116TH CONGRESS
1ST SESSION

S. 474

To amend title XI of the Social Security Act to require drug manufacturers to publicly justify unnecessary price increases.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 13, 2019

Mr. WYDEN (for himself, Mr. CARDIN, Mr. CARPER, Mr. COONS, Ms. DUCKWORTH, Ms. KLOBUCHAR, Mr. MENENDEZ, Ms. STABENOW, and Mr. TESTER) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XI of the Social Security Act to require drug manufacturers to publicly justify unnecessary price increases.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Stopping the Pharmaceutical Industry from Keeping drugs Expensive (SPIKE) Act of 2019''.

SEC. 2. DRUG MANUFACTURER PRICE TRANSPARENCY.

Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128K the following new section:

"SEC. 1128L. DRUG MANUFACTURER PRICE TRANSPARENCY.

"(a) IN GENERAL.—Effective beginning on July 1, 2019, subject to subsection (e), the Secretary shall require a manufacturer of an applicable drug to submit to the Secretary the justification described in subsection (c) in accordance with the timing described in subsection (d).

"(b) DEFINITIONS.—In this section:

"(1) APPLICABLE DRUG.—Subject to paragraph (2), the term 'applicable drug' means a drug, as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)), that is subject to section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)), and that the Secretary determines is described in either of the following subparagraphs:

"(A) The drug (per dose)—

"(i) has a wholesale acquisition cost of at least $10 dollars; and

"(ii) had an increase in the wholesale acquisition cost of the drug, with respect to determinations made—

''(I) during 2020, of at least 100 percent since the date of the enactment of this section;

''(II) during 2021, of at least 100 percent in the preceding 12 months or of at least 150 percent in the preceding 2 years;

''(III) during 2022, of at least 100 percent in the preceding 12 months or of at least 200 percent in the preceding 3 years;

''(IV) during 2023, of at least 100 percent in the preceding 12 months or of at least 250 percent in the preceding 4 years; or

''(V) on or after January 1, 2024, of at least 100 percent in the preceding 12 months or of at least 300 percent in the preceding 5 years.

''(B) The drug (per dose)—

''(i) is in the top 50th percentile of net spending under title XVIII or XIX in at least one of the preceding 5 years; and

"(ii) had an increase in the wholesale acquisition cost of the drug, with respect to determinations made—

"(I) during 2020, of at least 15 percent since the date of the enactment of this section;

"(II) during 2021, of at least 15 percent in the preceding 12 months or of at least 20 percent in the preceding 2 years;

"(III) during 2022, of at least 15 percent in the preceding 12 months or of at least 30 percent in the preceding 3 years;

"(IV) during 2023, of at least 15 percent in the preceding 12 months or of at least 40 percent in the preceding 4 years; or

"(V) on or after January 1, 2024, of at least 15 percent in the preceding 12 months or of at least 50 percent in the preceding 5 years.

"(2) SPECIAL RULE.—For purposes of applying paragraph (1), the Secretary may substitute for each percentage described in subparagraph (A) or (B) of

such paragraph (other than the percentile described subparagraph (B)(i) of such paragraph) a percentage within a de minimis range specified by the Secretary below the percentage so described.

''(3) MANUFACTURER.—The term 'manufacturer' has the meaning given that term in section 581(10) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee(10)).

''(4) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given that term in section 1847A(c)(6)(B).

''(c) JUSTIFICATION DESCRIBED.—The justification described in this subsection is all relevant information and supporting documentation necessary to justify the increase in the wholesale acquisition cost of the applicable drug of the manufacturer, which may include the following:

''(1) The individual factors that have contributed to the increase in the wholesale acquisition cost.

''(2) An explanation of the role of each factor in contributing to such increase.

''(3) Total expenditures of the manufacturer on—

''(A) materials and manufacturing for such drug;

''(B) acquiring patents and licensing for each drug of the manufacturer; and

''(C) costs to purchase or acquire the drug from another company, if applicable.

''(4) The percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds.

''(5) The total expenditures of the manufacturer on research and development for such drug.

''(6) The total revenue and net profit generated from the applicable drug for each calendar year since drug approval.

''(7) The total costs associated with marketing and advertising for the applicable drug.

''(8) Additional information specific to the manufacturer of the applicable drug, such as—

''(A) the total revenue and net profit of the manufacturer for the period of such increase, as determined by the Secretary;

''(B) metrics used to determine executive compensation;

''(C) any additional information related to drug pricing decisions of the manufacturer, such as total expenditures on—

"(i) drug research and development; or

"(ii) clinical trials on drugs that failed to receive approval by the Food and Drug Administration.

"(d) TIMING.—

"(1) NOTIFICATION.—Not later than 60 days after the date on which the Secretary makes the determination that a drug is an applicable drug under subsection (b), the Secretary shall notify the manufacturer of the applicable drug of such determination.

"(2) SUBMISSION OF JUSTIFICATION.—Not later than 180 days after the date on which a manufacturer receives a notification under paragraph (1), the manufacturer shall submit to the Secretary the justification required under subsection (a).

"(3) POSTING ON INTERNET WEBSITE.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 30 days after receiving the justification under paragraph (2), the Secretary shall post on the internet website of the Centers for Medicare & Medicaid Services the justification, together with a summary of such justification that is written and formatted

using language that is easily understandable by beneficiaries under titles XVIII and XIX.

''(B) EXCEPTION.—The Secretary shall establish a process under which a manufacturer of an applicable drug may submit a request to the Secretary that certain proprietary information disclosed as part of justification in subsection (c) be excluded from the posting described in subparagraph (A) if, as determined by the Secretary (in consultation with the Inspector General of the Department of Health and Human Services), the public disclosure of such information would directly lead to increased prices of prescription drugs. If proprietary information is excluded from the posting pursuant to the preceding sentence, to the extent feasible, the summary of the information described in subparagraph (A) shall include a summary of such proprietary information.

''(e) EXCEPTION TO REQUIREMENT FOR SUBMISSION.—The requirement to submit a justification under subsection (a) shall not apply in the case where the manufacturer, after receiving the notification under subsection (d)(1) with respect to an applicable drug of the manufacturer, reduces the wholesale acquisition cost of a drug so

that it no longer meets the definition of an applicable drug under subsection (b) for at least a 6-month period, as determined by the Secretary.

''(f) PENALTIES.—The provisions of subsection (b)(3)(C) of section 1927 shall apply to a manufacturer that fails to submit the justification required under subsection (a) on a timely basis or that knowingly provides false information in the same manner as such provisions apply to a manufacturer with an agreement under that section.''.

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