Let There Be Light: Improving Transparency in the Biopharmaceutical Supply Chain

Guru Madhavan, PhD, MBA; **Francis Kwadwo Amankwah, MPH**, National Academies of Sciences, Engineering, and Medicine, Washington, DC, USA; **Charles Phelps, PhD, MBA**, University of Rochester, New York, NY, USA

KEY POINTS

The biopharmaceutical supply chain is opaque; who pays what, to whom, or why remains unknown. Moreover, most participants vigorously defend this opacity as essential to securing the most favorable prices for patients.

Improving the transparency of the various transactions between the participants in the biopharmaceutical supply chain is a necessary step in making medicines affordable, but probably is not sufficient on its own.

Transparency has demonstrated benefits in many other areas—with people expecting disclosure of information—from mortgages to specific aspects of financial trading and nutrition labeling to fuel economy and workplace safety.

The renowned Dutch artist M.C. Escher said, "We adore chaos because we love to produce order." This sentiment seems appropriate to the contentious challenge of making prescription medicines more affordable and available. Trying to understand the US biopharmaceutical supply chain—arguably one of the world's most complex markets—mirrors Escher's 1953 lithograph *Relativity*, full of impossibly interlocking stairways and multiple forces of gravity understandable only through viewpoint variation.

Developing novel medicines that prevent, manage, or cure conditions—and ultimately improve human welfare—represents an extraordinary human achievement. These medicines affect public health, social equity, and economic development. But their development comes neither cheaply nor easily. Many drug candidates fail for each success. Those that do succeed require millions to billions of dollars in research and development costs. Some drugs carry very high prices that few people in the United States can afford. The public has long desired concrete steps to increase availability and affordability of prescription drugs, but to this point policies have not yet culminated in effective solutions.

> Akin to Escher's *Relativity,* it's clear that the magnitude and effects of the problem—and how each participant conceives and presents it—is relative to their interests and varies with their position

Currently, potential profits create incentives for investment in biopharmaceutical research and development. Without this—in the current patents-based system—investment for new drug development could shrink. While patent protection enhances the availability of new drugs, eventual competition from generic products hopefully will enhance affordability. Health insurance mitigates the effects of high prices on patients but raises other concerns.

The United States today has no meaningful control of either launch prices or annual price increases, except through the power of competition and the bargaining power of large buyers such as retail pharmacy chains and prescription drug insurance plans, usually acting through pharmacy benefit managers (PBMs). Most other industrialized nations have centralized buying power for drugs. Governments of these nations generally can exclude drugs from formularies, and many also use essential medicines lists to guide purchasing decisions. In the United States, PBMs have consolidated bargaining power in the biopharmaceutical supply chain to some extent, but it is not clear how much savings are shared (if at all) with patients. Some manufacturers have begun to discuss eliminating their current discounts to PBMs and simply offering lower prices.

Concurrently, bargaining power of the federal government as a purchaser is limited by legislation. By no coincidence, the United States pays higher prices for branded drugs than virtually all industrialized nations and devotes a greater fraction of its total spending on supply chain intermediaries than do other countries.

Recently, prescription drug pricing has gained increased prominence. In 2018, the White House released *American Patients First*, a blueprint to lower drug prices. A report from the Council of Economic Advisers outlined policy reforms: *Reforming Biopharmaceutical Pricing at Home and Abroad*. For-profit and non-profit institutions continue to disseminate position statements—often stating the same problem from different vantage points with their preferred solutions. Akin to Escher's *Relativity*, it's clear that the magnitude and effects of the problem—and how each participant conceives and presents it—is relative to their interests and varies with their position. One can also readily find examples of how each segment of the >

biopharmaceutical supply chain blames other participants for high and rising prices.

Early in 2018, the National Academies of Sciences, Engineering, and Medicine also published *Making Medicines Affordable: A National Imperative*. This report recommends various pathways—through congressional legislation and federal and state agency actions as well as industry-based approaches—to improve the affordability of prescription drugs without discouraging the future development of new and more effective drugs. One key recommendation, with 3 actions, focused on improved understanding of how the biopharmaceutical supply chain works, who the participants are, and what their financial transactions and profit margins are.

In brief, the first action centers on gathering quarterly information, at the National Drug Code Level, from insurance plans (about average net prices paid for drugs, including patient cost-sharing) and from biopharmaceutical companies (about average net volume of and prices for drugs across each sales channel, including discounts to PBMs and insurance plans). These data would illuminate which entities capture what share of payment along the supply chain. The second action focuses on requiring biopharmaceutical companies to submit an annual public report stating list prices, (changes to) rebates and discounts to payers, and the average net price of each drug sold in the United States to identify all the net drug price increases exceeding the growth of consumer price index. The final action expands disclosure requirements on all sources of income by organizations in the biopharmaceutical sector that are exempt from income taxes under the Internal Revenue Code. Some of these organizations appear to rely heavily on biopharmaceutical industry support.

Improving the transparency of the various transactions between the participants in the biopharmaceutical supply chain is a necessary step in making medicines affordable. In this regard, we can fruitfully examine how transparency works within the finance industry. Regulators devote considerable effort to making financial markets transparent, usually by imposing disclosure and reporting requirements and by creating incentives for transactions to occur through public exchanges. The belief behind this approach is that transparency will benefit customers by enabling them to make informed decisions. Thus, the financial industry has rules governing "market-sensitive" data and "insider trading," designed to ensure that all market participants have equal access to potentially influential information.

> The United States today has no meaningful control of either launch prices or annual price increases, except through the power of competition and the bargaining power of large buyers such as retail pharmacy chains and prescription drug insurance plans, usually acting through pharmacy benefit managers.

Information alone provides many benefits in financial markets. With sufficient information, the market effectively "polices" suppliers. Financial markets operate with a broad sense that competition squeezes out bad behavior, thus reducing the need for regulation. In some cases, regulation extends further to protect consumers. Reserve requirements of insurance companies provide one example: life insurance companies must maintain financial reserves at least equal to their outstanding obligations. But in general, financial markets rely relatively strongly on competition rather than regulation to limit undesirable behavior.

Transparency has also demonstrated benefits in several other areas. From nutrition labeling (as well as on content and benefit claims) to occupational safety policies in the workplace, people expect transparent disclosure of information. Mandatory posting of fuel economy data on all new vehicles helps consumers make prudent choices about vehicle purchases. The federal Truth in Lending Act mandates information regarding mortgages for prospective home owners in the real estate market, thus improving their ability to make prudent decisions both about the choice of mortgage and the financial obligations that they can afford. Many similar examples regarding the benefits of information exist.

In contrast, the prescription drugs market, especially the highly complex supporting supply chain, is opaque. Little to no relevant data illuminate who pays what and to whom (or why). Moreover, most participants defend this opacity as being essential to securing the most favorable prices for patients. This emphasis on the benefits of opacity contradicts prevailing wisdom in financial and many other markets, where opacity is seen as benefiting intermediaries and transparency as benefiting the public.

This brings us to another important difference. Prescription drug markets are dominated by three features not present in financial markets: stringent requirements for product safety and efficacy; product patent protection; and health insurance coverage for consumers' purchases of medicines. The first of these, through the Food and Drug Administration regulations, has evolved into a complex and expensive system for testing new drugs before they can be marketed, all on the premise that market forces cannot sufficiently prevent releasing unsafe (or ineffective) drugs. Delays in that process can sometimes inhibit competition.

Patent protection for inventors, while considered essential to induce investment in new product development, also inhibits competition by providing exclusive marketing power to sellers. Further, insurance coverage for prescription drugs not only increases overall demand for products—potentially increasing prices even in competitive markets—but it also blunts people's sensitivity to price increases, thus inviting sellers with patent protection to raise prices extensively. As insurance coverage expands, the potential for market forces to control product prices evaporates. At present, almost 90% of the costs of retail prescription drugs are covered by insurance. This further diminishes the ability of competition to "police" the market.

With these issues in mind, we believe that increased transparency has 2 vital roles in biopharmaceutical markets. First, it may increase the benefits of competition

by exposing noncompetitive arrangements and contracts. The "blame-the-others" rhetoric of various participants in the biopharmaceutical supply chain evokes the image of a circular firing squad. Unfortunately, the patient sits at the center of this process. Better information should end this unproductive behavior.

The second role of transparency would lay the groundwork for necessary regulation. Without improved understanding of how the various levels of the biopharmaceutical supply chain interact with one another, one cannot meaningfully know where regulation is needed in the absence of competition. Bringing light into the biopharmaceutical supply chain is a necessary step to improve our understanding, guiding future actions, and ultimately, increasing people's health and well-being.

The views expressed in this article are those of the authors and not necessarily of the National Academies of Sciences, Engineering, and Medicine.

Additional Information:

The preceding article is based on an issue panel given at ISPOR 2018. To view the author's presentations, go to https://www.ispor.org/conferences-education/conferences/past-conferences/ispor-2018/conference-presentations