6. Corporate Research and Development Investments Are Exaggerated

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Quigley, Fran.

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Part II

Profits over Patients
We have reviewed the undeniable evidence that the pharmaceutical industry ignores the development of medicines needed by billions of people across the globe. Yet corporate spokespersons still defend the high costs of patent-protected medicines by claiming they are necessary to conduct research and development. Alan Holmer, former president of the industry trade association PhRMA, said, “Believe me, if we impose price controls on the pharmaceutical industry, and if you reduce the R&D that this industry is able to provide, it’s going to harm my kids and it’s going to harm those millions of other Americans who have life-threatening conditions.”

To buttress that argument, Holmer and his colleagues have long pointed to figures that they claim represent enormous industry expenditures for researching and developing new medicines. The most recent estimate comes from a 2014 report by the Tufts Center for the Study of Drug Development, which concluded that the average cost of bringing a drug to market is a whopping $2.6 billion. That figure was quickly promoted by John J. Castellani, Holmer’s successor as head of PhRMA, in newspaper...
articles and by his organization in colorful brochures defending existing medicine patent laws.³

But the accuracy of this $2.6 billion figure is highly questionable. First, consider the source: the Tufts Center reports that the institution receives 40 percent of its overall funding from the pharmaceutical industry.⁴ Second, the Union for Affordable Cancer Treatment and leading medicine researchers have raised concerns about the $2.6 billion figure overstating the number of patients in and costs of the average medicine clinical trial, and the main author of the report has admitted the figure does not reflect the benefits of tax credits for the industry research, credits that could reduce corporate costs by as much as 50 percent.⁵

The questions raised about this most recent cost estimate are important because academic analyses of previous and similar reports have shown the costs to be wildly overstated. For example, Donald Light and Rebecca Warburton, health and economics researchers writing in 2011 for the London School of Economics and Political Science journal *BioSocieties*, conducted a blistering critique of a prior Tufts study of the industry research and development costs.⁶ Echoing others’ concerns, Light and Warburton criticized the Tufts analysis for failing to make adjustments for the substantial public investment in research and development, and for failing to identify the drugs reviewed by their therapeutic classification.⁷ According to Light and Warburton, the lack of specificity in the report indicated that the cost estimates could have been conducted on a sample that was skewed toward medicines that are more expensive to develop. In fact, an unpublished appendix to the Tufts study suggested that this was indeed the case.⁸

It is similarly unclear whether the research and development estimates in the earlier Tufts study included marketing-oriented expenses, such as payments to physicians to promote the drugs or instructional courses to provide information about the drugs to prescribing physicians.⁹ Light and Warburton’s review suggested that half the Tufts estimate of the financial cost of research did not represent real research investments at all. Rather, it was a calculation of the income the corporations potentially would have reaped if they had not invested in research and development—a calculation that ignores the fact that those research and development costs are deducted from the taxable profits of the company each year.¹⁰ Further, the Tufts estimate was based on clinical trials whose costs and lengths far exceeded the averages the U.S. government has reported, again suggesting the overall cost numbers were skewed upward.¹¹
Not surprisingly, then, the claims by the industry for its research and development costs are widely dismissed as unreliable. Even a pharmaceutical CEO, Andrew Witty of GlaxoSmithKline, has said that the prior $1 billion estimate for developing a drug was “one of the great myths of the industry.” The Economist has labeled the current $2.6 billion figure “questionable,” making special note of the padded estimates for loss of capital. In addition, a coalition of academics has echoed the charge that the current Tufts estimate is “a myth.” Other industry observers have called into question the oft-quoted corporate estimate of thousands of compounds being tested to discover just one drug that is brought to market, noting that computerized screening of a large number of compounds is relatively quick and inexpensive.

The costs to develop a medicine are variable. But, in their 2011 article, Light and Warburton concluded that the actual cost of developing a new medicine could be as low as $43.4 million, one-eighteenth of the figure the industry was promoting at the time. More recent data from the nonprofit Drugs for Neglected Diseases Initiative estimate that the cost for development of a new medicine is in the range of $112 million to $169 million. The Global Alliance for Tuberculosis Drug Development provides an even lower estimate for developing a new TB medicine. While the industry has claimed that it costs nearly $1 billion to develop a vaccine, independent analyses put the cost at less than half that amount, and possibly as low as $150 million.

Although these estimates are a fraction of the industry-promoted figures, they are still large numbers. Clinical testing of medicines is an expensive phase of the research process. Private corporations are far more eager to be involved at this stage that immediately precedes the hoped-for profits than they are in the riskier early stages, so private industry shoulders most of the clinical trials costs. Nevertheless, placed in the context of a trillion-dollar industry, the costs simply do not back up the argument that the purpose of high corporate medicine profits is to support research and development investments. For example, it has been estimated that the company Novartis contributed somewhere between $38 million and $96 million to the research and development of its leukemia drug imatinib, which it markets as Gleevec. (Novartis has not disclosed its exact research and development investment, so this estimate is based on publicly available records and on past reporting of the costs of clinical trials and other research.) Novartis makes $4.7 billion in annual sales of Gleevec,
which in 2016 had a wholesale U.S. cost of $120,000 per patient.\textsuperscript{21} So, even assuming corporate costs at the highest point of the estimated range, it takes Novartis only thirteen days of Gleevec sales revenue to cover its research and development investment.\textsuperscript{22}

More broadly, giving the pharmaceutical corporations a very generous benefit of the doubt about their actual research and development costs, and without factoring in the tax breaks associated with those costs, the industry still spends less than 15 percent of sales revenue on research and development.\textsuperscript{23} As we see in chapter 7, the industry costs for marketing are much higher. Recent numbers reported by PhRMA suggest that the percentage of sales revenue spent on research and development is now less than 8 percent and trending downward.\textsuperscript{24}

As they defend high medicine prices and the patents that protect them, the largest corporations still promote themselves as tireless researchers: “Our industry is poised to translate our most promising scientific breakthroughs into meaningful treatments capable of tackling the most urgent and vexing medical challenges of our times,” is the quotation from Kenneth Frazier, Merck chairman and CEO, featured on PhRMA promotional material.\textsuperscript{25} But one of the reasons for the downward trend in industry research investments is that the large pharmaceutical corporations have increasingly transitioned to a model that is less innovative and less risky than developing new drugs. The large corporations that have themselves been less successful in developing new treatments have focused instead on buying up smaller biotech companies that have developed promising drug compounds.

Under this “buy not build” model, biotech companies that have drugs in their pipelines to treat cancer, muscular dystrophy, and other diseases are ripe for buyouts by the larger companies that are not as successful in their discoveries.\textsuperscript{26} The consulting firm Bain recently conducted a study that showed that the top pharmaceutical corporations were earning more than 70 percent of their sales from medicines that were developed by someone else, usually smaller companies more narrowly focused on a limited number of research projects.\textsuperscript{27} As Bernard Munos, a pharmaceutical industry consultant, told the journal Nature in 2016, “Most (pharmaceutical corporations) do not produce enough innovation to grow. In fact, half of them are shrinking. They try to mitigate this by escalating prices, which is dangerous. I think industry is misjudging the anger that
its practices are creating.”28 Also in 2016, one pharma CEO, Dr. Leonard Schleifer of Regeneron Pharmaceuticals, conceded the point: “The real reason we’re not liked, in my opinion, is because, we as an industry, have used price hikes to cover up the gaps in innovation.”29

An example of this dynamic is the massively profitable hepatitis C medicines (discussed in chapters 1 and 2), which have been priced out of the range of patients such as Sarah Jackson. The drugs were developed by the biotech firm Pharmasset. (As I explore further in chapter 14, these hepatitis C medicines are among the majority of important medicines whose late-stage development was built on a foundation of basic research that was largely government-funded.) In 2011, the larger corporation Gilead bought up Pharmasset and the patent rights to its wonder drugs for $11 billion.30 It was a big price tag, but the high prices of Sovaldi and Harvoni are allowing Gilead to make up that investment very quickly. Even while the pharmaceutical industry aggressively promotes itself as an innovator, occasionally a corporate executive will reveal the true nature of the current business model. “We’re not going to put our money in-house if there’s a better investment vehicle outside,” the chief operating officer (COO) of GlaxoSmithKline told the Wall Street Journal.31