

U.S. legislative proposals requesting the National Academies study feasibility and benefits of de-linking pharmaceutical innovation from drug prices

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Several members of Congress have asked the U.S. National Academies to study the feasibility and likely impact of proposals to de-link the incentives for investing in biomedical R&D from the grant of temporary monopolies. Beginning in the 112th Congress, there have been five similar versions of the terms of reference for the study, included in 10 legislative proposals.

The bills were introduced in both the House and the Senate. Most of the sponsors or co-sponsors were Democratic members of Congress, but three of the numbered bills and the 2024 bipartisan budget bill had Republican sponsors or co-sponsors.

Version 1 (Harkin/Enzi, 112th) is the most granular and mechanism-specific (open source dividend prizes, competitive intermediaries for interim research prizes); Versions 2 and 3 introduce the language of "progressive replacement" of monopolies and phased transition; Versions 4 and 5 are the most institutionally elaborate, adding public listening sessions, formal congressional committee reporting requirements, and a detailed societal impact assessment framework including effects on innovation, lifespan, disease burden, insurance markets, and federal spending.

None of the proposals have become law. S. 3187/112th Congress (Version 1) passed the Senate with the Section 906 study on delinkage intact, but the study was removed in Conference. S. 2333/118th Congress (Version 4) was placed on the Senate Legislative Calendar (Calendar No. 202), but the bill was never called up for a vote and died at the end of the 118th Congress. One version that came close was Version 5, included in a bipartisan continuing resolution / appropriations bill, during the 2024 lame-duck session of Congress. This bill was never officially introduced or voted on, following a campaign led by Elon Musk, who used X to rally opposition.¹

¹ Daniella Diaz and Katherine Tully-McManus, "Elon Musk fueled backlash to spending plan with false and misleading claims: The billionaire stirred Republicans into a frenzy with 100-plus posts on X," *Politico*, December 18, 2024. <https://www.politico.com/news/2024/12/18/elon-musk-false-claims-cr-00195252>

Table: Overview of Legislative Proposals on National Academies Studies on Delinkage

Version	Bill	Sponsors and co-sponsors
1 (112nd Congress)	S. 3187 (112th Congress), Food and Drug Administration Safety and Innovation Act, Engrossed in Senate (ES) Section 906 Independent Study on Medical Innovation Inducement Model	<ol style="list-style-type: none"> 1. Tom Harkin (D-IA); 2. Michael B. Enzi (R-WY)
2 (115th Congress)	H.R. 1776 (115th Congress), Improving Access to Affordable Prescription Drugs Act, Section 409K (j) Study	<ol style="list-style-type: none"> 1. Janice D. Schakowsky(D-IL); 2. Elijah E. Cummings (D-MD); 3. Rosa L. DeLauro (D-CT); 4. Peter Welch (D-VT)
	S. 771 (115th Congress) Improving Access to Affordable Prescription Drugs Act, Section 409K (j) Study	<ol style="list-style-type: none"> 1. Al Franken (D-MN); 2. Bernard Sanders (I-VT); 3. Sheldon Whitehouse (D-RI); 4. Sherrod Brown (D-OH); 5. Amy Klobuchar (D-MN); 6. Elizabeth Warren (D-MA); 7. Tammy Baldwin (D-WI); 8. Jack Reed (D-RI); 9. Kirsten E. Gillibrand (D-NY); 10. Margaret Wood Hassan (D-NH); 11. Richard J. Durbin (D-IL); 12. Chris Van Hollen (D-MD); 13. Jeff Merkley (D-OR); 14. Tom Udall (D-NM); 15. Richard Blumenthal (D-CT); 16. Cory A. Booker (D-NJ)
3 (116th and 117th Congress)	S. 1801 (116th Cong.), Affordable Medications Act, Introduced in Senate (IS), Section 409K (j) Study	<ol style="list-style-type: none"> 1. Tina Smith(D-MN); 2. Amy Klobuchar (D-MN); 3. Richard Blumenthal (D-CT); 4. Tom Udall (D-NM); 5. Sherrod Brown (D-OH); 6. Elizabeth Warren (D-MA); 7. Bernard Sanders (I-VT); 8. Margaret Wood Hassan (D-NH); 9. Sheldon Whitehouse (D-RI); 10. Jeff Merkley (D-OR); 11. Jack Reed (D-RI); 12. Tammy Baldwin (D-WI); 13. Cory A. Booker (D-NJ); 14. Richard J. Durbin (D-IL); 15. Kirsten E. Gillibrand (D-NY)

Version	Bill	Sponsors and co-sponsors
	S. 1898 (117th Cong.), Affordable Medications Act, Introduced in Senate (IS), Section 409K (j) Study	<ol style="list-style-type: none"> 1. Tina Smith(D-MN); 2. Elizabeth Warren (D-MA); 3. Richard Blumenthal (D-CT); 4. Amy Klobuchar (D-MN); 5. Jeff Merkley (D-OR); 6. Jack Reed (D-RI); 7. Tammy Baldwin (D-WI); 8. Margaret Wood Hassan (D-NH); 9. Cory A. Booker (D-NJ); 10. Bernard Sanders (I-VT); 11. Sherrod Brown (D-OH); 12. Kirsten E. Gillibrand (D-NY); 13. Sheldon Whitehouse (D-RI); 14. Richard J. Durbin (D-IL)
4 (118th Congress)	S. 2333 (118th Cong.), Pandemic and All-Hazards Preparedness and Response Act, Reported in Senate (RS), Section 308 National Academies Study on Prizes	<ol style="list-style-type: none"> 1. Robert P. Casey Jr.(D-PA); 2. Mitt Romney (R-UT); 3. Bernard Sanders (D-VT); 4. Bill Cassidy (R-LA)
5 (118th and 119th Congress)	House CR draft / bill-this-week PDF (118th Cong.), Sec. 634, National Academies Study on Prizes	This was the lame-duck reconciliation bill killed by Elon Musk.
	H.R. 10445 (118th Cong.), Further Continuing Appropriations and Disaster Relief Supplemental Appropriations Act, 2025, Introduced in House (IH), Sec. 634, National Academies Study on Prizes	<ol style="list-style-type: none"> 1. Tom Cole(R-OK); 2. Chuck Edwards (R-NC)
	S. 891 (119th Cong.), Bipartisan Health Care Act, Introduced in Senate (IS), Sec. 634, National Academies Study on Prizes	<ol style="list-style-type: none"> 1. Ron Wyden(D-OR); 2. Bernard Sanders (I-VT)
	H.R. 1768 (119th Cong.), Lower Costs for Everyday Americans Act, Introduced in House (IH), Sec. 634, National Academies Study on Prizes	<ol style="list-style-type: none"> 1. Frank Pallone, Jr. (D-NJ)

Version 1

- S. 3187 (112th Congress), Food and Drug Administration Safety and Innovation Act, Engrossed in Senate (ES), Section 906 Independent Study on Medical Innovation Inducement Model

Verbatim study text

“SEC. 906. INDEPENDENT STUDY ON MEDICAL INNOVATION INDUCEMENT MODEL.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into an agreement with the National Academies to provide expert consultation and conduct a study that evaluates the feasibility and possible consequences of the use of innovation inducement prizes to reward successful medical innovations. Under the agreement, the National Academies shall submit to the Secretary a report on such study not later than 15 months after the date of enactment of this Act.

(b) REQUIREMENTS.—

(1) IN GENERAL.—The study conducted under subsection (a) shall model at least 3 separate segments on the medical technologies market as candidate targets for the new incentive system and consider different medical innovation inducement prize design issues, including the challenges presented in the implementation of prizes for end products, open source dividend prizes, and prizes for upstream research.

(2) MARKET SEGMENTS.—The segments on the medical technologies market that shall be considered under paragraph (1) include—

(A) all pharmaceutical and biologic drugs and vaccines;

(B) drugs and vaccines used solely for the treatment of HIV/AIDS; and

(C) antibiotics.

(c) ELEMENTS.—The study conducted under subsection (a) shall include consideration of each of the following:

(1) Whether a system of large innovation inducement prizes could work as a replacement for the existing product monopoly/patent-based system, as in effect on the date of enactment of this Act.

(2) How large the innovation prize funds would have to be in order to induce at least as much research and development investment in innovation as is induced under the current system of time-limited market exclusivity, as in effect on the date of enactment of this Act.

(3) Whether a system of large innovation inducement prizes would be more or less expensive than the current system of time-limited market exclusivity, as in effect on the date of enactment of this Act, calculated over different time periods.

(4) Whether a system of large innovation inducement prizes would expand access to new products and improve health outcomes.

(5) The type of information and decisionmaking skills that would be necessary to manage end product prizes.

(6) Whether there would there be major advantages in rewarding the incremental impact of innovations, as benchmarked against existing products.

(7) How open-source dividend prizes could be managed, and whether such prizes would increase access to knowledge, materials, data and technologies.

(8) Whether a system of competitive intermediaries for interim research prizes would provide an acceptable solution to the valuation challenges for interim prizes.”

Version 2

- HR 1776 (115th Congress), Improving Access to Affordable Prescription Drugs Act, Section 409K (j) Study
- S. 771 (115th Cong.) Improving Access to Affordable Prescription Drugs Act, Section 409K (j) Study

Verbatim study text

“(j) Study.—

“(1) IN GENERAL.—The Director of NIH shall seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to conduct a study to examine—

“(A) the use of innovation inducement prize funds and push financing mechanisms as ways to stimulate investments in biomedical research and development that de-links costs from product prices;

“(B) models of different possible means of de-linking research and development costs from drug prices, including the replacement of the monopoly on new products as an incentive, with innovation inducement prize funds and push financing mechanisms as new incentives to stimulate the development of drugs, including drugs to treat bacterial infections, rare diseases, HIV/AIDS, and cancer; and

“(C) the size of prizes awarded under this section and the effectiveness of such prizes in stimulating innovation.

“(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated, and there are appropriated, \$3,000,000 for fiscal year 2018. Such funds shall remain available until expended.”.

Version 3

- S. 1801 (116th Cong.), Affordable Medications Act, Introduced in Senate (IS), Section 409K (j) Study
- S. 1898 (117th Cong.), Affordable Medications Act, Introduced in Senate (IS), Section 409K (j) Study

Verbatim study text

(j) STUDY.—

(1) IN GENERAL.—The Director of NIH shall seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to conduct a study to examine—

(A) the use of innovation inducement reward funds and push financing mechanisms as ways to stimulate investments in biomedical research and development that de-links costs from product prices;

(B) models of different possible means of de-linking research and development costs from drug prices, including the progressive replacement of the monopoly on new products with a combination of expanded research subsidies and new incentives from innovation inducement funds to stimulate the development of drugs, including drugs to treat bacterial infections, rare diseases, HIV/AIDS, and cancer;

(C) the size of market entry rewards, open source dividends and other innovation inducement prizes that would be necessary to achieve innovation objectives and the relative cost effectiveness of incentives delinked from the prices of products and services in stimulating innovation, compared to time-limited monopolies; and

(D) methods of progressively implementing policies that delink research and development funding from prices of products and services, including to the progressive reduction in the effective term of exclusive rights, accompanied by a progressive introduction and expansion of market entry rewards.

(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated \$3,000,000 for fiscal year 2020 to carry out this subsection.

Version 4

- S. 2333 (118th Cong.), Pandemic and All-Hazards Preparedness and Response Act, Reported in Senate (RS), National Academies Study on Prizes

Verbatim study text

SEC. 308. NATIONAL ACADEMIES STUDY ON PRIZES.

(a) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (referred to in this section as the “National Academies”) to conduct a study to examine—

(1) alternative models for directly funding, or stimulating investment in, biomedical research and development that delink research and development costs from the prices of drugs, including the progressive replacement of patents and regulatory exclusivities on new drugs with a combination of expanded support for research and innovation prizes to reward the successful development of drugs or achievement of related milestones;

(2) the dollar amount of innovation prizes for different stages of research and development of different classes or types of drugs, and total annual funding, that would be necessary to stimulate investment sufficient to achieve such successful drug development and related milestones;

(3) the relative effectiveness and efficiency of such alternative models in stimulating innovation, compared to the status quo that includes patents and regulatory exclusivities;

(4) strategies to implement such alternative models described in paragraph (1), including a phased transition over time;

(5) the anticipated economic and societal impacts of such alternative models, including an assessment of impact on—

(A) the number and variety of new drugs that would be developed, approved, and marketed in the United States, including such new drugs intended to prevent, diagnose, or treat a rare disease or condition;

(B) the rate at which new drugs would be developed, approved, and marketed in the United States;

(C) access to medication and health outcomes;

(D) average lifespan and disease burden in the United States;

(E) the number of manufacturers that would be seeking approval for a drug or bringing a drug to market for the first time;

(F) Federal discretionary and mandatory spending; and

(G) public and private insurance markets.

(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated \$3,000,000 for fiscal year 2024.

(c) REQUIREMENTS.—In conducting the study pursuant to subsection (a), the National Academies shall hold not fewer than 2 public listening sessions to solicit feedback from interested parties, including representatives of academia, professional societies, patient advocates, public health organizations, relevant Federal departments and agencies, drug developers, representatives of other relevant industries, and subject matter experts.

(d) REPORT.—Not later than 2 years after the date of enactment of this Act, the National Academies shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report on the study conducted pursuant to subsection (a).

Version 5

- House CR draft / bill-this-week PDF (118th Cong.), Sec. 634, National Academies Study on Prizes
- H.R. 10445 (118th Cong.), Further Continuing Appropriations and Disaster Relief Supplemental Appropriations Act, 2025, Introduced in House (IH), Sec. 634, National Academies Study on Prizes
- S. 891 (119th Cong.), Bipartisan Health Care Act, Introduced in Senate (IS), Sec. 634, National Academies Study on Prizes
- H.R. 1768 (119th Cong.), Lower Costs for Everyday Americans Act, Introduced in House (IH), Sec. 634, National Academies Study on Prizes

Verbatim study text

SEC. 634. NATIONAL ACADEMIES STUDY ON PRIZES.

(a) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (referred to in this section as the “National Academies”) to conduct a study to examine—

(1) alternative models for directly funding, or stimulating investment in, biomedical research and development that delink research and development costs from the prices of drugs, including the progressive replacement of patents and regulatory exclusivities on new drugs with a combination of expanded support for research and innovation prizes to reward the successful development of drugs or achievement of related milestones;

(2) the dollar amount of innovation prizes for different stages of research and development of different classes or types of drugs, and total annual funding, that would be necessary to stimulate investment sufficient to achieve such successful drug development and related milestones;

(3) the relative effectiveness and efficiency of such alternative models in stimulating innovation, compared to the status quo that includes patents and regulatory exclusivities;

(4) strategies to implement such alternative models described in paragraph (1), including a phased transition; and

(5) the anticipated economic and societal impacts of such alternative models, including an assessment of impact on—

(A) the number and variety of new drugs that would be developed, approved, and marketed in the United States, including such new drugs intended to prevent, diagnose, or treat a rare disease or condition;

(B) the rate at which new drugs would be developed, approved, and marketed in the United States;

(C) access to medication;

(D) health outcomes;

(E) average lifespan and disease burden in the United States;

(F) the number of manufacturers that would be seeking approval for a drug or bringing a drug to market for the first time;

(G) Federal discretionary and mandatory spending; and

(H) public and private insurance markets.

(b) REQUIREMENTS.—In conducting the study pursuant to subsection (a), the National Academies shall hold not fewer than 2 public listening sessions to solicit feedback from interested parties, including representatives of academia, professional societies, patient advocates, public health organizations, relevant Federal departments and agencies, drug developers, representatives of other relevant industries, and subject matter experts.

(c) REPORT.—Not later than 2 years after the agreement under subsection (a), the National Academies shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report on the study conducted pursuant to subsection (a).