The Medical Innovation Act of 2019

Section 1. Short Title

Section 2. Authority to Assess and Use Supplemental Payments to Increase Congressional Investments in Medical Research

(a) In General.—Section 301 of the Public Health Service Act is amended by adding at the end the following:

(i) Authority to Assess and Use Supplemental Payments to Increase Congressional Investments in Medical Research.—

(1) Definitions.—

(A) Covered Blockbuster Drug.—A product that generates over $1 billion in revenue and was developed in whole or in part through federal investments in medical research, including if the drug—

- is based on research conducted by a person who received federal research funding.
- relates to a signaling pathway, receptor, or other scientific discovery made in whole or in part through research funded by the Federal Government.
- is manufactured or tested with technology that was developed in whole or in part through research funded by the Federal Government.

(B) Covered Manufacturer.—A person that holds an approved application or license for a blockbuster drug.

(C) Covered Settlement Agreement.—A settlement agreement totaling $1,000,000 or more, including payment of civil or criminal penalties to any parties, between a covered manufacturer and the Federal Government for alleged violations of anti-kickback laws, fraud against government health programs, the False Claims Act, the Food, Drug, and Cosmetic Act, or any other violation of Federal law. Settlements that are not criminal and are not allegations of fraud that cost taxpayers money or are not allegations of conduct that could have jeopardized public health do not qualify as covered settlements.

(D) Person.—Includes an individual, partnership, corporation, and association.

(E) Product.—An approved prescription drug or biologic.

(2) Supplemental Payments to Increase Congressional Investments in Medical Research.—

(A) Supplemental Payment Assessment and Collection.—The Secretary of HHS shall assess and collect supplemental payments from covered manufacturers who meet the assessment criteria.

(B) Criteria for Assessing Payments.—Supplemental payments will be assessed from covered manufacturers who have entered into a covered settlement agreement within the past five years, but not earlier than the date of enactment of the Medical Innovation Act of 2019.

(C) Payment Amount.—The payment owed by a covered manufacturer meeting the criteria

in subparagraph (B) is equal to a specified applicable percentage of the covered manufacturer's net income in the previous calendar year, multiplied by the number of blockbuster drugs of the manufacturer. This applicable percentage varies according to the size of the covered settlement agreement between a covered manufacturer and the Federal Government. Covered manufacturers entering into covered settlement agreements totaling less than $500 million will make a payment equal to 0.75% of the covered manufacturer's net income in the previous calendar year, multiplied by the number of blockbuster drugs of the manufacturer. Covered settlement agreements totaling between $500 million and $1 billion trigger an applicable percentage of 1%, and covered settlement agreements totaling more than $1 billion trigger an applicable percentage of 1.5%:

Settlement size	% of net income
< $500 million	0.75%
$500 million ≤ settlement < $1 billion	1.0%
Settlement ≥ $1 billion	1.5%

(D) Annual Limitation.—Covered manufacturers that entered into more than one covered settlement agreement during an applicable calendar year would only be assessed one supplemental payment for that year, and that supplemental payment would be calculated based on the covered settlement agreement requiring the highest payment.

(E) Publication of Payments.—60 days before the beginning of each fiscal year, the Secretary will publish in the Federal Register, with respect to the next fiscal year, the covered manufacturers subject to the payment, the covered blockbuster drugs of each covered manufacturer subject to the payment, the total payment owed by each covered manufacturer, and how the payments will be collected.

(F) Crediting and Availability of Supplemental Payments.—Supplemental payments are collected, available, and obligated only if included in appropriations Acts. An amount equal to the total amount of supplemental payments collected for each fiscal year is authorized to be appropriated.

(G) Remitting Payments.—Payments are due on the first business day of the fiscal year, or the first day after enactment of an appropriations Act.

(H) Collection of Assessed Payments That Are Not Remitted.—If the Secretary does not receive a supplemental payment assessed under subparagraph (A) within 30 days after it is due, the payment will be treated as a claim of the United States Government.

(I) Supplement Not Supplant.—Payments will be used to supplement and not supplant and other Federal Funds available to carry out the priorities listed in paragraph (4).

(3) Distribution of Payments to Agencies to Increase Congressional Investments in Medical Research.—

(A) Distribution to Agencies.—Payments will be distributed to the FDA and the NIH to be used for the purposes described in (4)(A) and (4)(B).

(B) Distribution Ratio Between Agencies.—The FDA and the NIH will receive a proportion of the payments equal to that of the agency's proportion of appropriated discretionary funding.

(C) Ensuring Stable Congressional Investments in Medical Research.—Payments will not be distributed to the FDA or NIH unless appropriations to the agencies (not including the payments or FDA user fees) are greater than or equal to the appropriations to the agencies the previous year (not including the payments or FDA user fees). If appropriations to the agencies decrease compared to the previous fiscal year, the payments will not be distributed to the agencies and will instead be used to reduce the federal debt.

(D) Considerations.—Amounts appropriated under paragraph (2) and FDA user fees will not be considered when calculating the amounts appropriated in subparagraphs (B) and (C).

(4) Prioritizing Urgent Needs in Medical Research.—Payments will be prioritized for, but not limited to, the following uses:

(A) FDA.—For the FDA, regulatory science initiatives, including research activities to promote the public health and advance innovation in regulatory decision-making.

(B) NIH.—For the NIH:

- Research that fosters radical innovation, including research and diagnosis on disease with unmet or under-met medical needs, research to evaluate new approaches to disease treatment, or research to identify new biomarkers.
- Fundamental research to advance knowledge and technology without clear clinical and therapeutic benefit to lay the foundation for the next generation of drug development.
- Research on diseases that disproportionally impact government spending through Medicare, Medicaid, CHIP, VA, TRICARE, and the Affordable Care Act, including disease that impact older individuals, degenerative diseases, and chronic diseases.
- Developing the next generation of scientists by increasing support for young researchers through research grants and grants to universities with innovative training programs.

(5) Annual Reports.—The Secretary will submit a report to the HELP and Energy and Commerce Committees with a description of the payments assessed, collected, and distributed, and a list of covered manufacturers assessed the payment. The FDA and NIH will both report on the use and impact of the supplemental payments in their annual budgets.

(b) Effect of Failure to Remit Payment.—If a supplemental payment is not remitted by a covered manufacturer, each blockbuster drug of the covered manufacturer will be considered misbranded under the Federal Food Drug and Cosmetic Act until the payment is made.

(c) Severability.—If any provision of the bill is held to be unconstitutional, the remainder of the bill shall not be affected.