

115TH CONGRESS
1ST SESSION

H. R. 3536

To require persons who undertake Federally funded research and development of drugs to enter into reasonable pricing agreements with the Secretary of Health and Human Services.

IN THE HOUSE OF REPRESENTATIVES

JULY 28, 2017

Mr. DEFazio introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To require persons who undertake Federally funded research and development of drugs to enter into reasonable pricing agreements with the Secretary of Health and Human Services.

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. REASONABLE PRICE AGREEMENT.**

4 (a) IN GENERAL.—If any Federal agency or any non-
5 profit entity undertakes Federally funded health care re-
6 search and development and is to convey or provide a pat-
7 ent for a drug, biologic, or other health care technology
8 developed through such research, such agency or entity

1 shall not make such conveyance or provide such patent
2 until the entity (including a nonprofit entity) that will re-
3 ceive such patent first agrees to a reasonable pricing
4 agreement with the Secretary of Health and Human Serv-
5 ices (referred to in this section as the “Secretary”) or the
6 Secretary makes a determination that the public interest
7 is served by a waiver of the reasonable pricing agreement
8 provided in accordance with subsection (c).

9 (b) PROHIBITION OF DISCRIMINATION.—

10 (1) IN GENERAL.—For purposes of subsection
11 (a), any reasonable pricing formula that is utilized
12 shall not result in discriminatory pricing for the
13 drug, biologic, or other health care technology in-
14 volved regardless of the number of bidders involved.
15 In carrying out this subparagraph, the Secretary
16 shall ensure that the Federal Government, with re-
17 spect to the drug, biologic, or other health care tech-
18 nology involved, is charged an amount that is not
19 more than the lowest amount charged to countries in
20 the Organization for Economic Co-Operation and
21 Development for the same drug, biologic, or tech-
22 nology, that have the largest gross domestic product
23 with a per capita income that is not less than half
24 the per capita income of the United States.

1 (2) DISCRIMINATORY PRICING.—For the pur-
2 poses of paragraph (1), a cost based reasonable pric-
3 ing formula that is utilized shall be considered to re-
4 sult in discriminatory pricing if the contract for sale
5 of the drug, biologic, or other health care technology
6 places a limit on supply, or employs any other meas-
7 ure, that has the effect of—

8 (A) providing access to such drug, biologic,
9 or technology on terms or conditions that are
10 less favorable than the terms or conditions pro-
11 vided to a foreign purchaser (other than a char-
12 itable or humanitarian organization) of the
13 drug, biologic, or technology; or

14 (B) restricting access to the drug, biologic,
15 or technology under this section.

16 (c) WAIVER.—No waiver shall take effect under sub-
17 section (a) before the public is given notice of the proposed
18 waiver and provided a reasonable opportunity to comment
19 on the proposed waiver. A decision to grant a waiver shall
20 set out the Secretary’s finding that such a waiver is in
21 the public interest.

○