

# Five Fatal Flaws in Rep. Katie Porter's Indictment of the U.S. Drug Industry

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In her sensationally titled report, "Killer Profits: How Big Pharma Takeovers Destroy Innovation and Harm Patients," the deputy chair of the Congressional Progressive Caucus issued an ideologically inspired jeremiad grounded in assertions that are easily refuted with data.

# **KEY TAKEAWAYS**

- Drug industry concentration has increased only modestly. The top eight firms increased their market share from 54 percent in 2002 to 58 percent in 2017, a ratio viewed by antitrust experts as unconcentrated.
- Large drug firms are not disinvesting in R&D to boost profits. In fact, the industry's R&D-to-sales ratio has increased and is now the world's most R&D-intensive industry.
- Contrary to the Porter report's claim that new drug innovation is declining, FDA data shows that it has been increasing.
- Contrary to the report's claim that drug prices are increasing dramatically and that the industry is earning excessive profits, the data show otherwise.
- Contrary to the assertion that the government is largely to thank for breakthrough drug development, patent and investment data show that private biopharma firms devote far more capital to develop and bring drugs to market than government.
- Efforts to paint America's private-sector-led drug-development system as failing are misleading and serve mainly to build the case for radical change that would undermine the country's capacity to drive drug innovation and create jobs.
- The private-sector-led system—with a healthy mix of large, midsized, and start-up firms, plus government funding for basic science—is working well.

# **INTRODUCTION**

Over the last few years, progressives have ramped up their attacks on the U.S. economic model, characterized mostly by for-profit firms, and in many industries large, efficient, and innovative firms. Whether attacking "Big Broadband," "Big Tech," or "Big Pharma," progressives no longer seek reform but rather transformation: fundamentally changing the U.S. economic system by moving to government production, price-regulated industries, and industry structures with vastly fewer large firms.

To achieve this goal, progressives must first convince thought leaders and voters that the current system of private enterprise with large firms is a failure. If they can do that, then the path to policies that undermine the current system becomes much easier.

One industry that has come under intense attack is biopharmaceuticals. Progressives fundamentally object to a system in which private companies, many of them large, create and sell drugs mostly by responding to market signals. They instead seek an industry with many fewer large firms, strict price controls, and government responsibility for drug discovery.

A recent entry into this biopharma attack came from U.S. Rep. Katie Porter (D-CA), deputy chair of the Congressional Progressive Caucus. Earlier this year, her office released a report with the sensational title "Killer Profits: How Big Pharma Takeovers Destroy Innovation and Harm Patients."<sup>1</sup> The report is largely grounded in assertions, almost all of which are contradicted by data. Daniel Patrick Moynihan once famously stated that "everyone is entitled to his own opinion, not his own facts." In the case of the Porter document, most of the facts are simply wrong:

- Contrary to the report's claim that industry concentration has exploded because of mergers and acquisitions, concentration has increased only modestly, with the top eight firms increasing their market share from 54 to 58 percent, a ratio viewed by antitrust experts as unconcentrated.
- Contrary to the report's claims that firms are cutting research and development (R&D) because of mergers and that large drug firms in particular are disinvesting in R&D, the industry's R&D-to-sales ratio has increased.
- Contrary to the report's claim that new drug innovation is declining, U.S. Food and Drug Administration (FDA) data shows that it has been increasing.
- Contrary to the report's claim that drug prices are increasing dramatically and that the industry is earning excessive profits, the data shows otherwise.
- Contrary to the assertion that the government plays a key role in drug development, evidence suggests that the role of the large biopharma firm is central.

The private-sector-led system, with its healthy mix of large and medium-sized firms and smaller start-ups, and which is supported with government funding of basic science, is working well. Efforts to paint the system as failing are misleading and in service of radical change that would disrupt needed drug innovation.

This report responds to five main claims made by the Porter report and then concludes by discussing needed policy reforms.

# THE REPORT'S FIVE FALSE CLAIMS

The Porter report's jeremiad against the industry relies on five major claims: 1) the industry has gotten extremely concentrated; 2) drug companies are cutting R&D in order to boost profits; 3) drug innovation has stalled; 4) drug prices have grown extremely fast; and 5) the government plays the lead role in drug development. Each is wrong or vastly overstated.

#### False Claim #1: The Industry Has Gotten Extremely Concentrated

The report claims that the industry has gotten extremely concentrated through mergers and acquisitions and that this has reduced drug innovation and boosted prices. The report argues that firms have engaged in mergers and acquisitions, largely to limit competition and prop up profits.

For example, the report asserts, "In just 10 years, the number of large, international pharmaceutical companies decreased sixfold, from 60 to only 10."<sup>2</sup> In the same paragraph, it then lists 14 "major" drug companies. Even worse, the article cited actually states, "Between 1995 and 2015, 60 pharmaceutical companies merged into just 10."<sup>3</sup> This is very different from the number of large pharmaceutical companies shrinking sixfold. Moreover, in 2006, the top 10 drug producers accounted for 56 percent of global industry sales, while the top 60 accounted for 92 percent. But by 2019, the top 10 accounted for 43 percent, and the top 60 86 percent.<sup>4</sup>

In 2006, the top 10 drug producers accounted for 56 percent of global industry sales, a number that fell to 43 percent by 2019.

Moreover, looking at combined output for firms in the United States (not imports), the sales for the top four in each industry (C4 ratio) in the Pharmaceutical Preparation Manufacturing and Biological Product Manufacturing industries (NAICS codes 325412 and 325414) increased only modestly from 2002 to 2017, from 36 percent to 43 percent, while the C8 ratio increased from 54 to 58 percent, and the C20 ratio fell slightly from 77 percent to 76 percent.<sup>5</sup>

Given that drugs are sold internationally, a more accurate measure of market concentration takes into account all drug firms. In 2019, the top 4 firms globally had just 21 percent of the market, with the top 8 having 37 percent, and the top 20 64 percent. While the C4 and C8 ratios were up slightly from 2006, when they were 18 percent and 31 percent, respectively, the C20 ratio actually fell to 64 percent.<sup>6</sup>

Finally, the report claims that mergers increase prices. However, when the Government Accountability Office (GAO) examined this issue, it found that this was only the case with respect to generic drug company mergers.<sup>7</sup>

#### False Claim #2: Drug Companies Are Cutting R&D to Boost Profits for Shareholders

The report goes on to assert that drug companies have little incentive to invest in R&D and new drug development. This is an odd assertion given that in 2020, an estimated 66 drugs went off-patent and were available to be produced by generic companies.<sup>8</sup> Without new drugs to replace those going off-patent, non-generic drug companies would soon be out of business.

Yet, the report argues, "Pharmaceutical companies have little incentive to invest in innovative new medicine without the threat of competition. Instead, they are free to devote their

considerable resources to merging with or acquiring companies that might otherwise force them to compete."<sup>9</sup> As noted, competition has not materially diminished in the last 15 years; if anything, it has gotten more intense, with new biologics producers challenging traditional small molecule drug producers.

The report also cites a Roosevelt Institute report that states, "Yet, as prices have skyrocketed over the last few decades, these same companies' investments in research and development have failed to match this same pace."<sup>10</sup> The report argues that "R&D has not matched price increases." In reality, from 2012 to 2016, drug sales increased \$5.8 billion a year, while R&D actually increased \$6.8 billion a year.<sup>11</sup>

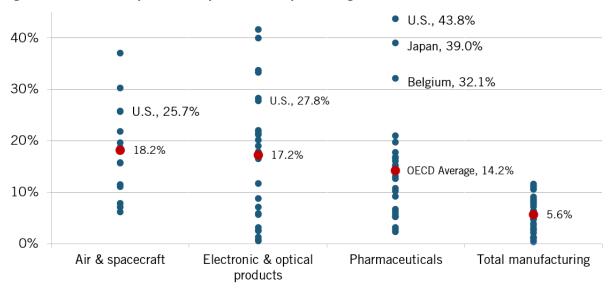
Drug companies in America are incredibly R&D intensive and have become even more so, with their R&D-to-sales ratio increasing from 11 percent in 2006 to 20 percent in 2018.<sup>12</sup> The ratio for the top 20 U.S. companies increased from 15 percent in 2006 to 23.6 percent.<sup>13</sup> Further, while drug revenues increased 56 percent from 2006 to 2018 (in nominal dollars), R&D increased by 85 percent.<sup>14</sup>

#### It is the largest firms, not the smallest, that are the most R&D intensive.

The report asserts that small firms invest more in R&D and that big firms use their revenue for other purposes, such as paying excessive CEO compensation. Actually, in 2016, the top 20 firms globally accounted for 66.5 percent of global sales yet made 64 percent of R&D investment.<sup>15</sup> In 2018, the R&D intensity of the largest 4 firms was 26 percent, of the top 8 was 25 percent, and of the top 20 was 22 percent, with the entire industry at 20 percent.<sup>16</sup> In reality, it is the largest firms, not the smallest, that are the most R&D intensive.

The Porter report complains that "the fraction of pharmaceutical sales revenue devoted to total R&D is generally under 20 percent."<sup>17</sup> Is 20 percent a lot, or a little? It turns out, a lot. The U.S biopharmaceutical industry is the world's most R&D-intensive industry, with firms in the United States investing over 21 percent of sales in R&D, while accounting for 23 percent of total domestic R&D funded by U.S. businesses—more than any other sector.<sup>18</sup> Over the last decade, biopharmaceutical companies in the United States have invested over half a trillion dollars in R&D, while more than 350 new medicines have been approved by the FDA.<sup>19</sup> The industry reinvested 43.8 percent of value added (value sales minus purchased inputs) into research in 2014, more than any other industry in any country. (See figure 1.)

The Porter report asserts that "the share spent on the basic research that often generates truly innovative new compounds is estimated to be far smaller [than total R&D]." In fact, companies' share of R&D classified as basic (14.3 percent) is higher than any other U.S. industry—and more than twice as high as the U.S. industry average (6.4 percent).<sup>20</sup>





Even though the U.S. industry invests more in R&D than any other industry in the world, the report implies that the industry is still too profitable. It cites a study that claims, "Pharma would still be the most profitable industry sector—even if it lost \$1 trillion in sales," implying that the industry could lose \$1 trillion in sales a year through price controls and still be very profitable.<sup>22</sup> This would be difficult, given global sales were around \$1.3 trillion in 2019, and the top 10 pharma companies earned \$392.5 billion.<sup>23</sup>

Actually, the study referenced refers to \$1 trillion over nine years, or \$110 billion per year. But even this amount is misleading. First, the authors use return on invested (ROI)capital as their measure of profitability. However, there are numerous metrics that can measure profitability, and this one poorly reflects the profitability of R&D-intensive industries since R&D is not capitalized but expensed.<sup>24</sup> As a result, this measure overstates the industry's profit advantage over less-R&D intensive industries. Data from New York University Professor Aswath Damodaran shows that in 2015, pharmaceutical return on equity (ROE) was 15.2 percent, while biotechnology ROI was 22.3 percent, compared with overall market profits of 10.8 percent.<sup>25</sup> But when this measure is adjusted for R&D spending, the delta is significantly less, with pharmaceutical ROE being 11.1 percent and biotechnology ROI 13.9 percent, compared with overall market-adjusted ROE of 9.9 percent.<sup>26</sup> Updated industry ROE data from Damodaran in 2021 finds that the traditional pharmaceutical industry ranks in the lower one-third of profitable U.S. industries.<sup>27</sup>

#### In 2016, of the top 659 companies globally, only one-third (259) even made a profit.

But these figures are only for survivors, and do not include all the biopharma companies that went bankrupt because their discoveries did not pan out.<sup>28</sup> In 2016, of the top 659 companies globally, only one-third (259) even made a profit.<sup>29</sup>

Moreover, even these modestly higher returns should not be cause for concern. As a study from the former Congressional Office of Technology Assessment finds, "Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary to induce companies to invest in

researching new chemical entities."<sup>30</sup> Likewise, as Harvard economist Frederick M. Scherer wrote, "Had the returns to pharmaceutical R&D investment not been attractive, it seems implausible that drug-makers would have expanded their R&D so much more rapidly than their industrial peers."<sup>31</sup>

Further, the report attacks the industry for engaging in stock buybacks, writing, "In 2018, the year that Donald Trump's tax giveaway to the wealthy went into effect, 12 of the biggest pharmaceutical companies spent more money on stock buybacks than on research and development."<sup>32</sup> But stock buybacks were high that year because tax changes enabled companies to bring back repatriated profits from overseas to the United States, which is what many industries did. In fact, as one study notes, "In the United States, massive distributions of cash to shareholders are not unique to pharmaceutical companies."<sup>33</sup>

Not only are drug industry profits not excessive but most academic studies find that drug price controls will harm drug development.

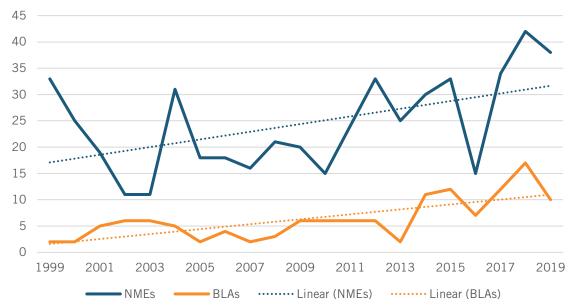
The Porter report also argues that drug price controls would not retard innovation because profits are so large. Not only are drug industry profits not excessive but most academic studies find that drug price controls will harm drug development.<sup>34</sup> In large part, this is because, as the Organization for Economic Cooperation and Development (OECD) noted, "There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures."<sup>35</sup> In addition, the Congressional Budget Office (CBO) examined the potential impact of the proposed House legislation H.R.3, which among other provisions would require drug companies to negotiate lower prices with the government. It concluded that reducing manufacturers' revenues by between \$500 billion and \$1 trillion over the next decade could result in 8 to 15 fewer new drugs coming to market.<sup>36</sup>

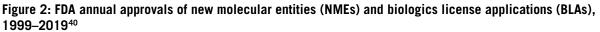
#### False Claim #3: The Industry Is Not Producing Enough Breakthrough Drugs

To press the case for dismantling the U.S. drug development system, opponents must argue that the system is not effectively performing its core function: producing effective treatments and cures. Given that leading drug companies have come up with COVID-19 vaccines in record time, using breakthrough technologies to literally save the world, this case is harder now. But undeterred, the report states, "Rather than producing breakthrough, lifesaving drugs for diseases with few or no cures, most companies focus on small, incremental changes to existing drugs in order to kill off generic threats to their government-granted monopoly patents."<sup>37</sup>

It notes that "the discovery of new molecular entities or novel drugs in the last decade (2000–2010) were in line with or slightly above those rates observed in the 1980s, despite technological improvements that should have catapulted new cures forward."<sup>38</sup>

But in reality, new drug approvals have significantly accelerated. The FDA's Center for Drug Evaluation and Research's five-year rolling approval average stood at 44 new drugs per year in 2019, double the lowest five-year rolling average of 22 drugs approved, realized in 2009. (See figure 2.) And the number of drugs in development globally increased from 5,995 in 2001 to 13,718 in 2016.<sup>39</sup>





Yet, the Porter report states, "Instead of taking risks to find new, critically needed drugs, large pharmaceutical companies are just repackaging the same products over and over: In 2018, only 1 in 3 new brand-name drugs that drug companies launched were 'first in class' drugs."<sup>41</sup>

Is 1 in 3 low? In the 1940s and 1950s, when there were few drugs on the market and almost all were first in class, 1 in 3 would have been low. But as more drugs hit the market, the share of first-in-class drugs declined as it became harder to discover new treatments and also because of the importance of producing multiple drugs to address the same disease. Nonetheless, the share of drugs that are new has risen since the 1970s, not fallen.<sup>42</sup>

The report criticizes the industry for investing in "me-too" drugs. But this fails to recognize the significant clinical benefits of new drugs complementing existing drugs. Sometimes an existing drug does not perform as well as the new drug. Sometimes certain individuals have adverse reactions to an existing drug but not the new drug.<sup>43</sup> In addition, follow-on drugs can be better in efficacy or methodology and convenience of use and administration. DiMasi and Faden found that 32 percent of follow-on drugs have received a priority rating from the U.S. FDA, indicating that these drugs are likely to provide an important improvement over the first-to-market drug.<sup>44</sup> They concluded, "Overall, these results indicate that new drug development is better characterized as a race to market among drugs in a new therapeutic class, rather than a lower risk imitation of a proven breakthrough."<sup>45</sup> Moreover, GAO found that the introduction of additional drugs lowers prices.<sup>46</sup>

The share of drugs that are new has risen since the 1970s, not fallen.

The report also implies that discovering new drugs is easier now because of "technological improvements." To be sure, technological improvements, such as big data analytics, genomics, nanotechnology, and others are improving drug development. But rather than becoming easier, as

the need for personalized medicines grows, developing new drugs is harder, especially for cancer, Alzheimer's, and thus-far intractable diseases.

The scholarly literature confirms this. In a study of productivity, research economists Bloom, Jones, Van Reenen, and Web found that over the last 20 years, in many industries, including biopharmaceuticals, it takes more R&D effort to get the same results.<sup>47</sup> This is reflected in a 2014 study by Tufts Center for the Study of Drug Development that estimates that the average cost of developing a new drug was \$2.56 billion up from \$1.1 billion in 2000 (in 2015 dollars).<sup>48</sup>

The average cost of bringing a new drug to market has increased by 67 percent since 2010.

Similarly, according to a 2018 report "Unlocking R&D Productivity: Measuring the Return From Pharmaceutical Innovation 2018" by the Deloitte Center for Health Solutions, "The average cost to develop an asset, including the cost of failure, has increased in six out of eight years."<sup>49</sup> The report estimates that the cost of developing a new drug almost doubled from an average cost of \$1.19 billion in 2010 to \$2.17 billion in 2018. The 2019 version of the report concludes that the average cost of bringing a new drug to market has increased by 67 percent since 2010 alone.<sup>50</sup>

# False Claim #4: Drug Price Increases Radically Outstrip Increases in Broader U.S. Health-Care System Costs

The Porter report asserts that drugs have seen "skyrocketing costs."<sup>51</sup> However, the data suggests otherwise.

According to the Peterson Center on Healthcare and Kaiser Family Foundation, the percentage of total U.S. health care spending going toward retail prescription drugs was consistent from 2000 to 2017, at mostly under 10 percent.<sup>52</sup> (See figure 3.)

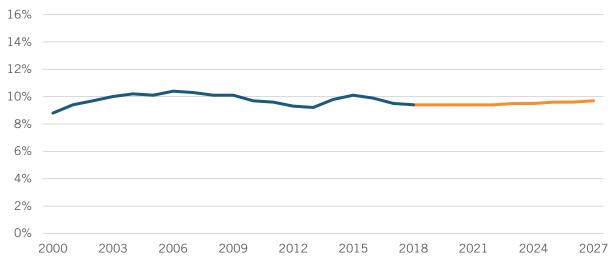


Figure 3: Percentage of total health spending that went to retail prescription drugs, 2000-2017; projected
2018–2027 <sup>53</sup>

When examining increases in prescription medicine costs from 2000 to 2019 compared with other facets of the U.S. health care system, such as "hospital and related services" and "medical care," the increase in prescription medicine costs has been right in line with the increase in medical care, and just slightly above the increase in the urban consumer price index, considering all items. (See figure 4.)

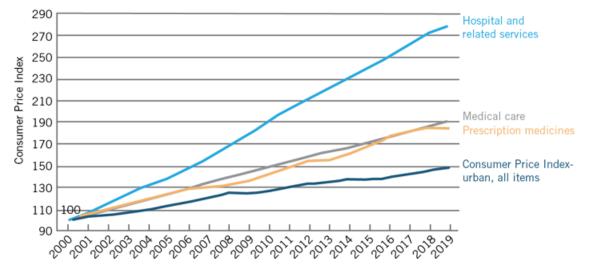


Figure 4: Average price levels, selected goods and services, 2000–2019<sup>54</sup>

# False Claim #5: Big Drug Companies Rely on Government, Universities, and Start-Ups to Innovate

The Porter report claims, "Companies with billions in profits have relied on our dollars to support research, unwilling to assume risk themselves. It's no different in the rest of the market, where Big Pharma relies on the creativity of academic researchers and small biotechnology firms, only to acquire them after they've discovered a blockbuster drug."<sup>55</sup>

It continues, "Big pharmaceutical companies are not responsible for most major breakthroughs in new drugs."<sup>56</sup> There is a healthy ecosystem wherein the National Institutes of Health (NIH) supports very basic research, both intramurally and at universities. But to believe that NIH alone could develop, produce, and distribute drugs is to misunderstand the industry.

The National Academies of Science wrote, relying on earlier data on costs, "The cost of developing a new drug has been estimated to be more than \$1 billion. Development of this scale involves multiple financing mechanisms, as well as the involvement of numerous partners throughout the process."<sup>57</sup> Zycher, DiMasi, and Milne identified 35 drugs and drug classes (a group of drugs used to treat a given medical condition in similar ways), finding that "the scientific contributions of the private sector were crucial for the discovery and/or development of virtually all of the thirty-five drugs or drug classes."<sup>58</sup> The authors continued, "Without the scientific advances yielded by private-sector research, most drugs would not be developed, and thus the economic returns to publicly funded research would be sharply reduced."<sup>59</sup> Updating this work in 2016, DiMasi, Milne, Cotter, and Chakravarthy concluded, "Industry's contributions to the R&D of innovative drugs go beyond development and marketing and include basic and applied science, discovery technologies, and manufacturing protocols, and that without private

investment in the applied sciences there would be no return on public investment in basic science."<sup>60</sup>

New research tests the hypothesis that government (i.e., NIH) funding, not private market investment, is largely responsible for the creation and approval of new therapies by identifying patents linked to NIH grants from a single year; identifying those associated with clinical trials and approved medicines; and quantifying the public and private investments made for those investigational and approved medicines. The study finds that 23,230 NIH grants in the year 2000 were linked—by NIH-supported patents—to 18 FDA-approved medicines by 2020. It concludes that not one of those medicines reached approval without significant private investment, with total private investment for the 18 approved medicines exceeding NIH funding by orders of magnitude: \$44.2 billion in private investment compared with \$670 million in NIH funding.<sup>61</sup>

This reinforces the essential point that considerable investment is required to bring a drug to market even after considerable amounts of basic research have been conducted. In fact, one study finds that biotechnology companies invest \$100 in development for every \$1 the government invests in research that leads to an innovation.<sup>62</sup>

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#### CONCLUSION

The Porter report selectively uses data to inaccurately paint a picture of the U.S. biopharmaceutical industry, the most successful drug development system in the world. It does so in order to undermine that system.

This is not to say that policy toward the industry cannot be improved. For continued industry success, policymakers will have to work to prevent China from doing to the U.S. biopharma industry what it did to other formerly successful U.S. industries, including telecom equipment and solar panels.<sup>63</sup> Congress needs to expand the research and experimentation tax credit, which now lags behind most U.S. competitor nations.<sup>64</sup> It and the Biden administration need to take steps to reduce the pressure from Wall Street for short-term profit performance—a drag not just on the biopharmaceutical industry, but on all U.S. industries.<sup>65</sup> It is important to fully fund antitrust authorities at the Federal Trade Commission and Department of Justice so they have adequate resources to thoroughly investigate merger reviews.

We are at the cusp of a new era of drug innovation, an era that will be more personalized, with more diseases having cures. But that era will be stillborn if policymakers buy into the notion that the U.S. biopharma system, including large, innovative drug firms, must be radically changed.

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# **ENDNOTES**

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