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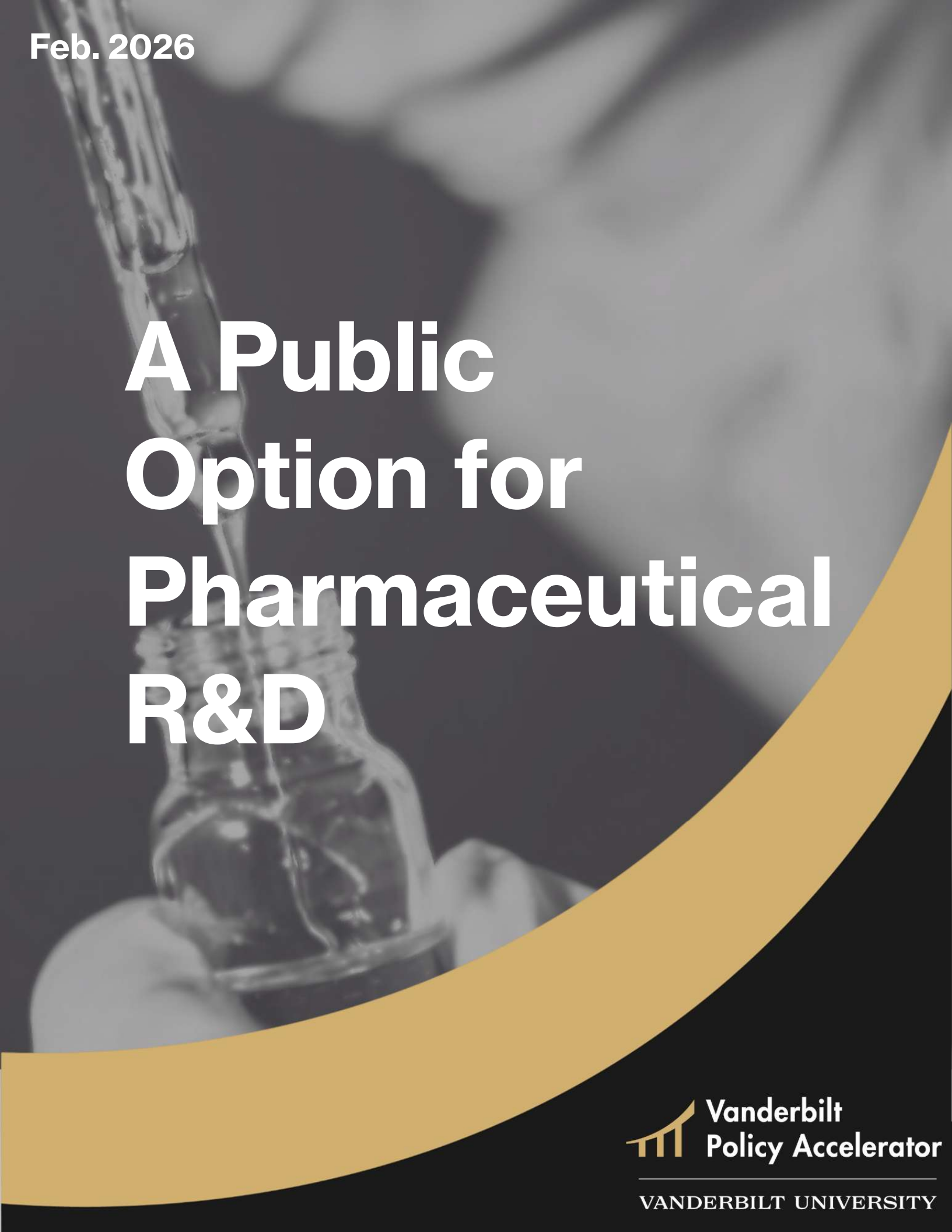
A Public Option for Pharmaceutical R&D



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Introduction

The United States has the world's most successful pharmaceutical industry, responsible for numerous blockbuster drugs and important scientific advances. But the vast majority of human diseases still have no treatments on the market,[1] and high prices preclude many from accessing the treatments where they do exist. Much time and many resources have been spent attempting to incentivize the industry to lower prices and ramp up research and development (R&D) in specific areas, however the central problem remains: an industry built entirely around the goal of maximizing profits falls short on social returns. To address the issue at its root, I propose the creation of a National Pharmaceutical Institute (NPI), a federal public pharmaceutical R&D institute that would engage in full-cycle drug development at scale, filling R&D gaps, providing competition in key market sectors and making public investment in the sector more efficient.

By all business measures, large private pharmaceutical companies are extremely successful. They live up to their promise to shareholders by maximizing returns on their investments so expertly that on average, these companies secure profit margins twice the Standard & Poor's 500 index (S&P 500).[2] For investors, pharmaceutical giants have long been a safe bet, in part because the most unpredictable part of their business (early stage scientific development) is largely de-risked by steady public investment. Big Pharma companies have also proven themselves very adept at all the usual tactics available to minimize their tax liabilities, cut costs, and grow their market share with minimal competition, allowing them to steadily rake in high profits.

So Big Pharma is clearly good at business, but how good is its business for society? Over and over, profit-motivated tactics that contribute to public health disasters have taken over the headlines and sparked widespread outrage—from the opioid epidemic to insulin-rationing deaths. Meanwhile, the industry has become *less* productive in terms of bringing new, clinically meaningful innovations to market. The number of new drugs approved for market per inflation-adjusted $1 billion spent on R&D has declined

[1] Of the roughly 19,000 recognized human diseases, only around 22% have FDA-approved treatments, and only 5% of the over 7,000 identified rare diseases have approved treatments. See: https://everycure.org/ and https://www.malacards.org/ for further information.
[2] Fred D. Ledley et. al., *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*, 323 JAMA, no. 9 (Mar. 3, 2020), at 834, 837, https://jamanetwork.com/journals/jama/fullarticle/2762308.

significantly since the 1950s, falling roughly 80-fold by the 2010s,[3] and though levelling off somewhat in the 2020s, continues to show overall decline.[4] All the while, many large pharmaceutical companies get away with contributing little or nothing at all to the tax base, while commanding higher and higher prices for their products.[5]

In recent years, untold hours of debate have occurred in Washington and around the country about how best to rein in rising drug costs and generally curb the excesses of Big Pharma. However, much of the debate—and virtually all the legislation and regulation in recent years that is supposedly aimed at fixing these problems—misses the point: Big Pharma is doing exactly what it's supposed to do for its bottom line. These companies are just doing business in an economy that rewards them for downsizing and outsourcing, amassing huge troves of intellectual property rights, and prioritizing shareholders over the larger public.

Current proposals for addressing drug prices, consolidation, and even waning innovation fall short because they do not address the underlying incentives of the industry. To truly rectify these issues requires a structural approach. Recognizing this, a "public pharma movement" has been coalescing and quickly gaining momentum in the United States. This movement—composed of patient advocates, academics, legal scholars, and increasingly, public officials—argues that regulation alone cannot assure a safe and adequate supply of the medicines we need at prices we can afford. Thus, these groups have united around demands for a public option in pharmaceutical production[6] as the necessary transformative solution to high drug prices and waning innovation. Nevertheless, this movement has yet to fully tackle the highest leverage point in the pharmaceutical value chain: research and development (R&D).

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[3] Mariana Mazzucato et. al., UCL Inst. for Innovation and Pub. Purpose, *The people's prescription: Re-imagining health innovation to deliver public value* (Oct. 2018), at 15, https://www.ucl.ac.uk/bartlett/public-purpose/wp2018-10.

[4] Kenneth D. S. Fernald et al., *The pharmaceutical productivity gap - Incremental decline in R&D efficiency despite transient improvements*, 29 DRUG DISCOV TODAY, no. 11 (Nov. 2024), https://www.sciencedirect.com/science/article/pii/S135964462400285X?via%3Dihub.

[5] Brad Setser & Tess Turner, *Big Pharma rakes in $215 billion a year in America — yet pays almost no taxes*, BUSINESS INSIDER (Aug. 3, 2023), https://www.businessinsider.com/big-pharma-companies-taxes-american-billion-dollar-profits-drugs-healthcare.

[6] Dana Brown, *Medicine For All: The Case for a Public Option in the Pharmaceutical Industry*, THE NEXT SYSTEM PROJECT (Sept. 2019), https://thenextsystem.org/medicineforall; *see also* GANESH SITARAMAN & ANNE ALSTOTT, THE PUBLIC OPTION (2019) (see for a discussion of public options generally).

This paper makes the case for the creation of a National Pharmaceutical Institute on the basis of 1) public return on public investment, 2) directing pharmaceutical innovation based on areas of greatest public health need and speeding up innovation, 3) building public power and reducing regulatory capture, and 4) providing meaningful market discipline to Big Pharma through competition in the brand-name drug market. Further, it shows that there can be significant economic, political, and health benefits to pursuing such a public option in pharmaceutical R&D.

I. The Problem: Business and societal needs don't align when it comes to medicine

Big Pharma's business model fails to meet our needs as a society and wastes critical research dollars in the process.[7] While the industry relies heavily on public investments, companies themselves capture virtually all of the returns on this investment,[8] walling off their discoveries behind thickets of patents and other intellectual property protections. By engaging in competitive science–as opposed to open science—the industry wastes key public R&D dollars by duplicating research unnecessarily.[9] Additionally, while benefitting from vast reserves and growing financial rewards for its work, the industry contributes little to closing a large existing R&D gap.[10] Moreover, its pricing practices, coupled with the U.S.'s patchwork health insurance system, are highly inequitable and impede access to essential medicines for millions of Americans.

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[7] *See* Mariana Mazzucato, *How taxpayers prop up Big Pharma, and how to cap that*, LA TIMES (Oct. 27, 2015), https://www.latimes.com/opinion/op-ed/la-oe-1027-mazzucato-big-pharma-prices-20151027-story.html.

[8] Ekaterina Galkina Cleary et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, 4 JAMA HEALTH FORUM, no. 4 (Apr. 28, 2023), at 1, 9, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378#248981925.

[9] *See The Open Pharma Revolution: Deconstructing the Business Models of Collaborative Drug Discovery*, DRUG PATENT WATCH (Aug. 3, 2025), https://www.drugpatentwatch.com/blog/the-open-pharma-revolution-deconstructing-the-business-models-of-collaborative-drug-discovery.

[10] *See* Roderik F. Viergever, *The mismatch between the health research and development (R&D) that is needed and the R&D that is undertaken: an overview of the problem, the causes, and solutions*, GLOBAL HEALTH ACTION (Oct. 10, 2013) at 1, 4-5, https://www.tandfonline.com/doi/full/10.3402/gha.v6i0.22450; *see also* Mark Sullivan, *Rethinking pharmaceutical development: A not-for-profit model to address global health inequities*, 12 FUTURE HEALTHCARE J., Issue 2 (Jun. 2025), https://doi.org/10.1016/j.fhj.2025.100255.

A. Socialized risk and privatized rewards

Public investment has long underpinned pharmaceutical R&D in the United States. Taxpayers invest billions in pharmaceutical development every year through the National Institutes of Health (NIH) and Department of Defense (DoD) and through numerous state initiatives like the Texas Cancer Institute and the California Institute for Regenerative Medicine. Research has shown that nearly 75 percent of novel medications (those that are not just simple tweaks on existing medications) are developed with NIH funding.[11] In fact, funding from The NIH contributed to every single one of the 356 novel drugs approved from 2010–2019.[12] Currently, the vast majority of NIH funds—over 80%—are directed towards extramural research (that is, granting out research funds to third parties like universities and companies) rather than intramural (i.e. in-house) research.[13] Almost all of the fruits of these public investments, however, accrue to private interests.

[11] Mazzucato, *supra* note 7.
[12] Ekaterina Cleary et al., *Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010–2019*, (Inst. for New Econ. Thinking Working Paper Series No. 133, 2020), https://ssrn.com/abstract=3731819.
[13] National Institute of Health, *Review of National Institutes of Health Structure, Policies, and Programs* 85, https://www.ncbi.nlm.nih.gov/books/NBK612401/.

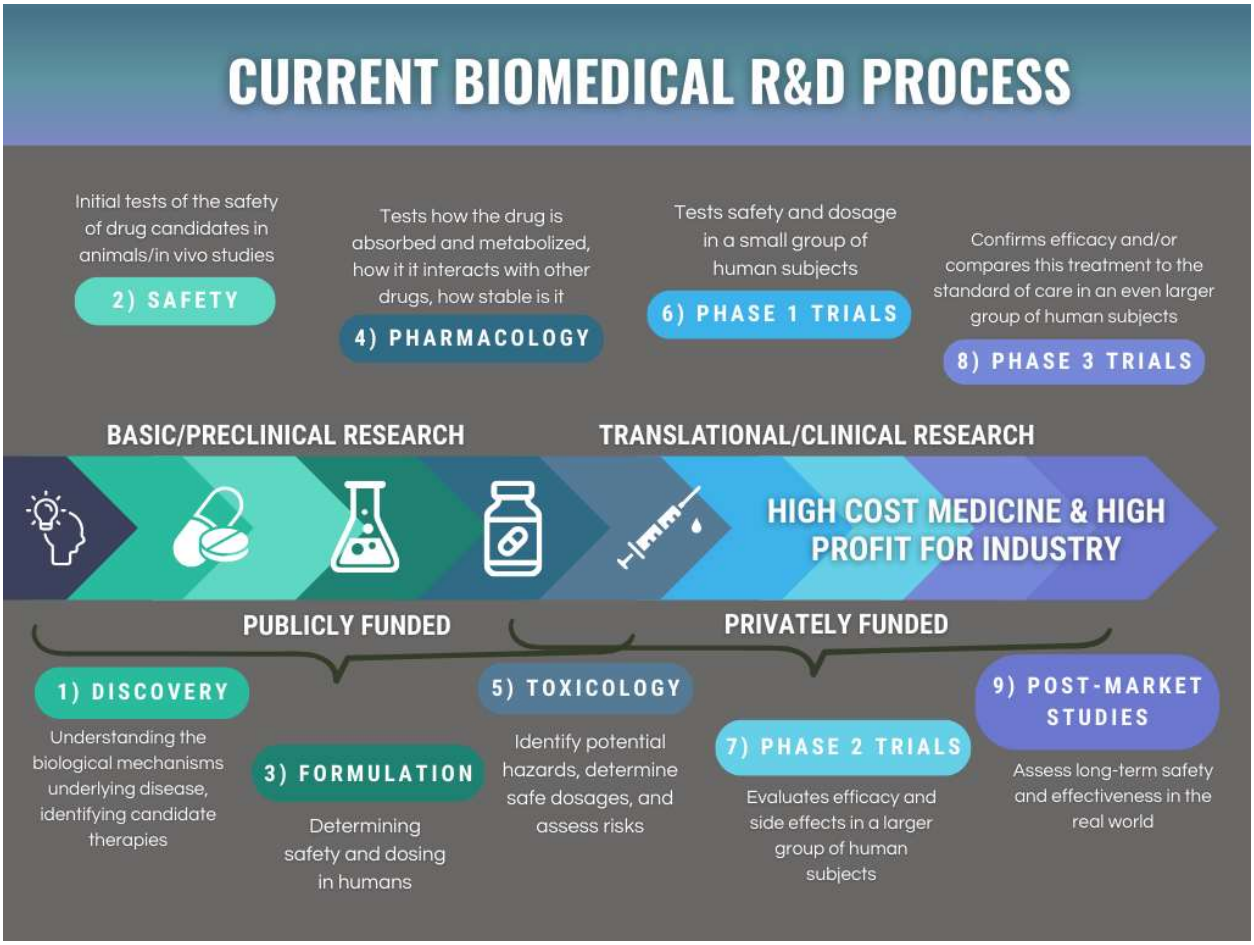

Figure 1: Simplified schematic of the current biomedical R&D process and its funding sources. The R&D process can be iterative, and there can be overlap in some of these steps. Additionally, there is overlap in funding sources as the public sector funds some clinical research, just as the private sector funds some basic research. (see Figure 2 for further information).

While publicly-funded researchers at government labs, universities, and small biotech companies often undertake the tedious and critical early phases that develop new chemical entities and medical technologies, prove their biological potential to treat disease, and test their safety in early trials, they currently rely on industry to fund and conduct the late-stage clinical trials needed to gain regulatory approval for new drugs. As the private-sector takes control of the product in this phase and protects it heavily with a complex set of intellectual property (IP) rights, only it has the ability to market the resulting product and reap the associated rewards.

Figure 2: Illustrative example: NIH vs Industry funded basic and translational biomedical research, 2010-2019.[14]

These IP rights are ostensibly extended to the industry to encourage innovation. Intellectual property law grants inventors exclusive rights on their products, allowing them to charge monopoly prices. However, as highlighted in the Congressional report, The Role of Patents and Regulatory Exclusivities in Drug Pricing, "because the exclusivity that IP rights provide may enable the rights holder (e.g., a brand-name drug manufacturer) to charge higher-than-competitive prices for a period of time, rights holders may have an incentive to lengthen that time period as much as possible."[15] In addition to the typical 20-year patents granted on a new drug, the industry takes advantage of several regulatory exclusivities.[16] Moreover, the industry has been accused of engaging in numerous forms of "trickery" from patent thicketing[17] to patent

[14] Illistruation adapted from Fred Ledley, *Who Really Pays for Drug Development? Both Government and Industry,* BIOSPACE (July, 14, 2023), https://www.biospace.com/opinion-who-really-pays-for-drug-development-both-government-and-industry.

[15] KEVIN J. HICKEY, ERIN H. WARD, CONG. RSCH. SERV., R46679, THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES IN DRUG PRICING (2025), https://www.congress.gov/crs-product/R46679.

[16] The FDA grants both data and marketing exclusivities to drug makers. Data exclusivities precludes other drugmakers from using the FDA's safety and effectiveness findings for a reference product and marketing exclusivities preclude the FDA from approving *any other application* for the same pharmaceutical product and use.

[17] Patent thicketing is the anti-competitive practice of securing numerous (sometimes hundreds) of overlapping patents on the same product to deter competition due to the risk of infringement. This is possible because patents can be conferred not only for a drug formulation but also for a combination of

evergreening[18] and pay-for-delay schemes[19] used to garner further extensions of these monopoly rights, even if the patent-holder has long recouped all R&D costs.

B. Inefficient and wasteful investments

Despite the fact that the public sector has largely de-risked the research process for Big Pharma, the industry still extracts exorbitant prices for its products, alleging that high prices are necessary in order to develop new medicines and account for the cost of failures. However, evidence suggests that these prices *do not* reflect the cost of R&D. A study of new drugs on the market between 2009 and 2018 found no association whatsoever between estimated research and development investments and list prices on new drugs.[20] These findings echo that of an earlier study which found that profits from high drug prices in the U.S. generated "substantially more than the companies spend globally on their research and development."[21]

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active and inactive ingredients, the purposes of the drug (e.g., to treat high blood pressure and to treat migraines), the methods used to administer the drug to a patient (e.g., an inhaler or an oral tablet), the method for manufacturing the drug, and other chemicals related to the active ingredient. AbbVie famously created an impressive patent thicket on their drug Humira, applying for over 300 patents, almost all of them filed after the drug was approved, blocking competition for many years. See Rebecca Robbins, *How a Drug Company Made $114 Billion by Gaming the U.S. Patent System,* N.Y. TIMES (Jan. 28, 2023), https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html.

[18] Patent evergreening is the practice of filing for new patents on secondary features of a drug just as prior patents are due to expire, thereby extending effective exclusivity past the original twenty years. Roche has been very successful at evergreening some of its cancer medications. For example, the original patent for Herceptin was filed in 1985, but subsequent patent filings could extend exclusivity all the way through 2033 for a total of 48 years of monopoly rights. See *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Price,* I-MAK (Aug. 2018), https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.

[19] Pay-for-delay agreements are "reverse settlements" in which brand-name manufactures pay off generic companies to not bring competitor drugs to market. A well-known case here involves Cephalon pharmaceuticals, which paid four generic drug makers over $200 million to delay generic versions of its popular narcolepsy drug, Provigil, for years. That allowed Cephalon to hike the price of Provigil while keeping generic competitors off the market. See Press Release, Federal Trade Commission, FTC Sues Cephalon, Inc. for Unlawfully Blocking Sale of Lower-Cost Generic Versions of Branded Drug Until 2012 (Feb. 13, 2008), https://www.ftc.gov/news-events/news/press-releases/2008/02/ftc-sues-cephalon-inc-unlawfully-blocking-sale-lower-cost-generic-versions-branded-drug-until-2012.

[20] Olivier J. Wouters et al., *Association of Research and Development Investments With Treatment Costs for New Drugs Approved From 2009 to 2018*, 5 JAMA NETWORK OPEN, no. 9 (Sept. 26, 2022), at 1, 1, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796669.

[21] Nancy L. Yu et al., *R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices*, HEALTH AFFAIRS BLOG (Mar. 7, 2017), https://www.healthaffairs.org/content/forefront/r-d-costs-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices.

Moreover, some pharmaceutical companies are not responsible for *any* of the research and development outlay behind their most profitable products. According to a 2019 study, an average of fewer than 20% of the best-selling drugs sold by companies like Pfizer and Johnson & Johnson were developed in-house.[22] For Big Pharma companies, many of their "innovations" are just acquisitions bought from smaller companies that have already proven safety and efficacy.

Industry also benefits from subsidies and tax breaks that help it maintain the high profits to which it has become accustomed. The result is that the U.S. pays more for its pharmaceuticals than any other country in the world—far more than other high-income countries. Moreover, the exorbitant prices on name-brand medications drive overall drug spending (and rising healthcare costs in general), comprising over 80% of drug expenditures[23] though only accounting for around 10% of prescriptions.[24] For example, in recent years new cancer drugs routinely sold for an average of over $150,000 per course of treatment[25] and the novel gene therapy drug, Lenmeldy, costs a whopping $4.25 million per treatment.[26]

Drugs developed with large amounts of public funding are no exception to high prices. For example, the prostate cancer drug Xtandi was developed with over $74 million in NIH and Department of Defense funds that brought the drug through Phase 2 clinical trials.[27] However, once commercialized by Astellas pharmaceuticals in 2012, Xtandi was brought to market at nearly $90,000 a year (soon rising to $200,000 a year) grossing

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[22] Emily H. Jung et al., *Do large pharma companies provide drug development innovation? Our analysis says no*, STAT: First Opinion (Dec. 10, 2019), https://www.statnews.com/2019/12/10/large-pharma-companies-provide-little-new-drug-development-innovation/.

[23] Office of Sci. & Data Pol'y, Asst. Sec'y for Planning & Evaluation, U.S. Dep't of Health & Human Servs., *Trends in Prescription Drug Spending, 2016–2021* (2022), https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf

[24] *Generic Drugs*, U.S. Food & Drug Administration (last updated: 03/13/2025), https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs.

[25] Patrict DeMartino, Miloš Miljkovic, & Vinay Prasad, *Potential Cost Implications for All US Food and Drug Administration Oncology Drug Approvals in 2018*, 181 (2) JAMA Intern. Med. 152-296 (Feb. 1, 2021), https://pubmed.ncbi.nlm.nih.gov/33165499/.

[26] Zoey Becker et al., *UPDATED: Most expensive drugs in the US in 2025*, Fierce Pharma (Aug. 11, 2025), https://www.fiercepharma.com/special-reports/most-expensive-drugs-us-2025.

[27] Bishal Gyawali et al., *Government Funding for the Development of Enzalutamide*, 11 JAMA Oncol., no. 2 (Feb. 1, 2025), https://pubmed.ncbi.nlm.nih.gov/39699929/.

$20 billion in global sales for the company by 2020[28] while costing public payers like Medicare billions. Some important biologic drugs have benefitted from *billions* in NIH investments, like Stelara and Enbrel which received $6.5 billion and $2.6 billion in NIH funding respectively.[29] Medicare alone has since spent tens of billions covering these drugs for their beneficiaries, leading to their inclusion in Medicare drug price negotiations under the Inflation Reduction Act.[30]

In addition to this exorbitant spending needed to subsidize Big Pharma's business model, the public sector loses substantial potential revenue because the industry offshores profits in order to evade taxes. Most large pharmaceutical firms reportedly paid no income tax at all in 2024.[31]

Moreover, a 2020 report revealed "while the financial reserves of 27 of the largest pharmaceutical companies grew drastically between 2000 and 2018, essential investment remained static, with an exponential increase in drug prices instead being used to maximize shareholder value."[32] That is, Big Pharma companies spend much of the investment on things like stock buybacks and dividends rather than pursuing new drug development.[33]

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[28] Memorandum from Knowledge Ecology International to Sec'y of the Dep't of Health and Human Services, *Memorandum in support of the petition to HHS to exercise the march-in or paid up royalty right in patents on the prostate drug Xtandi* (Jan. 25, 2022), https://www.keionline.org/wp-content/uploads/KEI-Memo-HHS-Xtandi-Bayh-Dole-March-in-Paid-up-Royalty-25Jan2022.pdf.

[29] Edward W. Zhou et al., *Considering Returns on Federal Investment in the Negotiated "Maximum Fair Price" of Drugs Under the Inflation Reduction Act: an Analysis*, (Inst. for New Econ. Thinking, Working Paper No. 219, 2024), https://www.ineteconomics.org/uploads/papers/WP_219-Federal-spending-on-drugs-Ledley-et-al-final.pdf.

[30] *See* PROTECT OUR CARE, MEDICARE NEGOTIATIONS FOR LOWER DRUG PRICES EXPLAINED: STELARA, https://www.protectourcare.org/wp-content/uploads/2024/08/Stelara.pdf; *see also* PROTECT OUR CARE, MEDICARE NEGOTIATIONS FOR LOWER DRUG PRICES EXPLAINED: ENBREL, https://www.protectourcare.org/wp-content/uploads/2024/09/Enbrel.pdf.

[31] Brad W. Sester, *American Pharmaceutical Companies Still Aren't Paying Tax in the U.S.,* COUNCIL ON FOREIGN RELATIONS (Mar. 14, 2025), https://www.cfr.org/blog/american-pharmaceutical-companies-still-arent-paying-tax-us.

[32] Editorial, *Drug pricing and pharmaceutical innovation: a false promise*, 406 THE LANCET (Oct. 25, 2025), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(25)02160-9/fulltext; *see also* Jung, *supra* note 22 (for research on pharmaceutical acquisitons).

[33] *See, e.g.*, Victor Roy et al., *Shareholder Payouts Among Large Publicly Traded Health Care Companies*, 185 JAMA INTERNAL MED., no. 4 (Feb. 10, 2025), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2829736; *see, e.g.*, William Lazonick et al., *US Pharma's Financialized Business Model*, (Inst. for New Econ. Thinking, Working Paper No.

C. Inequitable pricing that impedes access to essential medicines

Medications are equitably priced when they are affordable even for the poor and the health systems that serve them.[34] Equitable access to medicines implies that the poor should pay less for essential medicines than the rich (i.e. the out-of-pocket burden on the population should be based on a progressive pricing system). Despite being a high-income and highly-developed country, the U.S. has a very inequitable healthcare system that does not assure access to essential medicines for all—particularly for the uninsured and underinsured.

Indeed, each year millions of Americans report not taking medications as prescribed[35] due to prohibitive cost. A 2023 Kaiser Family Foundation poll found around 3 out of 10 Americans—approximately 27.5 million people[36]—reported not taking medication as prescribed due to cost. Rates are even higher in low-income populations, young adults, and those with disabilities or chronic diseases. Scholars note that the lack of price controls and the overall average drug price burden[37] create major barriers to equitable access to medicines both for our health system as a whole, and for millions of individual Americans. For consumers, the average out-of-pocket costs for pharmaceuticals has been growing,[38] and the percentage of overall healthcare

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60, 2017), https://www.ineteconomics.org/uploads/papers/WP_60-Lazonick-et-al-US-Pharma-Business-Model.pdf.

[34] "Equitable pricing" is not used as a term of art, here, but rather a moral and ethical position taken by many in the access to medicines movement. The underlying justification is a humanitarian and social one, based on the understanding that medications are medically useless if they are not taken when needed due to unaffordable pricing. The WHO defines equity as, "the absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other dimensions of inequality (e.g. sex, gender, ethnicity, disability, or sexual orientation)," and asserts that health equity is then "achieved when everyone can attain their full potential for health and well-being." In our estimation, health equity then implies that medications must be accessible to the people and health systems that need them. *See Health Equity*, WORLD HEALTH ORGANIZATION, https://www.who.int/health-topics/health-equity.

[35] This includes not taking a medication at all, despite medical necessity, and/or skipping doses, taking less medication, or delaying a prescription fill.

[36] Grace Sparks et al., *Public Opinion on Prescription Drugs and Their Prices*, KFF (Oct. 4, 2024), https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/.

[37] Amy Y. Tsou et al., *Ethical Perspectives on Costly Drugs and Health Care*, 97 NEUROLOGY J., no. 14, 685, 686 (Oct. 5, 2021), https://doi.org/10.1212/WNL.0000000000012571.

[38] Justine Mallatt et al., *Consumer Out-Of-Pocket Drug Prices Grew Faster Than Prices Faced By Insurers After Accounting For Rebates, 2007–20*, 43 HEALTH AFFAIRS, no. 9, 1284, 1286 (Sept. 2024), https://doi.org/10.1377/hlthaff.2023.01344.

spending devoted to pharmaceuticals—both for consumers and payers—has dramatically increased over the last two decades.[39]

While the pharmaceutical industry can by no means be blamed for the fragmented and highly variable insurance landscape in the United States, its exorbitant prices—which we have already shown bear no relationship to R&D costs—fuel the inequitable downstream effects on low-income, uninsured, and underinsured individuals as well as public payers.

D. Lack of investment in areas critical to human health

By and large there is a mismatch between where private pharma R&D dollars flow and society's greatest needs. While significant investment is made in bringing products to market that have little to no clinical benefit over existing drugs (i.e. "me-too" drugs[40]), less investment goes towards antibiotics, vaccines, and other therapies critical to sustaining population health. Additionally, less than one fourth of all human diseases have an FDA-approved treatment,[41] indicating that significant areas of development are neglected all together while the majority of funds are channeled towards a small subset of profitable causes.

Products like vaccines and antibiotics are critical to the health of all Americans. However, they aren't typically thought of as market goods, given the high levels of externalities associated with their use, along with significant barriers to market entry. For example, society will always have a need for new antibiotics due to the very nature of bacteria, which evolves to defend itself against all attacks. In fact, tens of thousands of Americans die each year from resistant infections,[42] a rate which is only expected to increase as the antibiotic pipeline has dried up. As paradoxical as it might seem given this "opportunity" to save many lives, Big Pharma companies have very few new antibiotics in development due to a lack of financial incentives to bring these products to market.

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[39] U.S. GOV'T ACCOUNTABILITY OFF., PRESCRIPTION DRUG SPENDING, https://www.gao.gov/prescription-drug-spending.

[40] "Me-too" drugs are medicines with small (patentable) tweaks on existing medications available on the market. Often they involve offering the same medication through a different route of administration or dosage. Sometimes they offer no clinical benefit to patients, but serve as a way for industry to continue to reap monopoly rents from what are essentially existing discoveries.

[41] *The Problem*, EVERYCURE, https://everycure.org/the-problem.

[42] *Antimicrobial Resistance Facts and Stats*, CDC (Feb. 4, 2025), https://www.cdc.gov/antimicrobial-resistance/data-research/facts-stats/index.html.

First, by nature, antibiotics are meant to be curative (i.e. taken for a short period of time in order to cure an infection) and thus cannot bring in the revenue of a drug meant to be taken long-term for a chronic condition. Second, due to antibiotic resistance, a new antibiotic has a limited shelf-life.[43] Third, regulators often hold new antibiotics in reserve in order to slow the development of said resistance to new drugs, resulting in lackluster initial sales. Altogether, this makes for a stunning lack of incentive for the private market to deliver the antibiotics that society needs.

Vaccines, drugs for neglected diseases, mental health, and even cardiovascular therapies also face significant underinvestment compared to the need. None of legislation or regulation to date meant to address these gaps has transformed the sector.

In sum, despite pumping billions of dollars of public funding into an industry of strategic importance, society has not reaped rewards of corresponding value. Big Pharma has failed to develop therapies for the majority of human maladies and keeps many of its existing therapies out of reach for many consumers. Moreover, it wields enormous political and economic power to maintain this status quo, effectively evading all attempts at serious reform in recent decades. These outcomes are not predetermined, but rather result from deliberate policy choices.

II. The Solution: A public pharmaceutical R&D institute

Instead of continuing to attempt to cajole industry to do something it's not designed to do, we can choose to develop many essential medicines in the public sector in order to maximize public return on public investment, ensure that the medications the public most needs are affordable, and provide meaningful market discipline on existing pharmaceutical companies. Indeed, the U.S. public sector has already brought medicines to market numerous times when deemed necessary for strategic purposes, and avoided the additional costs associated with private drug development and profit-seeking. Moreover, large-scale public-sector biomedical research seems to have some

[43] Overuse of antibiotics in high-income countries–especially the US–clearly contributes to the unsustainable speed at which antibiotic resistance develops.

advantages over industry and academic-based research, particularly for high-risk, high-reward projects, as are common in drug development.

Historically, U.S. labs of various sizes have delivered innovative essential medicines according to public health need. For example, the Massachusetts state-owned MassBiologics has developed and distributed vaccines and other biologic drugs like monoclonal antibodies for well over a century.[44] In the early 1900s, the New York State Public Health Department developed and manufactured diphtheria antitoxin to address a growing epidemic in the city.[45] In the 1980s and '90s, the California Department of Public Health created treatment for infant botulism and distributed it at cost,[46] and the Department of Defense has a long history of developing vaccines for troop readiness, including the meningitis vaccine and the Japanese encephalitis vaccine.[47] Further, discoveries of the NIH intramural program have led to Gardsil, the highly effective HPV vaccine as well as the first HIV test kits and a supplement that slows macular degeneration,[48] a leading cause of vision loss in people over 60.

Public pharmaceutical R&D is a tried-and-true approach to meeting public health needs internationally as well. For instance, in the 1920's Canada's famed Connaught Laboratories[49] at the University of Toronto brought the world insulin as a treatment for diabetes,[50] ultimately saving millions of lives. Before the development of insulin, Type 1 diabetics died painful deaths within just a few years of diagnosis. Additionally, Brazil's public laboratories provide critical research and development of diagnostics and treatments for neglected and tropical diseases. In addition to identifying Chagas

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[44] *Facilities*, UMASS CHAN MEDICAL SCHOOL, https://www.umassmed.edu/massbiologics/about/facilities/.
[45] *Wadsworth Center History*, NEW YORK STATE DEPARTMENT OF HEALTH, WADSWORTH CENTER, https://www.wadsworth.org/about/history.
[46] Stephen S. Arnon, *Creation and development of the public service orphan drug Human Botulism Immune Globulin*, 119 Pediatrics, iss. 4, 785, 786 (Apr. 1, 2007), https://publications.aap.org/pediatrics/article-abstract/119/4/785/70183/Creation-and-Development-of-the-Public-Service?redirectedFrom=fulltext.
[47] Rick Docksai, *DoD Vaccine Research Saves Military, Civilian Lives*, U.S. ARMY (Jun. 2, 2017), https://www.army.mil/article/188814/dod_vaccine_research_saves_military_civilian_lives.
[48] Jeffrey Alexander & Rossana Zetina-Beale, *The Real Returns on NIH's Intramural Research*, 41 ISSUES IN SCIENCE AND TECHNOLOGY, no. 4, 36, 36 (Summer 2025), https://doi.org/10.58875/YZSL6513.
[49] *History*, UNIVERSITY OF TORONTO: CONNAUGHT FUND, https://connaught.research.utoronto.ca/history.
[50] Unlike the current US model in which federal funds flow to universities that do early-stage research, patent it, and then license the patents out to industry to bring drugs to market, the publicly-employed researchers at Connaught Laboratories brought insulin all the way through the development process and even manufactured it in-house. Additionally, the inventors originally refused to patent it. An agreement was later made with Eli Lilly to grant it patent rights in exchange for investing in scaled manufacturing capacity for the production of insulin.

disease and its agents and developing a robust malaria treatment, Brazil's principle public health laboratory, the Oswaldo Cruz Foundation, has played a key role in developing and providing vaccines to the region, including the yellow fever vaccine, and vaccines currently in late-stage development for schistosomiasis[51] and leprosy.[52] Finally, state-owned labs in Cuba developed the world's first lung cancer vaccine,[53] and Thailand's Government Pharmaceutical Organization has developed its own formulas for HIV[54] and COVID-19[55] antivirals and recently co-developed a Hepatitis C treatment[56]—all of which have played a key role at addressing public health concerns in the region by providing affordable access to treatments.

To date, however, much of the public pharma R&D in the U.S. has been ad hoc responses to specific needs like an outbreak or the private sector withdrawing from a research area. A strategic public pharma R&D program could be proactive and catalytic, anticipating and meeting public health needs on a wide variety of fronts. Perhaps this is why over fifty European Members of Parliament recently supported[57] a proposal to build a publicly-owned European Medicines Facility (EMF) with similar aims.[58] The EMF was conceived as a public service to proactively develop and distribute

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[51] *Brazilian vaccine for schistosomiasis, unprecedented in the world, is approved in phase 1 of clinical trials*, INSTITUTO OSWALDO CRUZ (Dec. 6, 2012), https://www.ioc.fiocruz.br/en/noticias/vacina-brasileira-para-esquistossomose-inedita-no-mundo-e-aprovada-na-fase-1-de-testes.

[52] *Trial LEP-F1 + GLA-SE in Healthy Adult in Areas Endemic for Leprosy*, CLINICALTRIALS.GOV (Oct. 4, 2024), https://clinicaltrials.gov/study/NCT06627257#study-overview.

[53] *See* Pedro C. Rodríguez et al., *Clinical development and perspectives of CIMAvax EGF, Cuban vaccine for non-small-cell lung cancer therapy*, 12 MEDICC Rev., no. 1, 17, 17 (Winter 2010), https://mediccreview.org/clinical-development-and-perspectives-of-cimavax-egf-cuban-vaccine-for-non-small-cell-lung-cancer-therapy/.

[54] Robert Steinbrook, *Antiretroviral Medications — From Thailand to Africa*, 351 N. ENGL. J.MED., no. 8, 739, https://doi.org/10.1056/nejmp048201.

[55] Anthony Margetts, *Covid 19 Vaccines in Thailand*, ISPE: ISPEAK BLOG (Mar. 15, 2022), https://ispe.org/pharmaceutical-engineering/ispeak/covid-19-vaccines-thailand.

[56] *Thailand's Government Pharmaceutical Organization (GPO) partners with DNDi and Pharco to register an effective and affordable hepatitis C treatment*, DRUGS FOR NEGLECTED DISEASES INITIATIVE (DNDI) (Jul. 1, 2025), https://dndi.org/press-releases/2025/thailand-government-pharmaceutical-organization-partners-dndi-pharco-register-hepatitisc-treatment/.

[57] *Europe, Fifty MEPs from different parties propose an amendment to establish European infrastructure for health as a public good*, FORUM DISUGUAGLIANZE DIVERSITA (Apr. 5, 2024), https://www.forumdisuguaglianzediversita.org/europe-fifty-meps-from-different-parties-propose-an-amendment-to-establish-european-infrastructure-for-health-as-a-public-good-forumdd-we-hope-that-the-european-parliament-will-not-miss-this-oppo/.

[58] *Amendment 379 to Proposed Article 40, rules governing the European Medicines Agency*, (Apr. 4, 2024), https://www.europarl.europa.eu/doceo/document/A-9-2024-0141-AM-379-379_EN.pdf.

new vaccines and therapies at the scale of the successful European Organization for Nuclear Research (CERN).[59]

To address U.S. drug affordability and innovation issues in the long-term, the U.S. needs a similarly large-scale public option in biomedical R&D. Thus, this paper proposes the creation of a National Pharmaceutical Institute (NPI), housed at the NIH, that focuses public investment in biomedical research on the areas of greatest need, adheres to the highest standards of transparency, and produces novel drugs at prices society can afford.

A systemic solution to the monopoly that Big Pharma currently has on our medicines supply, the NPI could set a new bottom line for drug development: instead of maximizing shareholder value, it could seek to maximize social value.[60] The NPI proposal is designed to meet those same goals and more, by directing public funding where it is most needed and managing the resulting intellectual property in the public interest.

Housed at the NIH, the NPI would benefit from close collaboration with other NIH institutes, many of which are already engaged in research to further understanding of specific disease groups and potential therapies. Critically, however, it would close the loop on many medicines developed with federal funding by completing the R&D process in-house and assuring that all resulting inventions are managed in the public interest. In addition to existing NIH intramural and extramural funds.[61] the NPI would manage its own budget (roughly equal to annual extramural funding) intended to support full-cycle in-house development of innovator drugs and devices led by federal scientists.

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[59] *Our History*, ORGANIZATION FOR NUCLEAR RESEARCH (CERN), https://home.cern/about/who-we-are/our-history.

[60] This idea echoes some previous proposals, such as one aimed at creating 10 federal laboratories, distributed around the US, with a mission to develop new drugs that was introduced to Congress in 2004 (Free Market Drug Act, H.R. 5155, 108th Cong. (2004), https://www.congress.gov/bill/108th-congress/house-bill/5155). However, that proposal differs from ours, as it was based on developing new therapies without intellectual property rights, distributing them as generics from Day 1. That proposal would also have higher start-up costs than our proposal (to build 10 new labs around the country) and might see less benefit from the potential scientific collaboration available to those working at the same location.

[61] Intramural research refers to research conducted by NIH employees, whereas extramural research refers to research conducted by outside scientists–like academics and hospitals–via grantmaking.

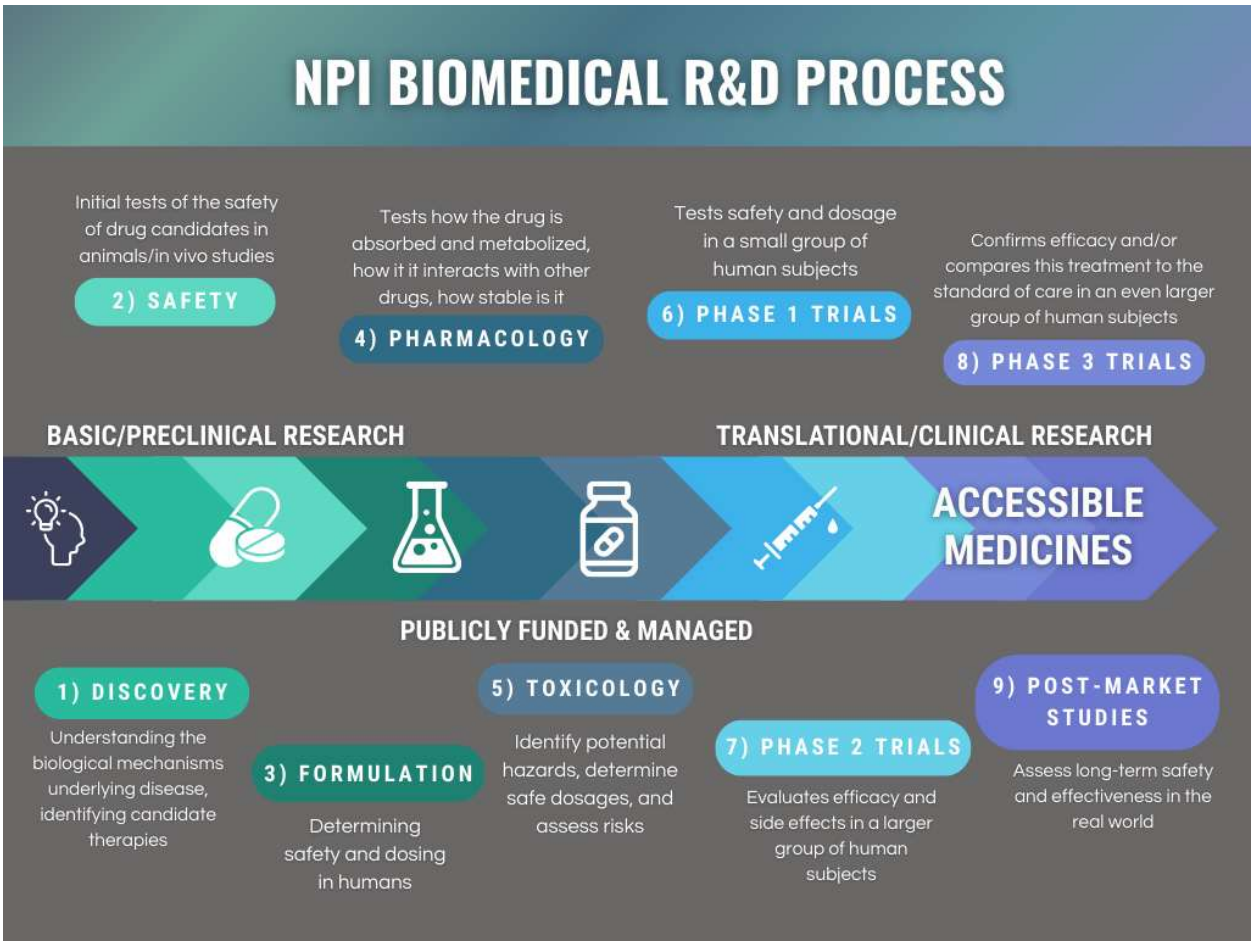

Figure 3: NPI Simplified Biomedical R&D Process.

In order to achieve these goals, the NPI should:

a) Engage in in-house full-cycle development of both drugs and medical devices. This means taking new products all the way through clinical trials and the FDA approval process to bring them to market,[62] rather than handing them off to industry after initial successful trials. This is essentially an expansion of NIH intramural research, but via a new institute with a specific mission to deliver innovative therapies for the public good;
b) Make these drugs and devices available to the public at equitable and accessible prices via at-cost, cost-plus, or even below-cost pricing where merited. This might include selling many new drugs at-cost or cost-plus prices in order to help

[62] Federal entities have brought some pharmaceuticals all the way through trials and to market in the past. The aim of this proposal is to proactively pursue that approach at scale in order to correct for market failure and address public health and equity concerns.

sustain the Institute, while subsidizing the cost of some medicines critical to public health (e.g., vaccines) or ensuring affordable access (e.g., asthma inhalers, epipens) in order to maximize social good. The Institute could contract with existing FDA-approved manufacturers to bring these drugs to market (if not directly manufacturing itself), with a preference for public and non-profit manufacturers in order to keep the public interest centered and costs controlled;[63]

c) Identify and acquire candidate discoveries:
    i) The Institute should monitor the results of research conducted or supported by the NIH and by other appropriate public and private entities in order to identify discoveries that, if subjected to further research and development activities, may be suitable for the submission of applications for approval by the FDA as drugs, biological products, or devices for use in humans.
    ii) The Institute should have the right of first refusal[64] to choose whether or not to develop promising candidates from publicly-funded research before allowing private companies to pick the most profitable prospects. This would enable the Institute to utilize robust early-stage research capabilities that public funds already support while leaving private companies significant development opportunities.
d) Prioritize investments based on need, not profit-making potential: In allocating the Institute's budget and human resources, candidate discoveries should be prioritized according to the degree of potential public health impact (determined both by the total burden of disease addressed and by health equity measures), unmet needs in current product development, and potential for scientific breakthrough.
e) Model the highest levels of transparency: The Institute should adhere to the highest standards of transparency by sharing pre-clinical and clinical trial data,

[63] This approach works with the status quo in which the federal government does not operate large-scale public manufacturing facilities for all types of pharmaceuticals. However, it gives preference to existing and future public and non-profit manufacturers, recognizing that there is both existing small-scale capacity at the state and federal level as well as pending legislation in numerous states and at the federal level to create more public manufacturing capacity.

[64] The public sector already employs a right of first refusal in various ways, including for the preservation of affordable housing, land use and conservation, for new utility transmission projects, and some service contracts. For example, in the housing sector, some cities, counties and housing authorities have codified rights of first refusal for affordable housing. In practice, this means that a government entity (or sometimes a designated non-profit) has the opportunity to buy affordable rental properties (within a given time frame) before the owner can sell to anyone else, thus preserving affordability.

cost data, and prioritization methods in an open and timely fashion. Such information shall include, but is not limited to:

i) Identification of candidate discoveries that are receiving priority;
ii) All safety and effectiveness data and information submitted in application to the FDA for new drug approval;
iii) Summary findings made in carrying out such activities;
iv) Copies of all licensing agreements and contracts entered into with both public and private entities.

f) Manage Intellectual Property in the public interest: The Institute should own and manage the intellectual property related to its discoveries in the public-interest.
   i) Like other NIH Institutes, it should take out patents on its inventions (defensive patenting, to prevent enclosure by the public sector),[65] however no trade secrets or other forms of intellectual property should be sought as these tend to slow down the innovation process and wall-off scientific discoveries from the public;
   ii) The Institute will establish a patent pool[66] to hold its patents and facilitate speed of innovation as well as public-interest access to scientific developments. The patent pool could serve as the basis for a growing federal repository of all publicly-held patents that serve as a collective body of scientific knowledge.
   iii) Patents in the patent pool should be licensed to other public and non-profit entities free of cost. Licenses to private entities should ensure public-interest terms like non-exclusivity, fair pricing terms, and reciprocity rules.[67]
g) Reinvest Royalties from licenses into the Institute to further research and development or meet other public-interest aims.

[65] Scholars disagree on the necessity of defensive patenting by the public sector, but it is presented here as the most cautious option. Perhaps patenting by the NPI could be phased out over time if deemed unnecessary. Nevertheless, patenting the NPI's inventions would allow the NPI to recoup some funds by licensing out its technologies.

[66] Patent pools are an agreement between two or more patent owners to license one or more of their patents to one another, or to third parties. Patent pools reduce transaction costs and can help speed up scientific innovation.

[67] The idea is to mimic CopyLeft rules but to do so for patents. Our analysis is that CopyLeft has been an important innovation that democratizes access to knowledge and encourages collaboration and innovation while providing clear and enforceable legal framework guaranteeing the rights of creators while also protecting them from the possibility of others profiting off their work.

The Institute could be financed by new appropriations, recognizing the public return that society would reap on this investment.[68] However, the need for new appropriations could be offset by implementing a tax on drug companies proportional to their advertising spend, as countries like Italy do.[69] Other forms of income from the industry itself could also be leveraged to fund public R&D, from windfall taxes to settlement funds from cases brought against pharmaceutical companies for violations of the law. Additionally, over time, the savings to public payers on innovator drugs should offset some of the initial costs of capitalizing and running the Institute.

A. Economic benefits

The NPI approach to drug development would also have a range of economic benefits. First, it would mean lower prices on brand-name drugs. It would directly reduce prices because it would develop new therapies and sell them at cost or below. As shown in Figure 4 below, even the highest estimate for NIH costs to develop a new therapy ($515.8 million) is 5.4 times less than what industry reports are its estimated R&D costs. Moreover, drugs developed fully in the public sector should require less overall investment than those developed in the private sector, as none of this capital would be directed towards marketing, exorbitant CEO pay, share buybacks or dividends to shareholders. For a comparison of estimated costs to bring drugs to market at public, for-profit and non-profit institutions, see Figure 4 below. Note, however, that these figures are illustrative, but not directly comparative given the heterogeneity of study methodology and the time periods covered.

[68] While the Institute may become self-sustaining over time, significant start-up costs would need to be incurred in order to build out laboratory capacity, hire new federal scientists, and acquire promising IP rights on publicly-funded medications from the private sector.

[69] Italian Medicines Agency (AIFA) Research & Development Working Group, *Feasibility and challenges of independent research on drugs: the Italian Medicines Agency (AIFA) experience*, 40 EUR. J. CLIN. INVEST., no. 1, 69, 70 (Dec. 18, 2009), https://onlinelibrary.wiley.com/doi/10.1111/j.1365-2362.2009.02226.x.

Reported R&D costs			
Institution(s)	National Institutes of Health (public)	DNDi (International non-profit)	PhARMA (private industry)
Estimated cost of developing a new medicine	Anywhere from $172.7-515.8 million[70] according to different estimates	$110-170 million[71]	$1.4-$2.8 billion[72]
Notes	Only the higher-end figure includes the cost of failed projects	Includes the cost of failed projects	Only the higher-end figure includes the cost of failed projects

Figure 4: Reported R&D costs of different institutions.

Indirectly, the entry of a new, major competitor in the name-brand pharmaceutical market could provide pressure for for-profit firms to reduce their prices. For instance, the NPI could strategically develop therapies in concentrated markets, like cancer immunotherapies. By entering a market like this that is subject to little competition at the moment, it could change the landscape for all players—public and private—driving overall launch prices down in this therapeutic class. In short, the NPI would create new competition in the pharmaceutical industry—creating an incentive for big pharma companies to operate more efficiently and to invest more in R&D themselves.

Moreover, as a public, not-for-profit initiative with a clear mission to deliver new therapies at accessible prices, the NPI would have no incentive to game the patent

[70] Aylin Sertkaya et al., *Costs of Drug Development and Research and Development Intensity in the US, 2000-2018*, 7 JAMA NETW. OPEN., no. 6, 1 (Jun. 28, 2024) https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820562.
[71] Amy Maxmen, *Busting the billion-dollar myth: how to slash the cost of drug development*, 536 NATURE, 388, 389 (Aug. 24, 2016), https://doi.org/10.1038/536388a.
[72] *See* Joseph A. DiMasi, *The Cost of Drug Development*, 372 N. Engl. J. Med., no. 20 (May 14, 2015), https://www.nejm.org/doi/full/10.1056/NEJMc1504317; *see also* Joseph A. DiMasi, *Assessing Pharmaceutical Research and Development Costs*, 178 JAMA INTERN. MED., no. 4, 587 (Apr. 2018), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2677016.

system the way that for-profit pharmaceutical companies do. With no shareholders to satisfy with short-term gains, the Institute could afford to invest in the long-term research needed to create breakthroughs in medicine and only minimally utilize IP rights to protect public inventions from private capture. Pharmaceutical companies spend tens of millions amassing and protecting their IP rights. The practice of secondary patenting alone costs payers and consumers billions every year[73]—a practice with the NPI would have no incentive to pursue.

All together, these reductions in brand-name medicine prices would help rein-in overall rising healthcare spending and potentially free up spending power that could be used on other goods and services, benefitting the economy as a whole. Furthermore, any revenues generated from the sale of the Institute's medicines would be used for purposes that benefit the wider public, whether to offset the costs of running the institute, subsidize the distribution of some essential medicines (like insulin or vaccines) or reinvest in research, all of which could help address rising healthcare costs over time. Without the need to maximize profits, the Institute would be free to make the best use of revenue to maximize social returns on our collective investment in advancing biomedical science.

B. Scientific and health benefits

The creation of the NPI would build on the existing success of the NIH intramural research program (IRP) and leverage the advantages it has over private sector and academic institutions when it comes to drug development. It would also speed up the scientific process by being fully transparent with its data and analyses. Lastly, it would focus funds where they are most needed to address critical gaps in the current innovation landscape.

The IRP model has some distinct advantages in terms of biomedical R&D. First, its government researchers are fully funded and not required to teach, so they can focus their full attention on long-term research goals. They also enjoy significant intellectual freedom due to the long-term and retrospective nature of federal funding for intramural research. Lastly, the internal diversity of scientists employed by the IRP—and the fact that they need not compete for funds—lends itself to interdisciplinary collaboration, which is essential to the innovation process.

[73] Dee Gill, *$52.6 Billion: Extra Cost to Consumers of Add-On Drug Patents*, UCLA ANDERSON REV., (Apr. 24, 2024), https://anderson-review.ucla.edu/52-6-billion-extra-cost-to-consumers-of-add-on-drug-patents/.

Intramural researchers are generally guaranteed funding for a four-year term with internal and external evaluations after each cycle. Depending on the evaluation, the researcher either maintains their existing budget for another cycle, or has it increased or decreased. Two consecutive negative reviews can result in a researcher's projects being shut down. By not having to constantly seek out new grant funds to support research projects, NIH researchers can afford to experiment and pursue long-term projects that are less feasible under other funding arrangements.[74]

As a result, IRP researchers can "develop a research agenda with near total freedom over what research projects they pursue and when they pursue them—all provided that they are later able to defend their choices at their next retrospective review."[75] This funding approach favors the high-risk, high-reward type of research project needed to advance biomedical science and drug development—a notoriously long and uneven process in which failure is much more common than success.

With the Institute's commitment to full transparency, the scientific process will speed up by reducing the transaction costs of research and assuring timely access for all to new discoveries. The current model of competitive science based on amassing intellectual property and sharing as little data as possible with competitor firms slows down scientific progress and contributes to wasteful duplication across firms. However, a large public R&D Institute, such as the NPI, that publishes all of its data for common use would contribute to the advancement of biomedical innovation across the field, reducing R&D costs even for for-profit firms. Open science accomplishes these goals by facilitating collaboration, reducing redundancies, simplifying access to information, and increasing the reliability of findings by enhancing their reproducibility.[76]

In addition to facilitating the growth of open science in the biomedical field, the NPI would help close the innovation gap by targeting R&D to areas of need like neglected diseases, antibiotics, and vaccines. Moreover, the institute's approach would also likely

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[74] Nicholas Graves et al., *Funding grant proposals for scientific research: retrospective analysis of scores by members of grant review panel*, BMJ, 343 (Sept. 27, 2011), https://www.bmj.com/content/343/bmj.d4797.
[75] Dan Traficonte, *Government Research*, 135 YALE L. J., 110, 148 (Oct. 31, 2025).
[76] The global approach to managing flu research and mitigation efforts illustrates the advantages of open science. The World Health Organization's "Global Influenza Surveillance and Response Network" provides a reliable and accessible platform for sharing critical influenza data. As such, it has supported global surveillance and research efforts critical to responding to seasonal and pandemic flu threats, allowing the whole world to quickly develop flu vaccines and responses appropriate for the specific circulating variants.

drive greater investment in early-stage research by private companies. Currently, many U.S.-based drug companies spend significantly less of their revenue on research and development, with substantially more going to profit-motivated activities like marketing and stock buybacks.[77] If companies could no longer exclusively capture government basic research, they would have to invest a greater share of their profits on their own research to remain competitive. This would help make the entire pharmaceutical sector more effective at innovating as basic science is crucial to the discovery process.

C. Political benefits

Critically, public full-cycle R&D will also increase public power and create political space for further policy and regulatory change. By eroding Big Pharma's regulatory capture and breaking its monopoly on our medicine supply, the public would have more power to negotiate private-sector drug prices and implement further transparency and accountability measures that keep the industry's excesses in check. As the NPI's contributions to science grow over time, corporate influence over politics from the pharmaceutical sector should show a corresponding decline.

Currently, drug pricing in the U.S. is an extraordinarily opaque process. Deals are cut by pharmaceutical companies to sell at different prices to different payers with a variety of discounts and rebates complicating the picture. Moreover, the details of these deals are generally treated like trade secrets. This creates confusion for consumers and lawmakers, but also challenges for payers' attempts to negotiate fair prices. By establishing a public R&D institute that openly publishes all pricing and contract data, the public (and lawmakers) will suddenly be privy to a large amount of data on the true cost of drug development, empowering them with critical insights they can use in negotiating fair contracts with the industry going forward.

Conclusion

While the U.S. pharmaceutical sector has made many important contributions to our society and economy, it has increasingly become a vehicle for extraction as the sector has consolidated its economic and political power. Moreover, despite the large and steady public investments channeled towards the industry, it has become less

[77] Arvis Angelis et al., *High drug prices are not justified by industry's spending on research and development*, BMJ, 380 (Feb. 15, 2023), https://www.bmj.com/content/380/bmj-2022-071710.

productive at bringing truly innovative products to market that help solve critical population and public health needs.

All attempts to date to remedy the situation through legislative and regulatory changes have failed to address the underlying mismatch between public health needs and private sector incentives. A public option in pharmaceutical R&D via the NPI model would serve as an antidote to the ills of Big Pharma's business model by increasing the pro-social impact of the whole sector through reduced and more equitable costs, greater innovation where its most needed, and a rebalancing of power between the public and private sectors in an industry critical area to human health and wellbeing.