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):

TITLE IX—ADDITIONAL PROVISIONS RELATED TO PRESCRIPTION DRUG PRICE SPIKES

SEC. 901. IDENTIFICATION OF PRESCRIPTION DRUG PRICE SPIKES.

(a) DEFINITIONS.—In this section:

(1) APPLICABLE ENTITY.—The term ''applicable entity'' means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or of a license issued under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a drug described in paragraph (5)(A).

(2) AVERAGE MANUFACTURER PRICE.—The term ''average manufacturer price''—

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

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

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

(4) INSPECTOR GENERAL.—The term ''Inspector General'' means the Inspector General of the Department of Health and Human Services.

(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.—

(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 which the medical care consumer price index detailed expenditure category for all urban consumers (United States city average) for that year exceed such index for the preceding calendar year.

(7) PRICE SPIKE REVENUE.—

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

(i) the gross price spike revenue, minus

(ii) the adjustment amount.

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

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

(ii) the total number of units of the prescription drug which were sold in commerce in such calendar year.

(C) ADJUSTMENT AMOUNT.—The adjustment amount is the amount, if any, of the gross price spike revenue which the Inspector General has determined is due solely to an increase in the cost of the inputs necessary to manufacture the prescription drug subject to the price spike.

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

(1) IN GENERAL.—For each prescription drug, the applicable entity shall submit to the Inspector General a quarterly report that includes the following:

(A) For each prescription drug of the applicable entity—

(i) the total number of units of the prescription drug which were sold in commerce in the preceding calendar quarter;

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

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

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

(C) Such information related to any anticipated increased input costs for the subsequent calendar quarter as the applicable entity may wish the Inspector General to consider in making a determination under clause (ii) of subsection (c)(2)(B) or an assessment in clause (iii) of such subsection for such calendar quarter.

(2) PENALTY FOR FAILURE TO SUBMIT.—

(A) IN GENERAL.—An applicable entity described in paragraph (1) that fails to submit information to the Inspector General regarding a prescription drug, as required by such paragraph, before the date specified in paragraph

(3) shall be liable for a civil penalty, as determined under subparagraph (B).

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

(i) an amount, as determined appropriate by the Inspector General, which is—

(I) not less than 0.5 percent of the gross revenues from sales of the prescription drug described in subparagraph (A) for the preceding calendar year, and

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

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

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

(II) the date on which the Inspector General receives the information described in paragraph (1) from the applicable entity.

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

(c) ASSESSMENT BY INSPECTOR GENERAL.—

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

(A) complete an assessment of the information the Inspector General received pursuant to subsection (b)(1) with respect to sales of prescription drugs in the preceding calendar year; and

(B) in the case of any prescription drug which satisfies the conditions described in paragraph (1) or (2) of subsection (d), submit a recommendation 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), may exempt any prescription drug which has been subject to a price spike during the preceding calendar year from application of the tax imposed under section 4192 of the Internal Revenue Code of 1986 for such year, if the Secretary determines that—

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

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

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

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

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

(B) shall exclude from such consideration any information submitted by the applicable entity threatening to curtail or limit production of the prescription drug if the Secretary does not

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

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

(1) IN GENERAL.—Subject to paragraph (3), not later than the last day in February of each year, the Inspector General shall transmit to the Internal Revenue Service a report on the findings of the Inspector General with respect to the information the Inspector General received under subsection (b)(1) with respect to the preceding calendar year and the assessment carried out by the Inspector General under subsection (c)(1)(A) with respect to such information.

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

(A) The information received under subsection (b)(1) with respect to the preceding calendar year.

(B) The price spikes identified under subparagraph (A) of subsection (c)(2).

(C) The price spike revenue determinations made under subparagraph (B)(i) of such subsection.

(D) The determinations and assessments made under clauses (ii) and (iii) of subparagraph (B) of such subsection.

(3) NOTICE AND OPPORTUNITY FOR HEARING.—

(A) IN GENERAL.—No report shall be transmitted to the Internal Revenue Service under paragraph (1) in regards to a prescription drug unless the Inspector General has provided the applicable entity with—

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

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

(B) NOTICE.—The notice required under subparagraph (A) shall be provided to the applicable entity not later than 30 days after completion of the assessment under subsection (c)(1)(A).

(C) REQUEST FOR HEARING.—Subject to subparagraph (E), an applicable entity may request a hearing before the Secretary of Health and Human Services not later than 30 days after the date on which the notice under subparagraph (B) is received.

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

(i) make a final determination in regards the accuracy of such assessment; and

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

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

(4) PUBLICATION.—

(A) IN GENERAL.—Not later than the last day in February of each year, subject to subparagraph (B), the Inspector General shall make the report transmitted under paragraph (1) available to the public, including on the Internet website of the Inspector General, subject to subparagraph (B).

(B) PROPRIETARY INFORMATION.—The Inspector General shall ensure that any information made public in accordance with subparagraph (A) excludes trade secrets and confidential commercial information.

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

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

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

"SEC. 4192. PRESCRIPTION DRUGS SUBJECT TO PRICE SPIKES.

''(a) IMPOSITION OF TAX.—

''(1) IN GENERAL.—Subject to paragraph (3), for each taxable prescription drug sold by an applicable entity during the calendar year, there is hereby

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

''(A) the annual price spike tax for such prescription drug, or

''(B) subject to paragraph (2), the cumulative price spike tax for such prescription drug.

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

''(3) EXEMPTION.—For any calendar year in which the Secretary of Health and Human Services has provided an exemption for a taxable prescription drug pursuant to section 601(d) of the Lower Drug Costs Now Act of 2019, the amount of the tax determined under paragraph (1) for such drug or device for such calendar year shall be reduced to zero.

''(b) ANNUAL PRICE SPIKE TAX.—

''(1) IN GENERAL.—The amount of the annual price spike tax shall be equal to the applicable percentage of the price spike revenue received by the applicable entity on the sale of the taxable prescription drug during the calendar year.

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

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

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

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

''(c) CUMULATIVE PRICE SPIKE TAX.—

''(1) IN GENERAL.—The amount of the cumulative price spike tax shall be equal to the applicable percentage of the cumulative price spike revenue received by the applicable entity on the sale of the taxable prescription drug during the calendar year.

''(2) APPLICABLE PERCENTAGE.—

"(A) IN GENERAL.—For purposes of paragraph (1), the applicable percentage shall be equal to—

"(i) in the case of a taxable prescription drug which has been subject to a cumulative price spike percentage greater than the cumulative price increase allowance but less than the first compounded percentage, 50 percent,

"(ii) in the case of a taxable prescription drug which has been subject to a cumulative price spike percentage equal to or greater than the first compounded percentage but less than the second compounded percentage, 75 percent, and

"(iii) in the case of a taxable prescription drug which has been subject to a cumulative price spike percentage equal to or greater than the second compounded percentage, 100 percent.

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

''(i) the average manufacturer price of the taxable prescription drug in commerce for the preceding calendar year, exceeds

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

''(C) CUMULATIVE PRICE INCREASE ALLOWANCE.—For purposes of clause (i) of subparagraph (A), the cumulative price increase allowance for any calendar year is the percentage (rounded to the nearest one-tenth of 1 percent) by which the medical care consumer price index detailed expenditure category for all urban consumers (United States city average) for that year exceeds such index for the preceding calendar year.

''(D) COMPOUNDED PERCENTAGES.—For purposes of subparagraph (A), the first compounded percentage and second compounded percentage shall be determined in accordance with the following table:

''Number of years in applicable period	First compounded percentage	Second compounded 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.

''(E) APPLICABLE PERIOD AND BASE YEAR.—

''(i) APPLICABLE PERIOD.—The applicable period shall be the lesser of—

''(I) the 5 preceding calendar years,

''(II) all calendar years beginning after the date of enactment of this section, or

''(III) all calendar years in which the taxable prescription drug was sold in commerce.

''(ii) BASE YEAR.—The base year shall be the calendar year immediately preceding the applicable period.

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

''(A) an amount equal to the product of—

''(i) an amount (not less than zero) equal to—

''(I) the average manufacturer price of such prescription drug in

commerce for the preceding calendar year, minus

''(II) the average manufacturer price of such prescription drug in commerce for the base year, and

''(ii) the total number of units of such prescription drug which were sold in commerce in the preceding calendar year, minus

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

''(d) DEFINITIONS.—For purposes of this section—

''(1) TAXABLE PRESCRIPTION DRUG.—The term 'taxable prescription drug' means a prescription drug (as defined in section 601(a)(5) of the Lower Drug Costs Now Act of 2019) which has been identified by the Inspector General of the Department of Health and Human Services, under section 2(c)(2)(A) of such Act, as being subject to a price spike.

''(2) OTHER TERMS.—The terms 'applicable entity', 'average manufacturer price', 'price spike',

'price spike percentage', and 'price spike revenue' have the same meaning given such terms under section 601(a) of the Lower Drug Costs Now Act of 2019.' ''.

(b) CLERICAL AMENDMENTS.—

(1) The heading of subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by striking ''Medical Devices'' and inserting ''Certain Medical Devices And Prescription Drugs''.

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

''SUBCHAPTER E. CERTAIN MEDICAL DEVICES AND PRESCRIPTION DRUGS''.''.

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

''Sec. 4192. Prescription drugs subject to price spikes.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after the date of the enactment of this Act.

SEC. 903. STUDY ON MONOPOLY MEDICAL PRODUCTS.

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

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

(2) alternative methods that have been proposed for setting the price of new drugs.

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

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

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

(2) how initial pricing decisions by drug manufacturers and health plans affect costs and use of services for patients and public programs such as the Medicare and Medicaid programs;

(3) efforts by health plans to limit costs, including through benefit design or coverage limitations;

(4) how prices change in the first few years following a new drug's launch; and

(5) recommendations manufacturers, health plans, and other experts have for alternative approaches to establishing new drug prices and the benefits and challenges associated with such alternative approaches.

SEC. 904. REVENUES COLLECTED.

There are authorized to be appropriated to the Secretary of Health and Human Services such sums as are equal to any increase in revenue to the Treasury by reason of the provisions of this Act or the amendments made by this Act for the purposes of increasing amounts available to the National Institutes of Health for research and development of drugs.

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