The progressive delinking of biomedical R&D incentives from temporary legal monopolies and high prices

Dec 22, 2025
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This is a description, a long abstract,of the paper we would like to present. It's not the paper itself.

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Introduction

Beginning in the 1990s, there has been an interest in changing the trade framework for sharing the burden of costs of R&D for new biomedical products and services, as well as reforming the incentives that induce private investments in R&D.

Beginning in 2000, a series of discussions and negotiations began on the feasibility of delinking the costs of R&D from the costs of new drugs, including most importantly, on the incentives to induce investments in biomedical R&D. These included negotiations and expert commissions initially associated with The World Health Organization (WHO) and subsequently the UN Secretary General, and discussions at the national levels, including significantly, in the United States. The discussions in the WHO and a UN SG commission included proposals offered by experts as well as by national governments on a range of topics, including delinkage proposals for specific diseases, such as Chagas, cancer, TB or HIV, or categories such as neglected tropical diseases, antibiotic drugs, rare diseases or areas of (other) health priorities.

The discussions in the United States included a series of legislative proposals, beginning with one drafted in 2004 and introduced in 2005, for the elimination of legal monopolies for all pharmaceutical drugs and vaccines, to be replaced by large innovation inducement prizes. Several revisions of the “big” proposal were subsequently introduced, as well as more narrow proposals that focused only on drugs to treat HIV, or for the development of new antibiotic drugs.

The U.S. proposals were often associated with (now) Senator Bernie Sanders, but also included a variety of players, including Senator John Edwards, during the 2008 U.S. presidential primary, and a number of Representatives and Senators who have a times sponsored bills to either implement delinkage for all drugs or for antibiotic drugs, and/or proposed that the National Academies undertake a study of the feasibility of delinkage, including Senator Cassedy (R-LA), the current chair of the Senate HELP committee.

While the various proposals for delinkage have significant differences, the most important feature was to replace the incentive provided by the temporary legal monopoly with large market entry rewards (annual funding of 55 basis points of US GDP in some legislative proposals), a 10 year period to qualify for rewards from the fund, allocations based in part on the real world evidence the products have improved health outcomes, and competition among suppliers of innovation (drug or vaccine developers) for shares of the payouts.

Motivation for delinking R&D incentives from market exclusivity

The proposals to delink R&D incentives from market exclusivity are designed to (1) most importantly, reduce or eliminate access barriers that predictably flow from high prices associated with legal monopolies on drugs and vaccines, (2) permit more efficient incentive designs, that reward improvements in outcomes, (3) provide incentives where patent systems are ineffective, and (4) provide more space for the reform of patent laws, given that the total amount of innovation rewards are linked to GDP levels and independent on patent policies and practices.

Challenges to a transition from the current system that relies on market exclusivity to one that relies on market entry rewards (and other delinked financing mechanisms).

The technical details of how delinkage could be implemented have been discussed by a variety of supporters and critics, and in general, it is fair to say that the efficacy and benefits of replacing the temporary legal monopoly with very large market entry rewards are not seriously disputed, but there has been far less confidence of the feasibility of a transition from the current system.

Among the challenges of any transition are (1) the extensive lock-in associated with long term investments in R&D, (2) the political power of pharmaceutical and rights holders lobbies, and (3) the lack of scale, for countries other than the United States that attempt to implement a system based on the notion that inexpensive generic or biosimilar products will be available to a country that replaces market exclusivity with market entry rewards.

The original US proposals featured an immediate end of the legal protections against entry by generic or biosimilar products, and a two tiered allocation of market entry rewards, split between products already on the market and new approvals. This was considered, at the time, to be a placeholder for a better approach to the transition. There was some exploration of the costs of buyouts for existing IP, but in general, the lack of a well developed transition plan was a key reason why early delinkage proposals were not taken more seriously in the US debates over access and affordability.

The shrinking exclusivity approach for transition

Recent thinking about the transition challenge has focused on an initial (14 year) cap in the years of exclusivity, combined with initially market entry rewards or R&D subsidies, to offset the negative impact of the cap on exclusivity on R&D, followed by annual reductions in exclusivity cap, and progressively larger market entry rewards (and R&D subsidies or other innovation enhancing measures), eventually leading to the elimination of legal exclusivity altogether.

The generic/biosimilar entry challenge

To address the challenge of generic/biosimilar entry, there are proposals to require deep technology transfer, as a condition of entry in the U.S. market. One such proposal is found in Section 6 of HR 4811, 117th Congress, a bill with 80 sponsors, all democrats:

H.R.4811 - Medicare Negotiation and Competitive Licensing Act of 2021
117th Congress (2021-2022)

https://www.congress.gov/bill/117th-congress/house-bill/4811

SEC. 6. Manufacturer provision of information.

(a) In general.—In the case of a manufacturer of a drug or biological subject to a competitive licensing agreement under section 1860D–11(i)(5) of the Social Security Act, as added by this Act, such manufacturer shall, upon request from an entity electing to manufacture such drug or biological, provide to such entity materials, data, and information relating to the manufacture or supply of such drug or biological, including—

(1) cellular clones and hybridoma stocks;

(2) plasmids, plasmid maps, and sequences of antibody complementarity determining regions;

(3) physicochemical and biophysical characterization;

(4) growth conditions and protocols;

(5) attenuation or inactivation protocols;

(6) extraction and purification protocols;

(7) synthetic work-up and schemes;

(8) sufficient quantities of the drug or biological for testing;

(9) the protocols and methods used for testing the drug or biological; and

(10) the expected outcomes from those protocols.

(b) Enforcement.—The Secretary of Health and Human Services may impose a civil monetary penalty on a manufacturer of not more than $10,000 per day for a violation of subsection (a).

The 2024 Reconciliation Bill proposed study of Progressive Delinkage

At the end of 2024, Congress was poised to enact a 1547 page appropriations bill with bipartisan support. Elon Musk blew up the bill, mounting an attack on the bill through X, the social media platform he controls. The text of the full bill, which was never formally given a bill number, is available here.

Included in the bill were three pages, titled “Section 634. National Academies Study of Prizes.” (Text here: CR-prize-study-tor-2024)

The terms of reference for the study were the product of a negotiation between Senators Bernie Sanders (I-VT) and Bill Cassedy (R-LA). The bill would have required HHS to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to evaluate the feasibility of ”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.”

It read[1] as follows:

[1] Proposed in 2024: The 3 page terms of reference for a National Academies study of delinking R&D incentives for new drugs from monopolies. https://www.keionline.org/40860

Making further continuing appropriations for the fiscal year ending September 30, 2025, and for other purposes.

Pages 769-771
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 feed-back 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).

International implementation of delinkage

The US market is large enough to induce entry for generic or biosimilar products. Outside the US, it is not feasible for all or nearly all countries to implement delinkage for all prescription products, without moving together with other like-minded countries. There may be opportunities to implement delinkage for a smaller category of products, or to justify compulsory licensing or pricing regulations, on products for which generic/biosmilar entry is feasible.

Proposal for paper

The paper will describe each of these topics, and set out suggestions for methodology of the evaluation of progressive delinkage, such as the study recently proposed by Senators Cassedy and Sanders for the National Academies, for the US market, as well as commenting on the challenges of implementation outside the US.

The authors (which may be expanded) will include persons who have been intimately involved with the development of several proposals on delinkage, and followed the various negotiations and debates closely.