

## VIEWPOINT

# Funding of Pharmaceutical Innovation During and After the COVID-19 Pandemic

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**The coronavirus disease 2019** (COVID-19) pandemic has highlighted the available mechanisms for funding research, development, manufacturing, and distribution in the life sciences. The traditional innovation strategy started with scientific discovery supported by grants from governmental and philanthropic sources, followed by product commercialization supported by pharmaceutical industry revenues and capital investments. According to one estimate, governmental and philanthropic grants fund approximately one-third of the total investment in the life sciences (estimated total investment of \$194.2 billion in 2018) and the life sciences industry funds the remainder.<sup>1</sup>

Prior to the onset of the COVID-19 pandemic, drug prices charged in the US had come under scrutiny due to the burden they place on public and private budgets. Congress and the Trump administration proposed drug pricing legislation far more restrictive than previous initiatives; however, the proposed legislation was still substantially more limited than what is used in other high-income countries.<sup>2</sup> Criticism of the pharmaceutical industry was muted during the early stages of

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## The high prices allow non-US pharmaceutical companies to repatriate high profits from the US market and finance expanded research and production capabilities at home...

the pandemic but now is reemerging. The health care policy platform of President Joseph Biden includes authorization for Medicare to negotiate prices with drug manufacturers, linkage of prices charged in the US to prices charged in other high-income countries, and bans on postlaunch price increases.

There also has been a major shift in the funding of product commercialization during the pandemic. Government agencies and philanthropic organizations are offering large sums not only to support research but to fund late-stage product development, the expansion of manufacturing capacity, and efficient systems for distribution. In the past, these activities have been funded largely by the pharmaceutical industry. The policy question now becomes whether the tilt toward public and away from private sources will be sustained after the COVID-19 pandemic recedes, or whether the funding of the life sciences will revert to the status quo. Given the size and importance of drug discovery and product commercialization, this has important implications for the future of medicine and health care.

### Public and Private Funding

The broad outlines of funding are emerging for COVID-19 tests and treatments. Much, if not the majority, of global investments have been financed by governmental entities and, of these, the largest share is contributed by the US government. These investments reach far beyond scientific and clinical research. During 2020, the US federal government invested \$11 billion in late-stage vaccine development and expansion of manufacturing capacity through Operation Warp Speed and the Biomedical Advanced Research and Development Authority.<sup>3</sup> Some of these contracts include a pre-purchase component by which the firm commits to supply a defined number of vaccine doses. For example, the government inked pre-purchase agreements with Moderna, Pfizer, AstraZeneca, Johnson & Johnson, Novamax, and the joint venture between Sanofi and GlaxoSmithKline. It is unclear if the remarkable achievement of vaccine development, testing, and authorization would have occurred without this investment, although it is important to note that the vaccine developed by Pfizer was not supported by Operation Warp Speed.

Extensive public investments also are being made in therapeutics. The 2 most prominent monoclonal antibodies (by Regeneron and Lilly) have come to market with substantial governmental support for product commercialization. Both products derive from therapeutic research platforms established with governmental support before the COVID-19 pandemic, but product commercialization and manufacturing received major additional investments in 2020. Separately, the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics program has committed \$1.5 billion to supporting development of diagnostic tests related to COVID-19. The specifics of the federal contracts largely remain confidential.

The pharmaceutical industry has backed away from the position that prices should be based on what the market will bear without regard to actual research, development, and manufacturing expenditures. Some firms have pledged to set prices at nonprofit levels, at least during the COVID-19 pandemic. The Coalition for Epidemic Preparedness Innovations (a coalition of governmental and philanthropic organizations) is proposing advanced market commitments to fund vaccine research and development with the understanding that recipients will supply vaccines later at prices that only cover the cost of production.<sup>4</sup> With advanced market commitments, the purchaser contracts for a defined number of vaccine doses at a negotiated price (to be delivered after the product is developed and manufactured),

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in effect committing the manufacturer to prioritize the contracted purchaser over others.

### A Reassessment of Pricing

The COVID-19 pandemic is forcing experimentation throughout the health care system, including drug prices as a source of funding for innovation. Some of the new initiatives will recede as the pandemic ends. However, the changes observed reflect deeper trends that likely will persist.

The public and political resistance to high drug prices in the US is unlikely to abate. It is neither efficient nor equitable for US taxpayers and patients to pay drug prices substantially higher than those paid in other high-income countries, even though these prices likely help support drug development that benefits many individuals around the world. Postlaunch price increases not supported by new evidence of clinical benefit cannot be justified as either cost-based or value-based pricing principles. In the fragmented and competitive US health insurance market, rising drug prices are passed on directly to patients, further burdening the patients with the most severe illness who need access to the most expensive therapies. High drug prices in the US compared with other countries constitute a direct subsidy to foreign competitors. The high prices allow non-US pharmaceutical companies to repatriate high profits from the US market and finance expanded research and production capabilities at home, whereas US pharmaceutical companies do not gain commensurate profits from their sales abroad. This contrasts with public funding mechanisms, including grants and tax incentives, which are designed to favor research, product development, and manufacturing activities conducted in the US.

The limitations of pharmaceutical industry profits as a financing source extend beyond the scale of investment to include its direction. The traditional framework is concentrated on investments in therapeutic niches protected from competition, rather than those of the greatest social need. Prices remain high and investment remains robust for treatments targeting rare orphan conditions and for thera-

pies based on the newest gene and cell technologies. But the pharmaceutical industry has been restricting its investments for major public health conditions (such as cardiovascular disease<sup>5</sup>), for new antibiotics<sup>6</sup> that address drug-resistant infections, and for the treatment of neglected illnesses<sup>7</sup> prevalent in low-income countries. The prices that can be charged and the revenues that can be earned in these domains do not satisfy the return on investment thresholds required by the pharmaceutical industry's capital partners.

### A Reassessment of Innovation Funding

The shortcomings of the traditional framework for funding pharmaceutical research and development have been evident for many years. But only in 2020, in response to the imperatives created by the COVID-19 pandemic, has the government been willing to expand its role. The passing of the pandemic, when it occurs, may reinvigorate industry-funded investments. The US will not be able to sustain its leading research and development position in global markets if it does not seize the opportunity presented by the COVID-19 pandemic to rethink its innovation strategy. Public funding will need to expand beyond scientific research to support product development and manufacturing, building on the model of the NIH Small Business Innovation Research program as well as the new models of Operation Warp Speed and the NIH Rapid Acceleration of Diagnostics program.<sup>8</sup> The expansion in public funding likely will find bipartisan support in the light of rising concerns for China's aggressive protection of and subsidies for its domestic life sciences industry.<sup>9</sup>

The lesson of the COVID-19 experience is that, when innovation in the life sciences is imperative, the traditional reliance on pharmaceutical industry prices and profits is jettisoned in favor of governmental grants and procurement. Sustained public funding for product development and commercialization will permit the sustained financing of innovation, a renewed attention to major public health needs, and the global position of the US pharmaceutical industry.

#### ARTICLE INFORMATION

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