

**AMENDMENT TO**  
**RULES COMMITTEE PRINT 116–41**  
**OFFERED BY MR. DOGGETT OF TEXAS**

Add at the end of the bill the following new title  
(and conform the table of contents accordingly):

1 **TITLE IX—ADDITIONAL PROVI-**  
2 **SIONS RELATED TO PRE-**  
3 **SCRIPTION DRUG PRICE**  
4 **SPIKES**

5 **SEC. 901. IDENTIFICATION OF PRESCRIPTION DRUG PRICE**  
6 **SPIKES.**

7 (a) DEFINITIONS.—In this section:

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

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

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

4 (B) with respect to a drug for which there  
5 is no average manufacturer price as so defined,  
6 such term shall mean the wholesale acquisition  
7 cost of the drug.

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

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

14 (5) PRESCRIPTION DRUG.—

15 (A) IN GENERAL.—The term “prescription  
16 drug” means any drug (as defined in section  
17 201(g) of the Federal Food, Drug, and Cos-  
18 metic Act (21 U.S.C. 321(g))), including a com-  
19 bination product whose primary mode of action  
20 is determined under section 503(g) of such Act  
21 (21 U.S.C. 353(g)) to be that of a drug, and  
22 that—

23 (i) is subject to section 503(b)(1) of  
24 the Federal Food, Drug, and Cosmetic Act  
25 (21 U.S.C. 353(b)(1)); and

1 (ii) is covered by a Federal health  
2 care program (as defined in section  
3 1128B(f) of the Social Security Act (42  
4 U.S.C. 1320a–7b(f))).

5 (B) TREATMENT OF REFORMULATED  
6 DRUGS.—For purposes of this section, a pre-  
7 scription drug with respect to which the Sec-  
8 retary of Health and Human Services has ap-  
9 proved any minor reformulation that does not  
10 produce a meaningful therapeutic benefit, the  
11 drug that was approved prior to any such refor-  
12 mulation and the drug with any such reformu-  
13 lation shall be considered one prescription drug.

14 (6) PRICE SPIKE.—

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

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

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

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

4 (C) APPLICABLE PRICE INCREASE ALLOW-  
5 ANCE.—The applicable price increase allowance  
6 for any calendar year is the percentage (round-  
7 ed to the nearest one-tenth of 1 percent) by  
8 which the medical care consumer price index  
9 detailed expenditure category for all urban con-  
10 sumers (United States city average) for that  
11 year exceed such index for the preceding cal-  
12 endar year.

13 (7) PRICE SPIKE REVENUE.—

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

16 (i) the gross price spike revenue,  
17 minus

18 (ii) the adjustment amount.

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

22 (i) an amount equal to the difference  
23 between clause (i) of paragraph (6)(B) and  
24 clause (ii) of such paragraph; and

1 (ii) the total number of units of the  
2 prescription drug which were sold in com-  
3 merce in such calendar year.

4 (C) ADJUSTMENT AMOUNT.—The adjust-  
5 ment amount is the amount, if any, of the gross  
6 price spike revenue which the Inspector General  
7 has determined is due solely to an increase in  
8 the cost of the inputs necessary to manufacture  
9 the prescription drug subject to the price spike.

10 (b) SUBMISSION BY PHARMACEUTICAL COMPANIES  
11 OF INFORMATION TO INSPECTOR GENERAL.—

12 (1) IN GENERAL.—For each prescription drug,  
13 the applicable entity shall submit to the Inspector  
14 General a quarterly report that includes the fol-  
15 lowing:

16 (A) For each prescription drug of the ap-  
17 plicable entity—

18 (i) the total number of units of the  
19 prescription drug which were sold in com-  
20 merce in the preceding calendar quarter;

21 (ii) the average and median price per  
22 unit of such prescription drug in commerce  
23 in the preceding calendar quarter,  
24 disaggregated by month; and

1 (iii) the gross revenues from sales of  
2 such prescription drug in commerce in the  
3 preceding calendar quarter.

4 (B) Such information related to increased  
5 input costs or public health considerations as  
6 the applicable entity may wish the Inspector  
7 General to consider in making a determination  
8 under clause (ii) of subsection (c)(2)(B) or an  
9 assessment in clause (iii) of such subsection for  
10 the preceding calendar quarter.

11 (C) Such information related to any antici-  
12 pated increased input costs for the subsequent  
13 calendar quarter as the applicable entity may  
14 wish the Inspector General to consider in mak-  
15 ing a determination under clause (ii) of sub-  
16 section (c)(2)(B) or an assessment in clause  
17 (iii) of such subsection for such calendar quar-  
18 ter.

19 (2) PENALTY FOR FAILURE TO SUBMIT.—

20 (A) IN GENERAL.—An applicable entity de-  
21 scribed in paragraph (1) that fails to submit in-  
22 formation to the Inspector General regarding a  
23 prescription drug, as required by such para-  
24 graph, before the date specified in paragraph

1 (3) shall be liable for a civil penalty, as deter-  
2 mined under subparagraph (B).

3 (B) AMOUNT OF PENALTY.—The amount  
4 of the civil penalty shall be equal to the product  
5 of—

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

8 (I) not less than 0.5 percent of  
9 the gross revenues from sales of the  
10 prescription drug described in sub-  
11 paragraph (A) for the preceding cal-  
12 endar year, and

13 (II) not greater than 1 percent of  
14 the gross revenues from sales of such  
15 prescription drug for the preceding  
16 calendar year, and

17 (ii) the number of days in the period  
18 between—

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

21 (II) the date on which the In-  
22 spector General receives the informa-  
23 tion described in paragraph (1) from  
24 the applicable entity.

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

5           (c) ASSESSMENT BY INSPECTOR GENERAL.—

6           (1) IN GENERAL.—Not later than the last day  
7           in February of each year, the Inspector General, in  
8           consultation with other relevant Federal agencies  
9           (including the Federal Trade Commission), shall—

10           (A) complete an assessment of the infor-  
11           mation the Inspector General received pursuant  
12           to subsection (b)(1) with respect to sales of pre-  
13           scription drugs in the preceding calendar year;  
14           and

15           (B) in the case of any prescription drug  
16           which satisfies the conditions described in para-  
17           graph (1) or (2) of subsection (d), submit a rec-  
18           ommendation to the Secretary of Health and  
19           Human Services that such drug be exempted  
20           from application of the tax imposed under sec-  
21           tion 4192 of the Internal Revenue Code of 1986  
22           (as added by section 3 of this Act) for such  
23           year.

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



1 (A) Identification of each price spike relat-  
2 ing to a prescription drug in the preceding cal-  
3 endar year.

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

6 (i) a determination of the price spike  
7 revenue;

8 (ii) a determination regarding the ac-  
9 curacy of the information submitted by the  
10 applicable entity regarding increased input  
11 costs; and

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

14 (d) EXEMPTION OF CERTAIN DRUGS.—

15 (1) IN GENERAL.—The Secretary of Health and  
16 Human Services, upon recommendation of the In-  
17 spector General pursuant to subsection (e)(1)(B),  
18 may exempt any prescription drug which has been  
19 subject to a price spike during the preceding cal-  
20 endar year from application of the tax imposed  
21 under section 4192 of the Internal Revenue Code of  
22 1986 for such year, if the Secretary determines  
23 that—

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

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

8 (ii) such drug is marketed by not less  
9 than 3 other holders of applications ap-  
10 proved under subsection (c) or (j) of sec-  
11 tion 505 of the Federal Food, Drug, and  
12 Cosmetic Act (21 U.S.C. 355), where such  
13 applications approved under such sub-  
14 section (j) use as a reference drug the drug  
15 so approved under such subsection (c).

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

19 (A) has the discretion to determine that  
20 such information does not warrant a for-cause  
21 price increase exemption; and

22 (B) shall exclude from such consideration  
23 any information submitted by the applicable en-  
24 tity threatening to curtail or limit production of  
25 the prescription drug if the Secretary does not

1 grant an exemption from the application of the  
2 tax under section 4192 of the Internal Revenue  
3 Code of 1986.

4 (e) INSPECTOR GENERAL REPORT TO INTERNAL  
5 REVENUE SERVICE.—

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

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

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

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

23 (C) The price spike revenue determinations  
24 made under subparagraph (B)(i) of such sub-  
25 section.

1 (D) The determinations and assessments  
2 made under clauses (ii) and (iii) of subpara-  
3 graph (B) of such subsection.

4 (3) NOTICE AND OPPORTUNITY FOR HEAR-  
5 ING.—

6 (A) IN GENERAL.—No report shall be  
7 transmitted to the Internal Revenue Service  
8 under paragraph (1) in regards to a prescrip-  
9 tion drug unless the Inspector General has pro-  
10 vided the applicable entity with—

11 (i) the assessment of such drug under  
12 subsection (c)(1)(A); and

13 (ii) notice of their right to a hearing  
14 in regards to such assessment.

15 (B) NOTICE.—The notice required under  
16 subparagraph (A) shall be provided to the ap-  
17 plicable entity not later than 30 days after com-  
18 pletion of the assessment under subsection  
19 (c)(1)(A).

20 (C) REQUEST FOR HEARING.—Subject to  
21 subparagraph (E), an applicable entity may re-  
22 quest a hearing before the Secretary of Health  
23 and Human Services not later than 30 days  
24 after the date on which the notice under sub-  
25 paragraph (B) is received.

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

8 (i) make a final determination in re-  
9 gards the accuracy of such assessment;  
10 and

11 (ii) provide the report described in  
12 paragraph (2) to the Internal Revenue  
13 Service.

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

18 (4) PUBLICATION.—

19 (A) IN GENERAL.—Not later than the last  
20 day in February of each year, subject to sub-  
21 paragraph (B), the Inspector General shall  
22 make the report transmitted under paragraph  
23 (1) available to the public, including on the  
24 Internet website of the Inspector General, sub-  
25 ject to subparagraph (B).

1 (B) PROPRIETARY INFORMATION.—The  
2 Inspector General shall ensure that any infor-  
3 mation made public in accordance with sub-  
4 paragraph (A) excludes trade secrets and con-  
5 fidential commercial information.

6 (f) NOTIFICATION.—The Secretary of the Treasury,  
7 in conjunction with the Inspector General, shall notify, at  
8 such time and in such manner as the Secretary of the  
9 Treasury shall provide, each applicable entity in regard  
10 to any prescription drug which has been determined to  
11 have been subject to a price spike during the preceding  
12 calendar year and the amount of the tax imposed on such  
13 applicable entity pursuant to section 4192 of the Internal  
14 Revenue Code of 1986.

15 **SEC. 902. EXCISE TAX ON PRESCRIPTION DRUGS SUBJECT**  
16 **TO PRICE SPIKES.**

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

20 **“SEC. 4192. PRESCRIPTION DRUGS SUBJECT TO PRICE**  
21 **SPIKES.**

22 “(a) IMPOSITION OF TAX.—

23 “(1) IN GENERAL.—Subject to paragraph (3),  
24 for each taxable prescription drug sold by an appli-  
25 cable entity during the calendar year, there is hereby

1 imposed on such entity a tax equal to the greater  
2 of—

3 “(A) the annual price spike tax for such  
4 prescription drug, or

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

7 “(2) LIMITATION.—In the case of a taxable  
8 prescription drug for which the applicable period (as  
9 determined under subsection (c)(2)(E)(i)) is less  
10 than 2 calendar years, the cumulative price spike tax  
11 shall not apply.

12 “(3) EXEMPTION.—For any calendar year in  
13 which the Secretary of Health and Human Services  
14 has provided an exemption for a taxable prescription  
15 drug pursuant to section 601(d) of the Lower Drug  
16 Costs Now Act of 2019, the amount of the tax de-  
17 termined under paragraph (1) for such drug or de-  
18 vice for such calendar year shall be reduced to zero.

19 “(b) ANNUAL PRICE SPIKE TAX.—

20 “(1) IN GENERAL.—The amount of the annual  
21 price spike tax shall be equal to the applicable per-  
22 centage of the price spike revenue received by the  
23 applicable entity on the sale of the taxable prescrip-  
24 tion drug during the calendar year.

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

4           “(A) in the case of a taxable prescription  
5 drug which has been subject to a price spike  
6 percentage greater than the applicable price in-  
7 crease allowance (as defined in section  
8 601(a)(6)(C) of the Lower Drug Costs Now Act  
9 of 2019) but less than 15 percent, 50 percent,

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

14           “(C) in the case of a taxable prescription  
15 drug which has been subject to a price spike  
16 percentage equal to or greater than 20 percent,  
17 100 percent.

18           “(c) CUMULATIVE PRICE SPIKE TAX.—

19           “(1) IN GENERAL.—The amount of the cumu-  
20 lative price spike tax shall be equal to the applicable  
21 percentage of the cumulative price spike revenue re-  
22 ceived by the applicable entity on the sale of the tax-  
23 able prescription drug during the calendar year.

24           “(2) APPLICABLE PERCENTAGE.—



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

4           “(i) in the case of a taxable prescrip-  
5 tion drug which has been subject to a cu-  
6 mulative price spike percentage greater  
7 than the cumulative price increase allow-  
8 ance but less than the first compounded  
9 percentage, 50 percent,

10           “(ii) in the case of a taxable prescrip-  
11 tion drug which has been subject to a cu-  
12 mulative price spike percentage equal to or  
13 greater than the first compounded percent-  
14 age but less than the second compounded  
15 percentage, 75 percent, and

16           “(iii) in the case of a taxable prescrip-  
17 tion drug which has been subject to a cu-  
18 mulative price spike percentage equal to or  
19 greater than the second compounded per-  
20 centage, 100 percent.

21           “(B) CUMULATIVE PRICE SPIKE PERCENT-  
22 AGE.—The cumulative price spike percentage is  
23 the percentage (if any) by which—

1                   “(i) the average manufacturer price of  
2                   the taxable prescription drug in commerce  
3                   for the preceding calendar year, exceeds

4                   “(ii) the average manufacturer price  
5                   of such prescription drug in commerce for  
6                   the base year.

7                   “(C) CUMULATIVE PRICE INCREASE AL-  
8                   LOWANCE.—For purposes of clause (i) of sub-  
9                   paragraph (A), the cumulative price increase al-  
10                  lowance for any calendar year is the percentage  
11                  (rounded to the nearest one-tenth of 1 percent)  
12                  by which the medical care consumer price index  
13                  detailed expenditure category for all urban con-  
14                  sumers (United States city average) for that  
15                  year exceeds such index for the preceding cal-  
16                  endar year.

17                  “(D) COMPOUNDED PERCENTAGES.—For  
18                  purposes of subparagraph (A), the first com-  
19                  pounded percentage and second compounded  
20                  percentage shall be determined in accordance  
21                  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.

1                   “(E) APPLICABLE PERIOD AND BASE  
2                   YEAR.—

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

5                   “(I) the 5 preceding calendar  
6                   years,

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

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

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

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

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

21                  “(i) an amount (not less than zero)  
22                  equal to—

23                  “(I) the average manufacturer  
24                  price of such prescription drug in

1 commerce for the preceding calendar  
2 year, minus

3 “(II) the average manufacturer  
4 price of such prescription drug in  
5 commerce for the base year, and

6 “(ii) the total number of units of such  
7 prescription drug which were sold in com-  
8 merce in the preceding calendar year,  
9 minus

10 “(B) an amount equal to the sum of the  
11 adjustment amounts, if any, determined under  
12 section 601(a)(7)(C) of the Lower Drug Costs  
13 Now Act of 2019 for each calendar year during  
14 the applicable period.

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

16 “(1) TAXABLE PRESCRIPTION DRUG.—The  
17 term ‘taxable prescription drug’ means a prescrip-  
18 tion drug (as defined in section 601(a)(5) of the  
19 Lower Drug Costs Now Act of 2019) which has been  
20 identified by the Inspector General of the Depart-  
21 ment of Health and Human Services, under section  
22 2(c)(2)(A) of such Act, as being subject to a price  
23 spike.

24 “(2) OTHER TERMS.—The terms ‘applicable en-  
25 tity’, ‘average manufacturer price’, ‘price spike’,

1 ‘price spike percentage’, and ‘price spike revenue’  
2 have the same meaning given such terms under sec-  
3 tion 601(a) of the Lower Drug Costs Now Act of  
4 2019.’”.

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 “Certain  
9 Medical Devices And Prescription Drugs”.

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:

14 “SUBCHAPTER E. CERTAIN MEDICAL DE-  
15 VICES AND PRESCRIPTION DRUGS”.”.

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

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

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

22 **SEC. 903. STUDY ON MONOPOLY MEDICAL PRODUCTS.**

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

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

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

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

16          (c) **FACTORS.**—In conducting the study described in  
17          subsection (a), the Comptroller General shall consider—

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

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

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

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

3           (5) recommendations manufacturers, health  
4           plans, and other experts have for alternative ap-  
5           proaches to establishing new drug prices and the  
6           benefits and challenges associated with such alter-  
7           native approaches.

8   **SEC. 904. REVENUES COLLECTED.**

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

