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Proposals for Reform: Pricing, Innovation & Access to Biomedical Products

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Introduction

This document provides commentary and specific reform proposals on the pricing, innovation and access to biomedical products.

The United States has both the world's largest market for biomedical products and an extraordinary capacity to finance and carry out biomedical research. Yet the policies used to reward innovation often impose unnecessarily high costs on patients, taxpayers and health systems, and public investments in research are not accompanied by adequate protections for affordability and access.

Drug pricing reform is repeatedly stalled by a single argument: that lowering prices will undermine innovation. Congress does not have to choose between lower prices and biomedical innovation. Drug-pricing reforms can be combined with new and more efficient mechanisms to finance research and development (R&D) as well as improved and novel incentives and mandates for research.

This briefing note describes a set of practical reforms that Congress can consider to advance these objectives together. Some involve relatively modest changes to existing statutes and programs; others offer more transformative alternatives to the current reliance on high prices and lengthy monopolies to finance innovation. The common objective is Innovation + Access: a system that delivers both better biomedical innovation and more affordable access to its benefits.

This briefing note proposes a set of reforms. It begins with transparency, without which every other reform is harder to design and defend, and which is important for implementation of reforms. It then works through underused and flawed safeguards already in federal law, before turning to novel approaches: a more targeted and cost-effective replacement for the Orphan Drug Tax Credit subsidy, revenue-based rather than price-based tests for excessive pricing, research mandates, access to manufacturing know-how, and a progressive path toward delinking incentives to invest in R&D from exclusivity altogether.

Considering innovation and access together is essential

Over the past 40 years, virtually all significant efforts to reform drug pricing have been opposed on the grounds that they undermine innovation. In the United States, there is considerable support for biomedical innovation, including a willingness to pay for it, particularly if the direct R&D funding, subsidies, or incentives are reasonably efficient, and if there is a sense of fairness.

In practice, there is a system that has been highly successful in terms of innovation, and deeply flawed in terms of efficiency or fairness.

Reforms that only seek to lower drug prices will have a negative impact on innovation. The magnitude of that impact is an important issue, and to some extent, a tradeoff between innovation and affordability is appropriate. But it is not necessary to choose between innovation and affordability.

Biomedical innovation is already a heavily subsidized sector. This includes direct funding from a multitude of US government agencies, particularly the NIH, BARDA, and DOD, but also Veterans Affairs, DOE and other federal agencies. Other federal policies that enhance innovation are R&D related tax credits, and often overlooked, the required reimbursements of clinical trial expenses in the ACA. There are state and local government programs, such as the grants from the California Institute for Regenerative Medicine (CIRM), and research funding supported by private tax exempt charities (particularly important for rare disease development). Also largely ignored by trade officials are the direct funding, subsidies and incentives for biomedical research provided by foreign governments.

When considering measures to reduce prices, Congress can combine the reforms with enhancements in direct R&D funding, improved or new R&D incentives or subsidies, and by asking trading partners to increase their support for R&D related activities.

Poorly designed and inefficient incentives should be evaluated with an eye towards evaluating whether it is possible to get at least the same innovation for less money, or more innovation for the same amount of money, or ideally, more innovation for less money.

In one simple illustration, at a workshop in the Netherlands on biomedical innovation, the audience, which included pharmaceutical industry members, was asked what would provide more innovation: a 10 percent increase in drug prices in the United States or a doubling of the NIH budget (then a smaller cost than the 10 percent increase in drug prices). The unanimous opinion was that a doubling of the NIH budget would have had the larger and more beneficial impact on innovation. This is not to say that the audience did not value the role of the private sector in funding R&D, or having skin in the game. But it was a recognition that the innovation system includes, as an important role, funding by the public sector, particularly in areas where private investors did not value R&D spillovers, enhancements of general knowledge, or other areas where government funding is particularly important for innovation.

The central point of the anecdote is that innovation policy should be evaluated across alternative uses of public and private resources, rather than assuming that larger rewards to private firms necessarily produce the greatest marginal innovation.

One branding of these efforts could be I+A, for Innovation + Access. Putting innovation first sends a message that reforms are about improving the system of innovation, not dismantling it.

Transparency

Transparency is not a secondary issue. The extraordinary secrecy built around the pharmaceutical industry is not an accident but obtained, measure by measure, by an industry with massive lobbying power that perceives transparency to be a threat. This enables rent seeking and incentives that are clearly absurd when cost benefit analysis is applied based upon reliable evidence.

Transparency is important across the whole value chain, including facts about R&D costs and subsidies, manufacturing and marketing costs, prices, revenues, units sold, clinical trial outcomes, and manufacturing know-how. In the current Medicare price negotiations, companies have routinely claimed that R&D costs and subsidies, manufacturing and marketing costs, prices, revenues and units sold are confidential business information, to be redacted in any published documents. This policy is contrary to the norms set out in the 2019 WHO Resolution WHA72.8, titled “Improving the Transparency of Markets for Medicines, Vaccines, and Other Health Products”, an agreement the first Trump Administration strongly supported during the negotiations and upon its adoption at the World Health Assembly, but has not implemented.

During the 2019 WHO negotiations, the pharmaceutical industry lobbying effort was most intense over the issue of the transparency of clinical trial costs, even more so over than prices or other issues.

It is hard to overstate the importance of having more transparency and better data on clinical trial costs. The costs of clinical trials are the most important factor in bringing a new product to market, and unlike preclinical costs, relatively straightforward to assign to specific products and to evaluate risks according to the stage of development. Data on success and failure rates for trials by phase and disease are often published based upon data collected on IND approvals, clinical trial registries, and product approvals.

Some companies disclose trial costs in SEC filings, when they are material to the valuation of the stock price, although rarely in formats that are most useful for economic analysis. The reported numbers may include employee stock options as an R&D cost, the costs of acquiring intellectual property rights related to the product, corporate overheads, co-mingling costs of multiple trials, or by reporting outlays for some but not all years for a trial.

Having some public data on trial costs is helpful, but more is needed to make the type of inferences and estimates that are useful and credible for policy making.

KEI routinely asks federal agencies to disclose what they spend on trials the agency performs in-house, or funds externally, and results of our efforts have been hit and miss. Some agencies, like the Department of Veterans Affairs, provide this information, and other agencies, like the NIH or BARDA, resist disclosures.

The NIH's National Cancer Institute (NCI) used to publish data annually on the costs of the trials it funds, by the stage of development, and both the costs per patient and the costs per trial. This information was useful in evaluating industry claims about the costs of clinical trials for the development of cancer drugs. Some years ago, the NCI stopped doing this. When KEI asked the NIH for the cost of a CAR T trial conducted on its Bethesda campus, using cells manufactured by the NIH, the NIH replied that it did not know the trial cost, and lacked a way of tracking that information.

KEI asked BARDA for a list of the vaccine trials it funded, the enrollment and the costs, so we could provide estimates of vaccine development. BARDA sent KEI a list of trials, with the total amount of each trial, but redacted the name and ID of the trials, and the enrollment, making the reply useless.

KEI has also asked the NIH to include a field in clinicaltrials.gov for the cost of the trial and the share of the trial funded by the federal government and third parties.[1] However, the NIH has not acted on these requests. In 2017, during a major overhaul of the federal taxes, the Senate HELP Committee, under GOP leadership, reported a proposal to make the Orphan Drug Tax Credit transparent to the taxpayer, as for the drug and the disease or condition.[2] This provision was opposed by pharmaceutical industry lobbying and eliminated in subsequent versions of the bill:

> SEC. 13401. MODIFICATION OF ORPHAN DRUG CREDIT.
> (a) CREDIT RATE.—Subsection (a) of section 45C is amended by striking ''50 percent'' and inserting ''27.5 percent''.
> (b) DISCLOSURE OF CREDITS.—Section 45C is amended by adding at the end the following new subsection:
> ''(e) DISCLOSURE OF CREDITS.—The Secretary shall publicly disclose the identity of any taxpayer (in the case of a pass-thru entity, the name of the entity) to whom a credit is allowed under this section, as well as the amount of such credit, the drug with respect to which the qualified clinical testing expenses were taken into account under this section, and the rare disease or condition for which such drug was being tested.''.

There is excess secrecy over the Bayh-Dole Act provisions regarding the public's rights in taxpayer-funded inventions. The original 1980 version of the Bayh-Dole Act allowed federal agencies or the courts in FOIA cases to make more information about federal agency licensing of patented inventions public.

In 1984, Congress amended Section 202(c)(5) of the Act to provide that for any subject invention (an invention that benefited from federal funding, when the title is held by a contractor of grant recipient), the funding agency was required (shall replacing may) to treat periodic reporting on the utilization or efforts at obtaining utilization of invention, as well as any

[1] For example: Memorandum on measures to include data on the costs of trials in ClinicalTrials.Gov, September 15, 2023. https://www.keionline.org/40783
[2] Senate proposes to cut Orphan Drug Tax Credit to 27.5 percent, and make it public. November 29, 2017. https://www.keionline.org/23590

information as part of a federal march-in case, as privileged and confidential and not subject to disclosure under FOIA.[3]

> 202(c)(5)
> The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: Provided, That any such information may as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

In 2000, following litigation over a request from Public Citizen to simply make the royalties for government patent licenses public, the NIH issued an opinion that such information should be treated as confidential business information. While the price paid to acquire federal property is generally a matter of public record, in the case of a pharmaceutical drug, invented at the NIH and given a legal monopoly, the terms of the license are typically secret, unless a company chooses to disclose it through press releases or reports to investors (which they sometimes do, when it is relevant to investors).

In 2000, Congress amended Section 209 of the Bayh-Dole Act to take away the discretion of an agency to make public development plans or the reports on the utilization of a government owned invention.[4]

> ``(d) Terms and Conditions.--Any licenses granted under section 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions--
> . . .
> ``(2) requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with, except that any such report shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code;

As a consequence of the changes in Sections 202 and 209 of the Act, the actual use of federally funded inventions and the pricing, access, payment of royalties, or other terms are secret, unless disclosed by companies in press releases or reports to investors.

Five Proposed Reforms

1. Amend Sections 202 and 209 of the Bayh-Dole Act, to replace “shall” with “may”, the language found in the original 1980 version of the Act.

[3] Public Law 98-620, 98 Stat. 3366, https://www.keionline.org/bayh-dole-confidentiality-timeline
[4] In Public Law 106-404. See: https://www.keionline.org/bayh-dole/bayh-dole-timeline.

2. Mandate the NIH to create a field in ClinicalTrials.Gov for the cost of a trial, and separately, for the amount of funding received from federal agencies, through the Orphan Drug Tax Credit, from charities or other non-profit organizations, and from other (US or foreign) government agencies.

3. The Orphan Drug Tax Credit should be public and reported in a web-based publication, updated by the Treasury regularly. The disclosure should include the amount of the credit, by taxpayer, product, disease, year claimed, and trial identification codes.[5]

4. The pediatric exclusivity mechanism codified at 21 U.S.C. § 355a should require the entity doing the trial and receiving the six months of extended exclusivity to report on the cost of the trial and the US sales revenue during the six months of extended exclusivity.

5. All federal government exclusive patent licenses, and all federal CRADA agreements, involving a drug, vaccine, diagnostic device, cell or gene therapy, should be published in a web-accessible database, with redactions strictly limited to trade secrets involving proprietary technical know-how or confidential chemical/manufacturing processes, and personal identifying information (PII). There should be no redactions of the financial terms such as royalty rates, milestone payments, and minimum sales thresholds, and no redactions of licensing territories, patent lists, pricing or access conditions, and march-in triggers.

The Pediatric Extension

The pediatric exclusivity mechanism codified at 21 U.S.C. § 355a[6] provides a six-month extension of all patent or regulatory exclusivities. The mechanism requires the FDA to request a study from a company, and if the company agrees to undertake the study, the company gets the six-month extension, regardless of the outcome of the trial. Companies lobby the FDA to get these requests, and they are sometimes granted for very profitable drugs. The trials are typically small and inexpensive. A trial that costs less than $10 million can provide an extension of exclusivity worth billions of dollars to the company, and cost consumers even more. One obvious reform is to require the FDA to estimate the cost of conducting the trial it is seeking, and the cost of the extended monopoly to the consumers and reimbursement authorities that buy the drug.

[5] The ID code used by ClinicalTrials.Gov if available, and alternative identifier used by the sponsor of the trial or in publications about the trial.

[6] https://www.govinfo.gov/app/details/USCODE-2010-title21/USCODE-2010-title21-chap9-subchapV-partA-sec355a

The government can and should fund the trial directly, rather than use the six-month extended exclusivity, when the mismatch between the cost to the public of the extended monopoly and the cost of the trial are significant.

The FDA maintains a web page that provides a list of the 336 FDA requests for pediatric studies, in return for a six-month extension of patent or regulatory exclusivities.[7]

The list includes a large number of products that had U.S. sales exceeding a billion annually, before patents would have expired (prior to extensions). For example, the Sanofi/BMS drug Plavix had US sales of $6.5 billion. The six-month extension of exclusivity delayed a massive 9-generic simultaneous launch, preserving over $2 billion in revenue.

In 2023, KEI updated the estimates of the cost of the pediatric extension. See: “Mismatch between the cost to perform pediatric extension trials and the cost to the public of the six-month extension of the drug monopoly” KEI Briefing Note 2023:2 September 20, 2023 James Love, Manon Ress and Claire Cassedy.[8]

Reform 1:

As noted, a logical reform is for the federal government to pay a third party to do a study when the cost to the public of extending the monopoly is far greater than the trial cost. This does not require legislation, although reporting and transparency obligations would be helpful.

> (a) Cost-Benefit Determination.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by adding at the end the following:
>
> "(q) Mandatory Economic Assessment and Direct Trial Funding Alternative.—
> (1) PRIOR TO WRITTEN REQUEST.—Prior to issuing any Written Request under subsection (b) or (c), the Secretary, acting through the Commissioner and in consultation with the Administrator of the Centers for Medicare & Medicaid Services, shall publish a preliminary assessment of:
> (A) the estimated reasonable cost to conduct the requested pediatric studies; and
> (B) the projected net cost to public health programs and private purchasers resulting from a 6-month delay in generic or biosimilar market entry.

Reform 2:

The federal government could cap the period of exclusivity by annual sales. A revenue-tiered exclusivity might be the following:

- Annual Sales < $250M: 6-month extension.
- Annual Sales $250M – $1B: 3-month extension.

[7] https://www.fda.gov/drugs/development-resources/pediatric-exclusivity-granted
[8] https://www.keionline.org/wp-content/uploads/KEI-BN-2023-2.pdf

- Annual Sales > $1B: 1-month extension.

Reforming Bayh-Dole Act Safeguards

The Bayh-Dole Act has several safeguards, which are woefully underutilized, and this has been largely but not exclusively due to an unwillingness to undertake discretionary actions. These are some reforms that would reclaim some of the promises made in the 1980 Act and which have been eroded through lack of implementation, or the more restrictive language added in amendments over the years.

March-in Rights

The 1980 version of 35 USC § 203 on the March-in right included what is now 35 USC § 203(a). In 1984, and an appeal framework was added, which is now 35 USC § 203(b), and Section 202(c)(5) of the Act was amended to make “any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under Section 203 . . . shall be treated as . . . privileged and confidential and not subject to disclosure” under Section 552 of Title 5 of the United States Code.

Secrecy of invention utilization

The secrecy language should be amended to replace ‘shall’ with ‘may’ (the standard in the 1980 Act for utilization reports). Otherwise, the company facing a march-in request can disseminate misinformation and misleading information, while the best evidence of key facts will remain secret, influencing public opinion and subsequent scholarly and policymaker analysis and evaluation of decisions.

Stays During Appeals

The Section on what is now (b) on appeals should be eliminated, or at least the mandatory stay should be eliminated. Various administrations have cited the mandatory stay, which creates potentially long policy objective blocking delays, as an excuse to not use the march-in right. This mandatory stay provision, which was not in the 1980 Act, applies even when the abuse of the patent right is extreme, when the public interest in granting the march-in is high, and during an emergency. There is no reason to eliminate the discretion of the agency or a court to grant or withhold an injunction.

Requiring agencies to report on consequences of non-action on march-in request

Federal agencies, including HHS, DOD and DOE, have a long history of failing to act on public requests regarding biomedical inventions. The march-in right is a safeguard for the public. No one can really argue that there has NEVER been an abuse of a subject patent over the 46 years since the Act was passed. The failure of agencies to ever grant a march-in right is a pronounced structural flaw in the safeguard.

A number of the agencies' decisions rejecting march-in petitions have misstated the statutory standard for practical application by stating that the standard is that the invention is merely "available to the public". The statutory standard actually is "available to the public on reasonable terms". By collapsing the statutory inquiry into whether a product is physically obtainable, regardless of extortionate pricing, severe supply restrictions, or abusive licensing practices, agencies have hollowed out the core condition upon which public patent subsidies are granted.

Language can be added to 203(a)(1) to require the agency making the determination on a public petition to justify the reasonableness of the terms under which an invention is being made available to the public. More generally, for all of the grounds in 203(a), the agency, in a written and public finding published in the Federal Register, should be required to explain the impact on the public of rejecting a march-in request. This seems warranted given the long and embarrassing failure to grant march-in rights, despite very obvious abuses on pricing and access.[9]

SECTION 1. CLARIFICATION OF MARCH-IN RIGHTS AND PUBLIC REPORTING REQUIREMENTS.

Section 203 of title 35, United States Code, is amended—

1. In subsection (a)(1), by striking "to achieve practical application of the subject invention;" and inserting the following:

"to achieve practical application of the subject invention, including an affirmative determination by the agency that the benefits of the invention are available to the public on reasonable terms, which shall include an explicit assessment of whether the pricing, licensing, or commercial terms are reasonable;"

2. By adding at the end the following new subsection:

"(c) Written Determinations and Public Notice.—

(1) In General.— In any proceeding under this section initiated by a third-party petition or public request, if the Federal agency declines to exercise march-in rights or determines that grounds under subsection (a) have not been satisfied, the head of the agency shall issue a detailed, written determination.

(2) Requirements.— The determination required under paragraph (1) shall—

[9] This was the Wall Street Journal report on the first NIH march-in case. Bill Richards, "Baxter Beat CellPro in Court, But Some Say Dying Patients Lost," August 6, 1999. https://www.wsj.com/articles/SB933892068466213011

(A) explicitly evaluate and justify the reasonableness of the terms—including economic, licensing, and supply terms—under which the subject invention is made available to the public; and

(B) assess and explain the expected impact on public health, consumer access, and the public interest resulting from the decision not to exercise march-in rights.

(3) Publication.— Not later than 30 days after making a determination under paragraph (1), the agency shall publish the full written determination in the Federal Register and make all non-proprietary supporting records publicly accessible on the agency's website.

Government use licenses

Recently, patent holders challenged a contractor/manufacturer's invocation of a government authorization to use a patent "by or for the United States" under 28 U.S.C. § 1498, to distribute vaccines through commercial pharmacies during the COVID-19 pandemic.[10] The resolution of this case, now on appeal, also has implications for Section 202 and 209 licenses in the Bayh-Dole Act.

The federal government has issued thousands of government use authorizations to patents under 28 USC § 1498(a), typically by including a reference to FAR 52.227-1 in a contract. These include contracts that involve a wide range of activities, including about 50 or more cases during the COVID-19 crisis. For examples involving more than a dozen federal agencies and several hundred contracts see KEI's database on FAR 52.227-1 contracts.[11]

The federal government has historically exercised its Section 202(c)(4) rights to ensure broad access to patented tools and materials for biomedical researchers, and public health advocates have increasingly requested that agencies deploy these same rights to expand access to affordable medicines.

Clarify scope of government use rights

Congress may need to clarify that the scope of the government use license, in all three statutes (28 USC § 1498, 35 USC § 202 and 35 USC § 209) includes any case where the federal agency is authorizing the use of a patent to achieve a government objective.

Bayh-Dole government use rights

[10] Arbutus Biopharma Corp. & Genevant Sciences GmbH v. Moderna, Inc. & ModernaTX, Inc.
[11] https://drugdatabase.info/far-52-227-1-contracts/

SECTION __. CLARIFICATION OF SCOPE OF GOVERNMENT-USE LICENSES AND RESERVED RIGHTS.

(a) Standard Patent Rights in Funding Agreements (35 U.S.C. § 202(c)(4)).—

Section 202(c)(4) of title 35, United States Code, is amended by adding at the end the following:

“For the purposes of this paragraph, practice of the subject invention ‘by or on behalf of the United States’ or ‘by or on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States’ includes any authorization, procurement, manufacture, importation, or distribution directed toward achieving a statutory mission, authorized program, or public objective of the Federal Government, regardless of whether the subject invention is consumed directly by the Government, supplied to third parties, or ultimately utilized, administered to, or received by members of the public (including participants in Federal, State, or international public health, healthcare financing, insurance, research, defense, or foreign assistance programs).”

(b) Licensing of Federally Owned Inventions (35 U.S.C. § 209(d)(1)).—

Section 209(d)(1) of title 35, United States Code, is amended by striking the period at the end and inserting the following:

“, which shall include the unconditional right of the Federal agency to practice the invention, or have the invention practiced on its behalf, to advance any agency mission, public health or welfare objective, or statutory mandate, including where products embodying the invention are distributed to, reimbursed for, or used directly by the public.”

28 USC § 1498(a) government use rights

The proposed language below may be overkill in terms of statutory language for 28 USC § 1498(a), but it does address the policies that are appropriate for a government use authorization.

SECTION 1. CLARIFICATION OF GOVERNMENT-USE PATENT REMEDIES.

Section 1498(a) of title 28, United States Code, is amended—

In the first paragraph, by inserting ", including any contractor, subcontractor, manufacturer, distributor, health care provider, or other person acting with the authorization or consent of the Government" after "by a contractor, a subcontractor, or any person, firm, or corporation";

In the second paragraph, by striking the period at the end and inserting a colon and the following:

“Provided further, That for the purposes of this section—

‘(1) Use for the Government.— The use or manufacture of an invention is ‘for the Government’ whenever it is conducted to achieve, advance, facilitate, or fulfill any statutory authority, program, procurement, emergency response, national security requirement, foreign assistance obligation, or public health or welfare objective of the United States, regardless of whether—

‘(A) the United States takes physical custody or title to the end product;

‘(B) the product is distributed through private or commercial supply chains, pharmacies, or wholesalers; or

‘(C) the ultimate recipients, end-users, or beneficiaries are members of the public (including participants in Federal, State, or international healthcare, insurance, assistance, or reimbursement programs).

‘(2) Authorization and Consent.— Authorization or consent of the Government may be express or implied, and may be provided before, during, or after the use or manufacture occurs, including through funding agreements, purchase orders, reimbursement regulations, executive orders, emergency declarations, or formal agency statements of interest.

‘(3) Reasonable and Entire Compensation.— In determining ‘reasonable and entire compensation’ under this section, the Court shall—

‘(A) award reasonable royalties based on actual economic harm, taking into account any prior direct or indirect Federal contributions to the research, development, or clinical testing of the patented technology;

‘(B) disallow speculative lost profits, punitive enhancements, or price premiums attributable solely to the patentee’s exploitation of an emergency or public subsidy; and

‘(C) establish royalty structures that do not exceed standard commercial compulsory licensing benchmarks recognized in international practice or public health procurement.”

By adding at the end the following new paragraph:

“No court shall issue an injunction, temporary restraining order, or award of damages against any contractor, distributor, or third party for any use or manufacture occurring with the authorization or consent of the United States under this section, the exclusive remedy being an action against the United States in the United States Court of Federal Claims.”

Override of Hatch-Waxman 180-day generic exclusivity

In proceedings involving enzalutamide (marketed by Astellas as Xtandi), public interest petitioners requested that HHS deploy its royalty-free license under 35 U.S.C. § 202(c)(4) and authorize generic competition under 28 U.S.C. § 1498(a). In administrative discussions, federal officials raised the concern that even if the government exercised its patent authorities, the 180-day exclusivity granted to first-filer generic applicants under the Hatch-Waxman Act (21 U.S.C. § 355(j)(5)(B)(iv)), alongside private patent litigation settlements between the brand manufacturer and early generic filers, would create an independent regulatory barrier preventing the immediate marketing of alternative generic products.

This administrative impasse creates an artificial disconnect between federal patent law and food and drug regulation. When the federal government exercises its statutory safeguards under the Bayh-Dole Act, including 35 U.S.C. § 202(c)(4), 203(a), 209(d)(1), and 209(d)(3), or grants

authorization and consent under 28 U.S.C. § 1498(a), such actions should override, waive, or trigger an exception or waiver of the 180-day generic exclusivity. The FDA should have statutory authority to grant immediate final approval to any qualified generic applicant authorized to supply products for government use or public health programs, ensuring that private exclusivity settlements cannot neutralize the government's right to use or have used on its behalf patented inventions.

Possible Federal Food, Drug & Cosmetic Act Amendment

Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(5)) can be amended by adding:

(vii) Exception for Federal Government Use and Public Rights.—
(I) IN GENERAL.— Notwithstanding any other provision of this subsection, no 180-day exclusivity period under clause (iv) or private settlement agreement related thereto shall delay, prevent, or condition the final approval of an application under this subsection if the Secretary or an authorized Federal agency determines that the drug is subject to—

(aa) a license, march-in determination, or retained right exercised by the Federal Government pursuant to sections 202, 203, or 209 of title 35, United States Code; or

(bb) an authorization and consent or procurement action pursuant to section 1498 of title 28, United States Code.

(II) IMMEDIATE APPROVAL.— Upon notification of an action described in subclause (I), the Secretary shall grant immediate final approval to any application submitted under this subsection that meets the scientific and quality standards for approval, regardless of whether a first applicant has commenced commercial marketing or forfeited its exclusivity."

Reasonable pricing of drugs developed with public support

Related to the Bayh-Dole safeguards on reasonable terms for subject inventions is the broader issue of whether drugs that are developed with funding by government agencies, or that use subject inventions, have reasonable prices.

Background on the NIH reasonable pricing clause

Understanding some (of the extensive background on this issue is useful. In the late 1980s, there was a controversy over the price of AZT by Burroughs Wellcome, based in part on the fact that AZT was largely developed by the NIH.[12] In 1989, the NIH (under President George H.W.

[12] Hiroaki Mitsuya, M.D. Kent Weinhold Robert Yarchoan, M.D. Dani Bolognesi Samuel Broder, M.D. Bethesda, Md., Credit Government Scientists With Developing Anti-AIDS Drug, New York Times, Sept. 20, 1989

Bush) began including a reasonable pricing clause in license agreements on NIH-owned patents, and in NIH Cooperative Research and Development Agreement (CRADA) agreements.

Taxol, 1991

The first product to enter the market with such a reasonable pricing clause was taxol (the generic name before BMS acquired a trademark for Taxol), an unpatented cancer drug developed by NIH. The NIH had conducted ALL of the clinical trials for FDA approval of the drug, and through a CRADA, provided Bristol-Myers (Now Bristol Myers Squibb, or BMS) with the exclusive rights to use the data from the NIH clinical trials for approval (an FDA NDA). The rights in the test data were a significant barrier to entry, given the time necessary to conduct any new trials.

The rights in the test data had only been created in 1984, with the passage of the Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, which, among other things, created a 5-year period of exclusive rights to rely on trial data for the approval of a new chemical entity (3 years for new indications). The NCI issued a notice of intent to enter into a CRADA agreement for the development of taxol in August 1989, and signed the agreement with BMS in January 1991.

Congressman Ron Wyden (now a US Senator) used his chair of the Subcommittee on Regulation, Business Opportunities and Energy of the Small Business Committee to hold a series of hearings on the CRADA and subsequently other government funded drugs. I was asked to work with his staff and testify at a hearing evaluating the implementation of the reasonable pricing clause,[13] which included a negotiated price based upon an NIH reference price.

The ddI License

On October 9, 1991, the FDA approved ddI, an NIH-developed drug for the treatment of HIV. BMS had earlier obtained a patent license on ddI from the NIH, and this license also had a similar reasonable pricing clause. When the FDA approved Videx in October 1991, BMS introduced it at a price roughly 30 percent to 40 percent lower than Burroughs Wellcome's initial launch price for AZT (Retrovir). The NIH subsequently published a report on its experience with the ddI license,[14] which included these comments:

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https://www.nytimes.com/1989/09/28/opinion/l-credit-government-scientists-with-developing-anti-aids-drug-015289.html

[13]This 503 page hearing report is a very rich source of historical information. Exclusive Agreements Between Federal Agencies and Bristol-Myers Squibb Co. for Drug Development: Is the Public Interest Protected?: Hearing Before the Subcomm. on Regulation, Business Opportunities, and Energy of the H. Comm. on Small Business, 102d Cong. (1991) (Serial No. 102-35). July 29, 1991.

[14] Videx® Expanding Possibilities: A Case Study, National Institutes of Health Office of Technology Transfer, September 2003.
https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/VidexCS.pdf

> "The technology transfer challenge was to negotiate a license that would provide a strong incentive for a drug company to make the significant investment necessary for the rapid development of a new drug while ensuring the long-term public health benefits. This balance was struck by offering a license that was initially exclusive, but which could became non-exclusive early, prior to the expiration of the NIH patents."

The cap on exclusivity was 10 years from the first commercial sale, allowing entry by generics before the full term of the licensed patent.

I was involved in criticizing the NIH implementation of the pricing clauses. Both clauses moderated prices (products entered the market at prices below other similar novel compounds), but the NIH could have and should have gone further than it did, given its extensive role in the development of both products and the industry interest in the markets for cancer and HIV/AIDS treatments. The issue of the pricing of government funded drugs was subsequently featured in a series of hearings in the House and Senate by different committees.

In 1993, following notable Supreme Court decisions on the patenting of medicines and a sharp dip in the prices of biomedical stocks, drug companies and venture capital firms lobbied the Clinton Administration to eliminate the reasonable pricing clause. In 1994, Dr. Harold Varmus convened two panels reviewing the reasonable pricing issue.[15] In November, the GOP gained enough seats in a midterm election to make Newt Gingrich Speaker of the House of Representatives. On April 12, 1995, the New York Times reported[16] that the Clinton Administration had eliminated the clause and waived all future enforcement of pricing clauses in existing patent or CRADA agreements.[17]

Central to the narrative of the reasonable pricing clause was its assertion that it led to a decrease in the willingness to sign CRADA agreements with the NIH. This claim has been debunked several times,[18] including the misleading uses of statistics from the creation of a new and different category of CRADAs, the Material CRADA, to assert that the elimination of the reasonable pricing clause had led to more collaborations. Material CRADAs did not exist before 1996, and were significantly different instruments. When looking only at Standard CRADAs (the blue line on the chart), there was no notable change in the number of standard CRADAs

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[15] Reports of the NIH Panels on Cooperative Research and Development Agreements. Perspectives, Outlooks, and Policy Development. July 21, 1994 and September 8, 1994. https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH_%20CRADA_Report_on_Reasonable-Pricing_Clause_1994.pdf

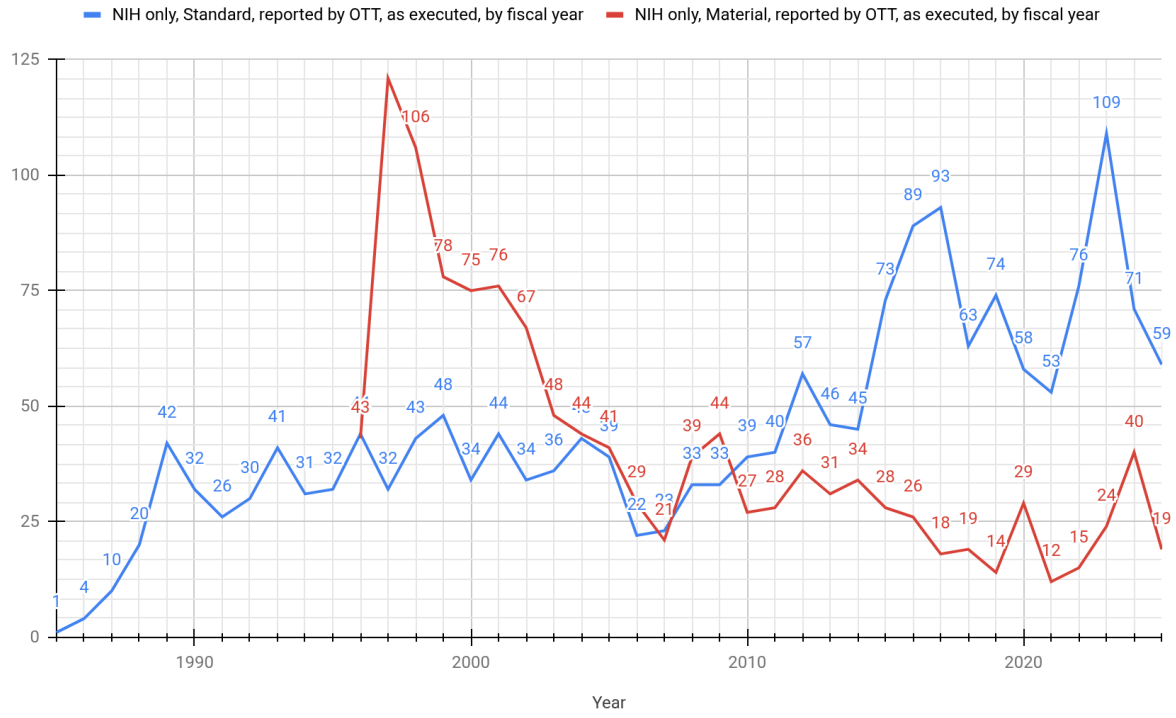
[16] Warren E. Leary. U.S. Gives Up Right to Control Drug Prices. New York Times. April 12, 1995. https://www.nytimes.com/1995/04/12/us/us-gives-up-right-to-control-drug-prices.html

[17] Press Release, NIH. April 11, 1995. https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

[18] See: The number of standard and material CRADAs executed by the NIH from 1985 to 2020 and the relationship to NIH reasonable pricing clause, KEI Briefing Note 2021:3; and

executed from 1989 (42) to 2011 (40), and the number of Material CRADAs (the red line on the chart) has its own unique path.

Figure 1: NIH Standard versus Material CRADAs, by fiscal year executed



The challenge of imposing standard pricing obligations when leverage varies

One criticism by opponents of any condition on a grant, license or other contract, is that it will block some collaborations from taking place at all. And this is true, to some extent, for some cases. The role of the government in supporting biomedical R&D varies considerably from product to product, as well as the costs, risks and other challenges to the development and marketing of products.

Some standard policies can make sense, like having a policy that, in general, US residents should not pay more than other high-income countries for products developed with US government financial support, a condition that many support even when there is no government funding of R&D involved. But beyond this, whatever the conditions are, there will be (or at least may be) cases where the obligation will be a barrier to investment or agreement. KEI (and CPTech before KEI existed) always recognized that these cases existed, and anecdotes, real or imagined, are a predictable feature of debates over the policy.

One solution that KEI has long endorsed and which has been included in a number of legislative proposals, beginning in the late 1990s, is to provide for the possibility of an exception or waiver to a clause on pricing or other access measures. The exception process changes the burden of justification. Instead of opponents defeating a general policy by pointing to hypothetical hard cases, the policy applies presumptively, while the agency can address an actual hard case when it arises.

Under the preferred approach, the agency would have to propose the exception publicly, explain why it is necessary on the basis of evidence, and provide an opportunity for public comment before granting it. This places the burden where it belongs: the general access obligation remains the default, while departures from the rule can be justified when the facts of a particular transaction warrant them.

The cisplatin case

There is a historical precedent for this approach. Before the Bayh-Dole Act, HHS had limited the exclusivity of patent licenses when HHS had funded an invention through a third party, such as Michigan State University. Bristol-Myers had already obtained an extension from 3 to 5 years of exclusivity, from the first sale of cisplatin, a drug to treat cancer. In 1983, Bristol-Myers sought an additional extension, for a cancer drug that had been on the market for 5 years. Bristol-Myers requested the extension on the grounds that the extended monopoly would allow it to invest money into new uses for cisplatin, including for different types of cancer.

The federal government published a notice in the Federal Register on February 4, 1983,[19] describing the Bristol-Myers request, and invited public comment. Several companies opposed the extension, and one company, Andrulis, proposed that the NIH could allow generic companies to compete with Bristol-Myers, but require each generic company to either invest in or fund R&D, in a manner the NIH approved.

Responding to the public comments, the NIH allowed the patent extension, for a shorter period than requested, but also required Bristol-Myers to lower its price by 30 percent,[20] and to fund cancer research, supervised by Dr. Robert Wittes (then an NIH official).

One important outcome of the cisplatin case, and a related case involving Bristol Myers and the cancer drug carboplatin, was political. Bristol-Myers, other drug companies and university patent holders lobbied to change a provision in the federal law that limited the years of exclusivity.

[19] 48 FR 5313.
[20] 48 FR 53177.

The 1984 amendments to the Bayh-Dole Act, eliminating caps on exclusivity

Often overlooked or forgotten, the original 1980 version of the Bayh-Dole Act had a statutory cap on the years of exclusivity that could be granted on a federally funded invention, licensed from a university or other nonprofit organization, to a large company, like Bristol-Myers. The cap was five years from first commercial sale or use of the invention or eight years from the date of the exclusive license. The statute allowed the funding agency to extend the exclusivity, on a case-by-case basis.

> 7) In the case of a nonprofit organization, . .
> (B) a prohibition against the granting of exclusive licenses under United States Patents or Patent Applications in a subject invention by the contractor to persons other than small business firms for a period in excess of the earlier of five years from first commercial sale or use of the invention or eight years from the date of the exclusive license excepting that time before regulatory agencies necessary to obtain premarket clearance unless, on a case~by-case basis, the Federal agency approves a longer exclusive license. If exclusive field of use licenses are granted, commercial sale or use in one field of use shall not be deemed commercial sale or use as to other fields of use, and a first commercial sale or use with respect to a product of the invention shall not be deemed to end the exclusive period to different subsequent products covered by the invention; . . .

On November 8, 1984, less than a year after the cisplatin decision, Congress amended the Bayh-Dole Act and eliminated the restriction, allowing life of patent exclusivity without conditions.

H.R.10094 - Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2026

On August 13, 2026, Congressman Val Hoyle (D-OR-4) introduced, with 11 co-sponsors, H.R.10094, the Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2026. This Act requires all federal agencies providing research funding or support through a grant, contract, cooperative agreement, or other agreement, and in any license of the rights to a patent or regulatory test data for a biomedical product or service, to require that the price of any biomedical product or service benefiting from such support, be reasonable (as determined by the Secretary) unless the Secretary waives the reasonable price obligation.

The waiver of the reasonable pricing obligation

The bill provides considerable flexibility on the types of pricing conditions that can be used, and includes such measures as lower prices or shortened exclusivity periods when revenues exceed targets. The provision on the waiver requires the Secretary to explain why it is necessary, publishes an economic analysis to justify the waiver, and gives the public the opportunity to comment both in written and at a public hearing. The conditions on granting a waiver prevent abuses, in my opinion, and the waiver itself is a very important feature, because it does directly address the issue of cases where a pricing condition is not appropriate.

> H. R. 10094, 119th CONGRESS
>
> (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.

Drug Pricing in General

Price-based tests

Much attention is given to whether or not the price of a drug is reasonable, and there are some appealing metrics one can consider. The international reference pricing standard is particularly appealing for a government-funded invention. NICE in the UK has taken as a starting point a benchmark financial benefit per QALY benefit, although this seems to have considerable flexibility, particularly when it comes to rare diseases. ICER has cited dollar per QALY cost-effectiveness thresholds and other benchmarks; often, the flexibility is associated with the practical challenge of negotiating prices on treatments that are medically very important, with few if any suitable substitutes, and also extremely expensive.

KEI has in the past recommended that governments look at the impact of a price on access, so when products end up with high co-payments and restrictive formularies, that is an indication the prices are excessive, unless some special justification is available, and have greater review of pricing when prices exceed some absolute levels.

Cumulative-revenue approach

One recommendation we have often made, and one that is underutilized, is to look at the cumulative revenue a treatment has generated. This is particularly useful for treatments that are essential for life or death, or have severe impacts on the quality of life. Rather than ask, only, if the price of a drug is excessive (for example: $9k per week for a cancer drug, $50,000 per year for HIV treatments, $370,000 per year for a treatment or cystic fibrosis, $300,000 per year for Fabry's disease, $2.6 million for a gene therapy for SMA, $1,200 a month for a GLP-1 drug, or $250 a month for insulin), begin by look at the revenue earned by the drug developer, and when the number is large, look further into the risk-adjusted costs of developing that type of product, if not that product itself.

What the list of prices above should make clear is that there is a wide range of prices for products that are all, in their own way, essential. That range is itself the problem for price-based tests: it is genuinely hard to say what the "right" price is for any one of these drugs. Reasonable people disagree over a QALY threshold, and rare disease pricing in particular resists any fixed benchmark. It is much easier to say when the overall revenue a product has generated has become excessive relative to what was needed to bring it to market. That also means the resulting system doesn't need to police every price. It can instead be targeted: reserved for the products having the largest impact on payer budgets, where the stakes of getting the incentive wrong — for the public or for future innovation — are highest.

In terms of consideration of development costs, policies should have good data on risks in the clinical stage, where risks are fairly straightforward and feasible to calculate, and data on the costs of clinical trials, not just for one product, but for a class (to avoid companies having incentives to run up the costs on trials, to influence hard or soft controls on pricing). The important point is not merely that the government should collect better R&D-cost data, particularly for trials. The relevant denominator should be the expected, risk-adjusted development cost for a class of comparable projects, rather than whatever a particular manufacturer reports spending on the successful product. That avoids rewarding inefficient development or strategic cost inflation (something to learn from utility pricing). This means the policies on clinical trial cost transparency are very important.

When a product generates a large amount of revenue, the U.S. government policy should be to progressively reduce prices or exclusivity terms or both. The thresholds for triggering reviews of prices or exclusivity terms can be tied to factors such as the impact of the product on health outcomes or when a product opens the door to a new approach or mechanism, so more important products can earn more, and the incentives are more favorable for products that are

more innovative and have more impact. The targeting of incentives in this way needs to be part of the approach to pricing, so long as incentives are linked to prices and exclusivity.

To summarize, there is a significant difference between price-based tests and revenue-based tests. International reference pricing, QALY thresholds, access restrictions, and absolute price thresholds all ask whether the price at a particular moment is excessive or produces undesirable consequences. A cumulative-revenue proposal is different: it asks whether the reward earned over time has become excessive relative to the incentive reasonably needed.

Research Mandates

Obligations that companies selling drugs fund research

As noted above, the pharmaceutical industry's standard objection to pricing reform is that lower prices will reduce R&D investments. Congress has a long-available tool to answer this objection. Rather than accept that trade-off as inevitable, Congress can require companies selling products to fund research. Research mandates can be implemented in a variety of ways. Companies can be required to devote a minimum share of revenue to qualifying R&D, through its own qualifying expenditures, or by making payments to one or more dedicated funds.

Congress already administers mandatory R&D-and-promotion assessments in other sectors.[21] For example:

- The Potato Research and Promotion Act, the Beef Research and Information Act, the Cotton Research and Promotion Act, and similar commodity programs under 7 U.S.C. §7401 impose assessments on producers and importers, with statutory findings that industry-funded, government-supervised research programs serve the national interest. The assessment formulas vary by commodity and include per-unit charges, ad valorem assessments and other formulas. These programs have operated for decades with established collection, reporting, and oversight mechanisms that a pharmaceutical analog could largely borrow.
- The Concrete Masonry Products Research, Education and Promotion Act imposes a fee of $0.01 per concrete masonry unit sold on industry members, and at least 50 percent of a manufacturer's assessments (after administration expenses) is used to support research, education, and promotion programs and projects in that manufacturer's own geographic region.
- The Softwood Lumber Research, Promotion, Consumer Education and Industry Information Order (7 CFR Part 1217) is financed by an assessment on softwood lumber domestic manufacturers and importers, administered by a board of industry members selected by the Secretary of Agriculture; the initial assessment rate was $0.35 per thousand board feet shipped within or imported into the

[21] https://www.keionline.org/research-mandates

United States (later raised to $.41), with the stated purpose of strengthening softwood lumber's market position, maintaining and expanding markets, and developing new uses, with research described as one of the strategic investment areas.

- The Beef Promotion and Research Act created a checkoff system that assesses $1 per head on the sale of live domestic and imported cattle, plus a comparable assessment on imported beef and beef products. Qualified State Beef Councils (QSBCs) collect the assessment and retain up to half of each dollar for state-level marketing and research; the remaining 50 cents flows to the national Cattlemen's Beef Board (CBB), which administers the national program under USDA oversight. One of the allowed areas for expenditures is research, including extramural research on food safety, meat science, nutrition, and product development, administered partly through grants-in-aid programs to university and industry scientists.

A somewhat different model is the federal government program to earmark offshore royalty payments to fund R&D, through the “Ultra-Deepwater" and unconventional (onshore) oil and gas R&D program, run as joint government-industry-academic research consortia.

Research mandates exist in many other countries, and have been proposed in discussions on innovation, access and public health,[22] to fund R&D for new antibiotic drugs,[23] and for a variety of other purposes.[24]

The FDA's own postmarket authorities, PREA (pediatric studies) and FDAAA §901/section 505(o) (postmarketing studies and clinical trials), already establish that Congress can condition continued marketing on specific, mandated research. What's missing is extending that authority from safety-focused postmarket studies to an affirmative R&D-investment requirement tied to revenue.

The pharmaceutical sector's own history shows both the mechanism's power and its capture risk. In 1983, when Bristol-Myers sought to extend exclusivity on cisplatin (then the second best-selling cancer drug, discovered at Michigan State University on a federal grant), a competitor proposing to enter the market - Andrulis Research Corporation - suggested the alternative to extending exclusivity would be to require whichever generic suppliers entered the market to fund R&D directly, through payments to NIH or a dedicated foundation. HHS instead granted BMS the extension, conditioned on a 30% price cut, but also a $35 million NIH-directed research commitment.

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[22] Marcus Low and Kristanna Perls. Research Mandates. UN Secretary's High Level Panel on Access to Medicines. https://www.unsgaccessmeds.org/inbox/2016/2/27/marcus-low;
[23] Antibiotics Innovation Funding Mechanism (AIFM). https://web.archive.org/web/20220119231958/http://www.who.int/phi/implementation/7.pdf; also described in Alternatives to the Patent System that are used to Support R&D Efforts, Including both Push and Pull Mechanisms, with a Special Focus on Innovation-Inducement Prizes and Open Source Development Models, WIPO, CDIP/14/INF/12; ANNEX C.
[24] https://www.keionline.org/research-mandates

Fourteen years later, at a 1997 Senate Appropriations hearing, a proposal was considered for a demonstration project whereby the exclusive rights in pharmaceutical test data could be extended from 5 to 10 years. Taxol was described as the primary beneficiary. The proposal was that a company would contribute 3 percent of the product revenues to fund NIH research, and also commit to invest not less than an equal amount in R&D in the general area of the eligible product.

This proposal was the product of lobbying by BMS, seeking to extend its monopoly on Taxol. BMS had flipped the script, and instead of using the research mandate to avoid an extension of exclusivity, it was proposed as a justification of extending exclusivity. In other words, the mechanism designed as a check on monopoly pricing power had been repurposed as a sweetener for extending it.[25]

In terms of the current pricing reform discussions, a research mandate is a free-standing policy tool and need not be tied to extended exclusivity. It can be bundled with measures that lower prices to offset the negative impact on R&D associated with lower prices.

Why research mandates belong in a pricing-reform package

It is ultimately the public that funds pharmaceutical R&D, through taxes, charities or indirectly through high prices. A mandatory reinvestment requirement can guarantee that a defined share of product sales are used to fund R&D, rather than leaving the R&D-to-revenue relationship to the discretion and direction of manufacturers. By including research mandates, the argument that any pricing measure "will kill R&D" is transformed into a discussion of how robust should the R&D mandates be. If the industry claims a given price reform threatens R&D, the mandate's percentage can be adjusted upwards; and innovation and affordability no longer have to be traded against each other in the same negotiation.

Congress could take different approaches on the design of research mandates, including a hybrid or a combination of approaches. For company-funded R&D, KEI suggests consideration of the following.

Option 1.

HHS creates rules concerning qualifying biomedical R&D expenditures. Companies are required to demonstrate that a minimum percentage of sales from a drug or other FDA-regulated treatment has been reinvested in qualifying R&D projects, in-house, or with another company.

[25] The proposal was not approved. The discussion on the proposal is in U.S. Senate, Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, Legislative Proposal to Increase Funding for Medical Research, Hearing, 105th Cong., 1st Sess., October 21, 1997, S. Hrg. 105-524 (Washington, DC: U.S. Government Printing Office, 1998)

Option 2.

Similar to 1, but with the additional requirement that a portion of the research mandated investments be managed in qualifying research consortiums, modeled after those now organized through the Foundation for the National Institutes of Health (FNIH). These include dozens of NIH and industry partnerships to jointly fund upstream research in areas of priority, with nuanced rules on intellectual property rights and sharing of data.[26]

Payer-mandated R&D funding through competitive intermediaries

Another type of research mandate is one that is imposed on consumers or payers of drugs. The various medical innovation prize fund bills introduced in Congress since 2005 have included obligations on health insurance providers, public and private, to fund R&D incentives, specifically a very large medical innovation prize fund, and in some versions, partially through a system of competitive intermediaries.

Some of the early work on these proposals was advanced in two collaborations between NGOs, academics and large drug companies. The first was a May 2001 meeting in Montreux, Switzerland, funded by life sciences companies and organized by the World Business Council for Sustainable Development ("WBCSD"). This was followed by the September 2002 Aventis scenario-planning exercise in Ottrott-le-Haut, France, on "Pharma Scenarios for Sustainable Healthcare.[27]

The discussions with Aventis in 2002 focused on blue-sky new models for biomedical innovation that did not depend on exclusive rights on pharmaceutical products. Among the proposals in what were then described as Radical Scenarios 1 and 2, where a change in the trade framework to focus on funding norms for R&D rather than norms for intellectual property rights, the use of large market entry rewards (innovations inducement prizes) to reward the development of successful products, and the use of "competitive intermediaries" funded by mandatory employer/employee contributions to provide money for various open science projects. As described in a subsequent paper:[28]

> These intermediaries would be similar to venture capital funds, but would target investments in projects that yielded scientific rather than financial returns. Employers

[26] https://fnih.org/our-programs/
[27] James Love and Tim Hubbard. "The Big Idea: Prizes to Stimulate R&D for New Medicines," Chicago-Kent Law Review, Volume 82, Number 3 (2007); James Love and Tim Hubbard, "Prizes for Innovation of New Medicines and Vaccines," Annals of Health Law, Vol. 18, No 2, pages 155-186, Summer; Tim Hubbard and James Love, "A New Trade Framework for Global Healthcare R&D," PloS Biology, February 17, 2004; James Love, From TRIPS to RIPS: A better Trade Framework to support Innovation in Medical Technologies, Agence nationale de recherches sur le sida/Institute d' Èconomie publique, Workshop on Economic issues related to access to HIV/AIDS care in developing countries, UniversitÈ de la MÈditerranÈe, Marseille, France, May 27th, 2003; Joseph A. DiMasi & Henry G. Grabowski, Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D (June 25, 2004);
[28] Ibid.

> would be required to contribute, but would also be given the freedom to choose to which intermediaries they would give money. Proponents of this approach argue that employers would rationally target intermediaries that invested in the most promising advances in medical science, even when the investments were directed at basic or translational research, rather than final products.

One proposal was that every employer would be required to contribute $200 per year into R&D, through one of multiple non-profit R&D funding organizations that were approved, regulated and audited by the government. This proposal was first put forth to address the legitimacy of funding of upstream research, where there are no metrics or consensus on approaches that can guide which projects should be funded.

It was one thing to design a mechanism to reward success products, as illustrated by the significant and thoughtful work on the design of market entry rewards. You have a product, patients, and patient outcomes, and all of these can be measured, and rewarded. Upstream research, on the other hand, can involve a large number of contributions, ideals, tools, data, materials, technologies and experiments, that product developers benefit from, but which can be difficult to identify and evaluate, in terms of their contributions or potential uses, since they occur before a product is on the market.

The competitive intermediary approach was seen as a decentralized alternative to having governments being the only source of decision making, and to convey legitimacy for funding open source and novel approaches. The fact that an employer (or insurer) would choose a specific R&D funding intermediary would convey legitimacy, and competition among intermediaries, each appealing to potential donors, would enable innovative funding approaches, and reward success, based on the research priorities, outcomes and performance metrics evaluated and valued by the donors (employers or insurers).

Competitive intermediaries have been included as possible vehicles for funding research in various legislative proposals. For example, in S.495, 115th Congress:

> SEC. 12. Competitive intermediaries for funding interim technologies.
>
> (a) In general.—The Board of Trustees may authorize multiple nonprofit intermediaries to reward projects for interim research and development of products, or for open source dividend prizes. Such intermediaries shall compete for funding from non-Federal entities that co-fund the Fund.
>
> (b) Availability.—Prizes awarded by competitive intermediaries shall be available to persons or communities that provide open, nondiscriminatory and royalty-free licenses to relevant intellectual property rights.

Among various proposals[29] for the National Academies to study delinking R&D incentives from legal monopolies, are terms of reference such as this:

> (c) ELEMENTS.—The study conducted under subsection (a) shall include consideration of each of the following:
>
> (8) Whether a system of competitive intermediaries for interim research prizes would provide an acceptable solution to the valuation challenges for interim prizes."

Reform Orphan Drug Incentives

The incentives and prices for rare or neglected diseases are particularly unmoored from consistent valuation methodologies. The R&D for treatments for rare diseases may be heavily subsidized by governments or charities, have very small clinical trials and undergo expedited and less rigorous regulatory reviews. Prices often have no relationship to normal QALY or DALY cost-benefit standards, and more importantly, have no relationship to the magnitude of incentives necessary for inducing investments in R&D.

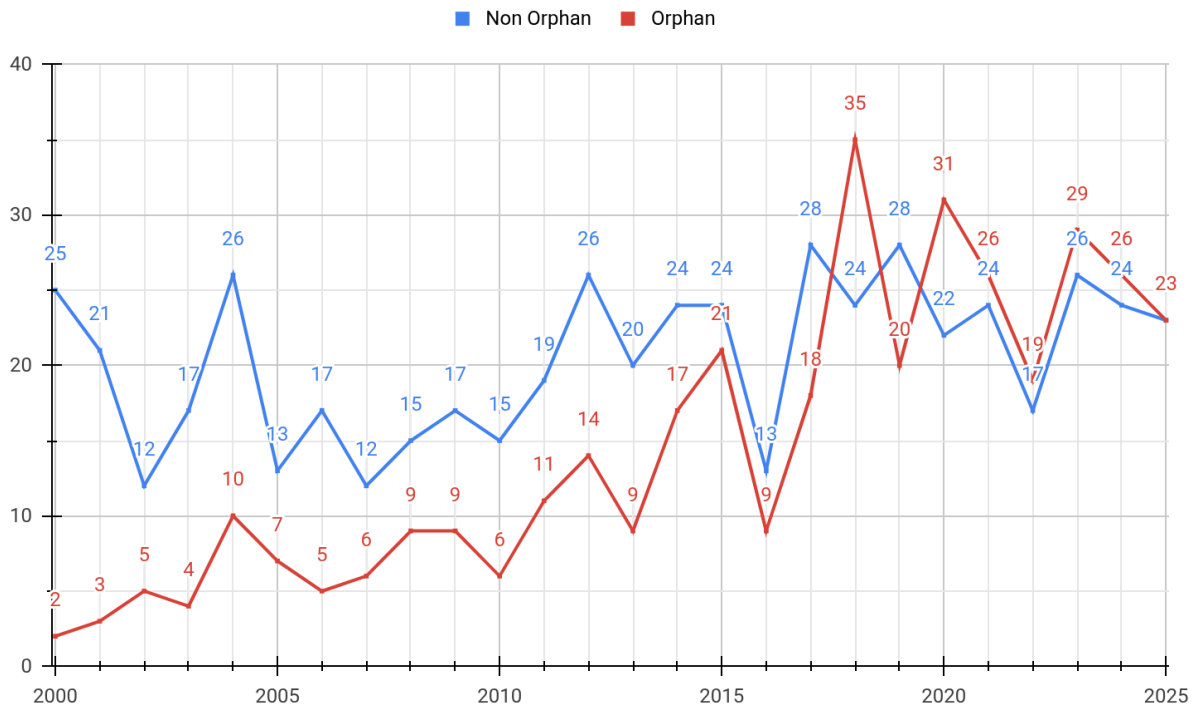
The U.S. government should consider reforming the incentives for the development of treatments for rare diseases in ways that are more economically efficient and which provide a better basis for achieving policy objectives regarding more equitable access.

Approvals for treatments for legally defined rare diseases have significantly increased

KEI tracks new drug approvals here: https://drugdatabase.info/novel-drug-approvals/. In 2000, the FDA approved 27 new drugs, including 2 for a designated Orphan Indication, or 7 percent of all approvals. In the next 5 years (2001 to 2005), the FDA approved 111 new drugs, including 29 with orphan drug status, or 26 percent of all approvals. From 2010 to 2019, 42 percent of all new drug approvals had an orphan drug designation. From 2020 to 2025, 53 percent of all new drug approvals had an orphan drug designation (see Figure 2).

[29] Zazie Huml, U.S. legislative proposals requesting the National Academies study feasibility and benefits of de-linking pharmaceutical innovation from drug prices, KEI Briefing Note 2026:3, May 4, 2026.

Figure 2: Orphan and non orphan new drug approvals (by year)



Orphan drug designations and product development risks

Through August 15, 2026, the FDA has approved 8,193 orphan drug designations. Of these, 1,369 had the designation withdrawn or revoked before an FDA approval, and 1,437 designations received an FDA approval, including 17 that eventually had the designation withdrawn or revoked.

Table 1: Number of FDA orphan designation approvals, from 1982 to August 15, 2026

Number of designations	8,193	
Designated and not approved	5,387	65.8%
Designated and approved	1,420	17.3%
Designated, but designation withdrawn or revoked	1,369	16.7%
Designated and approved, but designation withdrawn or revoked	17	0.2%

Based upon these statistics, and not taking into account the probability that existing designations will eventually obtain approvals, 17.5 percent of all designations led to the product

obtaining an FDA approval (one FDA approval for every 5.7 designations). When eliminating all designations withdrawn or revoked, the probability of approval is 20.8 percent, or one for every 4.8 designations.

One can also calculate the odds of approval by taking into consideration the mean or median days between designation and approvals, and look at the ratio of approvals to lagged designations. When there are a growing number of designations over time, this will show more favorable odds of approvals.

Table 2 provides the average and median times from designation to approval by period. The median for the 1985 to 2025 period was 4.7 years, with some significant differences over time. From 2000 to 2009, the median time was 2.6 years, and it was 6.0 years from 2020 to 2025. The 2020 to 2025 numbers are likely impacted by COVID-19.

Table 2: Average and Median Time from Designation to Approval, by Period

Days	Average	Median		**Years**	Average	Median
1985 to 2025	2,172	1,716		1985 to 2025	5.9	4.7
1990 to 1999	1,525	1,304		1990 to 1999	4.2	3.6
2000 to 2009	1,502	936		2000 to 2009	4.1	2.6
2010 to 2019	2,147	1,577		2010 to 2019	5.9	4.3
2020 to 2025	2,660	2,191		2020 to 2025	7.3	6.0
2000 to 2025	2,298	1,809		2000 to 2025	6.3	5.0

[a] *When the approval comes after, and not before, the designation.*

In this attached Google Sheet (link), the tab “byyear” provides comparisons of the number of designations and approvals by calendar year and provides calculations of the ratio of approvals to designations in the current year, as well as in lagged periods.

If you compare the Orphan indication approvals in 2025 to the designation 6 years before, in 2019, 27.7 percent, or one in 3.6 designations, led to an FDA approval.

The odds of obtaining an FDA approval for an orphan indication are less risky than assumed by many policy makers and commentators.

The Orphan Drug Tax Credit

Congress has provided and amended several times an Orphan Drug Tax Credit (ODTC) for clinical trial expenses on products for the treatment of rare diseases. The credit applies to outlays on qualifying expenditures on trials from the time a product obtains an FDA designation for its use for an indication classified as an orphan disease, until the FDA grants marketing approval for that indication.

The ODTC was available beginning in 1982, lapsed in 1996 and 1997, and is now permanent. The credit was 50 percent until 2017, when it was reduced to 25 percent beginning January 1, 2018.

The Treasury publishes estimates of the cost (referred to as a tax expenditure) of the ODTC, by fiscal year. From 1994 to 2025, the Treasury estimated the cost at $26.7 billion. From 2018 to 2025 (the tax credit was changed from 50 to 25 percent in 2018), the Treasury estimated the tax expenditures at $14.7 billion. During that period, the FDA granted 3,221 new orphan designations for products, gave approval to 710 orphan indications (one drug can be FDA approved for multiple orphan indications), and 209 drugs were first approved as an orphan product.

Table 3: Treasury estimate of tax expenditures for ODTC, 2018 to 2025 fiscal years

Treasury estimate of ODTC tax expenditures	$14,710,000,000
Number of orphan designations	3,221
Number of approvals of orphan designations	710
Number of new drugs with orphan indication	209
ODTC per designation	$4,566,905
ODTC per approved designation	$20,718,310
ODTC per approved new orphan drug	$70,382,775

The ODTC statistics understate the costs of trials for orphan indications and new orphan drugs because the credit is not available for all foreign trials,[30] excludes costs paid for by governments and charities, costs incurred before and after FDA designations and approvals of indications, and corporate overhead and some other costs. That said, they do provide considerable insight. The data on ODTC per approved indication or approved new drugs are risk-adjusted numbers, incorporating both successful and unsuccessful trials.

Because the ODTC was set at 25 percent between 2018 and 2025, dividing the Treasury's estimated tax expenditures by 0.25 (or multiplying by 4) provides the total qualifying clinical trial expenditures claimed on corporate tax returns. These empirical claims reflect real-world clinical trial spending across both successful and unsuccessful drug programs. The amount of expenses on trials taxpayers claimed on income tax returns, for this period, comes to $18.3 million per orphan designation, and $82.9 million per approved indication. Both numbers are significant but considerably less than what many policy makers and journalists assume.

[30] Foreign trials qualify for the credit when there is an insufficient patient population within the U.S. to gather reliable and reproducible clinical data for the testing.

The most widely cited academic study of drug development costs remains the 2016 paper by Joseph DiMasi, Henry Grabowski, and Ronald Hansen.[31] Using a confidential, industry-supplied sample of 106 investigational drugs, of which only two were originally approved for orphan indications, the authors estimated the average out-of-pocket cost of Phase I, II, and III clinical trials at $339.3 million per approved New Molecular Entity (NME), rising to $1.395 billion when adjusted for the risks of clinical failure (expressed in 2013 dollars, excluding the cost of capital).[32]

Differences between DiMasi trial cost estimates and ODTC data

The ODTC treasury data are for federal fiscal years, and the FDA approval data are for calendar years, both for the period 2018 to 2025.

The data from the 2016 DiMasi paper is both the estimated out-of-pocket cost on trials to support the approval of a new molecular entity, and the estimate of the risk-adjusted cost of those trials (taking into account outlays on failures). The DiMasi data are expressed in 2013 dollars.

Table 4 compares the Treasury estimates of ODTC outlays to the estimates of trial costs in the 2016 DiMasi paper. The ODTC data and DiMasi estimates have differences in what is being measured. The comparisons are not “apples to apples.” DiMasi focuses on trials relating to a NME, relies on company supplied data, and includes significant overheads on trial costs.[33] The ODTC data are related to orphan indications, of which there may be more than one on the same product, and exclude some direct trial costs (such as some foreign trials and expenses paid for by third parties) and corporate overhead, but are auditable numbers used on tax returns.

With these caveats, the differences are striking. When comparing the costs used to claim a tax credit for an orphan indication to DiMasi’s estimate of out-of-pocket costs on a NME, the DiMasi figure of $339.3 million is more than 18 times as high. DiMasi’s $1.395 billion estimate is for the pre-approval cost of trials, adjusted for failures, and this is nearly 17 times higher than the $82.9 million in costs claimed by companies for the ODTC, for each FDA approval of an orphan indication, a statistic which also includes the risks of failures.

If one compares the costs that a company used to claim the ODTC for all indications and, compared this to the number of drugs (209) the FDA, the data on the ODTC overstates the costs of approvals, because many of the ODTC trials are for new indications on older drugs. But

[31] DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ. 2016 May;47:20-33. doi: 10.1016/j.jhealeco.2016.01.012. Epub 2016 Feb 12. PMID: 26928437.
[32] Ibid. Page 30.
[33] 100 percent of direct costs in one of his earlier papers.

still, DiMasi's risk-adjusted out-of-pocket costs are 5 times higher than the ratio of ALL the costs claimed for the ODTC to the 209 new orphan product approvals.

Table 4: Amounts claimed to IRS for ODTC and DiMasi 2016 estimates compared

	Amount claimed to IRS for purposes of ODTC[a]		**DiMasi 2016 paper**
Per orphan Indication (3,221)	$18.3 million	Out-of-pocket trial costs on a product	$339.9 million
Per approved orphan indication (710)	$82.9 million	out-of-pocket trial costs adjusted for failures	$1,395 million
Per FDA approved novel orphan products (209). Note: The amounts claimed for the ODTC include multiple indications on the same product, AND trials on new indications for products already on the market.	$281.5 million	out-of-pocket trial costs adjusted for failures	$1,395 million

a. ODTC tax expenditure, x 4.

Changes in the Treasury estimates of the ODTC tax expenditures

In the past several years, the Treasury has significantly reduced its estimates of the ODTC tax expenditures.

Table 5: Treasury estimates of the ODTC tax expenditures by year, FY 2023 to FY 2027 (in millions)

	2025	2026	2027	2028	2029	2030	2031
FY 2023 estimate	$3,990	$4,800	$5,770	$6,940	$8,360	$10,060	$12,110
FY 2024 estimate	$3,120	$3,640	$4,250	$4,960	$5,790	$6,760	$7,900
FY 2025 estimate	$2,160	$2,420	$2,700	$3,020	$3,370	$3,770	$4,210

FY 2026 estimate	$2,150	$2,340	$2,410	$2,690	$3,010	$3,360	$3,760
FY 2027 estimate	$1,960	$2,140	$2,340	$2,560	$2,810	$3,360	$4,030

Why have the Treasury estimates of the ODTC changed so dramatically? Does this reflect a slowdown in spending on trials for rare diseases? Perhaps the number of new orphan products approved by the FDA peaked in 2018, the year after the credit was cut, and the number of new indications plateaued from 510[34] in 2017, the last year for the 50 percent credit, to 400 in 2025, the most recent full year.

There were and are impacts on eligibility for the Medicare Drug Price Negotiation Program that have influenced the interest in pursuing orphan indications.

- August 16, 2022. The IRA creates the Medicare Drug Price Negotiation Program with a narrow orphan drug exclusion. A drug or biologic was excluded from negotiation only if it was designated for a single rare disease or condition and its only approved indication (or indications) was for that one disease. The moment a drug picked up a second orphan designation, even without approval, or any non-orphan approved indication, it lost the exclusion.
- March/June 2023. CMS issued implementing guidance clarifying that once a drug lost the exclusion, CMS would use the date of the drug's first approval, not the date it gained the non-orphan indication, to measure negotiation eligibility. That was a significant change in the trigger: a drug could be on the market for a decade under its sole orphan indication, then pick up one broader indication and become immediately negotiation-eligible, since the eligibility clock had effectively been running the whole time.
- July 4, 2025. The One Big Beautiful Bill Act (OBBBA) rewrote the exclusion for initial price applicability year (IPAY) 2028 onward, in two ways:
    - Broadened who qualifies: orphan drugs designated for one or more rare diseases or conditions are now excluded, as long as every approved indication is for a rare disease, so a second (or third) orphan designation no longer disqualifies a drug, as it did before.
    - Changed the clock for drugs that eventually cross over: for a drug that does later get a non-orphan approval, the 7-year (small molecule) or 11-year (biologic) negotiation-eligibility countdown now starts from the day after that non-orphan approval, not from the drug's original approval date.
- September-October 2025. CMS finalizes guidance for IPAY 2028.
- June 12, 2026. CMS issued its first formal proposed rule (for IPAY 2029 and beyond), largely codifying the same standard.

Multi-orphan-only drugs (several rare-disease indications, no common-disease use) are now fully excluded from the Medicare price negotiations. Before the OBBBA, multi-orphan-only drugs

[34] Our numbers for calendar year orphan designations are based on data downloaded from the FDA on August 15, 2026.

were not excluded, which the pharmaceutical industry argued disincentivized companies from pursuing additional rare-disease indications for fear of losing the exclusion.

Pre-OBBBA, drugs that crossed into a non-orphan indication were immediately negotiation-eligible (the clock was measured from original FDA approval). Post-OBBBA, crossing over starts the clock fresh from the non-orphan approval date, which, for a drug that spent years on the market under an orphan indication first, pushes negotiation eligibility much further into the future than under the old rule.

Replacing the ODTC with a more targeted subsidy

The Treasury estimates of the tax expenditures on the ODTC have changed dramatically over the past five years. The FY 2028 cost estimates have changed from $6.94 billion in the FY 2023 estimate to $2.5 billion in the FY 2027 estimate. The FY 2027 estimates put the tax expenditure at $3.36 billion in 2030, compared to more than $10 billion in earlier estimates. While significantly reduced from earlier estimates, it represents both a significant federal outlay and, at the same time, a small subsidy for products that anticipate large global revenues.

The Vertex drug Trikafta, a treatment for cystic fibrosis, had sales of $2.5 billion in the second quarter of 2026. Evrysdi (risdiplam), a Roche drug to treat spinal muscular atrophy, had sales of CHF968 million in the first six months of 2026. Darzalex (daratumumab), a J&J drug for multiple myeloma, had sales of $8.2 billion in the first six months of 2026. Products like these are eligible for the tax credit and no concessions at all are made on pricing or access.

Congress should replace the ODTC with a more targeted subsidy for the development of drugs to treat rare diseases, one that places conditions on pricing and access, and targets trial subsidies to have more impact on innovation, providing deeper subsidies for products that will generate lower returns.

Proposal

Repeal the ODTC and replace it with a subsidy program that has a specific target level of funding, tied to US GDP levels. For example, a funding level of 1.25 basis points of GDP would provide for $4 billion in funding in 2026, and it would increase every year and could be increased or decreased by Congress, depending upon support for this type of biomedical R&D.

Entities seeking grants to subsidize trials would apply to a fund that required transparency of funding requests and trial outcomes, and an agreement to lower product prices or reduce the term of all relevant exclusivities, after product sales exceeded a set benchmark, which could be adjusted annually by HHS. Legislation would include the authority to condition grants on a binding, judicially enforceable waiver of a specific number of exclusivity-years, and/or to accept government set pricing in the US market, triggered by the sales benchmark.

The fund could set an initial subsidy level and benchmark revenue trigger, such as 60 percent of trial costs and $1 billion in cumulative global sales, and if the fund is was depleted too rapidly or too slowly, it could dynamically change the cumulative sales trigger, or the trial subsidy and reset the targets the following year. The US could also ask its trading partners to co-fund the subsidy, making more R&D funding, rather than higher global drug prices, the objective in trade negotiations.

Compulsory Licensing of Patents and Other Intellectual Property Rights

The United States has a number of separate mechanisms that can be used to override the exclusive rights of a patent. The march-in right in the Bayh-Dole Act is limited to cases where the federal government has funded an invention, and rarely does it extend to all patents used to block competition, for a novel FDA approved treatment. 28 USC § 1498(a) provides for more general authority to override patent rights, for uses deemed by and for the government (see discussion above). The DOJ or the FTC has obtained compulsory licenses in a variety of competition cases, not only on patents, but on know-how.[35] Following a Supreme Court Decision in eBay Inc. v. MercExchange, L.L.C., a large number of compulsory licenses have been ordered by courts (sometimes called running royalties on infringing uses of patents, when injunctions are withheld). There are also a number of specialized statutes on compulsory licensing, including those relating to nuclear energy, the Clean Air Act, rights in test data for agricultural chemicals, and a variety of cross licensing obligations in government lead research consortiums.

In the Bayh-Dole Act, for a march in, the licensing terms, including royalties, are set by the federal agency that funded the invention. Courts determine compensation in the 28 USC § 1498(a) competition and eBay/ injunction cases. In *sui generis* statutes, royalties and other terms depend on the specific statute. For example, in the nuclear energy case, the standard for compensation for non-voluntary use of a patent include:[36]

> (A) the advice of the Patent Compensation Board;
> (B) any defense, general or special, that might be pleaded by a defendant in an action for infringement;
> (C) the extent to which, if any, such patent was developed through federally financed research; and
> (D) the degree of utility, novelty, and importance of the invention or discovery, and may consider the cost to the owner of the patent of developing such invention or discovery or acquiring such patent.

[35] 2024:3 KEI Briefing Note: What measures do US competition authorities refer to in technology transfer mandates; 2024:2 KEI Briefing Note: Examples of US competition cases that mandate transfer of technology and know-how.
[36] 42 U.S. Code § 2187 - Compensation, awards, and royalties.

One of the major barriers to using compulsory licenses on medical inventions is the uncertainty over compensation that a court will eventually award. Proceedings on 28 USC § 1498(a) compensation cases can take years.

Congress should create a specialized authority to issue compulsory licenses on patents, data and regulatory exclusivities, with procedures that do not involve extensive delays, and provide guidance on standards for compensation.

Access to Manufacturing Know-How

Congress needs to mandate technology transfer once a period of exclusivity expires, in order to ensure that (1) biosimilar or generic entry occurs on a timely basis and price competition is vigorous, and (2) biosimilar or generic products are of a high quality, and patients are not subject to unethical experiments when known treatments exist.

Proposal

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 progressive delinking of R&D incentives from exclusive rights

Ultimately, the fundamental flaw in the current incentive system is the use of legal monopolies on inventions, data, regulatory approvals and know-how to reward successful investments in R&D. An alternative reward system based upon competitive claims on an innovation reward fund (such as the Medical Innovation Prize Fund proposal in several legislative proposals) is the leading example for an alternative. It has the following features:

- Reward fund fixed in size to a percentage of US GDP. Past bills provided for 55 basis points ($191 billion). KEI recommends 60 basis points ($208 billion), more than $4 billion in new drugs approved by the FDA,
- Funded pro-rata by entities that provide health insurance (public, private, employer, etc.),
- All products are available as generics or biosimilars, resulting in far lower prices, greater and more equitable access, elimination of cost-based coverage/reimbursement formularies, as well as considerable savings for governments, private insurers, employers and consumers,
- A competitive allocation of market entry rewards to developers based partly upon the impact of innovations on health outcomes, as well as other criteria, and
- An open-source dividend (2 to 5 percent of market entry rewards and/or revenues) to persons and entities openly sharing knowledge, technology, data and access to materials, which were determined by a jury of experts to have contributed to the successful development of a product.

Progressive implementation

The holdup in serious consideration of delinkage has always been the challenge of dealing with the transition. The breakthrough has been KEI's proposal to introduce delinkage progressively by capping all exclusivities at 14 years initially, combined with a combination of market entry rewards and R&D subsidies. This ensures that innovation is protected or enhanced. Then progressively (annually), there is a reduction of the years (or months) of exclusivity and an increase of the market entry rewards and R&D subsidies until eventually all incentives are delinked from exclusive rights and monopolies.

WTO TRIPS Flexibilities

Concerns about compatibility with WTO TRIPS Agreement flexibilities are based upon a naive and incorrect understanding of the WTO rules on intellectual property. Exceptions to patent exclusivities can be implemented within TRIPS Articles 30, 31 or 44. Articles 30 and 44 are the

most obvious choices, and both work because the delinkage system provides very substantial compensation or remuneration to patent holders, and both will be evaluated in connection with the 2001 Doha Declaration on TRIPS and Public Health[37], which states, in paragraph 4:

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.
>
> In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Studying the feasibility of delinkage

Congress will not consider radical changes in the system of biomedical innovation incentives unless there is a serious evaluation by objective and trusted institutions.

Zazie Huml has published a *2026:3 KEI Briefing Note* titled “U.S. legislative proposals requesting the National Academies study on the feasibility and benefits of delinking pharmaceutical innovation from drug prices.”[38] Since the 112th Congress, there have been five similar versions of the terms of reference for the study included in 10 legislative proposals, with bipartisan support from members from both the House and the Senate.

It is not obvious that the National Academies is the best entity to undertake such a study, and alternatives could include parts of HHS or a special commission or task force, given clear terms of reference and conflicts of interest.

Implementing delinkage in selected areas

There has been fairly broad support, including from industry, to implement delinkage for incentives for the development of antibiotic drugs where the objectives of innovation on the one hand, and restricting access to products, on the other, present conflicts.

Sir Andrew Witty, when CEO of GSK, proposed that delinkage be introduced for rare diseases, where prices were arbitrary.[39]

Senator Bernie Sanders once introduced a bill to introduce delinkage for drugs to treat HIV, a disease where many of the patients are already on public sector programs; the federal

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[37] Declaration on the TRIPS agreement and public health., WTO, WT/MIN(01)/DEC/2. 20 November 2001. https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
[38] https://www.keionline.org/bn-2026-3
[39] https://delinkage.org/gsk-ceo-andrew-witty-exploring-delinking-rd-charge/

government's role in R&D was significant, and there is public interest in ensuring that persons living with HIV are receiving transmission-reducing and health-improving treatments.[40]

There are challenges in designing a prize fund approach for a specific and narrowly defined disease. For example, at one point there was a significant interest in the development of treatments for HCV. Today, there are effective treatments available as generic products and less motivation for investing in new treatments.

IP and Technology Buy-outs

In some cases, it makes sense to buy rights in patents, data and know-how, in order to avoid a prolonged period of access and equity restrictive prices on important medical products. These buyouts can be voluntary or mandatory. Mandatory buyouts could involve 28 USC § 1498(a), or a *sui generis* authority.

A fund for voluntary buyouts could leverage the massive purchasing power of the United States, and could be particularly cost effective in cases where there is more than one acceptable product with relatively similar efficacy for the same disease. For example, in a world with three companies with similar products that were not colluding, the one company to sell the technology to the federal government would have a significant reward, and the remaining companies would be faced with competition from low priced generic products. There are plenty of markets where this could be done in a cost-efficient way.

Another area for technology buyouts is to clear out the patents on upstream or complementary inventions. For example, patents on ritonavir were blocking the most efficient uses of several other products, including, according to experts, better treatments. This was probably the case in the Cellpro patent dispute, and it took a DOE march-in case[41] to liberalize access to the FISH diagnostic test patents, and enable better testing options, and a court-ordered compulsory license on HCV patents to do the same for HCV tests.[42] In some cases, instead of using compulsory licensing, the government can just buy-out the technology, and either license it or place it in the public domain, with or without a geographic or disease field of use.

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[40] S.1138, 11th Congress. S.Hrg. 112-570 — THE HIGH COST OF HIGH PRICES FOR HIV/AIDS DRUGS AND THE PRIZE FUND ALTERNATIVE. 112th Congress (2011-2012). Also: Press Release. The High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative, May 15, 2012 https://www.sanders.senate.gov/press-releases/the-high-cost-of-high-prices-for-hiv-aids-drugs-and-the-prize-fund-alternative/

[41] A license was issued as part of a settlement between parties.

[42] Innogenetics v. Abbott Laboratories, 512 F.3d 1363 (Fed. Cir. 2008). Infringement case involving HCV genotyping diagnostics; permanent injunction denied, remanded to district court to determine terms of a compulsory license.