

120TH CONGRESS
1ST SESSION

H.R. _____

IN THE HOUSE OF REPRESENTATIVES

_____, 2026

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

A BILL

To require fair pricing agreements for pharmaceutical products developed with Federal research funding, to require recipients of early-stage Federal research grants to accept fair pricing obligations as a condition of funding, to ensure that pricing obligations follow intellectual property through downstream licensing and commercialization, to allow direct-to-consumer pharmaceutical sales bypassing pharmacy benefit managers for taxpayer-funded drugs, to require health insurers to pass negotiated drug cost savings to consumers, 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 “*Taxpayer Return on Investment in Pharmaceuticals Act*” or the “*TRIP Act*”.

SEC. 2. FINDINGS.

Congress finds the following:

- (1) Over the last decade, approximately \$200,000,000,000 of Federal taxpayer funds have been invested in pharmaceutical research grants, direct subsidies, and healthcare coverage programs.
- (2) Despite substantial public investment in pharmaceutical research and development, American consumers frequently pay higher prices for prescription medications than consumers in other developed nations.

- (3) The current structure of the pharmaceutical supply chain, including the role of pharmacy benefit managers (PBMs), adds unnecessary complexity, reduces pricing transparency, and inflates costs for patients and healthcare purchasers.
- (4) Prescription drug costs represent a significant share of total health insurance spending, and reductions in drug pricing would materially reduce insurance premiums for American families.
- (5) Public investment in pharmaceutical research should yield public benefit in the form of affordable and accessible medicines.
- (6) Tying Federal research grants to enforceable pricing agreements at the time funding is awarded would prevent the recurrence of taxpayers paying twice—once through tax-funded research and again at the pharmacy counter.
- (7) A substantial share of Federal research funding supports early-stage, pre-commercial research conducted by universities, academic medical centers, Federal laboratories, and nonprofit research institutions, the results of which are frequently licensed to private pharmaceutical manufacturers for further development and commercialization.
- (8) Without enforceable pricing conditions attached at the time of the original early-stage grant, the chain of public investment is severed when research findings are licensed or transferred to private entities, allowing the resulting pharmaceutical products to be priced without regard to the taxpayer contribution that made them possible.

SEC. 3. DEFINITIONS.

In this Act:

- (1) **COVERED PHARMACEUTICAL PRODUCT.**—The term “*covered pharmaceutical product*” means any drug, biological product, or therapeutic developed in whole or in part with the support of Federal research funding, including funding provided through the National Institutes of Health, the Biomedical Advanced Research and Development Authority, the Department of Defense, or any other Federal agency.
- (2) **FAIR MARKET PRICE.**—The term “*fair market price*” means the price negotiated between the Secretary and a pharmaceutical manufacturer pursuant to section 4 of this Act, reflecting the proportional Federal investment in the development of a covered pharmaceutical product, adjusted for reasonable costs of development, manufacturing, and a fair return on private investment.
- (3) **FEDERAL RESEARCH FUNDING.**—The term “*Federal research funding*” means any grant, cooperative agreement, contract, intramural research support, or other financial assistance provided by the Federal Government for purposes of biomedical or pharmaceutical research, development, or clinical trials.

(4) PHARMACY BENEFIT MANAGER.—The term “*pharmacy benefit manager*” or “*PBM*” means any entity that manages prescription drug benefits on behalf of a health insurer, group health plan, or other third-party payor, including the negotiation of rebates, the development of formularies, and the administration of claims processing.

(5) SECRETARY.—The term “*Secretary*” means the Secretary of Health and Human Services.

(6) EARLY-STAGE RESEARCH FUNDING.—The term “*early-stage research funding*” means Federal research funding awarded for basic science, preclinical research, discovery-phase investigation, proof-of-concept studies, or any other research activity that precedes the filing of an investigational new drug application with the Food and Drug Administration, regardless of whether the research is directed at a specific pharmaceutical product or therapeutic application at the time of the award.

(7) RESEARCH INSTITUTION.—The term “*research institution*” means any university, academic medical center, teaching hospital, Federal laboratory, nonprofit research organization, or other entity that receives early-stage research funding and is not primarily engaged in the commercial manufacture or sale of pharmaceutical products.

(8) DERIVED PHARMACEUTICAL PRODUCT.—The term “*derived pharmaceutical product*” means any drug, biological product, or therapeutic the development of which relied in whole or in part on research findings, data, biological materials, chemical compounds, methodologies, or intellectual property generated under or substantially attributable to a grant or award of early-stage research funding, regardless of the number of subsequent development stages, licensing transactions, or transfers of intellectual property between the original research and the final commercialized product.

SEC. 4. FAIR PRICING NEGOTIATION FOR TAXPAYER-FUNDED PHARMACEUTICALS.

(a) Mandatory Negotiation.—

(1) IN GENERAL.—The Secretary shall, as a condition of any award of Federal research funding in the field of a pharmaceutical development, negotiate a fair market price agreement with the recipient or licensee of such funding prior to or concurrent with the award of such funding.

(2) TIMING.—Fair market price agreements under paragraph (1) shall be executed—

(A) at the time of the initial award of Federal research funding; or

(B) in the case of an existing award without a fair market price agreement, not later than 180 days after the date on which the covered pharmaceutical product receives approval from the Food and Drug Administration.

(b) Negotiation Criteria.—

In negotiating a fair market price under subsection (a), the Secretary shall consider—

- (1) the total amount of Federal research funding provided for the development of the covered pharmaceutical product;
- (2) the proportion of total research and development costs borne by Federal funding relative to private investment;
- (3) the expected clinical benefit and patient population for the product;
- (4) the prices of therapeutic alternatives, if any;
- (5) the prices paid for comparable products in other countries that are members of the Organisation for Economic Co-operation and Development; and
- (6) the need to maintain incentives for continued private investment in pharmaceutical innovation.

(c) Price Cap.—

No covered pharmaceutical product for which more than 50 percent of total research and development costs were supported by Federal research funding shall be priced to the public at more than 200 percent of the total per-unit production and distribution cost of such product, unless the Secretary determines that a higher price is necessary to sustain continued research and development.

(d) Retroactive Application.—

Not later than 2 years after the date of enactment of this Act, the Secretary shall identify all pharmaceutical products currently on the market that were developed in whole or in substantial part with Federal research funding and shall initiate fair market price negotiations with the manufacturers of such products.

(e) Early-Stage Research Grant Conditions.—

(1) PRICING MODEL ACCEPTANCE AS CONDITION OF FUNDING.—No Federal agency shall award early-stage research funding to any research institution or other recipient unless such recipient, as a condition of accepting the award, agrees in writing to—

- (A) the application of the fair market pricing framework established under this Act to any derived pharmaceutical product;
- (B) the inclusion of enforceable pricing obligation provisions in any license, assignment, or other transfer of intellectual property, research findings, data, biological materials, or chemical compounds generated under the award; and
- (C) the reporting requirements described in paragraph (4).

(2) **FORM OF AGREEMENT.**—The agreement required under paragraph (1) shall be executed using a standardized pricing obligation rider, developed by the Secretary in consultation with the Director of the National Institutes of Health and the heads of other Federal agencies that award early-stage research funding, which shall be attached to and incorporated by reference into the grant agreement, cooperative agreement, or contract governing the award.

(3) **SCOPE OF OBLIGATION.**—The pricing obligation accepted under paragraph (1) shall—

(A) apply to all derived pharmaceutical products, as defined in section 3(8), regardless of—

(i) the number of years between the original early-stage research and the commercial introduction of the derived pharmaceutical product;

(ii) whether the derived pharmaceutical product was foreseeable at the time of the original award;

(iii) the number of intervening licensing transactions, sublicenses, assignments, or corporate transactions between the original research institution and the entity that ultimately seeks approval from the Food and Drug Administration; or

(iv) whether the derived pharmaceutical product incorporates additional privately funded research and development, provided that the contribution of the federally funded research was material to the development of the product;

(B) run with the intellectual property, such that any successor, assignee, licensee, sublicensee, or acquirer of the research findings or intellectual property generated under the award shall be bound by the same pricing obligation; and

(C) remain in effect for the duration of any patent, exclusivity period, or regulatory protection applicable to the derived pharmaceutical product.

(f) Downstream Licensing Requirements.—

(1) **MANDATORY PASS-THROUGH.**—Any research institution or other recipient of early-stage research funding that licenses, assigns, or otherwise transfers intellectual property or research findings generated under such funding to a third party shall include in the license, assignment, or transfer agreement—

(A) a provision requiring the licensee, assignee, or transferee to comply with the fair market pricing framework established under this Act with respect to any derived pharmaceutical product;

(B) a provision requiring the licensee, assignee, or transferee to include identical pass-through provisions in any subsequent sublicense, assignment, or transfer; and

(C) a provision granting the Secretary the right to enforce the pricing obligation directly against any downstream licensee, assignee, sublicensee, or transferee.

(2) NOTICE TO SECRETARY.—A research institution or other recipient shall notify the Secretary in writing not later than 60 days after executing any license, assignment, or transfer described in paragraph (1), including the identity of the licensee or transferee, a description of the intellectual property or research findings transferred, and a copy of the pricing obligation provisions included in the agreement.

(3) FAILURE TO INCLUDE PASS-THROUGH PROVISIONS.—

(A) Any license, assignment, or transfer that fails to include the provisions required under paragraph (1) shall not extinguish the pricing obligation, which shall continue to apply to any derived pharmaceutical product as if the provisions had been included.

(B) A research institution that fails to include the required provisions shall be subject to—

(i) a civil monetary penalty of not more than the greater of \$500,000 or 10 percent of the total consideration received for the license, assignment, or transfer; and

(ii) suspension of eligibility for new Federal research funding for a period of not fewer than 2 years and not more than 5 years.

(g) Fair Market Price Negotiation for Derived Products.—

(1) TIMING.—When a derived pharmaceutical product approaches commercial viability, the entity seeking approval from the Food and Drug Administration shall initiate fair market price negotiations with the Secretary not later than—

(A) the date of submission of a new drug application, biologics license application, or abbreviated new drug application to the Food and Drug Administration; or

(B) 90 days after the completion of a Phase II clinical trial, if the entity intends to seek expedited or breakthrough therapy designation.

(2) NEGOTIATION CRITERIA.—In negotiating a fair market price for a derived pharmaceutical product, the Secretary shall apply the criteria set forth in subsection (b), and shall additionally consider—

(A) the total amount of early-stage research funding that contributed to the development of the derived pharmaceutical product, including funding awarded to all research institutions in the chain of development;

(B) the proportion of total development costs attributable to publicly funded research relative to subsequent private investment;

(C) the degree to which the federally funded research was material to the creation of the derived pharmaceutical product; and

(D) any revenue or consideration already received by the research institution from licensing the federally funded research.

(3) FAILURE TO NEGOTIATE.—Any entity that commercializes a derived pharmaceutical product without completing the fair market price negotiation required under this subsection shall be subject to—

(A) a civil monetary penalty equal to 3 times the gross revenue from sales of the derived pharmaceutical product during the period of noncompliance;

(B) mandatory retroactive application of the fair market price, once negotiated, to all sales occurring during the period of noncompliance, with refunds issued to purchasers and payors; and

(C) referral to the Federal Trade Commission for investigation of unfair or deceptive practices.

(h) Registry of Federally Funded Research.—

(1) ESTABLISHMENT.—The Secretary, in coordination with the Director of the National Institutes of Health and the heads of other Federal agencies that award early-stage research funding, shall establish and maintain a public registry of all early-stage research grants and awards, including—

(A) the identity of each research institution receiving funding;

(B) a description of the funded research;

(C) the amount of each award;

(D) any patents, publications, or intellectual property resulting from the funded research; and

(E) any licenses, assignments, or transfers of such intellectual property, including the identity of the licensee or transferee.

(2) LINKAGE.—The registry shall be designed to enable the Secretary and the public to trace the chain of development from an early-stage research grant to any derived pharmaceutical product that reaches the market.

(3) REPORTING OBLIGATION.—Each research institution receiving early-stage research funding shall report to the registry not less frequently than annually on the status of the funded research, including any commercialization activity, licensing transactions, or patent applications.

SEC. 5. DIRECT SALES AUTHORIZATION FOR COVERED PHARMACEUTICAL PRODUCTS.

(a) In General.—

Any manufacturer of a covered pharmaceutical product subject to a fair market price agreement under section 4 may sell such product directly to pharmacies, health systems,

and consumers at the negotiated fair market price without the involvement of a pharmacy benefit manager.

(b) Prohibition on PBM Interference.—

No pharmacy benefit manager shall—

- (1) impose any fee, clawback, or rebate requirement on a covered pharmaceutical product sold at the fair market price;
- (2) restrict formulary placement of a covered pharmaceutical product based on the refusal of a manufacturer to participate in a PBM rebate program for such product; or
- (3) impose any penalty on a pharmacy for dispensing a covered pharmaceutical product at the fair market price.

(c) Effect on Existing Contracts.—

Any provision of a contract between a pharmacy benefit manager and a pharmaceutical manufacturer, pharmacy, health insurer, or group health plan that conflicts with subsection (a) or (b) shall be unenforceable with respect to covered pharmaceutical products beginning on the date that is 1 year after the date of enactment of this Act.

SEC. 6. REQUIREMENT TO PASS SAVINGS TO CONSUMERS.

(a) Premium Reduction Requirement.—

- (1) IN GENERAL.—Each health insurer or group health plan that realizes a reduction in pharmaceutical costs as a result of the fair market pricing provisions of this Act shall pass not less than 80 percent of such savings directly to enrolled consumers through reduced premiums, reduced cost-sharing, or both.
- (2) CERTIFICATION.—Not later than 180 days after the close of each plan year, each health insurer and group health plan subject to paragraph (1) shall certify to the Secretary the amount of savings realized from fair market pricing agreements and the manner in which such savings were passed to consumers.

(b) Enforcement.—

- (1) AUDIT AUTHORITY.—The Secretary shall have the authority to audit health insurers and group health plans to verify compliance with subsection (a).
- (2) CIVIL PENALTIES.—Any health insurer or group health plan that fails to comply with subsection (a) shall be subject to a civil monetary penalty of not more than \$100,000 per day for each day of noncompliance, to be assessed by the Secretary.
- (3) PRIVATE RIGHT OF ACTION.—Any consumer who is enrolled in a health insurance plan or group health plan that fails to comply with subsection (a) may bring a

civil action in a court of competent jurisdiction to recover damages equal to the amount of savings not passed through, plus reasonable attorney's fees.

SEC. 7. TRANSPARENCY AND REPORTING.

(a) Public Disclosure of Pricing Agreements.—

The Secretary shall establish and maintain a publicly accessible database containing—

- (1) the identity of each covered pharmaceutical product subject to a fair market price agreement;
- (2) the amount of Federal research funding contributed to the development of such product;
- (3) the negotiated fair market price; and
- (4) comparative pricing data from not fewer than 5 member nations of the Organisation for Economic Co-operation and Development.

(b) Annual Report to Congress.—

Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

- (1) the number and identity of fair market price agreements executed;
- (2) the estimated aggregate savings to consumers and the Federal Government;
- (3) the estimated impact on health insurance premiums;
- (4) an assessment of the impact of this Act on pharmaceutical innovation and research investment; and
- (5) any recommendations for legislative or regulatory improvements.

SEC. 8. ANTI-PRICE-GOUGING PROTECTIONS.

(a) Prohibition.—

No manufacturer of a covered pharmaceutical product subject to a fair market price agreement shall increase the fair market price of such product by more than the percentage increase in the consumer price index for all urban consumers (CPI-U) for the preceding calendar year, unless such increase is approved by the Secretary upon a showing of good cause.

(b) Penalty.—

Any manufacturer that violates subsection (a) shall be liable to the Federal Government for a civil monetary penalty equal to 3 times the amount of revenue attributable to the excess price increase.

SEC. 9. PRESERVATION OF INNOVATION INCENTIVES.

(a) Innovation Reinvestment.—

Nothing in this Act shall be construed to prevent pharmaceutical manufacturers from earning a reasonable return on private investment in the development of covered pharmaceutical products. The Secretary shall ensure that fair market price agreements preserve adequate incentives for continued private-sector research and development.

(b) Small and Emerging Manufacturers.—

The Secretary shall establish expedited and simplified negotiation procedures for small pharmaceutical manufacturers and emerging biotechnology companies, and may provide for graduated pricing agreements that account for the unique financial circumstances of such entities.

SEC. 10. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to the Secretary such sums as may be necessary to carry out this Act, including the costs of negotiation, administration, enforcement, and the establishment and maintenance of the public database under section 7(a).

SEC. 11. EFFECTIVE DATE.

(a) **IN GENERAL.**—Except as provided in subsection (b), this Act shall take effect on the date that is 1 year after the date of enactment of this Act.

(b) **REGULATIONS.**—Not later than 270 days after the date of enactment of this Act, the Secretary shall promulgate such regulations as are necessary to carry out this Act.

SEC. 12. SEVERABILITY.

If any provision of this Act, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this Act, and the application of the provisions of this Act to any person or circumstance not directly affected by such holding, shall not be affected thereby.
