 20 subsection (c)(1)(A); and

21 (ii) notice of their right to a hearing
 22 in regards to such assessment.

23 (B) NOTICE.—The notice required under
 24 subparagraph (A) shall be provided to the ap-
 25 plicable entity not later than 30 days after com-

1 pletion of the assessment under subsection
2 (c)(1)(A).

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

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

16 (i) make a final determination in re-
17 gards the accuracy of such assessment;
18 and

19 (ii) provide the report described in
20 paragraph (2) to the Internal Revenue
21 Service.

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

1 (4) PUBLICATION.—

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

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

14 (f) NOTIFICATION.—The Secretary of the Treasury,
15 in conjunction with the Inspector General, shall notify, at
16 such time and in such manner as the Secretary of the
17 Treasury shall provide, each applicable entity in regard
18 to any prescription drug which has been determined to
19 have been subject to a price spike during the preceding
20 calendar year and the amount of the tax imposed on such
21 applicable entity pursuant to section 4192 of the Internal
22 Revenue Code of 1986.

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

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

6 **“SEC. 4192. PRESCRIPTION DRUGS SUBJECT TO PRICE**
 7 **SPIKES.**

8 “(a) IMPOSITION OF TAX.—

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

14 “(A) the annual price spike tax for such
 15 prescription drug, or

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

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

23 “(3) EXEMPTION.—For any calendar year in
 24 which the Secretary of Health and Human Services
 25 has provided an exemption for a taxable prescription
 26 drug pursuant to section 2(d) of the Stop Price

1 Gouging Act, the amount of the tax determined
 2 under paragraph (1) for such drug or device for
 3 such calendar year shall be reduced to zero.

4 “(b) ANNUAL PRICE SPIKE TAX.—

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

10 “(2) APPLICABLE PERCENTAGE.—For purposes
 11 of paragraph (1), the applicable percentage shall be
 12 equal to—

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

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

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

1 percentage equal to or greater than 20 percent,
2 100 percent.

3 “(c) CUMULATIVE PRICE SPIKE TAX.—

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

9 “(2) APPLICABLE PERCENTAGE.—

10 “(A) IN GENERAL.—For purposes of para-
11 graph (1), the applicable percentage shall be
12 equal to—

13 “(i) in the case of a taxable prescrip-
14 tion drug which has been subject to a cu-
15 mulative price spike percentage greater
16 than the cumulative price increase allow-
17 ance but less than the first multi-year per-
18 centage, 50 percent,

19 “(ii) in the case of a taxable prescrip-
20 tion drug which has been subject to a cu-
21 mulative price spike percentage equal to or
22 greater than the first multi-year percent-
23 age but less than the second multi-year
24 percentage, 75 percent, and

1 “(iii) in the case of a taxable prescrip-
 2 tion drug which has been subject to a cu-
 3 mulative price spike percentage equal to or
 4 greater than the second multi-year percent-
 5 age, 100 percent.

6 “(B) CUMULATIVE PRICE SPIKE PERCENT-
 7 AGE.—The cumulative price spike percentage is
 8 the percentage (if any) by which—

9 “(i) the average manufacturer price of
 10 the taxable prescription drug in commerce
 11 for the preceding calendar year, exceeds

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

15 “(C) CUMULATIVE PRICE INCREASE AL-
 16 LOWANCE.—For purposes of clause (i) of sub-
 17 paragraph (A), the cumulative price increase al-
 18 lowance for any calendar year is the percentage
 19 (rounded to the nearest one-tenth of 1 percent)
 20 by which the C-CPI-U (as defined in section
 21 1(f)(6)) for that year exceeds the C-CPI-U for
 22 the base year.

23 “(D) MULTI-YEAR PERCENTAGES.—For
 24 purposes of subparagraph (A), the first multi-
 25 year percentage and second multi-year percent-

1 age shall be determined in accordance with the
 2 following table:

“Number of years in applicable period	First multi-year percentage	Second multi-year percentage
2 years	17.5	22.5
3 years	20.0	25.0
4 years	22.5	27.5
5 years	25.0	30.0.

3 “(E) APPLICABLE PERIOD AND BASE
 4 YEAR.—

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

7 “(I) the 5 preceding calendar
 8 years,

9 “(II) all calendar years beginning
 10 after the date of enactment of this
 11 section, or

12 “(III) all calendar years in which
 13 the taxable prescription drug was sold
 14 in commerce.

15 “(ii) BASE YEAR.—The base year
 16 shall be the calendar year immediately pre-
 17 ceding the applicable period.

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

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

2 “(i) an amount (not less than zero)

3 equal to—

4 “(I) the average manufacturer

5 price of such prescription drug in

6 commerce for the preceding calendar

7 year, minus

8 “(II) the average manufacturer

9 price of such prescription drug in

10 commerce for the base year, and

11 “(ii) the total number of units of such

12 prescription drug which were sold in com-

13 merce in the preceding calendar year,

14 minus

15 “(B) an amount equal to the sum of the

16 adjustment amounts, if any, determined under

17 section 2(a)(7)(C) of the Stop Price Gouging

18 Act for each calendar year during the applicable

19 period.

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

21 “(1) TAXABLE PRESCRIPTION DRUG.—The

22 term ‘taxable prescription drug’ means a prescrip-

23 tion drug (as defined in section 2(a)(5) of the Stop

24 Price Gouging Act) which has been identified by the

25 Inspector General of the Department of Health and

1 Human Services, under section 2(c)(2)(A) of such
2 Act, as being subject to a price spike.

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

8 (b) CLERICAL AMENDMENTS.—

9 (1) The heading of subchapter E of chapter 32
10 of the Internal Revenue Code of 1986 is amended by
11 striking “**Medical Devices**” and inserting “**Cer-**
12 **tain Medical Devices and Prescription**
13 **Drugs**”.

14 (2) The table of subchapters for chapter 32 of
15 such Code is amended by striking the item relating
16 to subchapter E and inserting the following new
17 item:

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

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

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

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

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

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

4 (1) how drug manufacturers and health plans
5 (including private insurers, the Medicare program,
6 and State Medicaid programs) establish initial
7 launch prices for newly approved drugs; and

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

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

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

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

23 (2) how initial pricing decisions by drug manu-
24 facturers and health plans affect costs and use of
25 services for patients and public programs such as
26 the Medicare and Medicaid programs;

- 1 (3) efforts by health plans to limit costs, includ-
2 ing through benefit design or coverage limitations;
3 (4) how prices change in the first few years fol-
4 lowing a new drug's launch; and
5 (5) recommendations manufacturers, health
6 plans, and other experts have for alternative ap-
7 proaches to establishing new drug prices and the
8 benefits and challenges associated with such alter-
9 native approaches.

10 **SEC. 5. REVENUES COLLECTED.**

11 There are authorized to be appropriated to the Sec-
12 retary of Health and Human Services such sums as are
13 equal to any increase in revenue to the Treasury by reason
14 of the provisions of this Act or the amendments made by
15 this Act for the purposes of increasing amounts available
16 to the National Institutes of Health for research and de-
17 velopment of drugs.

