

118TH CONGRESS
1ST SESSION

S. 1218

To require that the retail list price for certain prescription drugs and biological products may not exceed the average retail list price for the drug or biological product among certain nations.

IN THE SENATE OF THE UNITED STATES

APRIL 19, 2023

Mr. HAWLEY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To require that the retail list price for certain prescription drugs and biological products may not exceed the average retail list price for the drug or biological product among certain nations.

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 “Fair Prescription Drug
5 Prices for Americans Act”.

1 **SEC. 2. INTERNATIONAL REFERENCE PRICING FOR PRE-**
2 **SCRIPTION DRUGS AND BIOLOGICAL PROD-**
3 **UCTS.**

4 (a) DEFINITIONS.—In this section:

5 (1) BIOLOGICAL PRODUCT.—The term “biologi-
6 cal product” means a biological product licensed
7 under subsection (a) or (k) of section 351 of the
8 Public Health Service Act (42 U.S.C. 262).

9 (2) DRUG.—The term “drug” means a drug 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).

13 (3) SECRETARY.—The term “Secretary” means
14 the Secretary of Health and Human Services.

15 (b) CAP ON RETAIL LIST PRICE OF PRESCRIPTION
16 DRUGS AND BIOLOGICAL PRODUCTS.—The retail list
17 price in the United States for a drug or a biological prod-
18 uct may not exceed the average retail list price for the
19 drug or biological product among Canada, France, Ger-
20 many, Italy, Japan, and the United Kingdom, as cal-
21 culated under subsection (c).

22 (c) CALCULATION OF AVERAGE RETAIL LIST
23 PRICE.—The Secretary shall calculate on an annual basis
24 the average retail list price for each drug and biological
25 product sold in Canada, France, Germany, Italy, Japan,
26 and the United Kingdom, through a combination of data

1 reported by manufacturers of drugs and biological prod-
2 ucts under subsection (e) and data obtained through re-
3 view of publicly filed materials by manufacturers of drugs
4 and biological products in such countries.

5 (d) CIVIL MONETARY PENALTY.—

6 (1) IN GENERAL.—Any manufacturer that vio-
7 lates subsection (b) with respect to a drug or biologi-
8 cal product shall be subject to a civil monetary pen-
9 alty imposed by the Secretary in amount equal to
10 the product obtained by multiplying—

11 (A) the difference between—

12 (i) the list price for the drug or bio-
13 logical product sold in the United States;
14 and

15 (ii) the average retail list price for the
16 drug or biological product sold in Canada,
17 France, Germany, Italy, Japan, and the
18 United Kingdom, as calculated under sub-
19 section (c); and

20 (B) 10.

21 (2) REQUIREMENT.—The amount of a civil
22 monetary penalty under paragraph (1) shall be cal-
23 culated and charged for each unit of drug or biologi-
24 cal product sold.

1 (e) DATA COLLECTION.—Each manufacturer of a
2 drug or biological product shall submit to the Secretary
3 on an annual basis—

4 (1) the list price for the drug or biological prod-
5 uct sold in the United States; and

6 (2) the list price for the drug or biological prod-
7 uct sold in each of Canada, France, Germany, Italy,
8 Japan, and the United Kingdom.

9 (f) GUIDANCE AND REGULATIONS.—The Secretary
10 shall issue guidance and promulgate regulations to imple-
11 ment this section.

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