

116TH CONGRESS
1ST SESSION

S. _____

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

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 _____

A BILL

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

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 “Stopping the Pharma-
5 ceutical Industry from Keeping Drugs Expensive (SPIKE)
6 Act of 2019”.

1 **SEC. 2. DRUG MANUFACTURER PRICE TRANSPARENCY.**

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

5 **“SEC. 1128I. DRUG MANUFACTURER PRICE TRANSPARENCY.**

6 “(a) IN GENERAL.—Effective beginning on July 1,
7 2019, subject to subsection (e), the Secretary shall require
8 a manufacturer of an applicable drug to submit to the Sec-
9 retary the justification described in subsection (c) in ac-
10 cordance with the timing described in subsection (d).

11 “(b) DEFINITIONS.—In this section:

12 “(1) APPLICABLE DRUG.—Subject to paragraph
13 (2), the term ‘applicable drug’ means a drug, as de-
14 fined in section 201(g) of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 321(g)), that is sub-
16 ject to section 503(b)(1) of such Act (21 U.S.C.
17 353(b)(1)), and that the Secretary determines is de-
18 scribed in either of the following subparagraphs:

19 “(A) The drug (per dose)—

20 “(i) has a wholesale acquisition cost of
21 at least \$10 dollars; and

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

1 “(I) during 2020, of at least 100
2 percent since the date of the enact-
3 ment of this section;

4 “(II) during 2021, of at least
5 100 percent in the preceding 12
6 months or of at least 150 percent in
7 the preceding 2 years;

8 “(III) during 2022, of at least
9 100 percent in the preceding 12
10 months or of at least 200 percent in
11 the preceding 3 years;

12 “(IV) during 2023, of at least
13 100 percent in the preceding 12
14 months or of at least 250 percent in
15 the preceding 4 years; or

16 “(V) on or after January 1,
17 2024, of at least 100 percent in the
18 preceding 12 months or of at least
19 300 percent in the preceding 5 years.

20 “(B) The drug (per dose)—

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

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

4 “(I) during 2020, of at least 15
5 percent since the date of the enact-
6 ment of this section;

7 “(II) during 2021, of at least 15
8 percent in the preceding 12 months or
9 of at least 20 percent in the preceding
10 2 years;

11 “(III) during 2022, of at least 15
12 percent in the preceding 12 months or
13 of at least 30 percent in the preceding
14 3 years;

15 “(IV) during 2023, of at least 15
16 percent in the preceding 12 months or
17 of at least 40 percent in the preceding
18 4 years; or

19 “(V) on or after January 1,
20 2024, of at least 15 percent in the
21 preceding 12 months or of at least 50
22 percent in the preceding 5 years.

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

1 such paragraph (other than the percentile described
2 subparagraph (B)(i) of such paragraph) a percent-
3 age within a de minimis range specified by the Sec-
4 retary below the percentage so described.

5 “(3) MANUFACTURER.—The term ‘manufac-
6 turer’ has the meaning given that term in section
7 581(10) of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 360eee(10)).

9 “(4) WHOLESALE ACQUISITION COST.—The
10 term ‘wholesale acquisition cost’ has the meaning
11 given that term in section 1847A(c)(6)(B).

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

17 “(1) The individual factors that have contrib-
18 uted to the increase in the wholesale acquisition
19 cost.

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

22 “(3) Total expenditures of the manufacturer
23 on—

24 “(A) materials and manufacturing for such
25 drug;

1 “(B) acquiring patents and licensing for
2 each drug of the manufacturer; and

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

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

8 “(5) The total expenditures of the manufac-
9 turer on research and development for such drug.

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

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

15 “(8) Additional information specific to the man-
16 ufacturer of the applicable drug, such as—

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

20 “(B) metrics used to determine executive
21 compensation;

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

1 “(i) drug research and development;

2 or

3 “(ii) clinical trials on drugs that failed
4 to receive approval by the Food and Drug
5 Administration.

6 “(d) TIMING.—

7 “(1) NOTIFICATION.—Not later than 60 days
8 after the date on which the Secretary makes the de-
9 termination that a drug is an applicable drug under
10 subsection (b), the Secretary shall notify the manu-
11 facturer of the applicable drug of such determina-
12 tion.

13 “(2) SUBMISSION OF JUSTIFICATION.—Not
14 later than 180 days after the date on which a manu-
15 facturer receives a notification under paragraph (1),
16 the manufacturer shall submit to the Secretary the
17 justification required under subsection (a).

18 “(3) POSTING ON INTERNET WEBSITE.—

19 “(A) IN GENERAL.—Subject to subpara-
20 graph (B), not later than 30 days after receiv-
21 ing the justification under paragraph (2), the
22 Secretary shall post on the Internet website of
23 the Centers for Medicare & Medicaid Services
24 the justification, together with a summary of
25 such justification that is written and formatted

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

3 “(B) EXCEPTION.—The Secretary shall es-
4 tablish a process under which a manufacturer
5 of an applicable drug may submit a request to
6 the Secretary that certain proprietary informa-
7 tion disclosed as part of justification in sub-
8 section (c) be excluded from the posting de-
9 scribed in subparagraph (A) if, as determined
10 by the Secretary (in consultation with the In-
11 spector General of the Department of Health
12 and Human Services), the public disclosure of
13 such information would directly lead to in-
14 creased prices of prescription drugs. If propri-
15 etary information is excluded from the posting
16 pursuant to the preceding sentence, to the ex-
17 tent feasible, the summary of the information
18 described in subparagraph (A) shall include a
19 summary of such proprietary information.

20 “(e) EXCEPTION TO REQUIREMENT FOR SUBMIS-
21 SION.—The requirement to submit a justification under
22 subsection (a) shall not apply in the case where the manu-
23 facturer, after receiving the notification under subsection
24 (d)(1) with respect to an applicable drug of the manufac-
25 turer, reduces the wholesale acquisition cost of a drug so

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

4 “(f) PENALTIES.—The provisions of subsection
5 (b)(3)(C) of section 1927 shall apply to a manufacturer
6 that fails to submit the justification required under sub-
7 section (a) on a timely basis or that knowingly provides
8 false information in the same manner as such provisions
9 apply to a manufacturer with an agreement under that
10 section.”.