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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2021''.

SEC. 2. REASONABLE PRICE AGREEMENT.

(a) IN GENERAL.—All Federal agencies providing or receiving research funding, through a grant, contract, cooperative agreement, or other agreement, shall require in such agreement, and in any license of the rights to a patent or regulatory test data for a biomedical product or service, that the price of any biomedical product or service developed with the benefit of such research be reasonable (as determined by the Secretary) unless the Secretary waives such reasonable price obligation under subsection (d).

(b) PROHIBITION AGAINST CHARGING PRICES HIGHER THAN IN OTHER LARGE ECONOMIES WITH HIGH INCOMES.—

(1) IN GENERAL.—For purposes of subsection (a), any reasonable pricing formula shall ensure, without prejudice to any other standards or negotiated provisions for reasonable pricing, that residents of the United States are not charged more for the biomedical product or service involved than the reference price for countries with large economies and high incomes.

(2) REFERENCE PRICE.—For purposes of paragraph (1), the phrase ''reference price for countries with large economies and high incomes'' means—

(A) the median price charged for the biomedical product or service involved in Canada and the additional six reference countries; or

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

(c) ADDITIONAL REQUIREMENTS.—

(1) IN GENERAL.—In carrying out subsection (a), the Secretary may promulgate by regulation additional requirements to ensure that the price for the biomedical product or service described in subsection (a) be reasonable.

(2) REQUIREMENTS.—The additional requirements under paragraph (1) shall—

(A) address the public interest in ensuring that publicly supported innovations for biomedical products and services have reasonable prices; and

(B) take into account—

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

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

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

(A) mechanisms to—

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

(ii) lower prices that exceed a standard of cost per health benefit achieved; or

(iii) lower prices that constitute significant barriers to access or fiscal burdens on patients; or

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

(d) WAIVER.—

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

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

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

(A) the public is given notice of the proposed waiver and provided a reasonable opportunity to comment in writing and at a public hearing on the proposed waiver; and

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

(e) TRANSPARENCY.—

(1) REPORTING.—In order to evaluate additional requirements promulgated under subsection (c), agreements subject to subsection (a) shall include a requirement that the manufacturer or other companies commercializing the biomedical product or service involved report to the Secretary in formats determined by the Secretary—

(A) the costs of each clinical trial undertaken to support the Federal regulatory approval of the biomedical product or service involved;

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

(C) the annual revenues generated by the biomedical product or service involved, by county of sale.

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

(f) NO EFFECT ON OTHER REQUIREMENTS.—The reasonable pricing requirements imposed under this section are in addition to any other requirements to limit the price of biomedical products or services, including such requirements imposed—

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

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

(g) DEFINITIONS.—In this section:

(1) The term ''biomedical product or service'' means a drug, vaccine, medical device, diagnostic test, assistive technology, cell- or gene-based therapy, or other technology used to provide health care.

(2) The term ''medical device'' has the meaning given to the term ''device'' in section 201 of the

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

(3) The term ''Secretary'' means the Secretary of Health and Human Services.

(4) The term ''six reference countries'' means the six countries, excluding Canada, that over the previous three calendar years—

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

(B) have the largest gross domestic products; and

(C) have a per capita income that is at least 50 percent of the average per capita income of the United States.

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