

117TH CONGRESS
1ST SESSION

H. R. 4991

To require persons who undertake federally funded research and development of a biomedical product or service to enter into reasonable pricing agreements with the Secretary of Health and Human Services, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 10, 2021

Mr. DEFAZIO (for himself, Mr. DOGGETT, Ms. KAPTUR, Mr. COHEN, Ms. SCHAKOWSKY, Mr. POCAN, Mr. KHANNA, and Mr. GRIJALVA) 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 a biomedical product or service to enter into reasonable pricing agreements with the Secretary of Health and Human Services, 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 “Affordable Pricing for
5 Taxpayer-Funded Prescription Drugs Act of 2021”.

1 **SEC. 2. REASONABLE PRICE AGREEMENT.**

2 (a) IN GENERAL.—All Federal agencies providing or
3 receiving research funding, through a grant, contract, co-
4 operative agreement, or other agreement, shall require in
5 such agreement, and in any license of the rights to a pat-
6 ent or regulatory test data for a biomedical product or
7 service, that the price of any biomedical product or service
8 developed with the benefit of such research be reasonable
9 (as determined by the Secretary) unless the Secretary
10 waives such reasonable price obligation under subsection
11 (d).

12 (b) PROHIBITION AGAINST CHARGING PRICES HIGH-
13 ER THAN IN OTHER LARGE ECONOMIES WITH HIGH IN-
14 COMES.—

15 (1) IN GENERAL.—For purposes of subsection
16 (a), any reasonable pricing formula shall ensure,
17 without prejudice to any other standards or nego-
18 tiated provisions for reasonable pricing, that resi-
19 dents of the United States are not charged more for
20 the biomedical product or service involved than the
21 reference price for countries with large economies
22 and high incomes.

23 (2) REFERENCE PRICE.—For purposes of para-
24 graph (1), the phrase “reference price for countries
25 with large economies and high incomes” means—

1 (A) the median price charged for the bio-
2 medical product or service involved in Canada
3 and the additional six reference countries; or

4 (B) a modification to such price that is
5 adopted by regulation after providing notice
6 and the opportunity for the public to comment,
7 if the Secretary determines such modification to
8 be an appropriate and reasonable measure to
9 protect United States residents from paying
10 prices that are higher than prices in other coun-
11 tries with large economies and high incomes.

12 (c) ADDITIONAL REQUIREMENTS.—

13 (1) IN GENERAL.—In carrying out subsection
14 (a), the Secretary may promulgate by regulation ad-
15 ditional requirements to ensure that the price for the
16 biomedical product or service described in subsection
17 (a) be reasonable.

18 (2) REQUIREMENTS.—The additional require-
19 ments under paragraph (1) shall—

20 (A) address the public interest in ensuring
21 that publicly supported innovations for bio-
22 medical products and services have reasonable
23 prices; and

24 (B) take into account—

1 (i) the importance of providing robust
 2 incentives to invest in biomedical research
 3 and development; and

4 (ii) the challenges of administering
 5 agreements described in subsection (a), in-
 6 cluding in cases where third parties control
 7 relevant intellectual property, know-how, or
 8 other assets.

9 (3) POSSIBLE MECHANISMS.—The additional
 10 requirements for reasonable pricing authorized by
 11 paragraph (1) may include—

12 (A) mechanisms to—

13 (i) lower prices or shorten exclusivity
 14 periods when revenues exceed targets;

15 (ii) lower prices that exceed a stand-
 16 ard of cost per health benefit achieved; or

17 (iii) lower prices that constitute sig-
 18 nificant barriers to access or fiscal burdens
 19 on patients; or

20 (B) a combination of mechanisms listed in
 21 subparagraph (A) or other mechanisms.

22 (d) WAIVER.—

23 (1) IN GENERAL.—The Secretary may waive
 24 part or all of a reasonable pricing obligation under
 25 this section upon a demonstration that such a waiver

1 is in the public interest. A decision to grant such a
2 waiver shall set out the Secretary's finding that the
3 waiver is in the public interest.

4 (2) REQUIRED PROCESS.—No waiver under
5 paragraph (1) shall take effect before—

6 (A) the public is given notice of the pro-
7 posed waiver and provided a reasonable oppor-
8 tunity to comment in writing and at a public
9 hearing on the proposed waiver; and

10 (B) the Secretary publishes an economic
11 analysis to justify the waiver.

12 (e) TRANSPARENCY.—

13 (1) REPORTING.—In order to evaluate addi-
14 tional requirements promulgated under subsection
15 (c), agreements subject to subsection (a) shall in-
16 clude a requirement that the manufacturer or other
17 companies commercializing the biomedical product
18 or service involved report to the Secretary in formats
19 determined by the Secretary—

20 (A) the costs of each clinical trial under-
21 taken to support the Federal regulatory ap-
22 proval of the biomedical product or service in-
23 volved;

24 (B) subsidies of those costs by the Federal
25 Government; and

1 (C) the annual revenues generated by the
2 biomedical product or service involved, by coun-
3 ty of sale.

4 (2) PUBLIC AVAILABILITY.—The Secretary
5 shall make all reports under paragraph (1) publicly
6 available.

7 (f) NO EFFECT ON OTHER REQUIREMENTS.—The
8 reasonable pricing requirements imposed under this sec-
9 tion are in addition to any other requirements to limit the
10 price of biomedical products or services, including such re-
11 quirements imposed—

12 (1) through standards or negotiated provisions
13 on pricing in contracts; or

14 (2) under chapter 18 of title 35, United States
15 Code, to make the benefits of inventions funded by
16 the Federal Government available to the public on
17 reasonable terms.

18 (g) DEFINITIONS.—In this section:

19 (1) The term “biomedical product or service”
20 means a drug, vaccine, medical device, diagnostic
21 test, assistive technology, cell- or gene-based ther-
22 apy, or other technology used to provide health care.

23 (2) The term “medical device” has the meaning
24 given to the term “device” in section 201 of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 321).

3 (3) The term “Secretary” means the Secretary
4 of Health and Human Services.

5 (4) The term “six reference countries” means
6 the six countries, excluding Canada, that over the
7 previous three calendar years—

8 (A) are member countries of the
9 Organisation for Economic Co-operation and
10 Development;

11 (B) have the largest gross domestic prod-
12 ucts; and

13 (C) have a per capita income that is at
14 least 50 percent of the average per capita in-
15 come of the United States.

○