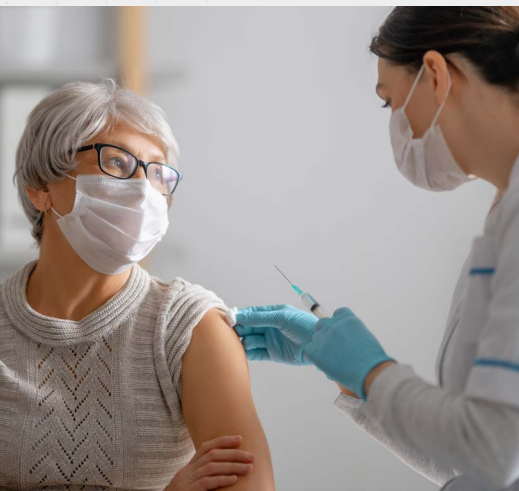


FEBRUARY 2021

# BIG PHARMA'S BIG LIE

THE TRUTH ABOUT INNOVATION & DRUG PRICES



**PATIENTS FOR AFFORDABLE DRUGS™**

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## OVERVIEW

### “Investments in life saving research, patient access to medicines, and future innovation could be at risk.”

- Ad sponsored by the trade association PhRMA opposing legislation to lower drug prices<sup>1</sup>

This is the claim – the threat the pharmaceutical industry has been hiding behind for decades. Multinational drug corporations tell us that if we do anything to curb their ability to dictate prices on brand drugs, research and development will dry up, innovation will grind to a halt, valuable new drugs will not come to market, and patients will die as a result.

*This report examines the well-worn claim from the pharmaceutical industry and documents why it is specious.*

Underpinning this analysis is a fundamental fact: No one cares more about innovation than patients. We represent patients with incurable cancers, patients who rely on drugs to manage chronic conditions that come with difficult side effects, patients who are taking old drugs like insulin that should have more modern, less expensive options.

Patients want innovation, but we also want balance. The most innovative drug in the world is worthless if it is not affordable and accessible. So we seek to maintain the pipeline for true innovation while ensuring prices are within reach of individuals and society.

The fact is, people in the United States are dying right now not only because there are no treatments for certain diseases, but also because existing drugs are too expensive. Indeed, more than 1.1 million Medicare patients could die over the next decade because they cannot afford to pay for their current prescription medications.<sup>2</sup> An enormous body of research supports the fact that lower prices for drugs result in better adherence to prescriptions and therefore better health.<sup>3</sup> Analyses from the Congressional Budget Office support this conclusion.<sup>4</sup>

*So the question we explore is this: Can we constrain drug corporations' unfettered pricing power in the United States and still get the innovation we seek? We look at Big Pharma's argument as a starting point.*

1 PhRMA. (2020). Charlie Baker's proposal puts government between you and your doctor [Advertisement]. Retrieved from <https://local.baystatebanner.com/washington-us-dc/phrma-202-835-3400/2020-12-23-11760636-chareg-bakers-rproposal-puts-government-between-you-and-your-doctor-government-price-setting-means-politicians-can-arbitrarily-decide-that-some-patients-and-diseases-are-worth-more-than-others-potentially-discriminating-against-seniors-t>

2 Council for Informed Drug Spending Analysis. (2020, November 18). *High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost*. <https://www.cidsa.org/publications/xcenda-summary>

3 Iuga, A. O., & McGuire, M. J. (2014). Adherence and health care costs. *Risk Management and Healthcare Policy*, 7, 35-44. <https://doi.org/10.2147/RMHP.S19801>

4 Congressional Budget Office. (2019, October 11). *Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare*. <https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf>

## PHARMA'S INNOVATION ARGUMENT

The drug corporations' argument can be summarized as follows: Research and development is risky and expensive.<sup>5</sup> When investors look to fund projects, they don't care if they make money on cell phones or cell therapy. So, if we limit the ability of drug corporations to charge whatever prices they want when research succeeds, investors will find something else to fund and cutting-edge cures will be left behind. They point to other countries that negotiate prices that have fewer drugs available as proof that patients will lose access to innovation if we restrain prices by any amount.

***The argument seems to make sense on its face. But when you look more closely, it doesn't hold up. Here's why.***

# 1

**Experts agree that some reduction in pharmaceutical revenue and profit is clearly possible without harming innovation.**

There is little doubt that if we zeroed out profits in the pharmaceutical industry—or any industry for that matter — innovation would suffer at some point as profits declined. But we're not arguing for policy proposals that zero out profits — not even close. We're advocating for a system that better balances fair prices and profit with innovation.

“When the biopharma industry says that any change to drug pricing

***“When the biopharma industry says that any change to drug pricing is going to destroy the innovation engine, that's not really true.”***

is going to destroy the innovation engine, that's not really true.”

So says Dr. Craig Garthwaite, a recognized microeconomist, research professor in hospital and health services, and director of the Program on Healthcare at the Kellogg School of Management at Northwestern University.<sup>6</sup> He has looked closely at this question, and his research demonstrates that some reduction in prices is possible without harming innovation.<sup>6</sup>

<sup>5</sup> Lieberman, S. M., Ginsburg, P. B., & Patel, K. (2020, November 24). Balancing Lower U.S. Prescription Drug Prices And Innovation – Part 1. *Health Affairs*. <https://www.healthaffairs.org/doi/10.1377/hblog20201123.804451/full/>

<sup>6</sup> Waikar, S. (2020, September 2). *Pharma Companies Argue That Lower Drug Prices Would Mean Fewer Breakthrough Drugs. Is That True?*. Kellogg School of Management at Northwestern University. <https://insight.kellogg.northwestern.edu/article/pharma-companies-argue-lower-drug-prices-fewer-breakthrough-drugs>

The critical distinction, Garthwaite says, is the degree to which prices are lowered: “The important point here is to distinguish between \*any\* decrease and very \*large\* decreases.”<sup>7</sup>

The Congressional Budget Office (CBO) analyzed the impact on drug development that could result from a large decrease in pharmaceutical industry revenue — as much as \$1 trillion dollars over 10 years — from H.R. 3, which was passed by the House of Representatives in 2019.<sup>4</sup> Even given that sizable reduction in revenue, CBO concluded that it would have only a modest impact — reducing the number of drugs coming to market by approximately eight out of 300 over an initial 10-year period and about 30 fewer drugs over the subsequent decade.<sup>8</sup> And as we’ll see later in this report, the absence of these relatively few drugs may have little or no impact on patient well-being.

The fact is that pharma is a highly profitable industry; there is plenty of room to trim profits while maintaining investment in innovation. The profit margins of drug corporations are

## Outrageous Margins Leave Plenty of Room To Lower Prices. Three Examples:

### *Insulin*

It costs between \$3.69 and \$6.16 to produce a vial of the most commonly used analog insulins, but the branded versions are **priced at between \$275 and \$289 per vial.**<sup>9,10</sup>

### *Albendazole*

Even though this antiparasitic pill can retail for **over \$400 per tablet**, it can be made and distributed for about \$13.<sup>11</sup>

### *Revlimid*

This anti-cancer drug costs less than a dollar per capsule to make, but is sold at **\$833 per capsule.**<sup>12,13</sup>

7 Garthwaite, C. [@C\_Garthwaite]. (2020, October 20). *It's important to read beyond the one quote — the important point here is to distinguish between \*any\* decrease and very \*large\* decreases like international reference pricing. I've long proposed sensible market based reforms that would lower revenues but lead to a better system* [Tweet]. Twitter. [https://twitter.com/C\\_Garthwaite/status/1318521220132995074](https://twitter.com/C_Garthwaite/status/1318521220132995074)

8 Congressional Budget Office. (2019, December 10). *Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act*. [https://www.cbo.gov/system/files/2019-12/hr3\\_complete.pdf](https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf)

9 Gotham, D., Barber, M. J., & Hill, A. (2018). Production costs and potential prices for biosimilars of human insulin and insulin analogues. *BMJ Global Health*, 3(5). <https://gh.bmj.com/content/bmjgh/3/5/e000850.full.pdf>

10 Patients For Affordable Drugs. (2019, November 11). *The Truth About Insulin Prices*. <https://patientsforaffordabledrugs.org/wp-content/uploads/2019/11/The-Insulin-Report-Final-V.-1-1-1.pdf>

11 McGrath, L., & Griffin, R. (2021, January 14). Mark Cuban Plans Low-Cost Generic Drugs With Pharma Startup. *Bloomberg*. <https://www.bloomberg.com/news/articles/2021-01-14/mark-cuban-cost-plus-drug-company-launches-to-give-cheaper-care?sref=g1mkOfvB>

12 Koons, C., & Langreth, R. (2018, January 2). The Loopholes Drug Companies Use to Keep Prices High. *Bloomberg Quint*. <https://www.bloombergquint.com/business/the-loopholes-drug-companies-use-to-keep-prices-high>

13 Drugs.com. (n.d.). *Revlimid Prices, Coupons and Patient Assistance Programs*. Retrieved January 26, 2021 from <https://www.drugs.com/price-guide/revlimid>



almost three times the average of the S&P 500.<sup>14</sup> Even though one in every five dollars of U.S. health care spending is on drugs, the pharmaceutical industry collects 63 percent of the profits for the entire health sector.<sup>15</sup> The money that U.S.-based drug companies make by charging Americans high prices is 76 percent greater than what's needed to fund their entire global research and development (R&D) expenditures.<sup>16</sup>

*The reality is that even if profits were reduced by billions, the drug industry would still be more profitable than most publicly traded companies...*

\$20 billion a year marketing their products to health care providers and another \$6 billion in direct-to-consumer advertising.<sup>17,18</sup> Nine out of 10 big pharmaceutical

companies spend more on marketing, sales, and overhead than on research.<sup>19</sup> In 2019, the drug makers that belong to the trade group PhRMA together spent more than \$120 million lobbying Congress.<sup>20</sup>

Pharma wants us to think that drug pricing reform will hurt innovation and new drug development by making the pharmaceutical industry unattractive to investors and impeding investments into R&D. The reality is that even if profits were reduced by billions, the drug industry would still be more profitable than most publicly traded companies, and therefore attractive to investors.

Additionally, if drug pricing legislation curbs profits, the industry can maintain or even increase R&D investment by shifting spending on marketing, advertising, and lobbying. Pharmaceutical companies spend



Drug companies would have us believe that any dollar cut from profits is a dollar less spent on inventing cures, but they fail to acknowledge that they choose how to direct dollars. Clearly there is money available from marketing, advertising, and lobbying to lower prices and protect innovation.

14 Yardeni Research. (2021, January 19). S&P 500 Sectors & Industries Profit Margins (quarterly). <https://www.yardeni.com/pub/sp500margin.pdf>

15 Herman, B. (2018, November 12). Pharma's grip on the health care economy. *Axios*. <https://www.axios.com/pharma-health-care-economy-q3-profits-53b950b2-5515-4d79-b1f5-7067bf3652d1.html>

16 Yu, N. L., Helms, Z., & Bach, P. B. (2017, March 7). R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices. *Health Affairs*. <https://www.healthaffairs.org/doi/10.1377/hblog20170307.059036/full>

17 Schwartz, L. M., & Woloshin, S. (2019). Medical Marketing in the United States, 1997-2016. *JAMA*. 321(1), 80-96. <https://doi.org/10.1001/jama.2018.19320>

18 Bulik, B. S. (2020, February 19). The top 10 ad spenders in Big Pharma for 2019. *FiercePharma*. <https://www.fiercepharma.com/special-report/top-10-advertisers-big-pharma-for-2019>

19 Swanson, A. (2015, February 11). Big pharmaceutical companies are spending far more on marketing than research. *The Washington Post*. <https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/>

20 Florco, N. (2020, January 23). Want to know how contentious drug pricing is in Washington? Check the receipts. *STAT*. <https://www.statnews.com/2020/01/23/lobbying-drug-pricing-receipts/>

## 2

## A new drug does not equal new innovation.

The drug industry talks a lot about how reforms to lower prices threaten cutting-edge breakthroughs, but in reality, only a fraction of new medications are truly innovative. Since 1975, only 10 to 15 percent of drugs entering the market represented therapeutic advances; instead, drug companies prioritized the development of existing drugs with minor variations that lack clinical significance.<sup>21</sup>

Drug patents offer a stark illustration of this point. Between 2005 and 2015, 78 percent of drug patents were related to drugs already on the market.<sup>22</sup> Instead of investing in R&D that could lead to new breakthrough therapies, drug companies spend resources obtaining patents on old drugs — not to improve user experience — but to extend patent protection, prolong monopoly pricing periods, and keep generic competitors off the market.

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So if we understand that new drugs are not the same as new cures, a small reduction in new drugs doesn't pose a threat to innovation. Harvard economist Richard Frank summed it up this way: "If drug companies claim lowering drug prices means somewhat fewer new drug launches, remember that there are numerous new products sold every year whose elimination

would have little to no impact on the health of Americans."<sup>23</sup>

If our current system of drug development does not result primarily in truly innovative drugs, we can't let the pharmaceutical industry use the threat of R&D cuts as a scapegoat to thwart reforms. We can create a system that incentivizes valuable

innovation that delivers meaningful clinical benefit to patients — instead of repurposing old drugs.

21 Light, D. W., & Lexchin, J. R. (2012). Pharmaceutical research and development: what do we get for all that money?. *BMJ*, 345. <https://doi.org/10.1136/bmj.e4348>

22 Feldman, R. (2018). May Your Drug Price Be Evergreen. *Oxford Journal of Law and the Biosciences*, 5(3),590-647. <http://dx.doi.org/10.2139/ssrn.3061567>

23 Frank, R. G. (2019, November 13). Drug companies exaggerate — controlling drug prices won't threaten innovation. *The Hill*. <https://thehill.com/opinion/healthcare/470266-drug-companies-exaggerate-controlling-drug-prices-wont-threaten-innovation>

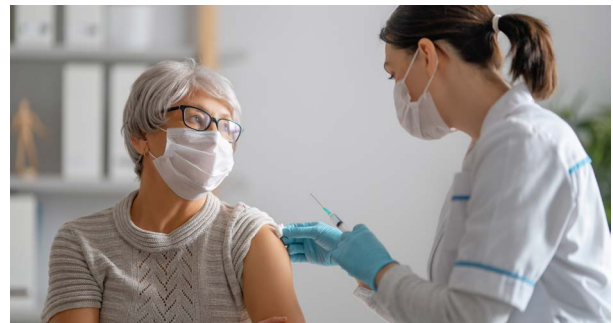
# 3

## Pharma exaggerates the cost of new drugs.

Pharma asserts that it costs \$2.87 billion to invent a drug, but that number is grossly exaggerated.<sup>24</sup> This oft-cited claim can be traced to researchers working out of a pharma-funded center at Tufts University whose methods have been widely criticized for their overestimates.<sup>25,26,27</sup> Additionally, source data is not disclosed, barring verification of results by independent researchers. Independent analyses put the cost closer to \$1 billion. One study in *JAMA Internal Medicine* put the cost of a new cancer drug at \$648 million.<sup>28</sup> Another study from the London School of Economics published in *JAMA* estimated the median capitalized research and development cost per therapeutic product from 2009 to 2018 was \$985 million – about a third of the Tufts estimate.<sup>29</sup>

Even if we accept the high range of estimates, policymakers must consider that the return on most drugs exponentially exceeds R&D investments during the monopoly pricing

period. In 2019, the top 10 drugs each made between \$4.7 billion and \$21 billion in sales, with taxpayers driving spending on these blockbusters through publicly funded insurance programs.<sup>30,31</sup>



Drug companies simply charge as much as they think they can get away with. An 18-month congressional investigation concluded that drug companies raised prices not to fund innovation – but to hit profit targets and trigger incentive payments for executives.<sup>32</sup>

24 DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, 20-33. <https://doi.org/10.1016/j.jhealeco.2016.01.012>

25 Tufts Center for the Study of Drug Development. (n.d.). *Financial Disclosure*. <https://csdd.tufts.edu/financial-disclosure>

26 Carroll, A. E. (2014, November 18). \$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions. *The New York Times*. <https://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html>

27 Light, D. W., & Warburton, R. (2011). Demythologizing the high costs of pharmaceutical research. *BioSocieties*, 6, 34-50. <https://doi.org/10.1057/biosoc.2010.40>

28 Prasad, V., & Mailankody, S. (2017). Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval. *JAMA Internal Medicine*, 177(11), 1569-1575. <https://doi.org/10.1001/jamainternmed.2017.3601>

29 Wouters, O. J., McKee, M., & Lutyen, J. (2020). Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA*, 323(9), 844-853. <https://doi.org/10.1001/jama.2020.1166>

30 Herman, B. (2020, August 12). The top-selling drugs in the U.S. in 2019. *Axios*. <https://www.axios.com/top-selling-drugs-america-2019-f32a8818-a37c-4581-a805-bcf73942c1de.html>

31 Patients For Affordable Drugs. (2019). *2,879 Medicare Part D Drugs Total \$151 Billion in Spending* [Infographic]. <https://patientsforaffordabledrugs.org/wp-content/uploads/2019/05/6.13-Combined-Chartpack.pdf>

32 Committee on Oversight and Reform. (2020). *Drug Pricing Investigation: Celgene and Bristol Myers Squibb—Revlimid*. <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Celgene%20BMS%20Staff%20Report%2009-30-2020.pdf>



# 4

## Innovation is coming from taxpayers.

The National Institutes of Health (NIH) is the single “largest biomedical research agency in the world.”<sup>33</sup> The trade association PhRMA says all the companies in the entire U.S. biopharmaceutical industry invested an estimated \$102 billion in research and development in 2018.<sup>34</sup> The NIH alone spent \$36.6 billion that year, a large share of which supported science that is foundational for drug development.<sup>35,36</sup>

In addition to the NIH, the U.S. government also funded drug-related research in 2018 through the Biomedical Advanced Research and Development Authority (BARDA) and the Defense Advanced Research Projects Agency (DARPA) that paved the way for rapid development of groundbreaking new mRNA COVID-19 vaccines.<sup>37</sup> (See “COVID-19 Vaccines Expose Pharma’s Lie” below.)

NIH funding contributed to research associated with all 356 new drugs approved by the FDA from 2010 to 2019, totaling \$230 billion.<sup>38</sup> NIH Director Francis Collins

confirms: “Finding new treatments thus requires NIH to play a lead role — by investing in the early stage of therapeutic development to ‘de-risk’ such projects.”<sup>39</sup> Increasingly, however, it’s not only early research into basic science.

*NIH Director Francis Collins confirms: “Finding new treatments thus requires NIH to play a lead role — by investing in the early stage of therapeutic development to ‘de-risk’ such projects.”*

33 National Institutes of Health. (n.d.). *About NIH*. Retrieved January 26, 2021 from <https://www.nih.gov/about-nih>

34 PhRMA. (n.d.). *Research & Development*. Retrieved January 26, 2021 from <https://www.phrma.org/Advocacy/Research-Development>

35 National Institutes of Health. (n.d.). *NIH Budget History*. Retrieved January 26, 2021 from <https://report.nih.gov/nihdatabook/category/1>

36 National Academies of Sciences, Engineering, and Medicine. (2020). *The Role of NIH in Drug Development Innovation and Its Impact on Patient Access: Proceedings of a Workshop*. The National Academies Press. <https://doi.org/10.17226/25591>

37 Allen, A. (2020, November 18). Government-Funded Scientists Laid the Groundwork for Billion-Dollar Vaccines. Kaiser Health News. <https://khn.org/news/vaccine-pioneers-basic-research-scientists-laid-groundwork-for-billion-dollar-pharma-products/>

38 Ledley, F., Cleary, E., & Jackson, M. (2020, September 2). *US Tax Dollars Funded Every New Pharmaceutical in the Last Decade*. Institute for New Economic Thinking. <https://www.ineteconomics.org/perspectives/blog/us-tax-dollars-funded-every-new-pharmaceutical-in-the-last-decade>

39 Collins, F. S. (2017, May 17). *Testimony on the Transformative Power of Biomedical Research*. National Institutes of Health. <https://www.nih.gov/about-nih/who-we-are/nih-director/testimony-transformative-power-biomedical-research>

Mark L. Rohrbaugh, NIH special advisor for technology transfer, says, “The public sector now has a much more direct role in the applied-research phase of drug discovery.”<sup>40</sup> In fact, about 1 in 4 new drugs over the last decade have had late-stage taxpayer support in drug development, and those drugs were more likely to be therapeutically significant.<sup>41</sup>

The NIH is the engine for science that leads to innovative new drugs. Research shows that 70 to 90 percent of priority review, first-in-class, or top-selling drugs can be traced to publicly funded research, and 20 to 30 percent of these drugs can be directly linked to publicly funded research.<sup>36</sup> Another extensive study of new drug development from 1984 to 2009 concluded that the “substantial public investment in drug discovery leads to many of the most transformative drugs.”<sup>36,42</sup> Importantly, as NIH Director Collins points out, taxpayer-funded research helps de-risk drug development for private companies, further undermining their claims to high prices based on high risk.<sup>39</sup>

A 2017 study found that “NIH funding generates large numbers of private-sector patents” with “large spillover from the lab to commercial activity.”<sup>43</sup> The lead researcher,

Pierre Azoulay, a professor at the MIT Sloan School of Management, noted: “If you thought the NIH exists in an ivory tower, you’re wrong. They are the nexus of knowledge that really unifies two worlds.”



Research shows “a sustained 10 percent increase in targeted, disease-specific NIH funding yields approximately a 4.5 percent increase in the number of related drugs entering clinical testing.”<sup>44</sup> Lower prescription drug prices will allow us to direct government savings to the NIH to support research aimed at drugs that address public health priorities – innovative medicines we need – not just drugs that will produce the highest profits for the pharmaceutical industry.

40 Pear, R. (2018, May 28). ‘Paying Twice’: A Push for Affordable Prices for Taxpayer-Funded Drugs. *The New York Times*. <https://www.nytimes.com/2018/05/28/us/politics/drug-prices.html>

41 Nayak, R. K., Avorn, J., & Kesselheim, A. S. (2019). Public sector financial support for late stage discovery of new drugs in the United States: cohort study. *The BMJ*, 367. <https://doi.org/10.1136/bmj.l5766>

42 Kesselheim, A. S., Tan, Y. T., & Avorn, J. (2015). The Roles Of Academia, Rare Diseases, And Repurposing In The Development Of The Most Transformative Drugs. *Health Affairs*, 34(2), 286-293. <https://doi.org/10.1377/hlthaff.2014.1038>

43 Dizikes, P. (2017, March 30). *Study: NIH funding generates large numbers of private-sector patents*. MIT. <https://news.mit.edu/2017/study-nih-funding-generates-large-numbers-private-sector-patents-0330>

44 Blume-Kohout, M. E. (2012). Does targeted, disease-specific public research funding influence pharmaceutical innovation?. *Journal of Policy Analysis and Management*, 31(3), 641-60. <https://doi.org/10.1002/pam.21640>

# COVID-19 VACCINES EXPOSE PHARMA'S LIE

We all celebrate the speed with which COVID-19 vaccines have been developed. Big Pharma claims credit for that innovation, but the truth is that taxpayers and tax-advantaged investment by not-for-profits made it possible to get those vaccines in record time.

In 2018, only 1 percent of research and development projects in pharmaceutical companies were for emerging infectious diseases.<sup>45</sup> In fact, of the 20 companies that spent \$2 billion on research and development in 2019, only four had units dedicated to vaccine development.<sup>46</sup>

But when corporations were not investing in vaccines, U.S. taxpayers did invest through the Defense Advanced Research Projects Agency (DARPA). Here's how the biopharmaceutical industry publication BioCentury explains it:

**“(DARPA) has taken risks where others wouldn't. DARPA was behind the creation of DNA and RNA vaccines, funding early R&D by Moderna Inc. and Inovio Pharmaceuticals Inc. at a time when the technologies were considered speculative by many scientists and investors.”<sup>47</sup>**

Kaiser Health News reports that government funding through a trio of taxpayer-supported entities was key to both early research and late-stage trials, accelerating the entire process to develop COVID-19 vaccines:

**“Basic research conducted...at the National Institutes of Health, Defense Department, and federally funded academic laboratories has been the essential ingredient in the rapid development of vaccines in response to COVID-19.”<sup>48</sup>**

The New York Times pointed out the reward derived from all the taxpayer investment:

**“A new method of developing vaccines was already waiting to be tested...The government was willing to spend whatever it took, eliminating financial risks and... allowing mass production to begin even before trials were done.”<sup>49</sup>**

When the moment came for Operation Warp Speed, the money for research, production, and distribution overwhelmingly came from the government.<sup>50</sup> The Washington Post reported:

**“These accomplishments are remarkable, but they are not ‘miracles,’ in the sense that they sprang fully formed from work that began in the spring. They relied on basic research done over decades in government, academic and company research labs. Even the financial model used to insulate vaccine makers from financial risk traced back to an agency that Congress created in late 2006 to incentivize companies to develop urgently needed medicines.”<sup>51</sup>**

One noted industry expert, Jack Scannell, summed it up this way:

**“Before we pat the drug industry on the back too much, one has to recognize it got involved in this partly because the whole thing has been de-risked by government.”**

Now analysts predict the drug corporations will realize \$40 billion in revenue from vaccines in 2021 alone, with windfall profits running as high as 50 to 60 percent.<sup>52, 53</sup>

45 Edwards, D. J. (2020, April 14). *New products alone are not enough. Pharma can do more to halt COVID-19*. Access to Medicine Foundation. [https://accessmedicinefoundation.org/media/uploads/downloads/5e95d85128fb9\\_ATMF\\_Viewpoint\\_Role\\_for\\_pharma\\_in\\_C-19\\_200414%20\(1\).pdf](https://accessmedicinefoundation.org/media/uploads/downloads/5e95d85128fb9_ATMF_Viewpoint_Role_for_pharma_in_C-19_200414%20(1).pdf)

46 Nisen, M. (2020, January 23). *Deadly Viruses Aren't Pharma's Top Priority. Why Not?. Bloomberg*. <https://www.bloomberg.com/opinion/articles/2020-01-23/drug-industry-may-lack-pandemic-preparedness?sref=g1mkOfvB>

47 Usdin, S. (2020, March 25). *DARPA's gambles might have created the best hopes for stopping COVID-19*. *BioCentury*. <https://www.biocentury.com/article/304691/darpa-jump-started-technologies-behind-some-of-the-leading-covid-19-vaccine-and-antibody-hopes>

48 LaFraniere, S., Thomas, K., Weiland, N., Gelles, D., Stolberg, S. G., & Grady, D. (2020, November 30). *Politics, Science and the Remarkable Race for a Coronavirus Vaccine*. *The New York Times*. <https://www.nytimes.com/2020/11/21/us/politics/coronavirus-vaccine.html>

49 U.S. Department of Health & Human Services. (2021, January 21). *Fact Sheet: Explaining Operation Warp Speed*. Retrieved January 26, 2021 from <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html>

50 Abutaleb, Y., McGinley, L., & Johnson, C. Y. (2020, December 14). *How the 'deep state' scientists vilified by Trump helped him deliver an unprecedented achievement*. *The Washington Post*. <https://www.washingtonpost.com/health/2020/12/14/trump-operation-warp-speed-vaccine/>

51 Neville, S., & Kuchler, H. (2020, November 27). *Covid vaccines offer Big Pharma a chance of rehabilitation*. *Financial Times*. <https://www.ft.com/content/75029036-13f3-4ca2-8954-5a7207c0c3db>

52 Taylor, N. (2020, September 3). *Analysts tip COVID-19 vaccines to generate \$40bn next year*. *BioPharma-Reporter*. <https://www.biopharma-reporter.com/Article/2020/09/03/Analysts-tip-COVID-19-vaccines-to-generate-40bn-next-year>

53 Gollom, M. (2020, November 25). *Some companies will make big money off their COVID-19 vaccines — but not as much as they could*. *CBC*. <https://www.cbc.ca/news/business/covid-vaccine-profits-pharmaceutical-companies-pfizer-1.5812619>

# 5

## Pharma's claim that drugs won't be available in the United States if we lower prices is a red herring.

Big Pharma likes to point out that more drugs are available — and are available faster — in the United States than in other wealthy countries. It frequently references a white paper from the White House Council of Economic Advisers (CEA) to explain why: “Drug manufacturers usually pursue market access in the United States before other markets due to the higher prices in the United States.”<sup>54, 55</sup> The CEA could also have mentioned the other big reason drug companies file for approval first in the United States: It is the largest market in the world.

Given that U.S. prices for drugs are almost four times what many other wealthy nations pay, we can lower prices by a meaningful amount and still offer the highest prices by far in the largest market in the world, preserving the incentive to file first for approval in the United States.<sup>56, 57</sup>

*U.S. prices for drugs are almost four times what many other wealthy nations pay.*

There are other important policies in the U.S. drug pricing system that lead to more drugs being available here compared to other countries, none of which would be altered by lowering prices:

- Medicare must cover all drugs in six protected classes, which even PhRMA acknowledges ensures access to these drugs.<sup>58,59</sup>
- Medicare must cover at least two drugs in each class of drugs.<sup>60</sup>
- Medicaid must cover every drug offered by a manufacturer in the United States if the manufacturer agrees to give Medicaid a best price guarantee.<sup>61</sup>

54 Association of Community Cancer Centers v. Alex M. Azar II. Civil Action No. CCB-20-3531 (2020). <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Complaint-on-MFN-Rule-Filed-2020-12-04.pdf>

55 The Council of Economic Advisers. (2018). *Reforming Biopharmaceutical Pricing at Home and Abroad*. <https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>

56 Mulcahy, A. W., Whaley, C., Tebeka, M. G., Schwam, D., Edenfield, N., & Becerra-Ornelas, A. U. (2021). *International Prescription Drug Price Comparisons*. RAND Corporation. [https://www.rand.org/pubs/research\\_reports/RR2956.html](https://www.rand.org/pubs/research_reports/RR2956.html)

57 Committee on Ways and Means. (2019). *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices*. [https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices\\_0.pdf](https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf)

58 Centers for Medicare & Medicaid Services. (2019, May 16). *Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F)*. <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f>

59 Powaleny, A. (2015, December 10). *Medicare Part D's six protected classes*. PhRMA. <https://catalyst.phrma.org/medicare-part-d-six-protected-classes>

60 *What Medicare Part D drug plans cover*. (n.d.). CMS.gov. Retrieved January 26, 2021 from <https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover>

61 Kaiser Family Foundation. (2019, May 1). *Medicaid's Prescription Drug Benefit: Key Facts*. <https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/>

Aside from the fact that drug corporations often choose to file for approval in other countries later, another reason drugs sometimes come to market abroad after they are available in the United States is that other nations have a more sophisticated process to evaluate the value of drugs to patients. In the United States, every drug approved by the FDA as safe and effective automatically comes to market. Virtually every other wealthy nation

in the world has another step post-approval called health technology assessment.<sup>62</sup> The countries examine the actual value of the drug in order to settle on an appropriate price. Drug companies have blocked efforts to use this step in the United States, although many health policy experts think it would improve fair pricing, affordability, and accessibility for patients over the longer term.

## CONCLUSION

Big Pharma's innovation argument just does not stand up to scrutiny. We can't allow drug corporations to continue to hide behind their threat that if we do anything to curb the industry's unilateral pricing power, innovation will die.

The truth is that if we don't do something to restore the balance between pricing to reward innovation while ensuring affordability and accessibility, **there is no doubt people will die because they cannot afford the existing drugs they need right now.** And we won't be able to afford the new drugs to come.



<sup>62</sup> Research and Markets. (2020, April 20). *Global Health Technology Assessment in Pharma: A Review of Major Decisions*. <https://www.researchandmarkets.com/reports/5014081/health-technology-assessment-in-pharma-a-review>