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 #3–What is reasonable drug pricing and how can it be achieved?

This workshop will explore what is meant by "reasonable drug pricing," both for COVID and other diseases, and strategies for ensuring that medicines crated form publicly funded science are affordable and available to the public.

The goal of this workshop is to conceptualize policies that recognize both the public and private sector investments in pharmaceutical innovation in ensuring reasonable drug prices.

Background

In 1961, the Subcommittee on Antitrust and Monopoly of the Senate Judiciary, chaired by Estes Kefauver, published a report titled "Study of Administered Prices in the Drug Industry" based on two years of investigation.[1] Part I of that report was titled "The reasonableness of price," and it began with the statement that "*The reasonableness of an industry's prices is typically appraised in the light of certain yardsticks or standards, principal among which are (i) unit production costs, (ii) prices in different markets (as in different countries), and (iii) profits.*" Three decades later in 1991, Roy Vagelos, then the CEO of Merck, addressed continuing concern about drug prices in a landmark article titled "Are Prescription Drug Prices Too High."[2] His article described increasing drug prices in the context of the increasing timelines, risk (failure rate), and costs of drug development, emphasizing the importance of the cost-benefit and availability of these products to patients and society.

The terms of the debate have not changed substantively in the ensuing thirty years. Drug prices have continued to rise faster than the rate of inflation, orphan and specialty drugs for restricted markets have been launched with seemingly exorbitant prices, an increasing number of drugs have come to market requiring lifetime treatment to prevent or manage disease, and the public continues to be concerned about both the cost-benefit of new drugs along with their affordability and availability. Both the industry and its critics continue to invoke the criteria articulated by Kefauver or Vagelos in arguing what constitutes a "reasonable" drug price. What has changed is that the industry has progressively withdrawn from the basic research that enables drug discovery and development in favor of a short

[1] Senate, U. S., and Judiciary Committee. "Administered Prices: Drugs." Report of the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary (1961). ipmall.law.unh.edu/sites/default/files/BAYHDOLE/4_PREPPED_FILES/1961.05.08_Senate_Report_on_Administered_Prices_Drugs.pdf

[2] Vagelos, P. Roy. "Are prescription drug prices high?." Science (1991): 1080-1084. https://science.sciencemag.org/content/252/5009/1080

term focus on development and commercialization, with an increase in the scale and significance of the public sector investment essential to innovation. These issues have been magnified by the exigency of the COVID pandemic, and massive government investments intended to stimulate the discovery and development of COVID vaccines and therapeutics, investments that were not accompanied for mechanisms to constrain prices or profits, or provide the public sector with a return on investment.

Our work

Numerous studies offer a framework for issues that the Center for Integration of Science and Industry seek to address. We have determined that NIH funding contributed to research associated with every new drug approved from 2010-2019, totaling over $180 billion.[3] In response to the pandemic, we have also identified $6.5 billion in NIH funding for research leading to remdesivir[4], and over $17 billion in NIH funding for foundational research for COVID-19 vaccines since 2000.[5] In addition, we have examined the contribution of NIH funding to new drug approvals from 2010-2016.[6] Specifically:

- The annual number of new drug approvals (NMEs) increased from 2010-2019.
- NIH funding for published research related to every one of the 356 NMEs approved by the FDA from 2010-2019 or their 219 biological targets.
- This body of literature comprised >2 million scientific publications, of which 424K cited funding from the NIH, with >90% of this research representing basic science on the drug target, rather than applied or translational research on the drug itself.
- NIH funding comprised 400K funding years **(Figure 1A)** of support and $180 billion in costs (C) NIH Project Years and Costs related to RdRp; (D) NIH Project Years and Costs related to NcAn**(Figure 1B)**.

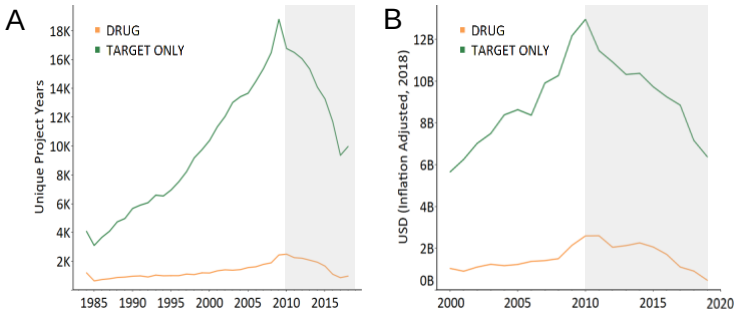

Figure 1 *(*A) Funding Years associated with NIH-funded PMIDs (1980–2019). (B) Project Costs (2000–2019). Note: the decrease in PMIDs, Funding Years, and Costs after 2010 is due to the experimental method, which considered only PMIDs published before the date of first drug approval.

[3] Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010–2019 www.ineteconomics.org/uploads/papers/WP_133-Cleary-et-al-Govt-innovation.pdf This work was funded, in part, by a grant from INET Economics.

[4] Cleary, E. G., Jackson, M. J., Wagner, Z. F., Ledley, F. D. (2020). Foundational research and NIH funding enabling Emergency Use Authorization of remdesivir for COVID-19. https://doi.org/10.1101/2020.07.01.20144576

[5] Kiszewski, A. E., Cleary, E. G., Jackson, M. J., Ledley, F. D. (2020). The role of NIH funding underlying candidate SARS-CoV-2 vaccines. https://doi.org/10.1101/2020.09.08.20187559

[6] Cleary, E. G., et al. "Contribution of NIH funding to new drug approvals 2010-2016." Proceedings of the National Academy of Sciences 115.10 (2018): 2329-2334.

- Between 2000-2019, the NIH contributed 6.6K funding years and $6.5B towards discovery of remdesivir's
  - Biological target, RNA-dependent RNA polymerase (RdRp): $1.9B **(Figure 2A)**
  - Chemical structure, nucleoside analogs (NcAn): $4.6B **(Figure 2B)**
- 51,530 vaccine technology-related publications were identified from 1980 through 2019; 8,420 (16%) of these vaccine technology publications acknowledged NIH funding **(Figure 3A)**
- Foundational research for COVID-19 vaccines was supported by >16,000 project years of NIH funding totaling over $17 billion since 2000, the majority through cooperative agreements and intramural programs **(Figure 3B)**

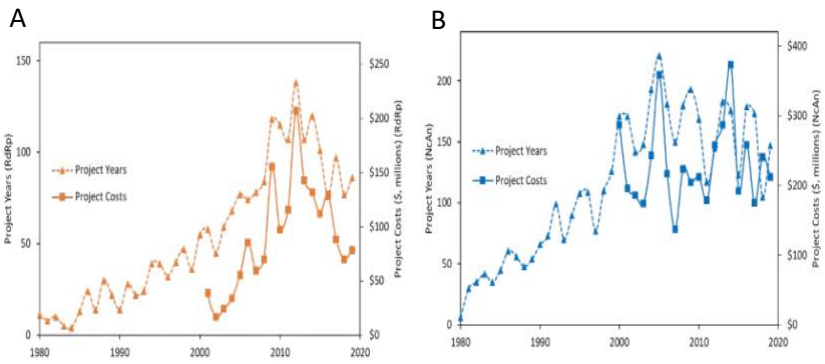

Figure 2 *(A) NIH Project Years and Costs related to RdRp; (B) NIH Project Years and Costs related to NcAn*

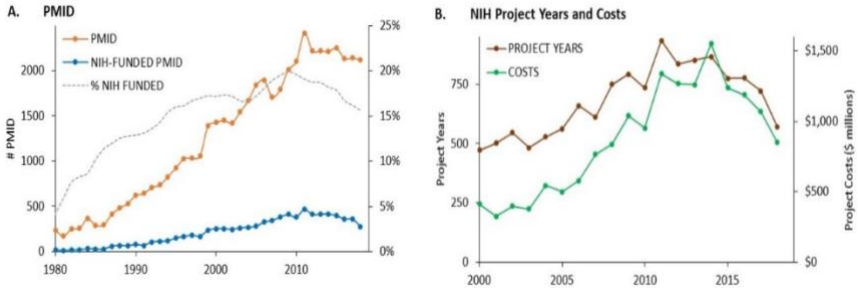

Figure 3 *NIH support for published research on ten vaccine technologies used in candidate COVID-19 vaccines. A. Annual PMID, NIH-funded PMID, and the fraction of PMID receiving NIH support for vaccine technologies. B. Annual project years and project costs associated with NIH-funded PMID 2000–2019.*

Questions raised by this work

- What factors should be considered to define a fair price?
- How do we recognize public investment and ensure proper returns on that investment?
- How can the NIH incorporate reasonable pricing to ensure that the "taxpayer isn't paying twice," while maintaining continued pharmaceutical innovation?

Discussants

- **Ameet Sarpatwari, PhD, JD** PORTAL; Brigham and Women's Hospital. https://bioethics.hms.harvard.edu/faculty-staff/ameet-sarpatwari
- **Rosie Collington, MS** UCL Institute for Innovation and Public Purpose. https://www.ucl.ac.uk/bartlett/public-purpose/people/rosie-collington
- **Peter Arno, PhD** Political Economy Research Institute, University of Massachusetts Amherst. https://www.peri.umass.edu/economists/peter-s-arno
- **Sarah Emond, MPP** Institute for Clinical and Economic Review. https://icer.org/who-we-are/people/leadership-staff/sarah-k-emond-mpp/

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.