

United States Senate

HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE

Bernard Sanders, Chair

Majority Staff Report

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Public Investment, Private Greed

Too many Americans cannot access the medicine they need. As millions of Americans ration treatments, the pharmaceutical industry continues to rake in huge sums of money. The U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP Committee) Majority Staff traced how pharmaceutical corporations use research funded by taxpayers to develop products to sell back to those same taxpayers for exorbitant profits. Key findings include:

- The federal government has a budget of \$54 billion to support medical research. The federal government helps in the search for new treatments and cures by:
 - Pushing forward research that sets the foundation for virtually all new prescription drugs;
 - Directly funding the invention of some medicines by researchers across the country;
 - Advancing clinical trials; and
 - Subsidizing manufacturing scale-up.
- With few exceptions, private corporations have the unilateral power to set the price of publicly funded medicines. The government asks for nothing in return for its investment. The consequences of this decision have never been examined systematically.
- In a first-of-its-kind analysis, HELP Committee Majority Staff documented the prices of federally supported prescription drugs, focusing on treatments developed with the help of scientists from the U.S. National Institutes of Health (NIH).
 - **The average (median) price of new treatments that NIH scientists helped invent over the past twenty years is \$111,000.**
 - **U.S. taxpayers virtually always pay more than people in other countries for treatments that NIH scientists helped invent.**

Name	Manufacturer	Condition	U.S. Price	International Price
Abecma	Bluebird Bio	Cancer	\$457,000	Germany: \$260,000
Ella	HRA Pharma	Emergency contraception	\$40	France: \$10
Hemgenix	uniQure/CSL	Hemophilia B	\$3.5 million	Unknown
Kepivance	Sobi	Severe mouth sores	\$19,000	Italy: \$5,000
Lumoxiti	AstraZeneca	Cancer	\$111,000	N/A
Luxturna	Spark Therapeutics	Inherited vision loss	\$850,000	France: \$630,000
Myalept	Amryt Pharma	Leptin deficiency	\$1.9 million*	France: \$580,000*
Prezcobix	Johnson & Johnson	HIV	\$29,000*	Japan: \$5,000*
Prezista	Johnson & Johnson	HIV	\$25,000*	Germany: \$4,000*
Spravato	Johnson & Johnson	Depression	\$25,000*	Canada: \$14,000*
Symtuza	Johnson & Johnson	HIV	\$56,000*	U.K: \$10,000*
Tecartus	Gilead Sciences	Cancer	\$424,000	Germany: \$306,000

Velcade	Millennium Pharmaceuticals	Cancer	\$54,000	France: \$11,000
Yescarta	Gilead Sciences	Cancer	\$424,000	Japan: \$212,000
Zokinvy	Eiger BioPharmaceuticals	Progeria	\$2.2 million*	Germany: \$2.4 million*

*per year

- HELP Committee Majority Staff also reviewed scientific records, financial filings, patents, and licensing agreements to uncover the crucial role of NIH scientists in developing two treatments with outrageous prices. In one case, HELP Committee Majority Staff identified royalty information that NIH keeps among its most closely guarded secrets.
 - **Case study #1 Hemgenix:** The world’s most expensive medicine—with a \$3.5 million price tag—is the culmination of major scientific breakthroughs led by researchers at St. Jude Children’s Research Hospital and NIH. However, NIH appears to have handed over taxpayer technology while obtaining vanishingly little in return. Licensing agreements reveal that NIH negotiated royalties of around 1% on sales, without any pricing constraints. Meanwhile, the company behind Hemgenix, uniQure, quietly disclosed that the price was “significant” and “most patients and their families will not be capable of paying for our products themselves.”
 - **Case study #2 Yescarta:** NIH scientists initially developed a cancer therapy that a small biotech worked to refine. The biotech told investors it was “highly dependent on [NIH] for research and development” but was scooped up by Gilead Sciences for \$11.9 billion, with its CEO, Arie Beldegrun, landing a \$694 million payout. Gilead initially set the U.S. price of Yescarta at \$373,000. It has since increased the price by more than \$50,000 to \$424,000—twice the cost of the therapy in Japan.
- **U.S. taxpayers should never pay more than what people in other wealthy countries pay for the drugs taxpayers helped develop.** Under existing law, federal agencies can require that pharmaceutical corporations set reasonable prices for new prescription drugs when they benefit from taxpayer support. This has been done before.
 - **After a pharmaceutical company launched an AIDS drug developed with the help of NIH scientists at \$10,000 per year, NIH responded in 1989 by inserting a “reasonable pricing clause” into contracts when taxpayers supported new drugs.** The clause was withdrawn six years later after industry pressure.
 - During the COVID-19 pandemic, the federal government included in some contracts a “most favored nation” obligation that required pharmaceutical companies to charge the U.S. government the lowest price among G7 countries like Canada, the U.K., France and Japan for initial vaccine doses. A similar requirement was applied to initial courses of the COVID-19 treatment Paxlovid.
- **The average price of new treatments that NIH scientists helped invent over the past twenty years is now more than ten times the price that led NIH to first introduce a reasonable pricing clause in 1989.** The federal government should reinstate and strengthen a “reasonable pricing clause” in all future collaboration, funding, and licensing agreements for medical research.

I. Introduction

There is a treatment rationing crisis in this country because of the outrageous price of prescription drugs. While the U.S. spent an astonishing \$629 billion on medicines, one out of four Americans cannot afford to take the medicine their doctors prescribe.¹ Americans pay, by far, the highest prices in the world for prescription drugs.²

As millions of people struggle to access medicines, the pharmaceutical industry continues to rake in huge sums of money. Last year, ten of the top pharmaceutical companies in the U.S. made a total of over \$112 billion in profits.³ That year, 50 top executives in these ten pharmaceutical companies took home over \$1.5 billion in compensation and stock awards.⁴ 50 pharmaceutical executives are also in line to receive golden parachutes equivalent to more than \$2.8 billion when they leave their respective companies.⁵

The pharmaceutical industry says it needs astronomical prices and profits to protect innovation. But the top pharmaceutical corporations spent more on sales and marketing than research and development (R&D) every year from 1999 to 2018.⁶ Over the past decade, 14 major pharmaceutical corporations spent \$87 billion more buying back stock and handing out dividends than investing in the development of new medicines.⁷ Most crucially, the pharmaceutical industry does not develop medicines alone. The federal government plays a foundational role in the search for new treatments and cures.

In this report, the HELP Committee Majority Staff trace how pharmaceutical corporations use research funded by taxpayers to develop products to sell back to those same taxpayers for exorbitant profits. The report documents the pricing for treatments invented with the help of scientists from the National Institutes of Health (NIH)—the first systematic attempt to quantify the price of federally supported medicines. The report also uncovers the role of federal scientists in developing two outrageously priced treatments. The report concludes with steps the federal government can take to ensure pharmaceutical corporations set reasonable and affordable prices for new medicines when they benefit from taxpayer support.

II. How the Federal Government Underpins Drug Development

The federal government sets the stage for new medicines with its substantial investments. Congress provided nearly \$54 billion for biomedical research across the U.S. government this year. The National Institutes of Health (NIH) alone has a budget of \$47.5 billion, making it the largest biomedical research funder in the world.⁸ Nearly 85% of NIH funding is given to external researchers based at universities and research labs across the country, with grants supporting more than 300,000 scientists.⁹ Over 10% of NIH funding supports research conducted by its nearly 6,000 scientists in federal laboratories.¹⁰ Other federal agencies, such as the U.S. Department of Defense, spend billions more in search of new breakthroughs.¹¹

Table 1: Congressional Appropriations for Biomedical R&D (FY 2023)¹²

Department	Agency and Program	Total
Health and Human Services (HHS)	National Institutes of Health	\$47.5 billion
	Advanced Research Projects Agency for Health	\$1.5 billion
	Biomedical Advanced Research and Development Authority	\$950 million
Department of Defense	Defense Health Program	\$3.0 billion
Veterans Affairs	Veterans Health Administration	\$916 million
Total		\$53.9 billion

The federal government helps accelerate research into new treatments and cures through a spectrum of support.

First, at the earliest stage, the federal government plays a role in pushing forward research for virtually all new medicines. Government scientists and federally funded researchers set the foundation for new medicines by making critical discoveries about how a disease works. This includes finding the right “biological target” to shoot for with new drug candidates. According to one study, NIH funding “contributed to published research associated with every one of the 210 new drugs approved by the Food and Drug Administration from 2010–2016” at a cost of more than \$100 billion to taxpayers.¹³ This underlying work is the riskiest and the most uncertain phase of research.

Second, the federal government directly funds the invention of some medicines. After identifying the right target, government scientists and federally funded researchers often identify the right drug candidate. One study found that publicly supported research had a major role in the invention of at least one in four new drugs.¹⁴ For newer, more complex medicines, that figure increased to four in ten new products.¹⁵ In a typical scenario, university or federal labs patent the medicines and then hand over monopolies to small biotech companies, often spinoffs, by signing a deal called an “exclusive license.” According to the U.S. Department of Health and Human Services, 245 therapeutics and vaccines have been brought to market using university and federal lab patents.¹⁶

Third, the federal government helps test some medicines. New medicines are required to go through extensive testing, including clinical trials, to receive U.S. Food and Drug Administration (FDA) approval. Government scientists and federally funded researchers help run these studies for some medicines. For example, in the case of cutting-edge gene therapies, researchers found the pharmaceutical industry sponsored or funded less than half of reported clinical trials, with the majority of trials receiving NIH and academic funding.¹⁷ If small biotech companies are developing the candidate, with each successful phase of testing, larger corporations become more interested in scooping up the drug candidate or the company, sometimes signing deals worth billions of dollars. These huge sums are not tied to any actual research and development investment, but instead reflect the massive profits larger corporations expect to make should the product receive FDA approval.

Finally, in some cases, the federal government even funds pharmaceutical corporations to help get medicines through the FDA approval process and to scale-up manufacturing. For example, the U.S. Biomedical Advanced Research and Development Authority (BARDA) helps medicines for public health emergencies get over the finish line. Many COVID-19 products developed as part of Operation Warp Speed benefited from this kind of support. Other agencies fund research into the latest manufacturing techniques.¹⁸

Beyond the targeted support outlined above, the federal government also provides many other kinds of support vital to medicine development. This includes tax breaks for research and development; patents and other government-granted monopolies called “exclusivities”; loans on favorable terms; and a pipeline of trained scientists.

Each medicine has a unique story. Some drugs rely more heavily on private investment. Others benefit from large public contributions at multiple stages. The federal government sometimes directly works with pharmaceutical corporations and, in other cases, funds researchers at universities that work with corporations. No matter the arrangement, with few exceptions, the result is the same: private corporations have the unilateral power to set the launch price of publicly funded drugs. The federal government asks for nothing in return for its investment. Part III describes the consequences of this decision. Part IV presents a path forward.

III. Taxpayers Pay Exorbitant Prices for Treatments NIH Scientists Helped Invent

One subset of federally supported medicines are drugs invented with the help of federal scientists. The NIH, for example, not only funds researchers in universities and labs across the country, but directly employs nearly 6,000 scientists. NIH scientists make remarkable breakthroughs, leading to the development of important medicines.

NIH scientists sometimes invent the medicine itself, or a key technology used in the medicine. Drug corporations gain permission to use the NIH patented invention through “licensing agreements.” NIH recently began publishing a list of these licenses and the corresponding medicines.¹⁹

Based on these disclosures, HELP Committee Majority Staff compiled a list of treatments using NIH patented inventions over the past twenty years.²⁰ Treatments using NIH patented inventions were considered to be developed with the help of NIH scientists. HELP Committee Majority Staff compared U.S. prices to other G7 country prices based on the NAVLIN database.²¹

Over the past twenty years, the median price of new treatments that NIH scientists helped invent is \$111,000. U.S. taxpayers virtually always pay more than people in other countries for treatments that NIH scientists helped invent. With the exception of one treatment, U.S. prices exceeded prices in other G7 countries.

Table 2: Prices for New Treatments NIH Scientists Helped Invent (2003-2023)

Name	Manufacturer	Condition	FDA Approval	U.S. Price	International Price
Abecma	Bluebird Bio	Cancer (Multiple myeloma)	2021	\$457,000	Germany: \$260,000
Ella	HRA Pharma	Emergency contraception	2015	\$40	France: \$10
Hemgenix	uniQure/CSL	Hemophilia B	2022	\$3.5 million	Unknown
Kepivance	Sobi	Severe mouth sores	2004	\$19,000	Italy: \$5,000
Lumoxiti	AstraZeneca	Cancer (Hairy cell leukemia)	2018	\$111,000	N/A
Luxturna	Spark Therapeutics	Inherited vision loss	2017	\$850,000	France: \$630,000
Myalept	Amryt Pharma	Leptin deficiency	2014	\$1.9 million*	France: \$580,000*
Prezcobix	Johnson & Johnson	HIV	2015	\$29,000*	Japan: \$5,000*
Prezista	Johnson & Johnson	HIV	2006	\$25,000*	Germany: \$4,000*
Spravato	Johnson & Johnson	Depression	2019	\$25,000*	Canada: \$14,000*
Symtuza	Johnson & Johnson	HIV	2018	\$56,000*	U.K.: \$10,000*
Tecartus	Gilead Sciences (Kite Pharma)	Cancer (Mantle cell lymphoma)	2020	\$424,000	Germany: \$306,000
Velcade	Millennium Pharmaceuticals	Cancer (Mantle cell lymphoma)	2003	\$54,000	France: \$11,000
Yescarta	Gilead Sciences (Kite Pharma)	Cancer (non-Hodgkin's lymphoma)	2017	\$424,000	Japan: \$212,000
Zokinvy	Eiger BioPharmaceuticals	Progeria	2021	\$2.2 million*	Germany: \$2.4 million*

*per year

The major limitation of this analysis is its scope. The treatments invented with the help of NIH scientists represent a small fraction of the medicines developed with NIH funding and support, which itself is only a portion of the entire federal government's support.²² But neither NIH nor other federal agencies publish detailed information about how the researchers they fund across the country support drug development. The analysis may also undercount the total number of treatments invented with the help of NIH scientists because it may exclude treatments where the corporation has not been required to secure a license (i.e., patent co-inventorship), or where a corporation has failed to secure a license (i.e., patent infringement). NIH does not publish this information. More transparency is needed.

The two case studies below illustrate how the federal government provides targeted support for drug development—and how the pharmaceutical industry uses this research to cash in.

a. Hemgenix (uniQure/CSL)

Hemgenix (etranacogene dezaparvovec) is a gene therapy used to treat a rare bleeding disorder called hemophilia B. Hemgenix works by sending genetic instructions to help the body produce a

protein that limits bleeding.²³ The instructions are sent using a delivery vehicle called a “viral vector.”

Hemgenix exists because of decades of public investment. The “viral vector” used in Hemgenix is derived from a virus discovered by NIH scientists in 1966, called adeno-associated virus (AAV).²⁴ NIH-funded scientists showed for the first time that AAV could be used to deliver genetic instructions in human cells, opening up the possibility of gene therapy.²⁵

In 1997, scientists at a Dutch academic hospital spun out a company called Amsterdam Molecular Therapeutics (AMT)—or what later become uniQure. Around the same time, researchers at St. Jude Children’s Research Hospital began studying gene therapies for hemophilia B, laying the groundwork for the genetic instructions contained in Hemgenix.²⁶

One big challenge in developing gene therapies is manufacturing. For this, AMT turned to the NIH. In 2002, NIH scientists invented a new manufacturing method that turned insect cells into a factory to produce AAV.²⁷ AMT signed a deal for the NIH manufacturing technology, and told investors that “in collaboration with scientists at the NIH, we developed a new manufacturing system.”²⁸ AMT also signed a separate “exclusive license” deal to get a monopoly on another NIH technology behind Hemgenix: a method of using a version of AAV called AAV5.²⁹

Based on the HELP Committee Majority Staff’s review of the full licensing agreements, NIH appears to have handed over taxpayer technology while obtaining little in return.

Table 3: NIH-AMT Licensing Agreements Terms

Agreement	Type	Key Royalty Terms
AAV Insect Cell Production (2007) ³⁰	Non-exclusive license	<ul style="list-style-type: none"> • \$12,000 license issue royalty • \$15,000 annually • 0.25-1% of net sales • Up to \$1 million milestone payments
AAV5 Treatments (2011) ³¹	Exclusive license for products delivered to liver and brain using AAV5	<ul style="list-style-type: none"> • \$140,000 license issue royalty • \$15,000 annually • 1.2% of net sales • Up to \$2 million milestone payments • Supersedes 2007 agreement

In addition to NIH, AMT eventually began formally collaborating with taxpayer-funded researchers at St. Jude Children’s Research Hospital, who were testing their own hemophilia B candidate using a set of promising genetic instructions.³² A few years later, St. Jude published breakthrough results for their candidate. “The data we are reporting mark a paradigm shift in treatment of hemophilia B and lay the groundwork for curing this major bleeding disorder,” said one of the St. Jude researchers.³³

This raised hopes for AMT’s candidate, which at the time used the same genetic instructions as St. Jude’s candidate.³⁴ The major difference between the two candidates was that AMT benefited more directly from NIH technology.³⁵

Hemgenix, in effect, is the culmination of major breakthroughs led by St. Jude researchers (hemophilia B protein genetic instructions) and NIH scientists (AAV5 and insect cell manufacturing).

In 2017, the genetic instructions were slightly tweaked based on the work of an Italian academic.³⁶ In 2020, a larger pharmaceutical company, CSL, swooped in and obtained rights to sell Hemgenix. uniQure got a payout of \$500 million, along with \$1.6 billion in potential milestone payments and double-digit royalties on net product sales.³⁷ uniQure would later sell part of its royalty interest for up to \$400 million.³⁸

In November 2022, FDA approved Hemgenix.

At \$3.5 million, Hemgenix is the most expensive medicine in the world.³⁹ Its production cost is estimated to be 2% of the current price.⁴⁰ uniQure is clear what the pricing strategy means. The cost of treatment will be “significant,” the company told investors, adding:

We expect that most patients and their families will not be capable of paying for our products themselves. There will be no commercially viable market for our product candidates without reimbursement from third party payers, such as government health administration authorities, private health insurers and other organizations. **Even if there is a commercially viable market, if the level of third-party reimbursement is below our expectations, most patients may not be able to afford treatment with our products...**(emphasis added)⁴¹

Hemgenix is expected to enter the market in the second half of 2023.⁴²

b. Yescarta (Gilead Sciences)

Yescarta (axicabtagene ciloleucel) is a gene therapy used to treat advanced blood cancer. NIH scientists initially developed what later became known as Yescarta. In 2010, Steven Rosenberg at the National Cancer Institute of the NIH reported successfully treating the first patient in a clinical trial with the initial version of the therapy.⁴³ That year, a former student of Rosenberg who had founded a small biotechnology corporation named Kite Pharma visited NIH and learned about the promising results.⁴⁴

By 2012, Kite had signed its first deal with NIH.⁴⁵ Kite soon entered into multiple agreements with the agency, including to provide funding for NIH researchers to test the therapy. Kite scientists also worked with NIH to improve and develop the therapy. Taxpayers spent at least \$10 million directly on Yescarta, according to one estimate, and at least \$200 million on foundational science.⁴⁶ Kite received tax breaks for some clinical testing.

In 2014, Kite disclosed in financial filings that it was

highly dependent on the National Cancer Institute for research and development and early clinical testing of our product candidates and on the National Institutes of Health for licensing

intellectual property rights to future product candidates...We have no experience as a company conducting clinical trials. All of the preclinical and clinical trials relating to our product candidates have to date been conducted by the NCI. (emphasis added)⁴⁷

Kite’s founder, Arie Belldegrun, also acknowledged the foundational role of the government. “We shouldn’t underestimate the value and the importance of NIH, not only to Kite but to the whole field of engineered T-cell therapy” he told the New York Times in 2016.⁴⁸ A competing executive noted, “They got 20 years of research all together in one scoop.”⁴⁹

In 2015, Kite’s financial models said a base price for Yescarta was \$150,000.⁵⁰ In 2017, Gilead Sciences acquired Kite, which did not have a single approved product, for \$11.9 billion.⁵¹ Belldegrun, Kite’s founder, was expected to rake in nearly \$700 million from the sale.⁵² Fifteen days after the acquisition was completed, Yescarta was approved by the FDA.⁵³ Gilead initially set the price at \$373,000 but has since increased the price by more than \$50,000.

Table 4: Yescarta International Pricing Comparisons

Country	Price
United States	\$424,000
Canada	\$358,000
France	\$354,000
Germany	\$306,000
Japan	\$212,000
United Kingdom	\$350,000

Gilead made more selling Yescarta in the U.S. than the rest of the world combined in 2022.⁵⁴ That year, Gilead recorded a profit of \$4.6 billion, and its CEO received more than \$32 million in total compensation.⁵⁵ Researchers estimate these next-generation medicines could be produced for as low as one-eighth of the current price.

IV. Reviving Reasonable Pricing

In 1987, the pharmaceutical company Burroughs Wellcome launched a new AIDS drug developed with the help of NIH scientists at a cost of \$10,000 per year. A political firestorm ensued.⁵⁶ The New York Times called it “the most expensive prescription drug in history” with an “inhuman cost.”⁵⁷

“I think it's outrageous profiteering,” remarked one AIDS activist, who noted that some people with AIDS were forced into poverty to pay for the drug.⁵⁸

Mounting protests led the company to cut its price, and the NIH to adopt a reasonable pricing clause in some agreements. The federal government now would require a “reasonable relationship between the pricing of the licensed product, the public investment in the product, and the health and safety needs of the public.”⁵⁹ Six years later, the clause was withdrawn after industry pressure.⁶⁰ Misleading narratives about chilling industry-government collaboration emerged as the government began counting the number of collaborations differently.⁶¹

During the COVID-19 pandemic, the federal government once again introduced pricing requirements after public criticism.⁶² This time, the federal government included in some contracts a “most favored nation” obligation that required pharmaceutical companies to charge the U.S. government the lowest price among G7 countries like Canada, the U.K., France and Japan for initial vaccine doses.⁶³ A similar requirement was applied to initial courses of the COVID-19 treatment Paxlovid.⁶⁴

The average price of new treatments that NIH scientists helped invent over the past twenty years is now more than ten times the price that led NIH to first introduce a reasonable pricing clause in 1989. Pharmaceutical corporations should not be allowed to monopolize or profiteer from publicly funded research. The federal government should reinstate and strengthen a “reasonable pricing clause” in all future collaboration, funding, and licensing agreements for biomedical research. The federal government should also stop giving away monopolies on public inventions. Taxpayers should not struggle to afford the medicines their tax dollars helped develop.

¹ IQVIA Institute, *The Global Use of Medicines 2023*, IQVIA Insights (Jan. 18 2023), <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2023>. Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It’s Difficult to Afford Their Medicines, including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age, KFF (March 1 2019), <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>

² RAND Corporation, Prescription Drug Prices in the United States Are 2.56 Times Those in Other Countries (Jan. 28 2021), <https://www.rand.org/news/press/2021/01/28.html>

³ HELP Committee majority staff analysis based on 2022 AbbVie, Pfizer, Johnson & Johnson, Eli Lilly, Merck, Moderna, Bristol-Myers Squibb, Amgen, Gilead Sciences, and Regeneron Pharmaceuticals annual reports. *See also* U.S. Senate HELP Committee Majority Staff, *The Pharma Pandemic Profiteers* (Feb. 15 2023), <https://www.sanders.senate.gov/wp-content/uploads/Pharma-Exec-Compensation-Report.pdf>

⁴ *Id.*

⁵ U.S. Senate HELP Committee Majority Staff, *The Pharma Pandemic Profiteers* (Feb. 15 2023), <https://www.sanders.senate.gov/wp-content/uploads/Pharma-Exec-Compensation-Report.pdf>

⁶ Aris Angelis et al., *High Drug prices Are Not Justified by Industry’s Spending on Research and Development*, 380 *BMJ* (2023), <https://www.bmj.com/content/380/bmj-2022-071710>

⁷ William Lazonick and Öner Tulum, *Sick with “Shareholder Value”: US Pharma’s Financialized Business Model During the Pandemic*, Institute for New Economic Thinking (Dec. 6 2022), <https://www.ineteconomics.org/perspectives/blog/sick-with-shareholder-value-us-pharmas-financialized-business-model-during-the-pandemic>

⁸ NIH, Impact of NIH Research, <https://www.nih.gov/about-nih/what-we-do/impact-nih-research> (last accessed May 15 2023)

⁹ NIH, Budget, <https://www.nih.gov/about-nih/what-we-do/impact-nih-research> (last accessed May 15 2023)

¹⁰ *Id.*

¹¹ GAO, Biomedical Research: Observations on DOD’s Management of Congressionally Directed Medical Research Programs (Jan. 31 2022), <https://www.gao.gov/assets/gao-22-105107.pdf>

¹² P.L. 117-328: Consolidated Appropriations Act, 2023.

¹³ Ekaterina Cleary et al., *Contribution of NIH funding to new drug approvals 2010–2016*, 115 *PNAS* 10 (2018), <https://www.pnas.org/doi/abs/10.1073/pnas.1715368115>

¹⁴ Rahul Nayak et al., *Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States*, 367 *BMJ* (2019), <https://www.bmj.com/content/367/bmj.l5766>

¹⁵ Rahul Nayak et al., *Public-sector Contributions to Novel Biologic Drugs*, 181 *JAMA* (2021), <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2782020>

¹⁶ U.S. Department of Health and Human Services, *Report to the White House Competition Council* (Sept. 9 2021), https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf

¹⁷ Zachary Kassir et al., *Sponsorship and Funding for Gene Therapy Trials in the United States*, 323 *JAMA* (2020), <https://jamanetwork.com/journals/jama/fullarticle/2762298>

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- ¹⁸ See e.g., NIH, The Accelerating Medicines Partnership® Bespoke Gene Therapy Consortium (BGTC) (May 5 2022), <https://ncats.nih.gov/programs/BGTC>. FDA, OCET Advanced Manufacturing Research and Projects (Nov. 21 2022), <https://www.fda.gov/emergency-preparedness-and-response/ocet-advanced-manufacturing/ocet-advanced-manufacturing-research-and-projects>
- ¹⁹ NIH, HHS License-Based Vaccines & Therapeutics, <https://www.techtransfer.nih.gov/reportsstats/hhs-license-based-vaccines-therapeutics>
- ²⁰ Ebanga was excluded because pricing information was not available. Zinbryta and didanosine delayed-release capsules were excluded because they are no longer marketed in the U.S. Stent systems were considered devices and out of scope of this analysis.
- ²¹ Drug pricing data retrieved from NAVLIN, <https://www.navlin.com/>
- ²² According to one study, NIH funding “contributed to published research associated with every one of the 210 new drugs approved by the Food and Drug Administration from 2010–2016”. Ekaterina Cleary et al., *Contribution of NIH funding to new drug approvals 2010–2016*, 115 PNAS 10 (2018), <https://www.pnas.org/doi/abs/10.1073/pnas.1715368115>. Another study found that publicly supported research had a major role in the invention of at least one in four new drugs. Rahul Nayak et al., *Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States*, 367 BMJ (2019), <https://www.pnas.org/doi/abs/10.1073/pnas.55.6.1467>
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