

# Reforming the Business of Pharmaceutical Innovation

Advising research, policy, and practice  
March 16-18, 2021 | 9:00 am - 12:00 pm EST



## Executive summary

### Workshop #4—Modeling the impact of drug pricing policy on the pipeline of new drug approvals

This workshop will focus on considering how proposed policies aimed at reducing drug prices may impact the pipeline of innovative pharmaceutical products. The biopharmaceutical industry is considered to be the dominant source of funding for drug discovery and development. In 2018, for example, the global biopharmaceutical industry spent over \$180 billion in R&D.<sup>1</sup> This amount represented ~16% of the \$1.2 trillion in global pharmaceutical sales,<sup>2</sup> 40% of which came from the United States, where drug prices are 3.7x higher than in comparator regions.<sup>3</sup> This workshop asks how proposed policies designed to lower drug prices<sup>4</sup> may impact pharmaceutical R&D spending and the pipeline of new therapeutics in the future.

The goal of this workshop is to identify ways to model the relationship between pharmaceutical revenue, R&D spending, and the rate of new drug approvals in the future.

## Background

A focus of our work has been on defining the economic inputs and outputs to pharmaceutical innovation. We have characterized the involvement of biotechnology companies with IPOs from 1997-2016 in new drug development as well as their financial performance<sup>5</sup>. These companies had an estimated 52% probability of contributing to an approved product, initiating

<sup>1</sup> The 2019 EU Industrial R&D Investment Scoreboard, [iri.jrc.ec.europa.eu/scoreboard/2019-eu-industrial-rd-investment-scoreboard#field\\_data](http://iri.jrc.ec.europa.eu/scoreboard/2019-eu-industrial-rd-investment-scoreboard#field_data)

<sup>2</sup> Of other companies, only China contributed >10% of sales [heatinformatics.com/sites/default/files/images-videos/FileContent/global-medicine-spending-and-usage-trends.pdf](https://heatinformatics.com/sites/default/files/images-videos/FileContent/global-medicine-spending-and-usage-trends.pdf)

<sup>3</sup> A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices. Prepared by Ways and Means Committee Staff, September 2019.

[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)

<sup>4</sup> For example, H.R.3 - Elijah E. Cummings Lower Drug Costs Now Act, 116<sup>th</sup> Congress. [www.congress.gov/bill/116th-congress/house-bill/3](https://www.congress.gov/bill/116th-congress/house-bill/3)

<sup>5</sup> McNamee, L.M., Zheng, S., Salim, U., Cleary, E.G., Ledley, F.D. (2020) Drug development in biotechnology companies with IPOs from 1997-2016. *Clinical Therapeutics* [https://www.clinicaltherapeutics.com/article/S0149-2918\(20\)30522-1/fulltext](https://www.clinicaltherapeutics.com/article/S0149-2918(20)30522-1/fulltext)

Cleary, E.G., McNamee, L.M., DeBoer, S., Holden, J., Fitzgerald, L., Ledley, F.D. (2021) Comparing long-term value creation after biotech and non-biotech IPOs, 1997-2016. *PLOS ONE* [journals.plos.org/plosone/article?id=10.1371/journal.pone.0243813](https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0243813)

development for 60% and contributing to clinical development of 97%. At the same time, these companies had median R&D expenses of \$32.9M, greater than their median revenues of \$10.1M, and leading to negative median net income (earnings) of \$36.2M. We have also described the finances of 35 of the largest pharmaceutical companies from 2000-2018. These companies reported \$11.5 trillion of sales with gross profits of \$1.9 trillion, distributed \$1.7 trillion to shareholders in the form of dividends or stock buybacks, and funded \$1.7 billion in R&D.<sup>6</sup>

## The present work

A project funded by the West Health Policy Center focuses on modeling the relationship between biopharmaceutical revenue, R&D expense, and its potential impact on the number of products progressing through the pharmaceutical pipeline. This work is based on the observation that, while R&D expense is strongly correlated with revenue/sales across the biopharmaceutical sector, a closer analysis indicates that this relationship is only significant for a small number of the largest pharmaceutical companies. In contrast, there is no association between revenue and R&D spending. Specifically:

- We collected company financial information from publicly traded pharmaceutical and biotechnology firms (GICS codes 352010, 352020) from 2000 to 2018 (Compustat).
- For the largest public companies, there was a strong association between R&D and revenue, which was not evidence for smaller companies (**Figure 1**).
- The historical relationship between revenue and R&D spending among pharmaceutical and biotechnology firms is modeled using median regression.
- The model estimates that for the largest public companies, a 1% year to year change in revenue was associated with a 0.8% year to year change in median R&D spending.
- For smaller public companies, there is no evidence of a relationship between the change in R&D spending and revenue, available capital, capital raised, or measure of profit.

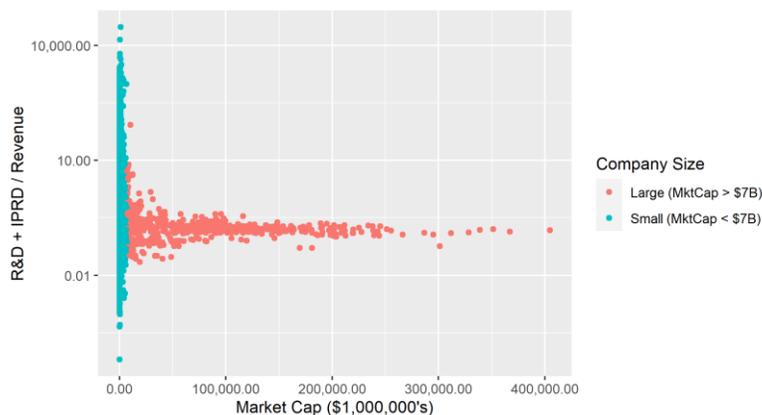


Figure 1. R&D expense as a fraction of revenue (Compustat: XRD-RDIP/REVT) versus market capitalization (Compustat: CSHOXPRCC\_F) for 1378 companies.

<sup>6</sup> Ledley, F.D., McCoy, S.S., Vaughan, G., Cleary, E.G. (2020) Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies. *Journal of the American Medical Association*, 323(9):834-843. doi:10.1001/jama.2020.0442 <https://jamanetwork.com/journals/jama/article-abstract/2762308>

- We are currently examining clinical trials in ClinicalTrials.gov to identify the proportion of trials at each phase sponsored by the largest pharmaceutical companies versus smaller biopharmaceutical companies. These data will be used to extrapolate from projected decreases in revenue for the largest companies to the impact on the drug pipelines.

### Questions raised by this work

These questions are intended to highlight issues that may be addressed in this workshop (and are not a set of discrete questions for the discussants or audience).

- How would reduced R&D spending be reflected in the pipelines of large pharmaceutical companies? Are these companies more likely to reduce investments in early stage discovery and development, cull products in late stage development, or eliminate entire therapeutic areas? Are companies more or less likely to invest in new molecular entities, follow-on products, reformulations, additional indications, generics, or biosimilars?
- How would smaller biopharmaceutical companies be impacted? Would it increase or decrease the role of biotechnology companies as a source of product innovation? Would it increase or decrease the premium paid for acquiring innovative products or companies? How would it impact capital investments in biotechnology?
- How would reduced R&D spending by large companies impact patterns of innovation? Would it decrease or increase investments in innovative approaches to drug discovery and development? Would it decrease or increase the premium on acquisition of highly innovative products?
- What financial strategies are large companies likely to pursue to maintain stock prices? Would there be increased pressure to buy back stock to maintain EPS? Would there be increased emphasis on innovation to achieve higher PE ratios?

### Convenors

- **Greg Vaughan, PhD**, Center for Integration of Science and Industry, Department of Mathematics, Bentley University.
- **Sean Dickson, JD, MPH**, Director, West Health Policy Center.

### Discussants

- **Mark Namchuk, PhD**, Executive Director of Therapeutics Translation, Harvard Medical School, *formerly* Alkermes, Vertex.
- **Bernard Munos, PhD**, Senior Fellow, FasterCures (Milken Institute), *formerly* Eli Lilly.
- **Richard Frank, PhD**, Margaret T. Morris Professor of Health Economics, Harvard Medical School, *formerly*, Assistant Secretary for Planning and Evaluation, US Department of Health and Human Services.

- **Craig Wheeler, MBA**, President and CEO, Headwaters Biotech Advisors, *formerly*, CEO, Momenta Pharmaceuticals.
- **Lawrence Stein. Esq.** *formerly* General Counsel, Genetics Institute; Celgene; Wyeth.

### Workshop plan

The session will begin with an informal introduction to the theme of this workshop, followed by 5-8 minute comments from each discussant describing their perspectives based on their work and experience. We hope these introductory comments will provide an opportunity for an open discussion between the discussants and other participants in the workshop.

If you wish to ask a question during the session, please indicate yourself or directly post the question in the Zoom Chat box. A member of our team will be monitoring this and will invite you to ask your question at an appropriate time.

For more information, please email [SciIndustry@bentley.edu](mailto:SciIndustry@bentley.edu).