

116TH CONGRESS
1ST SESSION

H. R. 3523

To require the Secretary of Health and Human Services to establish reference prices for prescription drugs for purposes of Federal health programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 26, 2019

Mr. WELCH (for himself and Mr. ROONEY of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Armed Services, Veterans' Affairs, Oversight and Reform, and Natural Resources, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To require the Secretary of Health and Human Services to establish reference prices for prescription drugs for purposes of Federal health programs, and for other purposes.

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 “End Price Gouging
5 for Medications Act”.

1 **SEC. 2. REFERENCE PRICES FOR PRESCRIPTION DRUGS.**

2 (a) REFERENCE PRICES.—The Secretary of Health
3 and Human Services (referred to in this section as the
4 “Secretary”), in accordance with subsection (b), shall es-
5 tablish annual reference prices for each prescription drug.
6 Notwithstanding any other provision of law, with respect
7 to enrollees or beneficiaries in any of the Federal health
8 programs described in subsection (c), the retail list price
9 for a drug shall not exceed the reference price for such
10 drug.

11 (b) CRITERIA.—

12 (1) IN GENERAL.—Each year, the Secretary
13 shall establish the reference price for each prescrip-
14 tion drug under subsection (a)—

15 (A) by determining the median retail list
16 price for the drug among the reference coun-
17 tries in which the drug is available, if drug pric-
18 ing information is available for at least three of
19 such countries; or

20 (B) in the case of a drug for which drug
21 pricing information or dosage equivalents are
22 not available for at least three of the reference
23 countries, by determining an appropriate price
24 based on the Secretary’s determination of—

25 (i) the added therapeutic effect of the
26 drug;

- 1 (ii) the value of the drug;
- 2 (iii) patient access to the drug;
- 3 (iv) the costs associated with re-
- 4 searching and developing the drug; and
- 5 (v) other factors, as the Secretary de-
- 6 termines appropriate.

7 (2) REFERENCE COUNTRIES.—For purposes of
8 paragraph (1), the reference countries are Japan,
9 Germany, the United Kingdom, France, Italy, Can-
10 ada, Australia, Spain, the Netherlands, Switzerland,
11 and Sweden.

12 (c) FEDERAL HEALTH PROGRAMS.—The reference
13 prices established under subsection (a) shall apply with re-
14 spect to covered inpatient and outpatient drugs under—

15 (1) the Medicare program under title XVIII of
16 the Social Security Act (42 U.S.C. 1395 et seq.);

17 (2) a State Medicaid plan under title XIX of
18 the Social Security Act (42 U.S.C. 1396 et seq.);

19 (3) the State Children’s Health Insurance Pro-
20 gram under title XXI of the Social Security Act (42
21 U.S.C. 1397aa et seq.);

22 (4) the TRICARE program under chapter 55 of
23 title 10, United States Code;

1 (5) hospital care and medical services furnished
2 by the Department of Veterans Affairs under chap-
3 ters 17 and 18 of title 38, United States Code;

4 (6) the Federal Employees Health Benefits
5 Program established under chapter 89 of title 5,
6 United States Code; and

7 (7) any health program, service, function, activ-
8 ity, or facility funded, in whole or part, under the
9 Indian Health Care Improvement Act (25 U.S.C.
10 1601 et seq.), including through direct or contract
11 care provided under such Act or through a contract
12 or compact under the Indian Self-Determination and
13 Education Assistance Act (25 U.S.C. 5304 et seq.).

14 (d) APPLICABILITY TO OTHER PURCHASERS OF
15 DRUGS.—Notwithstanding any other provision of law, a
16 drug manufacturer shall offer prescription drugs at the
17 reference price to all individuals, including individuals who
18 are not insured and individuals who are covered under a
19 group health plan or group or individual health insurance
20 coverage. In the case of individuals covered by a group
21 health plan or group or individual health insurance cov-
22 erage, such requirement is met if the amount covered
23 under such plan or coverage plus the cost-sharing amount
24 does not exceed the reference price.

25 (e) ENFORCEMENT.—

1 (1) CIVIL PENALTY.—A drug manufacturer who
2 does not comply with the requirements of subsection
3 (a) shall be subject to a civil penalty, for each year
4 in which the violation occurs and with respect to
5 each drug for which the violation occurs, in an
6 amount equal to 5 times the difference between—

7 (A) the total amount received by the man-
8 ufacturer for sales of the drug under the Fed-
9 eral health programs under subsection (c) for
10 the year; less

11 (B) the total amount the manufacturer
12 would have received for sales of the drug under
13 such programs for the year if the manufacturer
14 had complied with subsection (a).

15 (2) AMOUNTS COLLECTED.—Each year, the
16 Secretary of the Treasury shall transfer to the Di-
17 rector of the National Institutes of Health an
18 amount equal to the amount collected in civil pen-
19 alties under subsection (e) for the previous year. The
20 Director of the National Institutes of Health shall
21 use amounts so transferred for purposes of con-
22 ducting drug research and development.

23 (f) APPLICABILITY TO BRAND AND GENERIC
24 DRUGS.—The reference price established under subsection
25 (a) shall apply to drugs approved under subsection (c) or

1 (j) of section 505 of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 355) or under subsection (a) or (k)
3 of section 351 of the Public Health Service Act (42 U.S.C.
4 262).

○