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Biopharmaceutical Innovation: Corporate Governance for Equitable Global Health

Padmashree Gehl Sampath, Öner Tulum and William Lazonick[1]

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ABSTRACT

Every year, millions of preventable deaths in the Global South could be averted with timely access to affordable medicines. While achieving equitable pharmaceutical access is widely recognized as a critical global health challenge, the mechanisms for doing so remain contested. Prevailing debates focus narrowly on reconciling R&D incentives with access, overlooking deeper structural and political determinants.

This paper argues that the misalignment between innovation incentives and public health needs is a systemic outcome of an innovation regime in which large pharmaceutical corporations allocate resources based on financialized business models designed to maximize shareholder value (MSV). We term this "predatory value extraction" (PVE) governance and argue that addressing the access challenge requires structural reform oriented toward "progressive value creation" (PVC) governance as its antithesis.

[1] Padmashree Gehl Sampath is a Senior Fellow at the Harvard Kennedy School, the Founding Chief Executive Officer of the African Pharmaceutical Technology Foundation, and Visiting Professor of Practice at the London School of Economics. Öner Tulum is Executive Director of Research, and William Lazonick, President, of the Academic-Industry Research Network. Lazonick and Tulum also acknowledge a Catalyst grant from the Canadian Institute for Advanced Research program on Innovation, Equity, & the Future of Prosperity to study the development, manufacture, and delivery of the Covid-19 vaccines. The authors gratefully acknowledge funding from the Institute for New Economic Thinking as well as discussions with INET Research Director Thomas Ferguson. The authors presented this paper to a seminar at the Harvard University Kennedy School of Government on February 6, 2026.

The paper surveys the structural shortcomings behind persistent medicine access gaps in the Global South, then examines how PVE governance has undermined governments, international agencies and other stakeholders working on access initiatives. By tracing the financing of global health initiatives, we show how fragmentation, limited coordination, and donor funding dependencies entrench PVE-driven agenda-setting and exacerbate misaligned priorities in global health. We conclude by outlining steps that policymakers can take to shift the pharmaceutical industry's dominant corporate governance model from PVE toward PVC.

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1. Corporate Governance and Access to Medicines

Every year, millions of people die in the Global South from causes that are entirely preventable. Many of these deaths could be averted with timely and affordable access to medicines. According to the World Health Organization (WHO), of the roughly 2.7 billion people living in low-and middle-income countries (LMICs), more than 2 billion lack regular access to essential medicines (World Health Organization, 2023a). Although precise estimates of mortality linked to medicine shortages are not easy to come by, existing evidence indicates that poor-quality health care in LMICs—including limited access to medicines—is responsible for 5.7 to 8.4 million deaths annually (Kruk et al., 2018). A substantial proportion of these deaths could be prevented by enhancing access to life-saving pharmaceutical interventions for a wide spectrum of diseases both communicable, such as HIV/AIDS and tuberculosis, and non-communicable, like cancers and cardiovascular illnesses (Haseltine, 2024; Kruk et al., 2018).

The access gap is profoundly inequitable, producing stark disparities in life chances and quality of life across regions. Epidemiological data show that an infant born in sub-Saharan Africa faces a risk of dying before the age of five that is approximately *15 times higher* than that of a child born in a high-income country (United Nations Inter-agency Group for Child Mortality Estimation, 2024). Those children who survive these odds in sub-Saharan Africa are at a higher risk of not being able to lead their lives to the fullest potential due to a continued lack of access to pharmaceutical interventions for chronic and other illnesses throughout their lives. For example, during 2017 and 2018, there were over 120 localized disease outbreaks in Africa, which remained under treated (Saied et al., 2022). In the same time period, at least 10 million Africans died of causes that could have been prevented with sufficient coverage of anti-retroviral drugs alone (Happi & Nkengasong, 2022). Such dramatic divergences in life chances and life quality are ultimately traceable to structural inequities in global health and represent a critical challenge for policy making today.

While there is broad agreement that one of the most pressing challenges in global public health is ensuring the timely availability of affordable, high-quality pharmaceutical products to all in need, the mechanisms for achieving equitable access remain deeply contested. Much of the prevailing debate has centered on incentive structures and organizational arrangements aimed at reconciling the growing tension between R&D, innovation, and profitability, on the one hand, and access to medicines, on the other. This frame, however, adopts a narrow, market-oriented perspective that overlooks the deeper structural and political determinants shaping the global pharmaceutical industry today.

This paper argues for a change in the underlying framing considering the growing health divides between and within countries despite twenty-five years of intensified health investments in LMICs. Our departure point is that the misalignment between innovation incentives and public health needs is not merely a coordination failure, but a systemic outcome of an innovation regime in which large pharmaceutical corporations make resource-allocation decisions based on financialized business models, and use their global power to develop, manufacture, and deliver medicines to maximize shareholder value (Kapczynski, 2019; Pogge, 2013; Sell, 2003; Tulum & Lazonick, 2018). Addressing the access challenge

therefore requires serious structural reform that can align the global pharmaceutical industry closely with the goal of pharmaceutical innovation that creates value for all worldwide.

Our central argument is that significant improvement in access to medicines in the Global South requires a fundamental transformation of the mode of corporate governance that characterizes the global pharmaceutical industry. The dominant corporate-governance model is based on the premise that the purpose of a business corporation is to "maximize shareholder value" (MSV). This ideology of corporate governance, which has become increasingly influential since its initial articulation in the 1980s, is most deeply entrenched in the United States, but has been spreading widely among companies in the pharmaceutical industry internationally for some time now (Lazonick & Tulum, 2023). Given the centrality of the United States and its regulatory framework to the global pharmaceutical industry, MSV ideology has exerted a preponderant—and we contend, deleterious—impact on access to medicines around the world.

As we explain in this paper, MSV is an ideology that rationalizes and legitimizes a business model that enables "predatory value extraction" (PVE), when what is needed for pharmaceutical innovation for the Global South is "progressive value creation" (PVC) (Lazonick, 2024, 2025). PVE and PVC represent two antithetical models for governing the relation between value creation and value extraction within the business corporation, with polar-opposite outcomes concerning the quality and cost of products that are available on the market and the distribution of income and wealth derived from the development, manufacture, and delivery of these products.

A business corporation creates value when, through the combination of strategy, organization, and finance, it generates a product that it can sell for revenues on the market (Lazonick, 2019, 2024). Participants in the corporation *extract value* when they can lay claim to corporate cash for themselves. Employees extract value when they get paid wages and benefits. Suppliers extract value when they obtain prices for the goods and services that they supply to the corporation. Shareholders extract value in the form of cash dividends and share repurchases (aka stock buybacks). Governments extract value through corporate taxation and regulatory fees. Customers extract value through the quality of the goods and services that they receive relative to the prices that they pay for them.

PVE occurs when certain claimants on corporate revenues have the power to extract far more value from the business corporation than they contribute to value creation. For example, it is often argued that workers through unions, suppliers through monopoly, governments through taxation, or consumers through price regulation have the power to extract more value from business corporations than they contribute. In the case of the pharmaceutical industry, we contend that, in the era of MSV, it is shareholders who possess this power of PVE, at the expense of employees, suppliers, governments, and customers. If we want superior outcomes for pharmaceutical innovation in the Global South, the sources of PVE in the global pharmaceutical industry must be identified and effectively constrained.

PVC is the antithesis of PVE. It is a corporate-governance regime that, purposefully, seeks to ensure the equitable distribution of value among the various "stakeholders" in the business corporation, according to their contributions to the value-creation process. In the

pharmaceutical industry, claimants in PVC include (in addition to other stakeholders) a legacy of scientists engaged in foundational, translational, and clinical research, the vast majority of which is antecedent and external to the current value-creation activities of a given pharmaceutical corporation, (Tulum & Lazonick, 2025). As a rule, several of these legacy claimants are in no position to make their claims—many of them are dead—so society should make these claims for them for the sake of enhanced allocation of resources to medical research and superior access to medicines by patients. In the here and now, claimants also include suppliers of materials and distributors of products, and other kinds of producers who offer value in the pharmaceutical value chain, including generic companies, which are important for competitive pricing and greater access. Corporate tax revenues need to be paid to governments so that they can fund agencies that invest in human knowledge and physical infrastructure that pharmaceutical companies need to develop, manufacture, and deliver new products.

PVC governance has the explicit objective of providing accessible and affordable medicines to patients who are integral to the pharmaceutical value-creation process. Under PVC governance, the purpose of the business corporation is to generate a greater supply of accessible and affordable medicines worldwide. In the pursuit of this purpose, a pharmaceutical corporation can be supported by government agencies, international and regional bodies, and civil-society organizations, operating locally, nationally, and globally.

The defining characteristic of a business corporation is that, to survive over time, it requires product revenues that are at least equal to its product costs. This basic need to avoid persistent losses imposes financial discipline on the business corporation that can be met and overcome by the generation of products that are higher in quality and lower in cost than those of its competitors; that is, through innovation. Indeed, through innovation, the business corporation can generate a stream of profits that permit it not only to survive but also to grow, using the capabilities devoted to and the profits derived from its existing commercial products to invest in the next generation of higher-quality, lower-cost products. But the innovation model employed in the pharmaceutical industry today, in large part, does not devote capabilities to the creation of higher-quality, lower-cost products for all. As we stress in this paper, from the perspective of the theory of innovative enterprise, pharmaceutical profits *per se* are not the source of the access-to-medicines problem. The critical question is whether a pharmaceutical company uses its profits for PVC or PVE. Even if some companies do invest their profits in PVC, a large share of them do not. PVE prevails as the dominant model for an industry with one of the largest, immediate impacts on global public welfare.

Showing how the innovation model, and by extension, the use of profits for PVC and PVE matter, this paper argues for a paradigm shift in how the governance of the business corporation in the global pharmaceutical sector is conceptualized—from a PVE model to a PVC model. Such a shift would reorient the pharmaceutical value creation process toward delivering high-quality, low-cost products that enhance access to medicines *for all*, instead of treating innovation and access as opposing goals. The central challenge for governance reform is to identify the institutional conditions under which PVC governance can function as a sustainable business model.

Formulation of a response to this challenge entails determining how pharmaceutical corporations can succeed in constantly improving global access to medicines while allocating their resources to invest in the organizational capabilities needed to generate the next generation of innovative pharmaceutical products. Although the PVC-oriented business corporation would operate as a distinct unit of strategic control, its success—like that of any business corporation under any governance model, including PVE—would depend on value-creating contributions from various actors in the global pharmaceutical and health ecosystem. These contributors would include nation states, international bodies, regional and national agencies, other corporations in the business sector, advocacy organizations, philanthropic foundations, and external stakeholders as relevant. In such an ecosystem, innovation becomes a genuine driver of value creation through business competition based on organizational learning and economies of scale.

In contrast, when pharmaceutical corporations operate under PVE governance, it becomes difficult, if not impossible, for international and regional bodies, national governments, and other like-minded agencies seeking to promote PVC governance to have any meaningful impact. Even more concerningly, some of these institutions may inadvertently (or knowingly) pursue access-to-medicines policies that reinforce, rather than challenge, PVE dynamics.

The next section of this paper provides a comprehensive overview of the structural shortcomings that contribute to the persistent problem of lack of access to medicines for the Global South. We argue that a major barrier to solving the problem is the increasingly financialized business model that characterizes the global pharmaceutical industry today, with its strong tendency toward PVE governance in the name of MSV. Following this framing of the issues, we examine how PVE governance has undermined or distorted the work of governments and other agencies engaged internationally and/or regionally in access-to-medicines initiatives in LMICs.

We analyze the proliferation of current global health initiatives to demonstrate that the expansion of the PVE model internationally has led to the emergence of two distinct approaches for global access to medicines. One approach posits that distributional inequities (as reflected in low access for different groups of people) are an inevitable outcome of innovation, and that, therefore, access initiatives must be designed to address specific dire inequities as and when they arise. The other approach argues that greater access to knowledge and manufacturing capacity as well as more competition are core determinants of a competitive industry and are critical to promote access to medicines by facilitating better pricing in both innovator and generic categories.

Based on a PVC governance model, we propose a third, and more equitable and sustainable, way to solve the global access-to-medicines problem in this paper. We then trace the financing of global health initiatives since the early 2000s to show how the fragmentation among international and regional agencies, limited coordination capacity, and funding dependencies on donors have served to entrench the PVE-driven agenda-setting further in global debates and exacerbate the misalignment of priorities in the global pharmaceutical industry. The concluding section of the paper outlines the steps that policymakers can take to shift the industry's dominant mode of corporate governance from PVE to PVC and thereby promote pharmaceutical innovation and access for the Global South.

2. The Problem of Access to Medicines in the Global South

The challenge of ensuring access to medicines in LMICs is multifaceted, with several interlinked dimensions that reinforce one another and contribute to widening global health inequities. The World Health Organization (WHO) has identified four key factors shaping access to medicines: (i) availability, (ii) affordability, (iii) geographical accessibility, and (iv) acceptability and quality of medicines available (Ozawa et al., 2019). While WHO's four factors (Availability, Affordability, Accessibility, and Acceptability) provide a useful diagnostic tool for assessing the dimensions of access, they do not explain the root causes of the access-to-medicines problem that we face globally today.

The four "As" are better understood as symptoms of deeper, systemic shortcomings caused by a global pharmaceutical industry that has become organized around an innovation model more focused on preserving incumbent advantages—by prioritizing high-margin products and lucrative markets—than it is on generating new research-driven breakthroughs. In practice, this orientation means that value extraction takes precedence over value creation, prioritizing distributions of profits to shareholders over the use of those profits to fund investment strategies to deliver high-quality, low-cost medicines across all disease categories. By so doing, PVE corporate governance reinforces inequities in who benefits from pharmaceutical innovation.

In this section, we outline the three key structural failures of the current pharmaceutical model: (i) a shareholder-value-driven approach centered on the pursuit of blockbuster drugs; (ii) the dominance of exclusive intellectual property rights; and (iii) the broader financialization of the global pharmaceutical industry. We then discuss how these failures impact the achievement of the four 'A's that determine access to medicines.

2.1 Structural Failures Explained

A fundamental failure of the current global pharmaceutical model is its orientation towards "blockbuster" drugs and lucrative markets, often to the neglect of broader public health needs—an outcome shaped by several decades of industry evolution. By the late 1980s, estimates placed the cost of discovering a new chemical entity at approximately USD114 million (in 1987 dollars) (DiMasi et al., 1991), a figure the pharmaceutical industry frequently invoked to justify the need for expansive intellectual property protection at the global level. Arguing that the development, manufacture, and delivery of a single blockbuster drug to the market required pursuing several candidate molecules, many of which would fail in late-stage development, drug companies made the case for stronger intellectual property protection to recoup these enormous R&D expenses (ranging from several hundred million to several billion USD).[2]

During the negotiations on the General Agreement on Trade and Tariffs (GATT), which ultimately led to the establishment of the World Trade Organization (WTO) in 1995, major US pharmaceutical companies played a central role in the Intellectual Property Committee (IPC). Working closely with the US government, they advanced the argument that strong and

[2] More recent estimates of total average capitalized pre-launch R&D costs are widely varied, ranging from USD161 million to USD4.54 billion (2019 USD). See Schlander et al., (2021).

uniform global intellectual property protection was a top trade priority to ensure the incentives to invest in greater pharmaceutical R&D within the industry (Drahos & Braithwaite, 2002; Sell, 2003). European pharmaceutical companies lobbied in parallel through organizations such as the European Federation of Pharmaceutical Industries and Associations (EFPIA) (Hoen, 2009; Matthews, 2002). Eventually, US and European industry groups collaborated to draft a model agreement that later served as the foundation of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement (Drahos, 1995).

With the adoption of the TRIPS Agreement, the global IP system—now integrated and enforced through the WTO—established uniform standard protection for process and product patents for 20 years, with limited exceptions. Although this change represented only a three-year extension of patent duration relative to the existing standard in the United States in 1995, its global implications were profound. In many countries of the Global South, the TRIPS Agreement and its provisions on pharmaceutical patents effectively prohibited the production of drugs that, while patented elsewhere, had been legally manufactured as "generics" domestically up until then. The result was an immediate increase in prices, a marked reduction in the availability of critical medicines, and the consolidation of domestic pharmaceutical manufacturing in several LMICs.

The TRIPS Agreement established a uniform global standard of 20 years protection for both pharmaceutical product and process patents with varying rules on market exclusivity across jurisdictions. Advocates of the TRIPS Agreement argued that despite these initial setbacks, a global system of intellectual property protection would generate several benefits for countries in the Global South. Chief among these was the expectation of increased technology transfer and faster diffusion of knowledge, premised on the assumption that multinational pharmaceutical companies would be more willing to share technologies when their intellectual property rights were better protected. Supporters also argued that it would lead to a greater availability of new products in all countries, by encouraging global companies to introduce innovative products globally. Additionally, once a pharmaceutical product's patent protection and market exclusivity term expired, it would become subject to generic competition. Generics, proponents claimed, could enter the market within one to five years at significantly lower prices, thereby expanding access to medicines with the help of national regulatory frameworks designed to promote their speedy entry, such as the Hatch-Waxman Act of the USA.

In practice, however, this process has not worked as anticipated. The financialization of the global pharmaceutical industry has promoted a trend of excessive pricing, based on what the "market can bear" rather than the actual costs of developing, manufacturing, and delivering medicines. Pharmaceutical companies have used intellectual property protection and market exclusivity provisions as strategic tools to extend their monopoly positions across all markets globally. This business model allows them to set product prices based on two key parameters: recovering R&D costs (for which transparent estimates are rarely available) and extracting maximum value at a price just below the cost of foregoing treatment—a model known as "value-based pricing". This PVE model often makes medicines practically inaccessible for LMICs.

Sovaldi (brand name for sofosbuvir, a hepatitis C drug) serves to illustrate such price gouging. In the US, the drug was priced at USD84,000 per treatment, just below the cost of a liver transplant, which may result from leaving hepatitis C untreated (Peralta, 2017). Simultaneously, Sovaldi was priced at USD48,000 in middle-income countries, placing it out of reach for the tens of millions of people with the disease in the Global South (World Health Organization, 2018a). Following public health outcries, Gilead issued voluntary licenses to some Indian manufacturers, allowing them to produce generic versions of the drug for 91 low-income countries at a 7% royalty rate.

While these concessions helped some, over 75% of the 71 million people globally who were infected with the disease and live in middle-income countries in Asia and Latin America remained excluded. This problem prompted Malaysia to issue a compulsory license on the product in 2017 and Chile to embark on a similar effort in 2018 to address the public-health fallouts. The Sovaldi case also highlights a common flaw in how large companies approach access to medicines. By differentiating between middle-income country and low-income country markets in licensing or tiered pricing, they exclude over half of the world's poorest who live in middle-income countries from accessing lifesaving medicines (Gehl Sampath, 2021b).

The United States has also witnessed several high-profile cases of excessive drug pricing aimed primarily at boosting profits for distribution to shareholders in the form of increased dividends and stock buybacks. In these instances, companies have exploited a lack of competition and market information on the relevance of certain drugs (even in cases where the products in question were off patent) to enact drastic price hikes. For example, Mylan raised the price of its EpiPen from USD300 to USD900 after its main competitor's product was proven faulty (Pollack, 2016). Similarly, Turing Pharmaceuticals increased the price of Daraprim, an antimalarial drug discovered in 1953 and off patent for decades, from USD13.50 per tablet to USD750 per tablet. Valeant also engaged in this practice, raising the price of its heart drug Isuprel from USD40 to USD2,700, and its diabetes drug Glumetza from USD800 to USD10,000 for a 90-day dose (Lazonick et al., 2017; Peralta, 2017).

Delaying generic competition by just a few months can generate hundreds of millions in additional revenue. In 2014, when Sovaldi accounted for 64% of all US public hepatitis-C related spending totalling USD12.3 billion (Siders, 2015; United States Senate Committee on Finance, 2015), just three additional months without competition meant at least USD300 million in extra revenue for the company (Jung et al., 2016). Such company practices that focus on protecting incumbent advantages are commonplace especially amid the general decline in new product introductions based on pharmaceutical R&D (van der Gronde et al., 2017). Paradoxically, slowing innovation has led to increased patenting as companies focus on using R&D to retain product sales and market positions with new formulations of the same product that generate profits for a longer time (Cunningham et al., 2018; Jones et al., 2016). "Evergreening", also known as "product-hopping" or "forced switching" or "salami slicing", involves the filing for new patents over minor or incremental versions of existing drugs to extend patent protection (or, in the case of US orphan drugs, to get market exclusivity through new designations) (Kumar & Nanda, 2017). A 2020 public database created by the Center for Innovation (C4i) at San Francisco University College of Law found that major global pharmaceutical companies routinely use such tactics to extend the shelf life of their profits.

For instance, Johnson & Johnson's Janssen HIV drug Prezista ranked second for using 14 unique patents to secure 167 protections to delay competitor entry for 16 years. Gilead's HIV drug Truvada ranked fourth with 120 protections that extended the patent monopoly for more than 17 years, and its anti-retroviral drug Viread was fifth with 118 protections that extended the patent monopoly for more than 16 years (University of California, 2020).

Excessive pricing in search of greater corporate profits remains a systemic issue for new innovations and long-available, off-patent products alike, and is particularly acute in drugs based on newer technologies. For instance, Novartis's gene therapy Zolgensma became the most expensive drug ever approved in the United States in 2019, costing USD2.125 million per patient. That same year, the United States accounted for almost 50% of total global pharmaceutical sales (European Federation of Pharmaceutical Industries and Associations, 2019), and US-based companies posted total worldwide revenues of USD421 billion (Zippia, 2023).

2.2 Global Fallouts: How Structural Failures Impact the Four "As"

The structural failures discussed above jointly impact the four As—availability, affordability, geographical accessibility and acceptability of quality medicines—in the following ways.

i. Medicines are unavailable

Several factors drive the lack of availability of pharmaceutical products in the Global South: the absence of incentives to invest in R&D of specific relevance to the Global South, the lagged or low introduction of new products in Global South markets, and the slow decline in manufacturing in its regions.

We begin with the first one. A PVE model of R&D relies on lucrative markets that can generate outsized profits that can be distributed to shareholders as dividends and buybacks. It is the absence of lucrative markets that drives financialized companies to shy away from developing pharmaceutical products for health conditions that afflict low-income markets, including neglected tropical diseases, focusing pharmaceutical R&D spending instead on diseases that guarantee large profits. As a result, medicines simply do not exist for an increasing number of old and new diseases.

A 2022 study found that for the estimated one billion people worldwide suffering from neglected tropical diseases, global funding of neglected disease R&D totaled USD 4.137 billion of which business organizations spent 608 million in 2021, thus roughly amounting to only 14 cents per dollar despite the massive positive health impact of new pharmaceutical products for certain tropical illnesses (Policy Cures Research, 2022).[3] Data on product introduction underscores this finding. Of the 256 new therapeutic products approved between 2012 and 2018, only 8 (3.1%) targeted neglected diseases (Ferreira & Andricopulo, 2019). This result was just a slight improvement over the period between 2000 and 2011, where data show that only 1% of new pharmaceutical products were developed for neglected tropical

[3] (Policy Cures Research, 2024) finds that investing in R&D of this kind yields health and economic return to societies of USD405 for every USD1 invested.

diseases, despite these diseases accounting for 12% of the global disease burden for that period (Pedrique et al., 2013).

Second, while most LMICs now are fully TRIPS-compliant, and often provide intellectual property protection that go beyond the TRIPS Agreement due to TRIPS-Plus provisions in their free trade agreements with their industrialized partners, several important front-of-the-line pharmaceutical products are often delayed or not introduced in Global South markets because lower purchasing power constrains pricing and expected profits for companies. Coupled with cumbersome regulatory registration processes, these markets remain unattractive. It is therefore normal for patented pharmaceutical products to be introduced in LMICs with a time lag of seven to ten years (Wouters & Kuha, 2024), and in many instances, not to be introduced at all.

These late or non-introductions in the wider context of delayed market entry of generic medicines and extended patent protection on existing products aggravate access to medicines and keep important life-saving products continuously out of reach of people in the Global South who need them (Feldman & Frondorf, 2017).[4] For example, a 2020 WHO survey of non-communicable diseases, including cancer, found that, of all the important cancer drugs available worldwide, LMICs, including African countries, had access to less than 20% of the drugs recommended (World Health Organization, 2020a).[5]

Finally, the current model is facilitating a disinvestment from local manufacturing in the Global South, which has occurred in two ways. Since the early 2000s, buoyed by profit margins in the more well-to-do markets, global companies have consistently adopted business models that reduce their manufacturing footprint in the Global South, confining their business presence in these markets to exporting and distributing pharmaceutical products. Examples include Merck's closure of several plants after its acquisition of Schering-Plough in 2009 (CBS News, 2010b); Pfizer's closure of several facilities after its acquisition of Wyeth in 2010 (CBS News, 2010a); and AstraZeneca's closure of its R&D facility in India in 2014 (Broadwith, 2014). Significant recent changes include Pfizer's closure of two of its manufacturing plants in India after 2019 (Reuters, 2019) and its commercial operations in Nigeria in 2025 (CBS News, 2010a; Chukwu, 2025), Sanofi's closing of its vaccine manufacturing in India in 2023, and GSK's ceased commercialization of its prescription products and vaccines in Kenya and Nigeria in 2023 (Likuyani, 2024). These are just some examples of a broader trend over the past two decades where global companies have prioritized market reach strategies through imports. This business model also eliminates the

[4] (Feldman & Frondorf, 2017) write about three specific kinds: In "Generation 1.0," branded companies simply pay generics to delay entering the market, reaping billions of dollars of benefit. "Generation 2.0" involves paying for delay through multiple side deals that camouflage the value of the payment. Generation 2.0 also includes "boy scout clauses" agreements to behave honorably that actually mask anticompetitive collusion. The newest generation (3.0) moves from collusion to obstruction. Generation 3.0 uses administrative processes, regulatory schemes, and drug modifications to prevent generics from getting to market.

[5] (Fundytus et al., 2021) look at availability of cancer drugs within different groups of countries and note that universal availability of the top 20 medications on WHO's Essential Medicines List was 9–54% in among low income and low middle income countries.

other benefits that would normally accrue through subsidiary manufacturing, such as learning by doing, tacit know-how of production, and job creation for countries.

The TRIPS Agreement has also had an impact on weakening domestic manufacturing capacity in several countries of the Global South, including Brazil and Argentina. In these countries, domestic industry has been extensively consolidated, and several large domestic firms have simply been driven out of business due to their inability to compete with global companies in a sector where economies of scale and scope matter enormously. With the exception of Bangladesh, countries which lacked the infrastructure for robust manufacturing entirely prior to 1995 (and the TRIPS Agreement), have not been able to build this capacity in the past thirty years.

ii. Medicines are unaffordable

Excessive pricing renders pharmaceutical interventions prohibitively expensive globally. To address this, the practice of inter-country tiered pricing (the practice of offering pharmaceutical products at different prices in different markets, also called differential pricing) has often been advocated as a solution for the Global South, but has several shortcomings. To begin with, price discrimination is often not calibrated with the purchasing power of consumers in different markets, defeating the purpose of tiered pricing as a mechanism for increased access. Several studies on tiered pricing find that LMIC prices are often far higher than international reference prices for critical life-saving drugs. In the case of analog insulin, for example, despite tiered pricing, there is no systematic evidence that cheaper prices are offered to people in LMICs (Abbott & Gehl Sampath, 2025; Médecins Sans Frontières, 2013). A 2018 survey of insulin found that some critical insulin brands were priced lower in Australia than in South Africa, Pakistan, and Ecuador (United Nations Development Programme, 2022). This is not an exceptional finding. Earlier studies of the global market for a specific type of malaria treatment, artemisinin-based combination therapy (ACT), similarly found that in sizeable markets with several competitors, tiered pricing performed poorly when compared with competitive production of drugs to achieve sustained price reductions and affordable access to medicines (Moon et al., 2011). In short, drug prices vary considerably between different markets globally, and poorer countries often face higher real prices after accounting for differences in purchasing power (Wouters et al., 2025). Handing back pricing decisions to companies for tiered pricing, therefore, is not a guarantor of greater access. In the best case, it may serve to reduce the access burden in a few product categories, while amplifying the risk that price differentials in general are not reflective of greater access (Médecins Sans Frontières, 2013). Tiered pricing can also result in market foreclosure effects (by granting access to large companies to a wider range of markets) thus restricting competition from emerging in key product categories.

iii. Medicines are inaccessible

Equity would be best served if those in dire need of specific life-saving interventions had equal chances of accessing them globally, regardless of where they live (Gehl Sampath, 2021a). But this outcome remains a pipe dream in a world where the focus on lucrative markets for greater revenues dictates market strategies. Currently, even routine products listed on WHO's Essential Medicines List are not accessible in LMICs. Studies on essential

medicines' access for cancer treatment [in a recent survey of 82 countries and specific assessments in Sub-Saharan Africa, see (Fundytus et al., 2021; Kizub et al., 2022)]; cardiovascular and hypertension [in a survey of 53 and 18 countries, see (Husain et al., 2020; Khatib et al., 2016)]; pain medication and palliative care [in a survey of 44 countries, see (Pastrana et al., 2017)]; and hepatitis C, HIV and tuberculosis [in a study of 20 countries, see (Hellamand et al., 2025)] all underscore this gap. In general, studies across LMICs often conclude that the average availability of essential medicines in the public sector in LMICs can be as low as 30-50%. This proportion is drastically short of the WHO's 80% target in all countries.

Accessibility is also impacted by weak incentives among the global pharmaceutical companies to invest in distribution networks (including for vaccine cold chains) in the Global South, and by the strained public health budgets in countries themselves. Resultingly, supply chain failures (Joosse et al., 2025) and stockouts (Olaniran et al., 2022) are commonplace in public sector supplies in LMICs and critically impede health and wellbeing of those suffering from chronic conditions such as diabetes (e.g., insulin), asthma (e.g., inhalers), hypertension and HIV/AIDS.

In comparison, private retail pharmacies that supply pharmaceutical products at out-of-pocket expenses fare better in the Global South, with higher availability of medicines (e.g., around 60-70%). But these too remain below the target of 80% set by the WHO, and the prices of drugs in such private pharmacies are often financially impossible for many in need (Brown, 2025).

iv. Medicines are unacceptable

Even when a medicine is affordable, regulatory delays and/or weaknesses in regulatory processes can lead to unforeseen delays. Coupled with low-quality control, these delays can lead to the proliferation of sub-standard pharmaceutical products in the market. National regulatory authorities in many LMICs are understaffed and under-resourced, leading to long delays in approving any new pharmaceutical products being introduced into such markets, including generics. The infrastructural inadequacy no doubt creates a "regulatory lag" that delays patient access, while also resulting in low market-surveillance capabilities. In combination, regulatory delays or lack of regulatory oversight, high prices of originator drugs, and high domestic demand for the drugs in question, create ideal conditions for the entry of substandard and falsified (counterfeit) medicines in LMIC markets. Similarly, weak or opaque supply chains are prone to fragmentation and corruption, making it easy for illicit suppliers to enter with substandard and falsified (counterfeit) medicines, posing a direct health risk. Over time, consumers' inability to differentiate between good and bad quality medicines can become a factor in their rejection.

Given that the pharmaceutical industry primarily develops drugs for other markets, several products are not clinically tested across all LMIC regions. In addition, they may sometimes be incompatible with the realities or the practices/cultural contexts, which then limit their acceptance in several if not all LMICs. In some other cases, drugs/vaccines and their delivery methods are at odds with supply chain and transport realities available in LMICs, as in the case of the COVID-19 mRNA vaccines, which required a retooling of vaccine supply chains

in several countries to accommodate the -72 degree Celsius storage requirement of these vaccines.

2.3 The Chronic Access Puzzle and Global Health Governance

The bleak picture that emerges from our account above creates a vicious cycle:

1. High prices of pharmaceutical products impact affordability and routinely drain public health budgets.
2. Drained public health budgets in LMICs translate into even less money for public procurements and health systems infrastructure, thereby reducing accessibility.
3. Reduced accessibility and continuing high prices create a vacuum in several Global South countries for key products, which are then filled by the market through substandard/falsified drugs, destroying both acceptability and access to quality pharmaceutical products**.**
4. Poor health outcomes from this cycle depress economic productivity, keeping people in poverty and reinforcing the perception of LMICs as "unprofitable markets".
5. This perceived lack of profitability then further justifies the skewed R&D model, and the cycle begins again, ensuring that pharmaceutical products remain unavailable, unaffordable, inaccessible, and of questionable quality.

Without addressing the structural barriers that reinforce these outcomes, the vicious cycle cannot be broken. The focus of the global community needs to shift toward how new innovations in pharmaceutical formulation, delivery systems, and logistics can offer potential pathways to mitigate the challenges of availability and reach: *not only on a case-by-case basis when access demands become unavoidable, but as a matter of principle*.

In the first case of its kind, in the late 1990s, the high prices, and related unavailability of, patented Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (or HIV/AIDS) medicines in LMICs triggered a global health crisis. HIV/AIDS offers an interesting study, especially given that AIDS, in fact, forced the international community to tackle the moral and political fallouts of unequal access to life-saving medicines, and laid the foundations for the global health agenda (Brandt, 2013; Youde, 2012). Following early negotiations to reduce prices for first-line antiretroviral therapies (ARVs) relying on tiered pricing, global initiatives have increasingly prioritized improving access to second- and third-line treatments for people living in LMICs as treatment options failed (Ford et al., 2011).

Although greater access to ARVs in the initial stages of the crisis was achieved by lower drug prices (due to Indian generics), which also forced innovator companies to introduce cheaper prices more broadly (Gehl Sampath, 2020; Moon et al., 2011), global investments have inadvertently reinforced structural barriers to equity by leaving the underlying business model of pharmaceutical innovation largely unquestioned. A revealing example is the recent breakthrough for Gilead Sciences' lenacapavir for HIV prevention (Pre-Exposure Prophylaxis or PrEP) (Aizenman, 2024).

The highly effective twice-yearly injectable has demonstrated remarkable efficacy, including full effectiveness in preventing HIV acquisition among individuals. In principle, this mode of

delivery could improve patient adherence (a key aspect of effective accessibility and acceptability), reduce the burden of frequent clinic visits, thereby enhancing geographical accessibility for remote populations, and potentially simplify supply management for health systems, impacting availability.

But as in the past with several HIV/AIDS drugs, the introduction of this product has been marked by significant controversy surrounding Gilead's pricing decisions (Hill et al., 2024; Pallabi et al., 2024). Its initially announced cost of USD28,000 per person annually rendered it unaffordable and inaccessible for the very populations in high-burden LMICs who participated in clinical trials and stand to benefit most. In September 2025, however, the company announced that it would make the drug available at USD40 by 2027 across 120 LMICs in a landmark agreement brokered by the Clinton Health Access Initiative and the Gates Foundation (Haberson, 2025).

The Lenacapavir deal is widely viewed as a victory for access-to-medicines today. Nevertheless, it leaves unresolved the fundamental question at the center of the debate: how to transition to a pharmaceutical innovation model in which affordability is built in from the outset, especially when innovations are lifesaving and globally relevant? The deal also raises questions that the global health community has long sidestepped. Should access to affordable pharmaceutical innovation in the Global South continue to depend on case-by-case negotiations with a small number of pharmaceutical companies? Are tools such as voluntary licensing and tiered pricing the right approaches to expand access, given that they function primarily as temporary fixes and do not address the structural drivers of unaffordability?

While initiatives such as the agreement currently brokered for Lenacapavir help alleviate immediate access challenges, these arrangements should not be mistaken for lasting victories for global health. The truth of the matter remains, as some analysts have suggested, that the drug could be manufactured for less than USD100 per person per year, and yet the projected prices in high-income markets exceed USD25,000, thus highlighting the role of patents and pricing strategies in limiting affordability (Hill et al., 2024). Furthermore, voluntary licensing agreement on the product currently cover only a subset of LMICs, leaving several countries with significant HIV burdens outside the supply framework (Access to Medicine Foundation, 2025). Clinical trials of Lenacapavir showed that it took at least forty injections on average to prevent a single infection. At that rate, as Hill suggests, preventing the 1.3 million new infections that occur yearly will depend on the immediate and widespread introduction of the product in all LMICs. The current licensing deal excludes countries with high risks of infection—where about one-third of all global HIV infections occur—thereby limiting the possibility of achieving this outcome.[6] Finally, the Lenacapavir access agreement is heavily dependent on continued policy support and donor financing to ensure large-scale implementation (Foley, 2026; Lynch et al., 2025). For all these reasons, the licensing arrangement once again perpetuates a system in which access is secured through costly financing mechanisms, which, while saving a significant number of lives, fails to provide access for all those who need the medicine equally.

[6]https://open.spotify.com/episode/6cPyN3si7dif2Ej7FnyZbi?si=Q0RlsP55TmSEVJDSq2v7pA&nd=1&dlsi=d411c2b519af4814

The real challenge lies in developing a business model that moves beyond making individual products available and affordable in certain exceptional cases toward *ensuring that innovations are more accessible and available globally*, particularly to the people of the Global South. The latter is possible only when approaches focus more broadly on expanding innovation capabilities in the Global South to enhance the focus on manufacturing of products through conventional and new technology platforms. For instance, new and innovative approaches to drug formulation such as the thermostabilization method (Lawanprasert et al., 2024) or freeze-drying (lyophilization) directly target logistical hurdles for biopharmaceuticals (Amici & Pozzi, 2023). By converting liquid medicines and vaccines into stable powders with extended shelf-lives that often do not require stringent cold chains, lyophilization enhances product stability. This innovation dramatically improves availability by reducing spoilage due to temperature fluctuations and simplifies geographical accessibility by enabling easier, more cost-effective transport (due to reduced weight/volume) and storage in resource-limited settings lacking reliable refrigeration.

Placing the emphasis on technologies and capabilities more widely—as opposed to facilitating access for select products— can help achieve several objectives. It will expand pharmaceutical manufacturing for products across the value chain in the Global South and also promote the use of technologies that help overcome logistical barriers that are particularly crucial for expanding vaccine coverage and delivering sensitive biological products to remote areas. Over time, it will also prompt their use in the development of new products and processes that are relevant widely for global public health, as we now see among companies in India and South Korea. The larger challenge, therefore, is to align the global pharmaceutical industry closely with the goal of pharmaceutical innovation that creates value for all globally.

3. Global Pharmaceutical Industry: Predatory Value Extraction or Progressive Value Creation?

Across the globe, numerous government agencies, international bodies, philanthropic foundations, and advocacy organizations have developed strong networks through global health diplomacy to provide solutions to the access-to-medicines problem. But financialization, and the drive for MSV, pose extractive pressures within companies in ways that create inherent tensions with innovation of the kind that is needed for greater access and equity, which is, ultimately an organizational achievement based on learning that is collective and cumulative, as opposed to market achievements that seek to extract the commercial value of an enterprise. It is our contention that however well-intentioned the access-to-medicines initiatives, they will have little, if any, sustainable impact because of the tensions within business corporations, and how they view access. In particular, the tension lies in whether the profits made by companies are "retained and reinvested" into PVC or used for PVE through dividends and stock buybacks.

As we have argued in the introduction to this paper, significant improvement in access to medicines requires a progressive value creation (PVC) corporate-governance regime. Put simply, the success of these business corporations should be gauged in terms of their contributions to solving the global disease burden, and the access-to-medicines problem, rather than their ability to boost their stock yields. Our analytical task in this section of the paper is to specify the "social conditions of innovative enterprise" that empower PVC

governance, enabling a pharmaceutical corporation to develop, manufacture, and deliver high-quality, low-cost medicines for the Global South. We can then assess whether specific government agencies and civil-society organizations that seek to improve access to medicines in the Global South function to support or undermine PVC governance in pharmaceutical corporations.

In William Lazonick's "theory of innovative enterprise" (TIE), three social conditions of innovative enterprise—strategic control, organizational integration, and financial commitment—can enable a business corporation to generate a higher-quality, lower-cost product than was previously available (Lazonick, 2019, 2023, 2025). Through three social conditions, the business corporation to manage the *uncertain, collective, and cumulative* character of the innovation process.

- **Strategic control:** For innovation to occur in the face of technological, market, and other uncertainties, those who control the entity's resource allocation decisions must have the abilities and incentives to make strategic investments in innovation. Their abilities depend on their knowledge of how strategic investments in new productive capabilities can enhance the ecosystem's existing capabilities. Their incentives depend on alignment of their personal interests with the entity's purpose of generating innovative products.

- **Organizational integration:** Implementation of an innovation strategy requires integration of people working in a complex functional and hierarchical division of labor into collective and cumulative learning processes. Work satisfaction, promotion, remuneration, and benefits are important instruments in an employment system that motivates and empowers workers to engage in collective learning over a sustained period.

- **Financial commitment:** For collective learning to accumulate over time, the sustained commitment of money must keep the learning organization intact. A young company that, because it is a "start-up", has not yet been able to turn a profit, can seek various forms of "venture capital" to provide financial commitment. For a going concern that has achieved sustained profitability, retained earnings—leveraged, if need be, by debt issues—are the foundation of financial commitment.

The uncertainty of an innovation strategy is embodied in the fixed-cost investments that are required to develop the productive capabilities that may, if the strategy is successful, result in a higher-quality product. Fixed cost derives from both the size and the duration of the innovation strategy. If the size of investment in physical capital tends to increase the fixed cost of an innovation strategy, so too does the duration of the investment in human capabilities required for an entity to engage in the collective and cumulative—or organizational—learning that, by both transforming technologies and accessing markets, can result in an innovative product.

Note that an innovation strategy that does not access markets will, in and of itself, fail. An innovation strategy entails the high fixed cost of developing a higher-quality product. For innovation to succeed that high fixed cost must be transformed into low unit cost by accessing a large extent of the market, resulting in economies of scale. The development of a high-quality product opens access to that market, while the achievement of economies of scale

requires the maintenance of product quality (for example, the safe and effective characteristics of a medicine) in manufacturing and delivering a product on a mass scale. It is economies of scale that can, potentially, make the product available and affordable to low-income populations.

The generation of any safe, effective, accessible, and affordable medicine for people living in LMICs requires an innovative business model based on PVC governance. Strategic control must be exercised by senior executives whose purpose is to develop, manufacture, and deliver high-quality, low-cost pharmaceutical products to targeted low-income populations. It is our contention that without PVC governance, systemic pharmaceutical innovation for the Global South will not occur.

It is possible that the same pharmaceutical company that develops, manufactures, and delivers innovative pharmaceutical products for higher-income markets, which can afford to pay higher drug prices, makes use of the higher-margin product sales to subsidize them for people living in low-income countries. But the provision of such products for low-income countries *must* be a strategic purpose of the PVC pharmaceutical corporation, not a secondary goal that can be pursued or abandoned when it suits the interests of senior executives whose strategic purpose is the development, manufacture, and delivery of products for higher-income markets. Therefore, PVC governance may be secured more surely and sustainably by pharmaceutical corporations dedicated to serving low-income populations. The key questions are whether these dedicated PVC corporations can secure the people and money needed to develop, manufacture, and deliver pharmaceuticals to low-income countries, and whether they can do so profitably to sustain themselves as going concerns. PVC governance raises the question of what that rate of profit should be, but, more fundamentally, it raises the question of whether the corporation's business model views profits as the financial foundation for reinvesting in value creation or as a source of "free cash flow" available for shareholder value extraction (Tulum et al., 2022; Tulum & Lazonick, 2025).

Collective and cumulative learning is the essence of the innovation process (Lazonick, 2019). The pharmaceutical corporation (on its own or in collaboration with other organizations) must integrate the skills and efforts of teams of scientific, technical, and administrative personnel to develop, manufacture, and deliver pharmaceutical products (Gehl Sampath, 2011). There are strong arguments that, for superior results, the key dimensions of this organizational integration should occur in proximity to the low-income populations that will be served. Not only do local factors such as participatory clinical trial design impact treatment effectiveness (Epstein, 1998), through localization, scientists who are developing such innovations (products or processes) can gain deeper insights into the pathogen variation, transmission ecology, cross infection potential, resistance, and other host genetics of the diseases that they are seeking to treat (Bhadelia et al., 2024; Higgs et al., 2025). Proximity of personnel may also be critical for be convincing the intended patients and local health authorities that a medicine is actually "high quality" (safe and effective for specific indications). Thus, if carried out efficiently, local manufacturing and delivery can help create more effective treatments, while making the medicines affordable to the targeted populations and building capabilities (Gehl Sampath, 2011; Vieira et al., 2023).

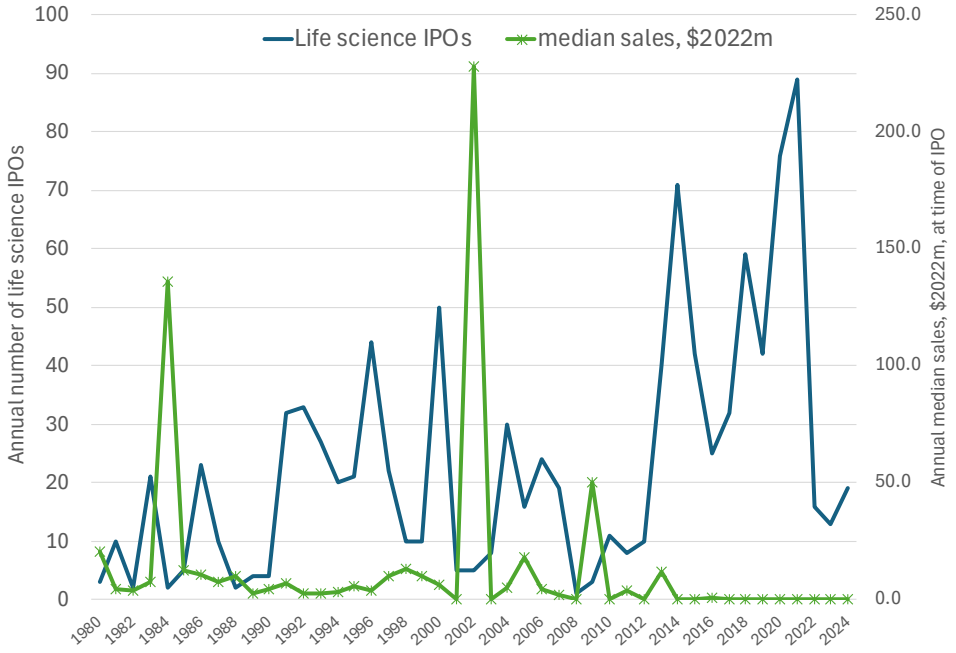
For new firms, PVC governance requires financial commitment by financiers who are content to reap a reasonable return on their investment in the firm's productive capabilities if it generates an innovative product. The return can take the form of dividends, if the corporation can afford to pay them while meeting its PVC objectives, or the sale of financiers' shares, either in a private transaction or, if the company has done an initial public offering (IPO), on the stock market. Under PVC governance, the yield to financiers occurs only *after* the pharmaceutical company has generated a successful product. When, through the development, manufacture, and delivery of a higher-quality, lower-cost pharmaceutical product, the new venture has transitioned to a going concern with a stream of profits, PVC governance requires that the corporation retain a substantial proportion of its earnings to invest in the next round of potentially innovative pharmaceutical products (Tulum & Lazonick, 2025).

Intuitively, this "patient capital" role for a firm's financiers may seem obvious. But it is not the role that "venture capital" has played in the startup segment of the pharmaceutical industry in the United States. Beginning with the IPO of the pioneering biopharma firm Genentech in April 1980, there were, through 2024, 1,020 life science IPOs in the United States (Ritter, 2025). Billions upon billions of dollars flowed into the startup segment in the form of venture capital, research contracts, initial and secondary stock issues, and acquisitions by established (typically publicly listed) pharmaceutical companies. Yet, as we document below, through a PVE business model, fortunes have been, and continue to be, made by "insiders" when companies do IPOs, even when no approved medicine is ever forthcoming.

Many innovative pharmaceutical products have been developed by biopharma startups (Lazonick & Tulum, 2011). But given the role of the speculative stock market—namely, the National Association of Security Dealers Automated Quotation (NASDAQ) system, created in 1971 with the backing of the US government—founding entrepreneurs, venture capitalists, and corporate executives who are given equity stakes in the company do not have to wait for an innovative drug to be developed, manufactured, and delivered to patients in order to cash in by selling their shares. Almost all biopharma startups that list on NASDAQ do so without a commercial product—a phenomenon that Lazonick, Sakinç, and Tulum have dubbed the "productless initial public offering", or PLIPO, business model (Lazonick & Sakinç, 2010; Lazonick & Tulum, 2011; Sakinç & Tulum, 2012). The result is that predatory value extraction has become systemic in the operation of the biopharma startup sector.

Regularly updated statistics on the sales, profits, and years since founding of life science IPOs from 1980s through 2024, compiled by Jay Ritter, confirm the prevalence of the PLIPO model. As can be seen in Figure 1, the median sales by companies at the time of their IPOs have typically been very low (the exceptions are 1984 and 2002, years with very few IPOs), and over the past decade most companies had zero sales at the time of their IPOs. Typically, life science companies go public without a commercial product.

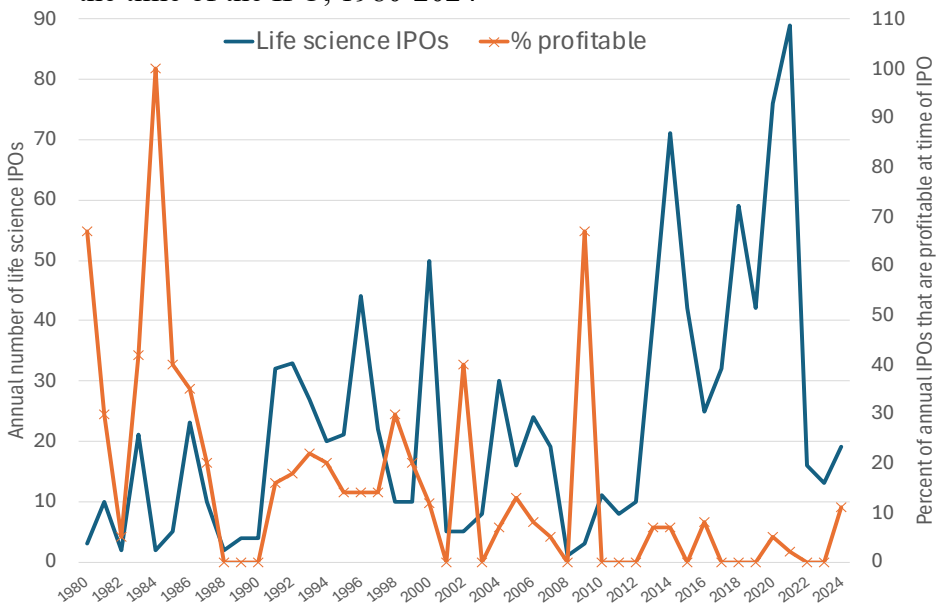
Figure 1. Life science IPOs in the United States and their median sales (in 2022USDm), 1980-2024



Source: (Ritter, 2025).

Figure 2 shows that since the end of the financial crisis, with the annual number of IPOs surging between 2013 and 2022, almost all the newly listed companies were unprofitable at the time of their IPOs. That is, through a listing on the stock market—invariably NASDAQ in the case of. biopharma startups—venture capitalists and other financiers have been able to "exit" from their investments, extracting enormous sums by selling the company's shares on the stock market, even when the company has not yet attained profitability and indeed does not even have a commercial product. In the case of many companies, no product is ever forthcoming.

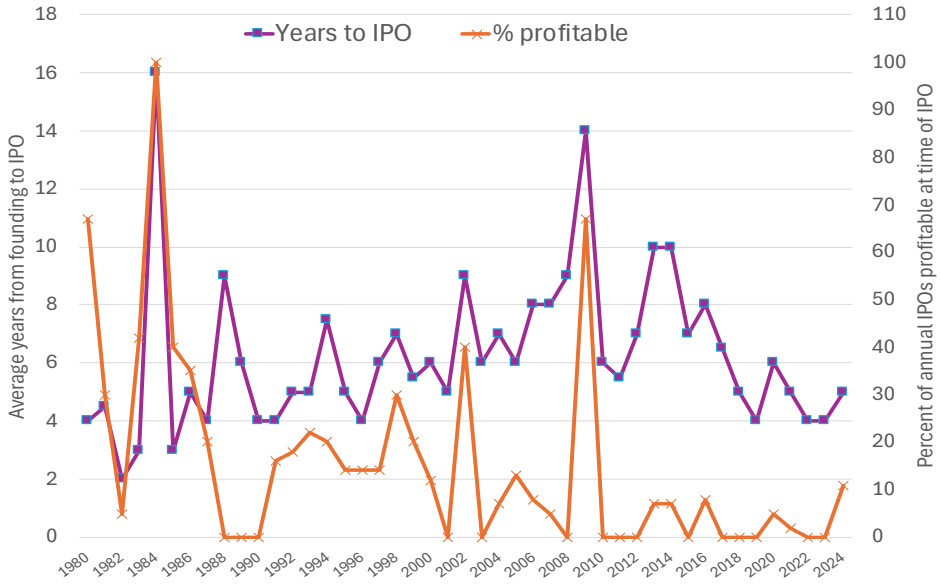
Figure 2. Life science IPOs in the United States and the percent profitable at the time of the IPO, 1980-2024



Source: (Ritter, 2025)

Over the 45 years 1980-2024, for the 1,020 IPOs documented by Ritter, the average length of time from founding to IPO was 6.1 years, As can be seen in Figure 3, as might be expected, the annual data on years from founding to IPO are positively correlated with the proportion of the companies that were profitable at the time of the IPO. The more rapidly a biopharma company can go from founding to IPO, the less likely it will be to have commercial sales or profits. Time to market has become shorter in recent years. From 2018 to 2024, the average number of years from founding to IPO was 5.0, while the percentage of companies that were profitable at the IPO was very low and even zero percent in some years.

Figure 3. Percent of life science IPOs in the United States that were profitable at the time of the IPO and the average number of years from founding to IPO, 1980-2024



Source: (Ritter, 2025)

Note that the "exit strategy" for some startups is to be acquired by an established pharmaceutical company even before they do an IPO, in which case they will not be included in Ritter's database. Also, many of the companies that are in his database have been acquired by established companies, which may or may not then use the acquired productive capabilities and intellectual property rights to develop an approved product. There is empirical work to be done on how, in the presence of the PLIPO model, the relation between value creation and value extraction has actually played out over the past 45 years in the US biopharmaceutical startup sector. The three graphics in Figures 1, 2, and 3 above are meant to motivate such a study.

Eventually a subset of the 1,020 life-science companies that did IPOs from 1980 to 2024 developed innovative pharmaceutical products that made it to the product market, providing immense income and wealth to founders and entrepreneurs who continued to hold a least a portion of their shares as well as executives who received shares in the form of stock-based pay (Lazonick & Tulum, 2023; Tulum & Lazonick, 2025). As these innovative companies have grown, they have been governed by the ideology that pervades the US corporate economy—and now by extension, the global economy—that, for the sake of economic efficiency, a business corporations should be run to "maximize shareholder value".

Adherence to MSV leads senior corporate executives and their boards of directors to prioritize the allocation of corporate profits as distributions to shareholders in the form of cash dividends and stock buybacks. Whether the major business corporations that now dominate the US pharmaceutical industry have grown through internal reinvestment or external acquisition, or (as is typically the case) some combination of the two, the analysis of the relation between value creation and value extraction must turn to how the successful

established enterprises allocate their often ample profits (Lazonick, 2023; Tulum & Lazonick, 2025).

Corporate financialization—the prioritization of allocating corporate profits to distributions to shareholders—has exerted a corrosive influence across all sectors of the US corporate economy, with the pharmaceutical industry among the most significantly affected. As Table 1 shows, for 2013-2022, the 14 pharmaceutical companies that were among the total of 478 business corporations in the S&P 500 Index in January 2023 that were publicly listed over all years of the previous decade distributed *105%* of net income to shareholders, a larger proportion than the highly financialized 98% for all 478 companies.[7]

These 14 pharmaceutical companies accounted for 3.2% of the revenues of all 478 companies but 6.6% of the net income, 5.8% of the buybacks, and 8.9% of the dividends. At 51%, pharmaceutical stock buybacks were below the proportion of 57% of net income for the 478 companies, but, at 54% versus 40%, pharmaceutical dividends as a proportion of net income far exceeded that of all the companies in the dataset. The USD773 billion that the pharmaceutical companies distributed to shareholders was 10% greater than the USD701 billion that these corporations expended on R&D over the decade.

Table 1. Financial data, 2013-2022, and 2022 employment, for 478 corporations, of which 14 are pharmaceutical companies, in the S&P 500 Index publicly listed for fiscal years 2013-2022

COMPANY (year founded; IPO)	2013-2022 TOTALS, $b						% of NI			R&D,	2022
	REV	NI	BB	DV	DV+BB	R&D	BB	DV	BB+DV	%	EMP.
BMS (1858; 1928)	273	24	27	31	57	82	*110*	*127*	***236***	*30*	34
ABBVIE (1888; 1929)	342	64	32	55	87	62	*50*	*87*	***137***	*18*	50
AMGEN (1980; 1983)	231	63	50	31	81	43	*79*	*49*	***129***	*19*	25
MERCK (1891; 1941)	451	78	42	57	98	99	*54*	*73*	***127***	*22*	69
J&J (1886; 1944)	799	147	57	93	150	114	*38*	*63*	***102***	*14*	156
ELI LILLY (1870; 1952)	235	42	16	25	41	63	*38*	*59*	***98***	*27*	39
BAXTER (1931; 1978)	125	14	7	6	13	7	*52*	*44*	**96**	*6*	60
PFIZER (1849; 1941)	584	157	61	77	138	93	*39*	*49*	***88***	*16*	83
BIOGEN (1978; 1983)	114	34	28	0	28	24	*84*	*0*	***84***	*21*	9
GILEAD SCIENCES (1987; 1992)	249	73	36	24	60	56	*49*	*33*	***82***	*22*	17
VIATRIS (1971; 1978)	116	4	2	1	3	7	*53*	*24*	***77***	*6*	37
REGENERON (1988; 1991)	71	24	13	0	13	23	*53*	*0*	***53***	*32*	12
VERTEX (1989; 1999)	37	10	3	0	3	16	*30*	*0*	***30***	*43*	5
INCYTE (1991; 1993)	17	1	0	0	0	11	*5*	*0*	***5***	*61*	2
TOTAL 14 PHARMA	**3,643**	**734**	**373**	**400**	**773**	**701**	***51***	***54***	***105***	***19***	**598**
TOTAL 478 in S&P500	**115,333**	**11,103**	**6,368**	**4,491**	**10,860**	**3,269**	***57***	***40***	***98***	***3***	**28,329**
14 PHARMA AS % OF 478 in S&P 500 = 2.9%	***3.20%***	***6.60%***	***5.80%***	***8.90%***	***7.10%***	***21.40%***					**2.10%**

Notes: IPO=initial public offering, REV=revenues, NI=net income, BB=stock buybacks, DV=dividends, R&D=research & development expenditures, EE=end-of-fiscal-year employment (in thousands); J&J is Johnson & Johnson; BMS is Bristol Myers Squibb; Baxter is Baxter International. The founding and IPO years listed for AbbVie are those of its predecessor company Abbott Laboratories; for BMS, the founding of Squibb and the IPO of Bristol-Myers; and for Viatris, its predecessor company Mylan.
Sources: S&P Compustat database and company 10-K reports.

[7] Note that, in an accounting period (e.g., a decade), a company can distribute more than 100% of profits to shareholders by taking on debt, laying off workers, divesting assets, and/or using cash reserves (including those that represent capital consumption allowances).

Senior corporate executives and their boards make these financialized allocation decisions. Under the PVE corporate-governance model that exists in the United States, the stock-based pay of senior executives incentivizes them to distribute corporate cash to shareholders because it inflates stock yields and hence the gains that these executives can realize from their stock options and stock awards. As shown in Table 2, from 2006 through 2022, the average total direct compensation (TDC) of the 500 highest-paid corporate executives in the United States ranged from, with the stock market depressed, a low of USD15.9 million in 2009, of which 60% were realized gains from stock-based pay, to, with the stock market booming, a high of USD49.1 million in 2021, of which 89% were realized gains from stock-based pay. In 2022, the average TDC of 500 highest-paid executives in 2022 was USD35.9 million, of which 85% were realized gains from stock-based pay. In 2021, when the average TDC of the two comparison groups peaked, pharmaceutical executives' average TDC of USD66.9 million was significantly higher than for the 500 highest-paid executives (Hopkins & Lazonick, 2016, 2024; Lazonick & Hopkins, 2016, 2017).[8]

In this process, high drug prices play an important role, helping to inflate executive pay by providing more profits that can be distributed to shareholders. Especially in the United States, pharmaceutical drug prices have remained unregulated, and efforts to rein in price increases, such as under the Biden administration's Inflation Reduction Act of 2022, have met with stiff resistance from US pharmaceutical executives and their lobbyists on grounds that such actions will stifle innovation. Price regulation for drugs is most commonly contended to deprive companies of the profits that they need to invest in innovation. The data show, however, that US pharmaceutical companies use high drug prices to fund distributions to shareholders for the sake of high stock yields, as we have documented here.

[8] Note that these data include realized gains from executives' stock-based compensation, the correct measure of the take-home pay of these executives, on which they pay taxes to the U.S. Treasury. Almost all data on stock-based compensation reported by the media, and even most progressive think tanks, are grant-date (so-called "fair value") measures, which ignore the stock-price increases that inflate executive pay—and hence the ways in which this pay is inflated (Hopkins & Lazonick, 2016).

Table 2. 500 highest-paid executives annually, US corporations and subset of pharmaceutical executives, with proportions of mean total direct compensation (TDC) from stock options and stock awards, 2006-2022

YEAR	All 500 highest-paid executives				Pharma executives				
	Mean, $m	% of TDC			Mean, $m	% of TDC			No. of execs
	TDC	SO	SA	SO+SA	TDC	SO	SA	SO+SA	
2006	25.6	56	17	73	25.7	47	30	77	23
2007	31.5	57	19	76	22.1	65	8	73	14
2008	20.7	48	23	71	22.1	64	13	76	21
2009	15.9	37	23	60	22.0	40	18	59	29
2010	19.8	38	26	65	20.8	50	24	74	25
2011	21.7	39	30	69	20.6	55	15	71	24
2012	32.3	41	37	78	34.9	61	24	85	24
2013	27.4	46	33	79	35.3	68	24	91	34
2014	32.7	46	34	80	43.7	69	19	88	41
2015	35.0	49	35	84	46.2	58	30	88	32
2016	27.5	37	42	78	31.5	48	23	71	26
2017	33.8	46	35	82	43.5	52	37	89	22
2018	33.6	43	42	85	34.5	67	21	88	22
2019	33.6	40	43	82	38.2	60	26	86	19
2020	43.4	52	35	87	49.7	63	27	90	31
2021	49.1	45	43	89	66.9	83	11	94	24
2022	35.9	30	55	85	45.0	64	24	88	28

Note: TDC=total direct compensation, SO=stock options, SA=stock awards
Source: S&P ExecuComp database

The argument that regulating drug prices will result in lower profits, which in combination with the unavailability of external finance to the pharmaceutical industry, will result in stifling innovation has dominated the discussion on access in the United States, and has found its way to global debates systematically over the past two decades. However, in the startup segment of the US pharmaceutical industry, there is no shortage of speculative funds flowing to companies in IPOs and secondary issues even when the issuing corporations have no products or profits because of the ease (under "normal" market conditions) of selling the shares to the speculative market. If anything, as suggested by the Ritter data presented above, there is too much money flowing into biopharma startups and not enough regulation of the extent to which insiders can engage in value extraction even in the absence of value creation.

As for established pharmaceutical corporations, they rarely do issues on the stock market as a source of funds. Take, for example, Merck, which was founded in 1891 and went public on the stock market in 1941. The last time Merck issued common stock on the public stock market was in 1952. Pfizer did its IPO in 1942, raising USD5.9 million (most of which was used to pay off debt, redeem preferred stock, and purchase the shares of a deceased

stockholder). The company did its only secondary public stock issue in 1951, raising USD29 million. Bristol Myers Squibb (BMS) was founded in 1858 and went public on the stock market in 1928. In line with Merck and Pfizer, the last time that BMS issued common shares on the public stock market was in 1952, when, as Bristol-Myers, it did a rights issue for USD4.2 million (Lazonick & Tulum, 2023; Tulum & Lazonick, 2025).

It is a myth, therefore, that, once profitable, established companies such as Merck, Pfizer, and BMS need high drug prices to induce public shareholders to fund investment in drug innovation. The stock market, as it functions in the United States, is a value-extracting, not value-creating, institution (Lazonick, 2018; Lazonick and Shin, 2020). Contrary to MSV ideology, it is households as taxpayers, workers, and patients who are value creators in the pharmaceutical industry. When workers, taxpayers, and patients contribute to innovation—that is, the generation of higher-quality, lower-cost products than were previously available—they have a legitimate claim to share in the gains of innovation if they occur.

The MSV argument, put forth by academic economists known as agency theorists, is that, of all the participants in a company, it is only shareholders who make risky investments in the firm without a guaranteed return and, hence, it is only shareholders who have a claim on the firm's profits, if they occur (Lazonick, 2018, 2023). The theory assumes that other stakeholders in the corporation, including workers, receive guaranteed prices (e.g., employee's wages) for their productive contributions. Agency theory, however, overstates the risks borne by shareholders in making corporate investments, while ignoring risky investments by workers and taxpayers in productive resources that can enable business corporations to generate revenues and profits (Lazonick, 2017, 2021). In the pharmaceutical industry, patients also participate, in both everyday healthcare settings and formal clinical trials, in value creation by providing data critical to the drug development processes related to their diseases.

Through government investments in human knowledge and physical infrastructure, taxpayers regularly provide productive resources to companies without a guaranteed return. A formidable example is the spending on life-science research by the National Institutes of Health (NIH) with a 2025 budget of USD44.5 billion (but slated to be slashed by 38% in 2026). From 1938 through 2025, NIH funding of life-science research totaled more than USD1.8 trillion in 2025 dollars (U.S. National Institutes of Health, 2025). Business corporations that make use of NIH-sponsored research benefit from the public knowledge that it generates. NIH funding of foundational and translational scientific research has been fundamental to the growth of the pharmaceutical industry, not only in the United States but also around the world (Tulum et al., 2023; Tulum & Lazonick, 2025). As risk-bearers, taxpayers who fund investments in such research, or in physical infrastructure such as roads, have a claim on resulting corporate profits, if they are generated. Through the tax system, governments, representing households as taxpayers, seek to extract this return from corporations that make profitable use of government investment in human capabilities and physical infrastructure.

No matter what corporate tax rate prevails, however, households as taxpayers face the uncertainty that changes in technological, market, and/or competitive conditions may prevent

enterprises from generating profits and the related business tax revenues that serve as a return on the household taxpayers' investments in human knowledge and physical infrastructure. Moreover, tax rates are politically determined; households as taxpayers face the political uncertainty that predatory value extractors may convince government policymakers that they will not be able to make value-creating investments unless they are given tax cuts or financial subsidies that will permit "adequate" profits. Households as taxpayers face the risk that politicians may be put in power who accede to these demands for predatory value extraction (Ferguson et al., 2025).

Through their skills and efforts, workers regularly make productive contributions to the companies for which they work that are beyond the levels required to lay claim to their current pay. They do so, however, without guaranteed returns (Lazonick, 1990, 2019). Any employer who is seeking to generate a higher-quality, lower-cost product knows the profound difference in the productivity levels of those employees who just punch the clock to get their daily pay and those who are committed to supporting the company's goals of generating products that can compete in terms of quality and cost. An innovative company wants workers who apply their skills and efforts to organizational learning so that they can make enduring productive contributions—including those that will enable the development of the firm's next generation of high-quality, low-cost products.

For their part, in making these productive contributions, employees expect that they will be able to build their careers within the company, putting themselves in positions to reap future benefits at work and in retirement. Yet these potential careers and returns are not guaranteed. In fact, under the PVE governance regime that MSV ideology legitimizes, these careers and returns are generally undermined. More than that, for the pharmaceutical industry to take full advantage of artificial intelligence (AI) as a platform for the development, manufacture, and delivery of innovative pharmaceutical products, there will have to be an upgrading and expansion of careers in the pharmaceutical industry through which its professional, technical, and administrative employees gain expertise. The corporate use of AI to eliminate "entry level" jobs requiring less sophisticated knowledge and experience without making the complementary investment in upgrading and expanding human capabilities is, from our perspective, a form of PVE (Lazonick, 2026).

Workers, therefore, supply their skills and efforts to the process of generating innovative products that, if successful, could create value, but they take the risk that their endeavors could be in vain, resulting in downward pressure on their pay and less job security. Even if the innovation process is successful, moreover, workers face the risk that the institutional environment in which MSV prevails will empower corporate executives to cut some workers' wages and lay off other workers—all so that the value workers helped to create can be redirected to shareholders, including the senior executives themselves with their copious stock-based pay as well as to hedge-fund managers whose stock-trading strategies count stock buybacks as money in the bank (Lazonick & Shin, 2020).

In summary, legitimized and guided by MSV ideology, there is overwhelming evidence that PVE governance prevails among most of the major US pharmaceutical corporations. Given the importance of the United States for the supply of and demand for pharmaceutical products,

the US business model has a preponderant influence on the operation and performance of the global pharmaceutical industry. It is a business model that, in the name of MSV, is biased toward the development, manufacture, and delivery of high-profit pharmaceutical products for high-income economies in which healthcare systems can afford to pay high prices. Moreover, the high profits are not used to fund pharmaceutical innovation but rather to boost stock yields. To increase profits that can distributed to shareholders as dividends and buybacks, PVE governance has a strong bias toward condoning price-gouging patients, laying off workers, suppressing wages, selling assets, squeezing suppliers, and avoiding taxes (Lazonick, 2023).

The pharmaceutical industry is characterized by a concentrated global landscape, as we show in Table 3. The top 20 companies control 68% of the global prescription market (USD770.1 billion of USD1,133 billion). The US-based business model—which is increasingly dominated by MSV—sets the global standard for the industry, enabling it to capture greater profits. Table 3 also highlights the severe regional imbalances, with US companies alone accounting for 34% of worldwide sales.

Table 3. Market concentration in the global pharmaceutical industry as measured by prescription sales, 2024

Region	Company	National Base	2024 Prescription Sales ($B)	Market Share (%)
USA	Merck & Co.	USA	64.2	5.7
	Pfizer	USA	63.6	5.6
	Johnson & Johnson	USA	57.0	5.0
	AbbVie	USA	56.3	5.0
	Bristol Myers Squibb	USA	48.3	4.3
	Eli Lilly	USA	45.0	4.0
	Amgen	USA	32.0	2.5
	Gilead Sciences	USA	28.8	2.4
EU	AstraZeneca	UK/Sweden	54.1	4.8
	Roche	Switzerland	52.5	4.6
	Novartis	Switzerland	50.3	4.4
	Sanofi	France	44.5	3.9
	Novo Nordisk	Denmark	41.2	3.6
	GSK	United Kingdom	40.2	3.4
	Bayer (Pharma)	Germany	19.5	1.7
	Merck KGaA (HC)	Germany	9.1	0.8
Asia	Takeda (Pharma)	Japan	30.0	2.6
	Daiichi Sankyo	Japan	12.3	1.8
	Astellas	Japan	12.4	1.0
	BeiGene	China	3.8	0.8
Global		USA	395.1	34.5
		EU	311.4	27.2
		Asia	58.5	5.1
		Top 20 Combined	765.1	66.8
		Worldwide Prescription Drug Sales	1146.0	100.0

Note: Figures for Takeda, Daiichi Sankyo, and Astellas correspond to the fiscal year ended 3/31/2025.
Source: Company Annual Reports and (Evaluate, 2025).

Thus, with its focus on "creating" value for shareholders, PVE governance does not serve the needs and claims of other stakeholders even in the Global North. Why, then, would one expect that, under PVE governance, a pharmaceutical corporation would have any sustained interest in developing, manufacturing, and delivering products for the Global South? At the same time, it must be recognized that PVE governance is not inherent in the operation and performance of the corporate economy, having become entrenched in the US economy in the 1980s and then spreading abroad, as we have discussed in Section 2.

The challenge, in both theory and practice, is to build and support business corporations that embody and empower PVC governance. Drawing on the "social conditions of innovative enterprise" framework, PVC governance means that *strategic control* over corporate resource-allocation decisions should be exercised by those with an unwavering dedication to developing, manufacturing, and delivering pharmaceutical products to people who need them globally and equitably. In addition to PVC incentives, these executives must have the abilities, based on their career experience, to carry out this corporate purpose. The *organizational integration* of personnel should focus on the creation within the corporation and its ecosystem of stable and equitable employment opportunities that enable and empower collective and cumulative learning that is the essence of medicine innovation, be it for the Global North or Global South. Finally, the requisite *financial commitment* to sustain the pursuit of this purpose should come from sources that view the health benefits to low-income patients as an important part of the yield on their financial investments.

A PVC approach that can foster a sustainable transition of the kind that serves the Global South calls for an approach that looks beyond the 20 large companies in Table 3 to identify or build organizations where strategic control of the corporate enterprise is dedicated to medicines as a public good, with business profits as a critical source of finance for achieving this objective. To enable the existence of such companies, international bodies, governmental agencies, and civil-society organizations must provide recognition and support for PVC governance as the appropriate business model for pharmaceutical innovation for the Global South. By the same token, the roles of these agencies and organizations will be problematic if they fail to be critical of PVE governance as a business norm. The attainment of PVC governance in a PVE world will require aggressive regulation of the global pharmaceutical industry, with the very difficult transformation of institutions of corporate governance its core.

In the next section of this paper, we evaluate, from the PVC-PVE perspective, the current global health governance diplomacy architecture and the work of international bodies such as the World Health Organization, USAID, and NIH, philanthropic organizations such as the Gates Foundation and Wellcome Trust, and civil society organizations such as the Médecins Sans Frontières.

4. Mapping Key Global Government, Business, and Civil-Society Access-to-Medicines Actors

Managing the tasks of promoting biopharmaceutical innovation and improving access to medicines for the Global South is a wide network of actors whose investment strategies and organizational structures have direct consequences for the four "As" of access to medicines

outlined in section 2 of this paper. The diversity of interests among actors—government and donor agencies including finance organizations, international (multilateral and global) bodies, pharmaceutical companies, philanthropic foundations, and advocacy organizations—that seek to set or influence the discourse and outcomes on access to medicines poses difficult challenges for unified global efforts. But the fundamental tension between the shareholder-driven objectives of major pharmaceutical companies and the access objectives espoused by international bodies, government and donor agencies, and advocacy organizations has endangered the emergence of coherent and systematic support of strategies for the development, manufacture, and delivery of pharmaceutical products for the Global South (Alkhaldi et al., 2024). For some time, LMICs have called for an overhaul of the global health architecture to reflect the needs of the Global South, but the global health landscape is increasingly prone to competing priorities, "at-odds-with-each-other" mandates, and overlapping institutions. These differences have prevented the realization of consensual agendas on topics of global health diplomacy; a term loosely connoting the efforts of governments to align and promote a common health agenda on cross-border issues that impact health and wellbeing of all people worldwide.

This section analyzes the history of global health diplomacy, specifically examining how the mandates espoused by different governmental and donor agencies, international bodies, and advocacy organizations support or hinder (either deliberately or unintentionally) global access-to-medicine strategies. We embed our analysis in the PVC-PVE framework given the relevance of PVC for sustaining pharmaceutical innovation in the Global South and promoting sustainable access to medicines for all. Conversely, PVE's influence markedly undermines pharmaceutical innovation and access by prioritizing proprietary rights, market exclusion, and shareholder yields.

We show how a lack of coordination in pursuit of a PVC agenda among governments and donor agencies, international and multilateral bodies, including regional agencies, and financial bodies, coupled with funding dependencies of several key players in global health, empowers the dominance of PVE-based approaches favoring the perspectives of the global pharmaceutical industry. In what follows, we trace the evolution of global health diplomacy for access to medicines from 2000 to 2025 and link it to the two main approaches to access—PVC and PVE—as they have evolved to show how PVE-oriented objectives of several of these efforts undermine the business models necessary to deliver medicines to the Global South.

4.1 Tracing the History of Global Health Diplomacy for Access to Medicines

The right to health—of which, access to medicines is a critical component—was first recognized in Article 25.1 of the Universal Declaration of Human Rights, adopted in 1948 (Alkhaldi et al., 2024). But the global fight for access to medicines only gained traction a few decades later with the Alma Ata Declaration of the World Health Organization of 1978, which recognized that the provision of essential medicines is a key component of primary health care in all countries (Rifkin, 2018). This recognition coincided with, and triggered off, several efforts to build domestic manufacturing in the Global South, including in countries such as India, Bangladesh, Brazil, and Argentina.

But by the 1990s, the issue of access to medicines had reached a political impasse, driven by divergent interests between industrialized countries with strong pharmaceutical industries and many LMICs. The impasse was shaped by two key developments we highlighted in Section 2: the financialization of the industry in the US economy with a drive for greater profits from offshoring, along with increasing globalization, and the establishment of uniform global intellectual property rules under the TRIPS Agreement. As US and European pharmaceutical companies offshored their production, they also wanted a globalized regime with the full protection of intellectual-property rights abroad similar to the one at home. Since the HIV/AIDS crisis of the late 1990s, global health diplomacy emerged as a means to balance the growing reach of the global pharmaceutical industry with rising inequity in access through a variety of political commitments.

4.2 Actor Coalitions and Agenda Setting for Access to Medicines

Table 4 highlights the political declarations in the 21st century that have sought to keep the momentum and focus on access to medicines globally. Over the same period (2000-2025), however, the field of global health has gone through momentous changes in the way it operates. Primarily, while international and multilateral bodies, especially the World Health Organization, still play key roles in setting global health agendas, they have ceded much ground to a multitude of other agencies. As a result, the global effort to coordinate and improve health outcomes worldwide today is managed by a wider variety of actors and initiatives (Hogge & Franz, 2011).

Critical for this reshuffle are key changes that occurred in the late 1990s, when, faced with forging a global response to the HIV/AIDS pandemic, the issue of access-to-medicines began to occupy the global center stage. Coming on the heels of the just-negotiated TRIPS Agreement, the HIV/AIDS crisis led to two kinds of reaction—which then culminated into two dominant forms of advocacy—around global access to medicines.

The first approach focused on explaining away the distributional inequities as an inevitable outcome of innovation. Proponents of this approach proposed facilitating greater access to medicines on a case-by-case basis, much in line with the argument advanced within the USA on keeping innovative incentives intact. Proposals included increased funding for the distribution of specific pharmaceutical products that are in dire need in the Global South, such as those for HIV/AIDS, malaria and tuberculosis, and to make financing available specifically to support R&D for these and other specific neglected diseases (Shiffman, 2014).

A second approach argued that the access gap was increasing because of global intellectual-property protection. According to proponents of this approach, addressing the growing divides in access to knowledge particularly because of rising intellectual-property barriers and regulatory interventions such as those for compulsory licensing of patented innovations was critical to maintain the balance. The focus of this approach remained on greater transfer of technology and know-how to enhance manufacturing capacity in the Global South, and to facilitate greater competition in the pharmaceutical industry by reducing barriers to entry for greater production of key pharmaceutical products (Correa, 2013; World Health Organization, 2006).

In the late 1990s and early 2000s, these two approaches played out globally amidst several other important developments. First, capabilities in India's pharmaceutical sector provided the means to focus on domestic manufacturing of antiretrovirals (ARVs) for supply to many Global South countries, thus reducing the price of these drugs radically. In some cases, even when the "generic versions" of patented HIV medicines were not directly supplied from India, the threat of supplies led to lower prices from patent holder companies (Gehl Sampath, 2020).

Table 4. Political declarations on access to medicines: 2000 to 2025

Organization/Declaration/Date	Content
United Nations General Assembly. United Nations Millennium Declaration, A/RES/55/2 (2000).	While not exclusively about medicines, MDG 8 ("Develop a Global Partnership for Development") included a specific target (8.E): "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries."
Committee on Economic, Social and Cultural Rights, CESCR, General Comments, Ref. No 14 (2000)	Outlines the four overlapping dimensions of access as: non-discrimination, and access in physical, economic and information domains.
United Nations General Assembly (2001)	*Declaration of Commitment on HIV/AIDS* (A/RES/S-26/2)
International Convention on Economic, Social and Civil Rights, ICESCR (2003)	Article 12 recognized the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health"
Committee on Economic, Social and Cultural Rights, CESCR, General Comments, Ref. No. 17 (2006)	Reiterates the responsibilities of all States in preventing high costs of essential medicines.
United Nations General Assembly (2006)	*Political Declaration on HIV/AIDS* (A/RES/60/262)
HRC Special Rapporteur, A/HRC/63/263 (11 August 2008)	Provides for human rights guidelines for pharmaceutical companies in relation to access to medicines.
World Health Assembly (2008)	WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) (2008)
HRC Special Rapporteur, A/HRC/23/42 (1 May 2013)	Reiterates the universal right to enjoy the highest attainable standard of physical and mental health.
HRC Social Forum, A/HRC/29/44 (2015)	Presents a new report of the Social Forum on access to medicines reiterating the need to reinforce measures.
UNGA Sustainable Development Goals (UN General Assembly Resolution 70/1 (September 2015)	Target 3.8 (of Goal 3), specifically aims to ensure access to safe, effective, accessible, and affordable essential medicines and vaccines for all by 2030.
Human Rights Council (HRC's resolution 32/15 (July 2015)	Reiterated the right to access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
UN Secretary General's High-level Panel on Access to Medicines (September 2016)	The Panel came up with a series of recommendations in its report on promoting innovation and access to health technologies.
UN General Assembly resolution 71/3 (October 2016)	Declared the need for greater access to medicines to fight anti-microbial resistance.
UN General Assembly resolution 73/2 (October 2018)	Focused on a political declaration of the General Assembly on the prevention and control of non-communicable diseases.
UN General Assembly resolution 73/3 (October 2018)	Focused on a political declaration of the General Assembly on the prevention and control of tuberculosis.
Human Rights Council Resolution 41/10 (July 2019)	Declared the right to access medicines and vaccines in the context of the right of everyone's enjoyment of the highest attainable standard of physical and mental health.
World Health Organization (2019)	WHO Roadmap for Access to Medicines, Vaccines and Health Products 2019-2023.
Human Rights Council, Ref: 46/14 (March 2021)	Emphasized the need to ensure equitable, affordable, timely, and universal access vaccines for all countries in response to COVID-19.
WHO *Solidarity Call to Action* (2000)	Launched by Costa Rica, led to the creation of the WHO COVID-19 Technology Access Pool (C-TAP)
WTO discussions on the "TRIPS Waiver" (2020)	Health Diplomacy by India and South Africa at WTO for a TRIPS-waiver for COVID-19 medicines, therapeutics, and diagnostics.
WHO (2025)	The Pandemic Treaty

Source: Modified by authors, based on (Chattu et al., 2023).

Eventually, discussions around domestic manufacturing and compulsory licensing paved the way for the Doha Declaration on the TRIPS Agreement and Public Health of 2001. This accord was arguably the most important declaration of its kind (United Nations General Assembly, 2006), explicitly confirming the right of countries to use compulsory licensing and other TRIPS flexibilities to overcome patent barriers and facilitate pharmaceutical manufacturing during public health crises. Other political declarations on HIV/AIDS followed suit in this period as listed in Table 4, committing countries to an urgent coordinated response to HIV/AIDS (see also United Nations General Assembly, 2006). Support by the Committee on Economic, Social and Cultural Rights Declarations emphasized the right to equal access to medicines, and declarations explicitly recognized the need to reduce the cost of ARV drugs, overcome intellectual property barriers in line with the Doha Declaration, and massively scale up access to treatments, among others (see Table 4).

Second, momentum emerged during this period to focus specifically on access to knowledge issues that underpinned the gap in access to medicines. The access-to-knowledge (A2K) movement coalesced internationally by 2004 as a response to the increasing imbalance between privatized knowledge (controlled by intellectual-property rights holders) and the global public interest (Hogge & Franz, 2011). Prompted by the large price reductions achieved for patented ARV drugs as an outcome of the competition offered from large Indian generic companies, advocates argued for facilitating competition over other approaches for greater access to medicines (F. M. Abbott et al., 2014).

Third, the first ever mention of access to medicines in a global development framework in the form of MDG 8 (target 8E) after the AIDS crisis enabled new aid sources to enter the field of global health: individuals, philanthropic foundations, and corporations. This evolution offered a large role for private philanthropy to shape global health (Gotham et al., 2016; Stuckler et al., 2011).

Immediately thereafter, several events triggered off the large participation of private donors and philanthropic foundations in global health. In no specific order, they included: a tremendous shortage of essential vaccines required for immunization of under 5s in LMICs that was leading to severe child mortality from preventable causes by the end of the 1990s; the rapid spread of HIV/AIDS in the Global South along with the accompanying pressure to massively scale up access to lifesaving HIV/AIDS treatments; and the weakening of the WHO due to several funding cuts (Kennedy & Thakrar, 2025).

These events facilitated the emergence of a wider coalition of actors in global health with a fragmentation of approaches: some focused explicitly on expanded supplies of specific pharmaceutical products to LMICs, and some others focused on facilitating greater investment in R&D for specific diseases and some continuing to work on building capabilities across the Global South. The newer approaches—focused on expanding supplies of specific products and creating new R&D ventures—opted for a new organizational structure. They relied on government-business collaborations (GBCs, also known as "public-private partnerships") as a means of delivering new products or promoting greater access to existing products (Chataway & Smith, 2006).

These new international initiatives made increased funding available for the supply and distribution of proprietary drugs mainly to improve public health in LMICs, with a specific focus on LICs, including those in Africa. The initiatives were preferred by several advanced country governments and non-State actors (pharmaceutical industry coalitions and philanthropic foundations) for specific reasons. First, the newly created initiatives operated with higher degrees of autonomy when compared with the more member States-driven, multilateral UN institutions, which were bogged down by differences over structural reform of the pharmaceutical industry with widespread disagreement over intellectual property, technology transfer, transparent pricing, and competition issues. Second, the new initiatives offered the possibility of structuring health interventions with a focus on specific products/objectives only. Third, they allowed the discussion on global health and access to be removed entirely from a scrutiny of patents, pricing, and the wider pharmaceutical innovation ecosystem. Some early studies note that many foundations, including the Bill and Melinda Gates Foundation, which were engaged in facilitating such initiatives themselves held corporate stock in food and pharmaceutical companies and preferred to find other options that did not call for a rethink of the prevailing international pharmaceutical innovation model (Stuckler et al., 2011).

Given that new initiatives offered a greater degree of control and catered to the value for money approach advocated by several funders, by the late 2000s, GBCs (i.e., "public-private partnerships") became the go-to model of engagement to substitute "privatization" with "alternate delivery systems" for "partnerships" (Hodge & Greve, 2007; Linder, 1999; Teisman & Klijn, 2002). Important examples of such initiatives include Gavi (created in 2000), the Global Fund for AIDS, Malaria and Tuberculosis (created in 2002), the International AIDS Vaccine Initiative (IAVI created in 1996), the Medicines for Malaria Venture (MMV, created in 1999), the Global Alliance for TB Drug Development (TB Alliance, created in 2000), among others.

In general, these initiatives—many of which are now important international agencies in the global health landscape—were chosen to fulfil at least three goals: (i) engage the global business sector (particularly MNCs or other companies) that held the proprietary technologies and related important pharmaceutical products without fundamentally questioning the prevalent model of innovation; (ii) provide incentives (financial, intellectual property-related, or technical) to bridge the gap between business innovation interests of large companies and government interest goals such as R&D into neglected diseases and/or greater access, and (iii) utilize existing capacity in LMICs in an effort to create collaborations/ build supply capacity (Gehl Sampath, 2018).

High-income country donors, particularly the United States, played key roles in this reorganization of the global health architecture. In 2000, when the Millenium Development Goals were adopted, the United States expanded its contribution to global health to USD1.5 billion, and began to focus specifically on HIV/AIDS, malaria, and tuberculosis, among other infectious diseases. By 2007, over 95% of the US global health budget was devoted to these three diseases, which were prioritised over and above health systems strengthening, domestic production, capacity building, or any other related activities in global health. Between 2000-2024, the US government contributed USD278.1 billion to global health in LMICs, with key

focus on HIV/AIDS (47.8%), maternal and reproductive health (11.5%), newborn and child health (8.4%), malaria (5.9%), and tuberculosis (3.8%) (Dieleman et al., 2024).

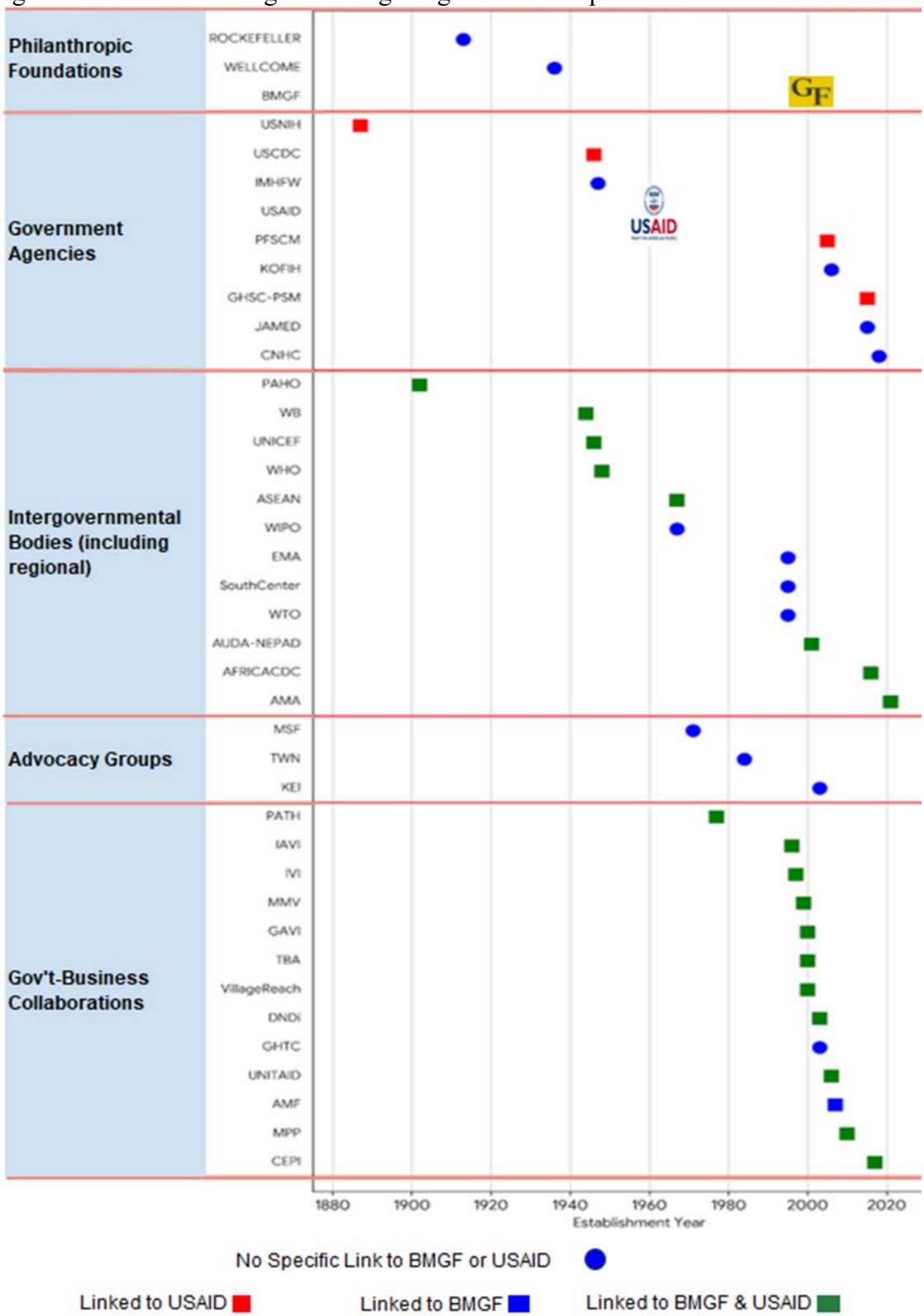
The US contribution to global health as the largest bilateral donor worldwide has enabled it to lead coordinated responses with international agencies. The achievements of these responses include, but are not limited to: (i) funding and creating key global health agencies, especially Gavi and the Global Fund, which have achieved significant health impact outcomes; (ii) combating HIV, tuberculosis, and malaria (through the President's Emergency Plan for AIDS Relief (PEPFAR), and the President's Malaria Initiative (PMI)); (iii) achieving substantial improvements in maternal and child health through immunization (contributing to the vaccination of over 400 million children annually); (iv) strengthening responses to neglected tropical diseases (via large-scale R&D funding); (v) enabling reductions in malnutrition (with up to USD11 billion committed between 2018 and 2021); and (vi) promoting contributions to global health security, as demonstrated by responses to COVID-19 and Mpox in 2020-2021, and Marburg in 2024—where US funding played a key role. These strides, however, were not achieved alone. Other important donors have played key roles including Britain, Sweden, Norway, France, Germany, Belgium, and Japan. Philanthropic foundations, such as the Bill and Melinda Gates Foundation (now the Gates Foundation, referred to as BMGF in this section) have also played significant roles.

Two initiatives have been highly successful over time. The first, Gavi, has strengthened immunization and healthcare systems across the Global South and scaled up the outreach and use of critical vaccines to reach zero-dose children and communities. In so doing, Gavi has saved 20.6 million lives over the past 25 years (Gavi, 2025b). The Global Fund, similarly, disbursed over USD19 billion in grants and programs aimed at tackling its three focus diseases (HIV/AIDS, malaria, and tuberculosis) in 151 countries in its first ten years (Hanefeld, 2014). Since its inception in 2002, the agency has saved 70 million lives (The Global Fund, 2025).

The agenda setting for health financing was influenced by the Millenium Development Goals, which emphasized HIV/AIDs, malaria, and tuberculosis, as well as the goals to reduce maternal and infant mortality (emphasizing immunization). It was also equally set by an emphasis on the so-called "orphan" diseases (neglected diseases in the context of the Global South), in favor of approaches that posed no direct challenge to the prevalent model of innovation. Thus, while the disease focus was born out of the HIV/AIDS activism of the late 1990s (Oppenheimer & Bayer, 2009), donors have preferred initiatives that shifted focus from targeting the structural shortcomings of the pharmaceutical industry or healthcare systems to those that "fix the problem of access" through direct vertical interventions (Birn, 2009; Birn et al., 2017). As a result, the new global health agendas espoused by several of these agencies have come to be embedded in the PVE mode, with interventions that explicitly pivot attention toward supply or partnership creation for specific products for "affordable treatments", instead of targeting any of the structural failures of the current business model such as intellectual property, excessive pricing, etc. Figure 4 below maps the funding relationships between major global health institutions over time, showing the central and pervasive role of the US Agency for International Development (USAID) and the BMGF in supporting the new initiatives in global health.

Figure 4 lists organizations within different categories. Philanthropic foundations, government agencies (which includes donors), intergovernmental bodies (which includes international, multilateral, regional bodies and financial institutions), government-business collaborations (so-called public-private partnerships), and advocacy organizations (civil society) are listed in order of their establishment date, moving from the earliest (top) to the most recent (bottom). The x-axis displays the decade in which these organizations were established, illustrating a clear timeline of institution formation within each category. Figure 4 uses a specific color code to denote funding ties: organizations marked with a red square indicates a collaboration or funding relations with USAID, those in blue squares indicates a tie with BMGF, and those in green squares indicates a collaboration or funding arrangements with both USAID and BMGF.

Figure 4. Role of financing in shifting the global landscape



Source: Authors' own analysis based on public data in Annex 1.

The fragmented ecosystem: a conflict between PVE and PVC

Figure 4 demonstrates several important features of today's global health landscape. First, the timeline along the x-axis immediately shows a notable clustering of the establishment of new initiatives particularly GBCs with significant PVE influences from the late 1990s through the 2010s. This high density of new organizations operates side-by-side with the WHO, which remains the key international body within the United Nations system responsible for global health. Other international agencies dealing with topics of health, such as UNICEF (health for children, and global procurement), WIPO (health and intellectual property), WTO (health, trade and intellectual property), UNIDO (health and industrial development for pharmaceutical production), and UNFCCC (health and climate change) co-exist in their spheres of specialization.

Second, Figure 4 shows how, within the funding landscape, allocative decisions and the governance of global health diplomacy have been heavily influenced by a small, concentrated group of donor agencies, most notably the USAID (until its evisceration at the hands of the Trump administration in 2025). Although Figure 4 has not mapped all major donors exhaustively (such as UK, Germany, France, Denmark, Belgium, the EU, etc.), it helps to demonstrate how over time a handful of high-income countries and some other donors, have wielded disproportionate influence in restructuring global health architecture over the past 25 years. These countries work closely with philanthropic foundations, specifically BMGF, but also Wellcome Trust, the Rockefeller Foundation, as well as several new foundations that have emerged over the past decade and play a dominant role in setting the focus and scope of global health interventions.

The BMGF remained the most influential philanthropic foundation in the period 2000-2025, having played a key role in global health since its establishment in 2000 and its positions have directly influenced the pathways toward access to medicines over this period, with an annual investment of roughly USD3 billion since the 2000s. The BMGF is both a funder and an implementing agency in global health with a vast network of personnel actively working to further its programs in several different regions worldwide. Its overarching strategy has involved promoting an 'evidence-based' global health agenda through new initiatives and innovations, strengthening global cooperation among various stakeholders, creating market incentives for the development and delivery of essential health tools, and generating high-quality data to inform progress (Bill & Melinda Gates Foundation, 2025b). To achieve these goals, BMGF often funds research and development of new medicines and vaccines in specific categories, supports the strengthening of regulatory systems in LMICs, promotes universal immunization, and facilitates access to essential health products through various mechanisms (Bill & Melinda Gates Foundation, 2025a).

The BMGF has had important wins in its global health portfolio. It overwhelmingly supported the creation of Gavi with a USD750 million grant in 2000 and has been a financer of the agency over time, helping it to expand and deliver on its mandate. As noted earlier in this section, Gavi has successfully promoted universal immunization of children in LMICs bridging the divides in vaccine availability between high income countries and their LMIC counterparts (Gavi, 2025a). BMGF also invests in supporting R&D in specific cases. For example, in vaccines, where innovation or supply has been lagging in specific therapeutic categories, BMGF supported product development of new vaccines by two Indian companies: the Serum Institute of India and Bharat Biotech, to expand Gavi's global rotavirus vaccine

supply, which was initially dominated by two companies, GSK and Merck, with supply disruptions (DCVMN International, 2018; Gehl Sampath, 2021b; PATH, 2018). It continues to support similar projects across companies worldwide.

The BMGF's R&D investments into neglected diseases and the exploration of alternative drug discovery models can also be viewed as indirect challenges to the traditional pharmaceutical business model, even though these investments are made primarily in those categories in which the global pharmaceutical industry has historically had little or no incentives to invest. Outside of the vaccines sector, by funding initiatives like the Tuberculosis Drug Accelerator and the Gra, m-Negative Antibiotic Discovery Innovator (Gr-ADI), BMGF directly promotes research in areas of high unmet need (Bill & Melinda Gates Foundation, 2025a). These initiatives aim to generate new treatments for diseases that might not otherwise attract significant investment from pharmaceutical companies.

But, on the whole, BMGF's commitments to enhancing affordability and access to medicines are truncated by its broader approach to the topic, which has historically sought to align its strategies and influence within the existing financialized business model of the global pharmaceutical industry. Rather than directly confronting the shareholder-driven objectives of these corporations, BMGF frequently focuses on approaches for existing pharmaceutical products that while focusing on their supply to LMICs often extend the spheres of market influence of patent-holding pharmaceutical and vaccine companies.

These preferences, shared by a variety of funders, can be seen at the agency level, in several agencies, as we discuss in this section. Pooled procurement and demand forecasts from Gavi, for example, led to the emergence of new players from the Global South in the global vaccine industry, but its market shaping works within the dominant innovation model of the global pharmaceutical industry. In that same process, Gavi also defines the 'lowest price' for each of the vaccines, the countries that should benefit from this 'lowest' price, and how much those countries should pay for it (MSF, 2015). Despite Gavi's successes an important question in global health remains: What is the best way to negotiate the lowest sustainable price? Can the lowest price be achieved through a system that negotiates differently with innovator companies, which set prices, and generic manufacturers, which largely take them—compressing generic margins while allowing innovator firms to apply tiered pricing without transparent benchmarks? Or does such a model merely reproduce the very access problems it seeks to solve? For example, the HPV vaccine market has been dominated by just two companies for a long period of time, with Gavi itself identifying a "limited supplier base" as a key constraint (Gavi, 2024).

As a result, despite the entry of new companies from the Global South, the vaccines sector is split between a large generics segment that operates on volumes rather than value (up to 80% of the companies fall under this category but account only for around 20% of the total value), and a small innovator segment (with up to 20% of companies accounting for 80% of the value) (Gehl Sampath & Pearman, 2021). There remains a strong divide between innovator and generic companies (Gehl Sampath, 2021b), and companies from the Global South have found it especially difficult to make the transition to the innovator categories (Gehl Sampath, 2026b). A fundamental issue remains that of clinical trials, which often account for 80% of vaccine development costs especially in the case of complex infectious diseases (Sertkaya et

al., 2024). These resources limit the R&D aspirations of Global South companies and will require much more support from governments, foundations, and other stakeholders in the future. To what extent this support will materialize, especially in those therapeutic categories in which large companies have R&D portfolios and interest, remains unclear. Up until now, BMGF's collaborations with large pharmaceutical companies in various initiatives (Bill & Melinda Gates Foundation, 2025d) indicate a preference for working alongside the industry to achieve shared goals, which have limited its willingness to challenge the fundamental principles of the PVE business model (Bill & Melinda Gates Foundation, 2025c).[9] Similarly, the Global Fund's grant-making process requires the countries seeking funds to propose technical, measurable approaches to each of its three focal diseases instead of the underlying determinants of the health systems for HIV/AIDS, malaria or tuberculosis (Birn, 2009). As some authors note, by making funding available based on these conditionalities, and by standardizing national strategies, the Global Fund has depoliticized the fight against the three diseases (Tchiombiano et al., 2019). A further consequence of the Global Fund, as well as initiatives such as PEPFAR and the Clinton Health Access Initiative, is that pooled procurement mechanisms for LMIC markets, coupled with strict WHO GMP prequalification requirements, may inadvertently raise barriers to entry for manufacturers from low-income countries. Companies in LMICs often face increased financial and technical hurdles to upgrade their production facilities as required for GMP prequalification. Doing so knowing that their final price may be outbid by another established competitor in the international procurement system poses tremendous market uncertainties for these companies. As a case in point, a Kenyan company, Cosmos Pharmaceuticals, waited for over ten years after its GMP prequalification to receive an order for supply from the Global Fund.

4.3 Priority, Agenda Setting and Crowding Out Effects

The ways in which different global health initiatives and institutions view access are shaped predominantly by their relative institutional mandates and funding. As noted above, the focus of the US government and the BMGF—as supported over time by several high-income countries—has been, with some exceptions, on communicable diseases, specifically polio, HIV/AIDS, malaria, and tuberculosis. Tracing the agencies that have received financing from USAID and the BMGF in Figure 4 shows how this expanded emphasis on communicable diseases, as supported initially by the US government and USAID and then by several high-income countries, has led to the kinds of agencies that have been set up in the global health diplomacy landscape.

During the same time frame 2000-2025, the WHO has transformed radically, with shrinking abilities to tackle its core themes for several reasons. Declining contributions from Member States since the 1980s resulting in increasing reliance on extra-budgetary resources to run

[9] At Microsoft, the company that he co-founded in 1975, Bill Gates oversaw its transformation into one of the most financialized companies in the two decades before he stepped down as chairman in 2014. As Lazonick and Hopkins (2020, p. 36) document in a paper on US corporate financialization coming into the Covid-19 pandemic, "for the years 2005-2019, [Microsoft] spent $190 billion on buybacks, equal to 68% of its net income, for the purpose of giving manipulative boosts to its stock price. These buybacks were done in addition to dividend payments of $147 billion, absorbing 52% of net income. During this period, Microsoft was the third largest repurchaser of its own stock, after Apple with $306 billion in buybacks and Exxon Mobil with $227 billion."

core programs; a growing reliance on private donors and large philanthropic foundations like BMGF and Wellcome Trust for financing; and the ever-diverging expectations of its Member States have weakened the agency significantly over time (Fazi, 2023). As an outcome, WHO's capacity to address the systemic barriers to global health became heavily circumscribed over the years 2000-2025 (Bell, 2023).

For example, concerned that the mainstream pharmaceutical innovation model is market-driven and leads to prioritizing the most profitable disease targets, Member States requested the WHO to debate structural reforms of the pharmaceutical innovation model in the early 2000s to address the lack of incentives for large pharmaceutical companies to invest in diseases affecting most people living in the Global South. Initial consultations led to the establishment of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) by the WHO, which concluded in its final report that intellectual property is insufficient to deliver the innovation model required globally and called for new global mechanisms to facilitate structural changes to the prevailing model of innovation in the industry (World Health Organization, 2006). Following this initiative, in 2008, the WHO adopted the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (WHA61.21, also known as GSPoA), which reflected a compromise: while the Strategy recognized and called for new R&D financing, it did not provide any binding obligations to WHO Member States in this regard.

After the GSPoA, in response to requests from several countries in the Global South for leadership on R&D and domestic manufacturing issues, WHO convened a Consultative Expert Working Group on R&D in 2010. The Expert Group, in its final report of 2012, recommended a Global Treaty on Funding and Coordination of Medical Research and Development. The report suggested that the treaty could require Member States to spend at least 0.01% of their GDP on R&D that addresses the special health needs of developing countries, and at least 20% of that funding to be spent through a single pooled funding mechanism to finance global funding of pharmaceutical R&D (World Health Organization, 2012). It also advocated for open licensing and data sharing mechanisms (Abbott, 2013). The developments, however, coincided with another large funding cut of nearly USD1 billion at the World Health Organization in the aftermath of the global financial crisis, which led to at least 300 job cuts in the agency and a greater reliance on donor funding (Nebehay & Lewis, 2011). The declines in funding and employment further weakened WHO's leadership in these areas, and the R&D Treaty, despite being a technically detailed proposal developed by WHO expert bodies, was politically abandoned by the mid-2010s.

The delinking of R&D financing from prices—as proposed in the treaty—threatened the dominant pharmaceutical innovation model, and the mandatory financing of R&D through a global pool was opposed by high income countries (USA, EU, Japan, among others). Thus, even though several countries in the Global South continued to push the agency toward leadership on the issue, the Treaty suffered a quiet political death while at the same time, voluntary funding mechanisms led to the strengthening of existing international initiatives, including UNITAID, and even paved the way for the creation of new ones, such as the Medicines Patent Pool in 2010.

In the resulting global health ecosystem, there is a crucial status quo bias toward the PVE model in interventions for promoting global health outcomes (Dhlamini, 2021). Strategies and initiatives proposed largely involve working within existing constraints rather than questioning them; focusing on negotiating lower prices for LMICs, expanding voluntary licensing of patented products, and ensuring more equitable distribution of innovator drugs as and when needed only, rather than advocating for a radical overhaul of the model of pharmaceutical innovation, with a focus on greater equitable supply, or greater competition in innovator categories.

The creation of numerous agencies has increased competition for limited resources, forcing alignment across the PVC-PVE spectrum. Among the three biggest philanthropic foundations in global health currently, the BMGF remains the largest private funder of global health initiatives, while the Rockefeller Foundation mainly played a dominant role in global health between the two World Wars; and the Wellcome Trust is one of the largest philanthropic funders of clinical research today.

The differences in focus notwithstanding, the growing financial power of non-state philanthropies in global health diplomacy, working alongside a few powerful national donors, have had the following outcomes:

- Agenda setting: the power to fund preferred solutions shapes the entire global health agenda (McGoey, 2015). This dominance can result in some priorities and approaches receiving disproportionate funding and attention (such as universal immunization or technocratic solutions to a systemic problem) (Birn, 2005), while other critical areas (such as domestic manufacturing, primary care, health systems strengthening, or sanitation) have come to be neglected.
- Market distortionary effects: By making billions available for specific technologies or diseases, the BMGF or other foundations can refocus university research, non-governmental/advocacy group activities and even influence governmental priorities (The Lancet, 2009). A “follow the money” effect, where scientists and organizations tailor their grant proposals to funders priorities is currently a defining feature of global health, potentially stifling alternate priorities and strategies even to achieve the same outcomes.
- Ideological positioning and rivalry: Over time, these financing efforts have created ideological positioning and rivalry among international bodies actively working to promote access to medicines with a critical lack of accountability toward overall global health goals and outcomes (Edwards, 2008).

The evolution of global health financing in this manner has transformed the epistemic landscape by prioritizing some kinds of academic and policy research over others that redefined global health successes and supplanted the role of key international bodies in global health.

For example, our analysis of the grants data from the Wellcome Trust from 2005-2024 shows that of the GBP 5.4 billion of grant money awarded during this time frame, 94.0% was directed toward entities located in high-income countries. Similarly, BMGF data for 1994-2026 shows that 85.6% of grant recipients were in high-income countries. Our findings are

supported by another recent study analyzing the past twenty years of funding patterns of the BMGF, Rockefeller Foundation, and Wellcome Trust, which found that although all three private foundations spread their granting across a range of organizational types, the Rockefeller Foundation favored non-governmental organizations (NGOs) (50.2% of funding, USD100 million), the Wellcome Trust favored universities (56.6% of funding, USD1.8 billion), while the BMGF also granted most to NGOs (34.3% of funding, USD2.7 billion) (Breen & Kumar, 2023). Both the Rockefeller Foundation and BMGF allocated almost one third of their grant expenditure to international organizations (33.0% and 31.8% respectively), unlike the Wellcome Trust (2.4%) (Breen & Kumar, 2023). Moreover, all three private foundations funded grant recipients in high-income countries (HICs) over LMICs; for the Wellcome Trust, Rockefeller Foundation, and BMGF, 94.0%, 83.9%, and 81.4% of their granting was to HICs, respectively (when funding to international organizations was removed) (Breen & Kumar, 2023). This allocative pattern was most explicit for universities, with over 90% of university funding from all three foundations awarded to those in HICs—a finding that remains consistent with earlier studies documenting similar concentrations of resources that favor established institutions in the Global North (Sridhar & Batniji, 2008).

Two fundamental implications follow from these research financing trends. First, they matter given the outsized role played by foundations in financing such activities. Second, the prioritization reinforces the unequal control over knowledge production and decision-making of LMIC actors in global health (Abimbola & Pai, 2020). Research capacity in LMICs is now widely recognized to be essential and well-developed in many countries (Franzen et al., 2017). India, Brazil, and South Africa, as examples, host advanced research institutions and play major roles in clinical trials and infectious disease research. It is that indigenous capacity that came in handy in South Africa in 2022 to reverse engineer the mRNA sequence 1273 of Moderna's COVID-19 vaccine, when both Moderna and BioNTech refused to license their technology to WHO's mRNA Hub initiative (Gehl Sampath, 2022a). But this capacity remains uneven and constrained due to underinvestment, limited infrastructure, and unequal participation in global research systems (Bowsher et al., 2019; Fosci et al., 2019). The key issue, therefore, is hardly the lack of scientific capacity, but the fact that the capacity is currently not adequately supported and utilized.

The concentration of decision-making power has several critical strategic implications. First, global health priority setting tends to reflect the strategic interests of a small group of donors and entities, dictating which diseases, technologies, and approaches are prioritized, rather than being more evidence-based. While some of the emphasis on HIV/AIDS, malaria and tuberculosis is a mark of continuity among several donors given their emphasis on these disease categories and interventions, on the whole, it eliminates the strategic autonomy and participation of the countries whose health outcomes it is intended to improve from the agenda-setting process. Tuberculosis kills over a million people every year, and estimates suggest that over ten million cases are diagnosed each year, and many remain undiagnosed. Malaria, similarly, kills over half a million people. The point we are making here is not to stop financing or focusing on these areas of public health. Rather, our concern relates to how a narrow conception of global health success, centered on case-by-case, disease-specific interventions, has come to dominate prevailing approaches to addressing the access to medicines problem.

A second critical strategic implication of the power concentration is the steady hold on the kinds of interventions that are chosen in agenda setting for action without questioning the increasing financialization of the pharmaceutical industry, or the pre-eminence of shareholder value maximization over R&D in major pharmaceutical companies worldwide, both of which manifest in tacit and overt defense of the current model of innovation in global forums and agencies at the expense of empowering actors in the Global South. A brief review of global health priorities internationally shows that while immediately after the HIV/AIDS crisis and the Doha Declaration on the TRIPS Agreement and Public Health, there was a significant amount of discussion on domestic manufacturing, it never became the dominant strategy. Global health policy shifted toward financing and procurement-based models, prioritizing the large-scale delivery of medicines through global supply chains, which became the dominant strategy (Harman & Papamichail, 2024). While the WHO continued to recognize the importance of local production, it began to be framed as a complementary strategy rather than a central solution and was ultimately overshadowed by approaches focused on international procurement and supply.

To be clear, intellectual property plays a key role in innovation in the PVC mode of corporate enterprise as well. What is problematic is the wider misuse of intellectual property in the dominant model of pharmaceutical innovation today, and a lack of scrutiny over its scope and application (Syed, 2025). Several major donors, both governmental and non-governmental, support the view that the existing intellectual property (IP) framework constitutes the appropriate ecosystem for pharmaceutical R&D and innovation. This position aligns with a prevailing model of private value extraction and shareholder value maximization, while often overlooking questions of adequacy and the extent of its current misuse. A pharmaceutical industry in which a handful of players create intellectual-property monopolies and enhance barriers to entry to newcomers is not conducive to greater innovation. It ultimately promotes practices by which the global pharmaceutical industry prioritizes distribution of profits to shareholders, even within the global health ecosystem's access approaches.

Global health, as LMICs have called for time and again, should focus equally on the structural conditions for each person globally to access pharmaceutical products and equitable healthcare when they critically need them. To be made accessible, these interventions should be affordable. Such an outcome requires that the global health community remains open to addressing the causes of inequity, not just the consequences. As evidence, the World Bank recently concluded that health indicators have declined in 86 of 129 LMICs between 2010 and 2025 (Holla et al., 2026). This call is contradictory to the current strategy employed to achieve global health outcomes or to measure global health success, which focuses more on pushing forward particular agendas through agencies set up with a greater business orientation. The narrow focus measurable through performance milestones of these agencies is justified on specific past successes (or misperceived recollections thereof) (Birn, 2009; Glassman & Temin, 2016), without a consideration of the structural impediments to access. The way we account for success also matters. For example, in the Lenacapavir case that we have discussed in this paper, success measured by the lives saved by the current licensing agreement could look substantially different from success if we considered the lives that can be saved in all LMICs, including the one-third that are currently excluded. As clarified earlier, some of these agencies—particularly Gavi and the Global Fund—have been significantly impactful. But on the whole, the donor emphasis on such initiatives has also facilitated a

fragmentation of the global health architecture to a very large extent, enabling the sidelining of a discussion on structural issues in favor of treating access as a separate issue from the processes of developing, manufacturing, and delivering new pharmaceutical products—the structuring of which is now left to the global pharmaceutical corporations.

The end result of these changes is that global health is now a canvas of different agendas and approaches, implemented by agencies of which many are less accountable than WHO operate (World Health Organization, 2018b). Overlapping mandates and lack of regional and national representation where their target populations are based raises further questions of legitimacy, which remain unaddressed. The multitude of these initiatives are also often overwhelming for LMIC agencies—both national and regional—which structure their programs mainly in the direction of available financing and not on a needs' basis.

In parallel, with the expansion of other initiatives, WHO's programmatic areas of work have also undergone constant revisions. The agency's assessed contributions (which offer flexibility in programmatic activities based on its core mandate) have shrunk to just 20% of its budget, and the agency has come to rely heavily on voluntary funds (also known as voluntary contributions) for over 80% of its budget (Nenmini, 2025). This funding model circumscribes its ability to prioritize areas according to their relevance to global health. For example, over the course of 2000-2024, the focus on communicable diseases from the BMGF resulted in the outcome that 82.6% of grants to WHO (2000-2024) from the BMGF targeted infectious diseases, and <1% targeted non-communicable diseases (NCDs). While this allocation of resources could be justified given BMGF's focus on such diseases, it skews WHO's focus, given its reliance on BMGF financing for its programs.

Table 5, which presents WHO's budget for 2022-2023, provides a snapshot of who its main donors were at the peak of the pandemic. The Programme Budget for the 2024–2025 biennium of the WHO was USD6,834.2 million, of which the top 10 contributors account for approximately 57% of all funds. But almost all these funds are earmarked for specific purposes, and the agency relies on new donations consistently, from an expanding pool of donors, including foundations created by large drug companies. In 2025, for example, the Novo Nordisk Foundation pledged USD57.76 million to the WHO (Nenmini, 2025). The Programme Budget for the 2024–2025 biennium of the WHO was USD6,834.2 million, of which the top 10 contributors account for approximately 57% of all funds.

Table 5. WHO's Budget for 2022-2023 (assessed and voluntary contributions)

Rank	Contributor	Total Funding (2022–2023 Biennium, USDMillion)	% of Total Biennium Voluntary and Assessed Contributions
1	United States of America	1,237.6	17.16
2	Gates Foundation (Previously Bill & Melinda Gates Foundation)	829.5	11.50
3	Germany	780.9	10.83
4	GAVI Alliance	480.9	6.67
5	European Commission	468.2	6.49
6	Canada	201.5	2.79
7	Rotary International	176.5	2.45
8	Japan	166.9	2.31
9	United Kingdom	165.6	2.30
10	China	156.0	2.16
11	France	153.3	2.13
12	United Nations Central Emergency Response Fund (CERF)	139.9	1.94
13	World Bank	117.8	1.63
14	Norway	114.9	1.59
15	United Nations Children's Fund (UNICEF)	111.0	1.54

Note: Financial data (Total Funding and % of Total Budget) is based on voluntary (specified and Thematic contributions as well as Assessed Contributions made during the 2022–2023 Biennium. The percentage is calculated against the total voluntary contributions for 2022–2023 of approximately USD7.2 billion for the same period.
Source: (World Health Organization, 2023b)

4.4 How COVID-19 Helped Cement the PVE-based Agenda Setting

The COVID-19 pandemic offers one of the clearest contemporary illustrations of how pharmaceutical R&D outcomes are shaped by underlying governance logics—particularly a focus on predatory value extraction (PVE) approach at the expense of a progressive value creation (PVC) model (Lazonick, 2024). In fact, it shows how in a time of crisis, accelerated pharmaceutical innovation is possible when innovation systems temporarily shift toward PVC principles. Yet it also reveals how quickly PVE dynamics re-emerge to reproduce longstanding inequities in global access.

A central lesson is that the unprecedented speed of vaccine development was enabled by large-scale government investment, mission-oriented coordination, and risk-sharing across the innovation pipeline. Years of publicly funded basic research on mRNA technologies (Dolgin, 2021), combined with extensive state financing for clinical trials and at-risk manufacturing (Lalani et al., 2023), removed scientific and financial barriers that ordinarily slow R&D. In particular, the mRNA vaccines emerged from dense networks of public laboratories, universities, philanthropic agencies, and coordinated regulatory action—all of which are feature characteristics of PVC-oriented innovation ecosystems. The availability of

mRNA technology was not a product of isolated corporate ingenuity. It was the result of collective and cumulative learning processes in which the pharmaceutical companies that manufactured and delivered the vaccines were carrying out specific value-creating activities close to the market. The Covid-19 vaccines that were most effective against severe disease (Comirnaty by BioNTech/Pfizer, Spikevax by Moderna, and Vaxzevria/Covishield by AstraZeneca) built on years of research conducted in the government sector on related MERS and SARS viruses as well as the mRNA and viral vector platforms (Tulum et al., 2021). As Tulum and Lazonick document in the case of medicines subject to price negotiation under the US Inflation Reduction Act of 2022, the argument that the companies that sell medicines on the market should, as their executives typically claim, capture all the value to society of those medicines has no basis in logic or fact (Tulum & Lazonick, 2025).

A second important lesson concerns the transformative role of open scientific collaboration. The rapid release of the SARS-CoV-2 genome (Zhu et al., 2020), widespread use of preprints, and pre-competitive data sharing dramatically accelerated discovery and reduced transaction costs. These practices contrasted sharply with the proprietary, siloed information environments typical of PVE-driven pharmaceutical R&D.

Where openness prevailed, innovation accelerated; but where proprietary control reasserted itself—particularly in downstream manufacturing—global supply became constrained. As soon as product development agreements were entered into (BioNTech-Pfizer, AstraZeneca-University of Oxford), a handful of large global companies sought to assert control over limited manufacturing capacity, while exhibiting a reticence to license rights to other companies to produce the vaccines. “Vaccine nationalism” quickly asserted itself as a handful of countries became first in line to secure vast quantities of vaccines, subjecting LMICs to long waiting times in a context in which, to save lives, access time was of the essence (Santangelo et al., 2024). USA, EU, Switzerland, Canada, Japan , and Israel signed substantial deals with Pfizer, AstraZeneca, and Moderna, reserving to their own populations a significant portion of the initial vaccine supply (Kiernan, 2021). By late November 2023, 79.86% of people in high-income countries had received at least one dose, compared to a strikingly lower 32.82% in low-income countries (United Nations Development Programme, 2021). This divergence underscores that scientific openness is necessary but insufficient for equitable access unless paired with shared manufacturing know-how, distributed production capacity, and a global procurement plan.

Faced with a pandemic of that scale, governments and non-state actors responded in different ways. Several initiatives were proposed internationally to solve the collective problem of vaccine innovation and distribution, which show how the various coalitions of actors and institutions can complicate PVC outcomes. Key among these were the Access to COVID-19 Tool Accelerator (ACT-A) and the COVID-19 Vaccines Global Access Facility (COVAX Facility); the WHO’s COVID-19 Technology Access Pool (C-TAP); and the TRIPS Waiver Discussion (2020-2023)—all of which are diverse in their scope and ambition.

A pandemic blueprint for global collaboration was created in the form of the Access to COVID-19 Tools (ACT) Accelerator launched on April 24, 2020. Aiming to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines on a global scale (Gehl Sampath, 2021a), the initiative provided the basis for the COVID-19

Vaccines Global Access (COVAX) Facility, which was led by WHO in collaboration with Gavi and the Coalition for Epidemic Preparedness Initiative (CEPI) (Knowledge Ecology International, 2020).

At the same time, the severe lack of access to vaccines, therapeutics, and personal protection equipment in many LMICs, especially Africa, reopened the discourse on domestic manufacturing internationally after a long time. There was intense pressure for licensing of technologies and related tacit know-how, beyond the routine commercial manufacturing agreements (Gehl Sampath, 2021a). A second initiative, the WHO's COVID-19 Technology Access Pool (C-TAP), was officially launched in May 2020 after a solidarity call from the government of Costa Rica to the WHO to promote open, non-restricted access to all COVID-19 technologies through transparent, voluntary, non-exclusive licensing (World Health Organization, 2020b). Finally, the governments of South Africa and India proposed a temporary waiver of the WTO's TRIPS Agreement for COVID-19 vaccines and treatments on October 2, 2020 to allow manufacturers in developing countries to produce generic versions without fear of patent lawsuits.

Both the TRIPS Waiver and the C-TAP were not viewed favorably by several high-income countries, which considered the vaccines' race predominantly as an issue of economic security. The TRIPS Waiver was vehemently opposed by the European Union (especially Germany), the UK, Switzerland, Norway, Japan and Australia among several others. Almost no major HIC supported or used the CTAP (with the exception of Belgium), including several such as the United States, United Kingdom, Germany, Switzerland and most of European Union that did not participate in it. HICs and several non-State actors formed a larger support coalition primarily around ACT-Accelerator and the COVAX Facility, lending it the possibility to emerge quickly as the most viable global collaboration model for COVID-19 vaccine supply. Meanwhile, discussions for the TRIPS waiver proceeded much slower than anticipated and finally resulted in a watered-down compromise. The initial proposal aimed to suspend forty provisions of the TRIPS Agreement, but after twenty months of negotiations, the final text of the negotiated TRIPS waiver only suspended one of them (Syam & Abbas, 2025). The C-TAP, aiming to promote open sharing of knowledge and technology transfer, was mostly sidelined and received very little by way of financing as well as support from most high-income countries during the pandemic.

Despite widespread support for the COVAX Facility on the international level, bilateral deals by wealthy countries and the prioritization of their own populations reduced the available supply and weakened COVAX's ability to procure and equitably distribute vaccines (Prasad et al., 2022). As Gehl Sampath demonstrates, this created widespread vaccine access gaps in the Global South, especially during the first twenty months of the pandemic that were overcome through vaccine supplies from China (Gehl Sampath, 2026b).

What remains remarkable is the either/or choices exercised by countries as well as other actors in the global health landscape in response to these three initiatives. Given their very different significances for health security, why were countries unable to support widespread domestic manufacturing in addition to supply through the COVAX Facility? The answer is simple. COVID-19 vaccine innovation and supply soon became a story of political economy in the worst sense: companies backed by their countries including for the protection of their

intellectual property however large the public welfare fallouts, or companies prioritizing supplies to a handful of powerful countries that jointly defended the status quo. The pandemic, in short, reinforced the drive amongst pharmaceutical companies to defend stronger intellectual-property rights, especially patents, to generate profits even in a time of global crisis, rather than tame them (U.S. Government Accountability Office, 2007), and strengthened the acceptance of such an outcome internationally. In some ways, it even pushed us farther into the PVE mode, legitimizing a number of practices that were contested earlier. For instance, leading pharmaceutical companies with frontrunner pandemic vaccines patented the final products that were the outcome of decades of government-sector investments without the stipulation of conditions toward the public for pricing or greater access to the results of such publicly funded R&D (Tulum & Lazonick, 2025).

Notably, initial work to develop the mRNA technology was supported by grants from the National Institute of Allergy and Infectious Diseases (NIAID) and was then used by BioNTech to research cancer immunotherapies before venturing into mRNA technologies for pandemic preparedness (Lalani et al., 2022). A number of intellectual property disputes on the mRNA vaccines continue currently, and for several related platform components of the newest platform technology in medical science, a few countries and companies now hold most of the intellectual property, ranging from viral matter to stabilizers, adjuvants, delivery devices and methods, such as the one used by Moderna that covers the method of producing an mRNA vaccine (Fougerolles et al., 2013).

Secondly, the pandemic was the first time in global health that, despite a raging public crisis, no compulsory licenses were employed to facilitate speedier production, and calls from LMICs and advocacy organisations for technology transfer and voluntary licensing went unheeded. These calls did not spin off into a global movement of the kind that emerged during the HIV/AIDS crisis because in the past twenty-five years, a handful of global players have used global health financing to redefine the set of options that can be tabled in the first place. Domestic manufacturing, compulsory licensing, technology transfer are no longer an easy ask, simply because the agencies that could vociferously argue in the public interest are also endangered—if not annihilated—in the global health landscape today.

In fact, two of the most prominent vaccine companies—BioNTech/Pfizer and Moderna—refused to transfer the technology to produce the vaccines during the pandemic, including to WHO's mRNA hub that was established in South Africa (see discussion in the next section). Instead, Moderna and BioNTech proposed two different ways to set up manufacturing in the African continent. BioNTech, in an agreement with the Government of Rwanda, proposed setting up a BioNTainer (a modular manufacturing facility) for the manufacture of specific vaccines for the African region, a solution that, while helpful, differed from comprehensive technology transfer that would empower local companies to independently produce vaccines (Wagner et al., 2021). Moderna agreed to set up a subsidiary vaccine manufacturing facility in Kenya, which it later cancelled.

These corporate decisions mark a turning point in global health diplomacy in that they have helped relegate access to medicines in LMICs to a secondary goal that comes after the defense and prioritization of the global pharmaceutical industry in the name of maximizing shareholder value, the prevalent corporate governance ideology that legitimizes PVE

(Lazonick & Shin, 2020; Lazonick & Tulum, 2023). But many countries that opposed broader licensing or technology sharing measures for COVID-19 technologies during this time and have generally expressed a preference for voluntary licensing arrangements over the past decades, have not followed through with that position in their own domestic policies. A recent study shows that high-income countries (HICs) have increasingly relied on compulsory licensing domestically, with their share of all recorded compulsory licensing instances rising from 15% between 2005 and 2014 to 54% between 2015 and 2024 (Dunn et al., 2026). This pattern suggests a selective application of intellectual property flexibilities, whereby measures resisted in global health negotiations are nonetheless utilized domestically when aligned with national interests.

5. A New Global Pharmaceutical Innovation Model Centered Around Progressive Value Creation

The previous sections of this paper have made the following arguments. First, the structural failures of the contemporary pharmaceutical industry, its reliance on blockbuster-driven innovation, the monopolistic architecture of global intellectual-property protection, and the financialization of firm behavior are not anomalies but are predictably driven by a governance system dominated by PVE. When firms operate under incentives that reward value extraction rather than value creation, innovation systems tend toward underinvestment in socially valuable knowledge, inequitable distributions to shareholders, and the systematic neglect of public health needs (Lazonick, 2019). A PVC mode of governance seeks to provide the global community with the high-quality goods and services that they need and want at prices that they are able and willing to pay. Through equitable systems of compensation, the employment opportunities in developing, manufacturing, and delivering high-quality, low-cost products make those goods and services affordable. In pharmaceuticals, a shift toward PVC is needed to realign corporate behavior with the dynamics of investment in innovation, collective and cumulative learning, and equitable access to medicines on a global scale.

The prevalent PVE model, dedicated to maximizing shareholder value, systematically prioritizes the claims of financial interests who, over the past four decades, have been able to structure the system of corporate governance and related government institutions to extract far more value from business corporations than they contribute to value creation—*which is nil in cases in which these interests make these value-extracting claims by simply accumulating corporate shares on the stock market.* This financialized orientation contributes directly to the key structural failure in access to medicines that we have identified in this paper: a business model increasingly focused on acquiring or extending patents around lucrative therapeutic areas rather than generating new, socially valuable compounds and pharmaceutical products that meet the widest possible health needs.

5.1. Moving Toward an Approach for Value Creation

A *value-creating* corporation that makes profits by investing in the capabilities of its labor force, providing stable employment, and rewarding employees equitably is a qualitatively different place to work than a *value-extracting* corporation that makes profits by intensifying work, laying off workers, and suppressing wages. A corporation that uses its profits to upgrade the capabilities, security, and pay of its labor force engages in PVC, whereas a

corporation that prioritizes the allocation of its profits to shareholders in the form of cash dividends and stock buybacks engages in PVE.

A PVC corporation also recognizes that its value-creating capabilities depend on creating value for its customers in the form of high-quality, low-cost products, The generation of products that are of higher quality and lower cost than those previously available for a specified use (the economic definition of innovation) is the overriding strategic goal of the PVC corporation. In pharmaceuticals, that means making safer, more effective, accessible, and affordable medicines available to all patients, wherever they may reside in the world and whatever their economic circumstances.

PVC depends on a *retain-and-reinvest* corporate resource-allocation regime: from year to year, the corporation retains a substantial portion of its profits to upgrade the socioeconomic condition of its labor force, providing them with both the capabilities and incentives to participate in the collective and cumulative learning processes required to generate higher-quality, lower-cost products. In sharp contrast, PVE depends on either a *dominate-and-distribute* or *downsize-and-distribute* resource-allocation regime. Under dominate-and-distribute, the corporation generates a stream of profits, usually based on a prior era of retain-and-reinvest, and prioritizes distributions of corporate cash to shareholders. Eventually, through a failure to invest in renewed innovation, dominate-and-distribute devolves into downsize-and-distribute: from year to year, the corporation downsizes its labor force and distributes corporate cash to shareholders (Lazonick, 2023). The theory of innovative enterprise analyzes the social conditions under which, by investing in innovation, a business corporation can afford, and even profit, from engaging in PVC as well as how PVE can undermine these social conditions—strategic control, organizational integration, and financial commitment.

This is not an argument against intellectual-property protection. It is rather an argument for the clear need to ensure that intellectual-property protection, when granted, results in innovative outcomes of a PVC kind. Pharmaceutical companies have a clear and direct financial stake in maintaining robust intellectual-property rights. Intellectual-property rights such as patents, trademarks, trade secrets and the protection of manufacturing practices grant them temporary monopolies and market exclusivity, allowing them to charge higher prices for their products, and thus generate the profits they argue are necessary to fund further research and development. What needs a rethink is that while the industry frequently asserts that weakening intellectual-property protection would undermine innovation by reducing the incentive for companies to invest in the costly and risky process of drug discovery and development, many of the large pharmaceutical companies do not use their high profits to augment their investments in drug innovation. We need a clearer and transparent pathway to oversee the gains to innovation, and to ensure that they do not end up becoming rent-extracting instruments for shareholders.

Globally, we need a paradigm shift to foster an environment where a PVC model, dependent on relevant R&D, can become profitable (given various grants and subsidies), while paying modest dividends to public shareholders—who are simply households as savers, not investors in the firm's capabilities. As has always been the case with publicly held corporations, retained earnings are the foundation of financial commitment. For PVC governance, those

who exercise strategic control must have the abilities and incentives to invest in pharmaceutical innovation and production for all who need their products globally, which, given the heretofore neglect, is first and foremost the people of the Global South. With the social conditions of strategic control and financial commitment in place, the challenge for innovative pharmaceutical enterprise is to engage in the collective and cumulative learning that is essential to the generation of safe, effective, accessible, and affordable medicines.

5.2. Africa's Medicine Self-Reliance Efforts: Can There be a New Blueprint for the Global South?

Africa's health security has been profoundly shaped—and significantly undermined—by the global fragmentation of efforts to promote access to medicines, and the financialization of the global pharmaceutical industry (Gehl Sampath, 2026a). For decades, the continent has faced persistent challenges in securing reliable access to essential medical products, remaining heavily dependent on imports to meet the bulk of its pharmaceutical needs (Buckholtz, 2021). This structural reliance has not only heightened vulnerability to international supply chain disruptions and price volatility (Kamara & Essien, 2022) but also necessitated the allocation of substantial shares of national health budgets toward procuring pharmaceutical products from abroad for the most basic health needs. Prior to the COVID-19 pandemic, African countries imported nearly all their vaccines and an estimated 70 to 90% of their pharmaceutical products, underscoring the depth of this dependence. As this paper has highlighted, greater shifts toward PVE have manifested in widening the access gap further in critical ways both for communicable and non-communicable diseases in the region.

If there was any positive outcome of the COVID-19 crisis, it was the global recognition of these long-standing vulnerabilities (Assefa et al., 2024). The pandemic starkly exposed the consequences of Africa's reliance on external suppliers for critical health technologies (Buckholtz, 2021). During the global scramble for vaccines, therapeutics, diagnostics, and other medical supplies in 2021 and 2022, African countries were repeatedly not afforded any priority, resulting in acute shortages and substantial delays in the delivery and distribution of life-saving products across the region, including frontline healthcare workers, pregnant women and people living with co-morbidities.

This experience injected renewed urgency into continental discussions on the need to develop Africa's own robust pharmaceutical manufacturing base (Buckholtz, 2021). It also revived broader debates about strengthening pharmaceutical innovation and production capacity within the Global South. Building such capacity is now widely recognized as not only a matter of health equity but also a central pillar of regional health security, economic resilience, and the ability to respond effectively to future pandemics and public health emergencies (Gehl Sampath, 2022b).

Some of the recent efforts to expand pharmaceutical manufacturing and innovation capacity in Africa following the COVID-19 pandemic represent a significant structural shift toward a PVC model in the region. It is built on a growing recognition by African governments, regional institutions, and global health actors that sustained access to essential medicines cannot be ensured through reliance on fragmented global markets, donor funding, and rent-driven multinational suppliers. Instead, it requires building domestic and regional capabilities

across the pharmaceutical value chain, from R&D to regulatory oversight to advanced manufacturing, building on the following:

i. Reorienting from import dependence to indigenous capabilities

For decades, pharmaceutical supply in Africa has been shaped by structural import dependence. This is no surprise, since under PVE conditions, African countries occupy the terminal point of the value chain, functioning as consumers of monopolized or oligopolistic products (with one or a few producers only) that are either not introduced in their markets, or priced excessively when introduced. This positioning within the global pharmaceutical value chain at once makes Africa the eternal market for pharmaceutical imports. Considering access to medicines on a case-by-case basis and focusing on promoting supplies to the continent from companies located elsewhere has also inhibited investments into the accumulation of technological capabilities in Africa, exposing African countries to recurrent shortages, price shocks, and inequities (Gehl Sampath, 2022b).

The African region has sought to address these shortcomings through regional and national institutional efforts over time. Acknowledging the need for a regional response to the shocks of the HIV/AIDs crisis, a first region-wide effort materialized in 2007, when the African Union's Pharmaceutical Manufacturing Plan for Africa (PMPA) was set out by the African Union, and developed as a Business Plan for building Pharmaceutical Manufacturing for the region with the help of UNIDO in 2012. In addition, the region began the process of regulatory harmonization in 2009 with the launch of the African Medicines Regulatory Harmonization (AMRH) initiative. These efforts, however, did not result in clear and strong regional mobilization.

During the COVID-19 crisis, African countries witnessed first-hand how the lack of manufacturing capacity in the region could result in severe dependence on a global health architecture that was incapable of ensuring equitable outcomes. By the time African countries received the first doses of the vaccine through the COVAX Facility, most of the high-income countries had vaccinated their populations with two or more doses.

This inequity jolted the continent into action in many other ways. In 2021, African Union and Africa CDC created a new Public Health Vision for the region, with a target of production of 60% of vaccines in the African region (Africa Centres for Disease Control and Prevention, 2022). This initiative led to the creation of the Partnership for African Vaccine Manufacturing (PAVM) and lent a new emphasis on building local production capabilities in the region. A treaty adopted in 2019, that had established the African Medicines Agency (AMA), was finally ratified by a large enough threshold of Member States allowing for the creation of the AMA in November 2021, which has now been inaugurated in Kigali, Rwanda in 2025 with an inaugural Director General.

The lack of vaccine availability during COVID-19 also led to a rethink on the structural constraints in the region. Responding to calls from the African Union, the main regional financial agency, the African Development Bank assumed a leadership position to create a 2030 Continental Pharmaceutical and Vaccine Manufacturing Vision and Action Plan, and in 2022 also set up a new regional agency, the African Pharmaceutical Technology Foundation

(APTF) to transform the technology landscape for the sector in the region (African Development Bank, 2022). In addition, a number of countries have announced pharmaceutical and vaccine manufacturing plans and initiatives.

ii. Value creation and development, manufacturing, and delivery capabilities

A core distinction between PVC and PVE governance lies in their respective approaches to knowledge. PVE models rely on exclusive intellectual property, secrecy, and the use of strategic, legal, and bureaucratic power by financial interests to extract revenues from the firm that are far in excess of contributions by those parties to value creation. PVC governance may use intellectual-property protection to support investment in innovation, but with the recognition that pharmaceutical innovation is fundamentally a cumulative and collective learning process carried out by labor within the firm and supported by knowledge creation that is both external and antecedent to the firm's learning processes (Tulum & Lazonick, 2025).

Africa's emerging innovation ecosystem embraces this PVC logic. The APTF was established with the specific mandate to address the critical barriers to technology access that have historically hindered the growth of Africa's pharmaceutical sector (Afronomicslaw, 2024). APTF has been commissioned with a pan-African mandate of building the capacities of African business corporations, research institutions, and government agencies to foster a pharmaceutical sector across the continent that can compete in terms of both quality and cost (Devex, 2025). To achieve this overarching goal, APTF's mandate is to build capabilities of both African companies and public research institutions by promoting technology transfer at low cost, providing technical and technological support to domestic companies seeking to expand manufacturing, and investing into building the African pharmaceutical value chain. A primary objective is to significantly enhance the continent's access to the crucial technologies required for the development and manufacture of a wide range of medical products, including medicines, vaccines, and diagnostics (Afronomicslaw, 2024).

The approach, recognizing the complexities involved in technology transfer, actively seeks to promote and negotiate technology transfer to African stakeholders from pharmaceutical multinationals and other entities to facilitate the sharing of essential technologies, know-how, and manufacturing processes (CBL-ACP, 2024). The agenda includes strengthening human and professional competencies within the sector and the broader research and development ecosystem, as well as fostering pharmaceutical and vaccine innovation to cultivate a thriving industry on the continent (CBL-ACP, 2024).

Other regional initiatives that have been created to promote knowledge networks and collective innovation capacity include the WHO mRNA Technology Transfer Hub in South Africa, which represents a major institutional innovation designed explicitly to diffuse platform technologies, train scientists, and lower the technological barriers that have historically excluded African manufacturers from advanced vaccine markets (World Health Organization, 2021). Despite the lack of licensing from the two mRNA vaccine companies, the hub progressed to build its own capabilities for mRNA vaccine R&D and production as part of a strong university-industry partnership framework and is led by the Department of Science and Innovation. Five universities—Witwatersrand University (Wits), the University

of Cape Town (UCT), the University of Kwazulu-Natal (UKZN), University of Stellenbosch (SUN) and the North-West University (NWU)—worked together to strengthen the preclinical development capacity, and the development of novel vaccine candidates for testing at the hub in South Africa (Gehl Sampath, 2026a). Ongoing efforts at the Institut Pasteur in Dakar reflect similarly a commitment to technological upgrading and learning which can benefit the entire region.

Such efforts are not just ongoing at the product development level in the region at present. The African Genomics Program (AGP) and the African Centre of Excellence for Genomics of Infectious Diseases (ACEGID) is an ambitious undertaking designed to address the historical underrepresentation of African genomic data in scientific research. Recognizing that genomic research provides crucial insights into how genetic variations influence human health, disease susceptibility, and responses to medications, AGP aims to accelerate genomic research across the African continent. The program's core objectives include expanding access to genomic data by supporting African institutions in hosting and managing this information while ensuring its open accessibility to researchers both within and beyond Africa. By sequencing over 50,000 genomes from diverse African samples and fostering research collaborations, AGP seeks to amplify the impact of genomic research on understanding and addressing health challenges. Furthermore, the program is committed to building capacity in genomic research by investing in talent development, infrastructure, and scientific networks across the continent. Ultimately, AGP envisions using population-level genomic data to inform health policies and develop precision medicine approaches that are specifically tailored to the unique health challenges faced by African populations (Byaruhanga, 2020).

The center has achieved significant milestones, including the rapid diagnosis of the first Ebola case in Nigeria and Sierra Leone, the development of a 10-minute rapid diagnostic test kit for Lassa fever, and the sequencing of the first SARS-CoV-2 genome in Africa (Byaruhanga, 2020). ACEGID continues to drive innovation in using genomics for surveillance, characterization, and diagnosis of infectious diseases, as well as for vaccine and drug development, positioning itself as a key contributor to strengthening Africa's preparedness and response to emerging health threats (African Centre of Excellence for Genomics of Infectious Diseases, 2025).

Understanding Africa's unparalleled genomic diversity holds immense potential to transform healthcare across the continent and beyond (Byaruhanga, 2020). By gaining deeper insights into how genetic variations influence health and disease in African populations, researchers can develop more effective and targeted treatments and diagnostics (Byaruhanga, 2020). Initiatives like AGP are building crucial clinical data sets and population-level data sets that can inform health policy and facilitate scientific research, ultimately leading to the delivery of better, more accessible, and personalized healthcare for all patients based on a deeper understanding of the African genome (Roche, 2025). Ongoing research efforts are focused on understanding drug metabolism in diverse African populations, which is essential for refining drug dosing and delivery to improve treatment efficacy and safety (Fletcher, 2024).

But some of these efforts are already endangered, including the APTF and the WHO's mRNA Hub, and run the risk that they simply end up embodying the status quo, rather than changing

the landscape (Cullinan, 2024). A recent study of the mRNA hub, for instance, warns of shortfalls of financing and the politicized origins, limiting the capacity of the hub to engage in biopharmaceutical innovation to address access in the Global South (Herder & Benavides, 2024).

iii. Regional market integration

Africa's recent institutional advances—including the African Continental Free Trade Area (AfCFTA), the African Medicines Agency (AMA), and the focus on regional pooled procurement initiatives—represent a shift toward creating large, predictable markets that support PVC-style capability accumulation for its companies and research institutions. Regulatory harmonization under AMA reduces transaction costs, accelerates approvals, and enhances trust, while pooled procurement enables demand aggregation and predictable purchasing commitments. These mechanisms improve the commercial viability of local manufacturing while fostering the iterative learning processes that drive innovation and quality upgrading.

5.3. The Case for a Global PVC Model to Support Change

Despite these efforts within Africa, the global push and pull to influence continues. Institutions such as the African Development Bank, Africa Export-Import Bank, and the Africa Finance Corporation are increasingly playing important roles in financing manufacturing infrastructure, R&D hubs, and workforce development programs that support regional productive systems. The focus on investments in the pharmaceutical sector marks a departure from the previous decades where finance for domestic pharmaceutical enterprise in Africa was hard to come by. They are also in stark contrast from the donor-driven, project-based financing that historically dominated the continent's health sector but still remain ideologically constrained by wider global health debates that prioritize established principles, norms and actors. Ultimately even with these changes, the African region continues to be heavily reliant on donors, not only for financing of health systems expenditures but also for agenda-setting and support for technical and technological capabilities.

New budget cuts in global health, both because of shrinking official development assistance (ODA) from several countries and the withdrawal of the USA from the WHO, are having extreme consequences. The withdrawal of US health funding means that the global community is suddenly trying to bridge an annual gap of roughly USD12 billion annually (Oum et al., 2025). A recent estimate suggests that 757,314 people have died in the Global South (the majority of deaths being children), after one year of US funding cuts to global health programs across the world (Cullinan, 2026). At the same time, there is no clear indication of how and in what way the development community will bridge this financing gap. Official development estimates released by the OECD suggest that ODA has fallen by an additional 10% to 18% in 2025 (Kumar, 2026). Early modelling exercises indicate that the termination of USAID funding could lead to 420,500 excess tuberculosis deaths by 2035, which alongside additional reductions in global health funding as announced by France, the USA, the United Kingdom and Germany, can lead to an extra 699,200, 63,100, 50,500, and 30,500 TB deaths respectively (Clark et al., 2025; Shaikh & Ashraf, 2025). It remains unclear who will fund the gap, given that the United Kingdom, France, Germany, Australia, Canada

and Japan have all announced significant budget cuts to development financing (Krugman, 2026).

The WHO is struggling once again with its 07 May 2025 proposed program budget tabled for the World Health Assembly reflecting 36% of its base program budget still without financing for the biennium 2026-2027 (World Health Organization, 2025). The good news is that in discussions in the May 2025 Assembly, WHO member countries have now agreed to a 20% increase in their fixed payments (assessed contributions), bringing it to a shortfall of 15%. The bad news is that even after this increase, WHO will undergo a further consolidation with around 25% of its staff capacity set to shrink (O'Neill, 2026). In addition, developments are constantly unfolding with the capacity to undo some of the strides, including the recent bilateral MoUs between the United States and African countries, which have linked health financing to conditions requiring sharing of pathogen samples and health data, raising concerns that such agreements could fragment global health governance further and undermine the Pandemic Treaty framework (Sekalala et al., 2026).

Presently, foundations wield tremendous power as the new agents of finance. Estimates show that the three foundations—Gates, Wellcome and Novo—are together the world's biggest source of charitable health funding, spending around USD10 billion per year on everything from malaria to malnutrition (Hudson, 2024). An opportunity now exists for foundations to rethink their agendas to create a better global health legacy for the future. If used appropriately, of course, that spending power can be leveraged to create a new global health architecture that moves the world toward a more equitable, PVC-based era of global health. Acting now could also prevent the global health landscape from falling prey to fragmented interventions competing with one another for financing without the critical mass or the coordination needed for impact, sidelining the interests of the very constituencies they seek to help (Pate et al., 2026).

Recognizing these risks, and reinforcing the need to align global health with where it seeks to make impact, in recent months, there have been several calls for a rehaul of the current global health architecture, including the Accra Reset,[10] an initiative pioneered by the President of Ghana to reimagine global health governance, the Gavi LEAP strategy,[11] the Lusaka Agenda,[12] among others. These initiatives call for recalibrating the global health agenda to make it fit for today's new reality.

Yet, the risks that these calls for reform remain just that, and that global health governance shrinks to accommodate the funding changes in ways that it further constrains our capacity to address global needs, is higher than ever before. The severe funding cuts lend a new urgency to rethink the current global health architecture, not just to preserve some of the current programs and portfolios, and streamline the institutions, but also to question and take stock of the role and relevance of global health institutions from the perspective of correcting long-standing inequities in health.

[10] See https://online.africa.com/accra-reset/
[11] See https://www.gavi.org/sites/default/files/2025/Gavi_Leap_brochure.pdf
[12] See https://futureofghis.org/follow_ups/lusaka-agenda-overview/

That is why, in this paper, we have focused not on *how* to reform the global health agenda, but *why*. To address the extractive nature of the dominant pharmaceutical business model, we propose that global health reforms consider the need to foster a PVC-based ecosystem for pharmaceutical innovation globally, with a key emphasis placed on collaborative innovation, sharing of knowledge, competition and the creation of capabilities strategically in all regions of the world. In addition, given that some funding institutions will wield more power than ever, we propose decision making to be coordinated between various institutions and an effort to be made to create a common understanding of global health needs for both pandemics and routine times.

To that end, we lay out a few of the key reforms that can help incorporate PVC principles to create such a reality in this last section for consideration. We believe that fostering a global ecosystem where PVC can flourish can not only support the African region to preserve its health sovereignty and economic security but also help increase health security and access to medicines for all globally, while also gradually decoupling donor funding and aid in health from influence of the PVE global pharmaceutical industry. The reforms proposed are aimed at two levels:

Reform of the corporate governance regime:

With the objective of moving from a system of PVE governance to one of PVC governance, we propose William Lazonick's five-part agenda for corporate-governance reform (Lazonick, 2023):

- First, ban stock buybacks done as open market repurchases. As Lazonick puts it in the subtitle of his 2014 *Harvard Business Review* article "Profits Without Prosperity," "Stock buybacks manipulate the market and leave most Americans worse off" (Lazonick, 2014).
- Second, reward senior corporate executives for PVC, not PVE. Senior executives should possess the abilities to implement innovative investment strategies, and they should be incentivized to retain-and-reinvest for the benefit of all contributors to corporate value creation.
- Third, fix the tax system so that it encourages PVC, not PVE. Corporate tax policy should be guided by the theory of innovative enterprise, balancing the need for profitable corporations to pay taxes—to help fund government investments in knowledge and infrastructure on which their business corporations depend—with the potential socioeconomic benefits of using tax credits to subsidize corporate investments in innovative goods and services.
- Fourth, restore collective and cumulative careers. For innovation to take place, the Old Economy norm of a career with one company—which has been essentially defunct in the 21st century—needs to be replaced by socioeconomic policies that support lifelong learning by members of the labor force—possibly across business, government, and civil-society organization—over the course of careers in which a duration of half a century of work is no longer unusual.

- Fifth, place representatives of workers and taxpayers on corporate boards. As Lazonick has explained (Lazonick, 2021), it is households as workers and taxpayers, not public shareholders, who make risky investments in the innovative enterprise and whose representatives, therefore, should oversee the implementation of those investments and the allocation of value gains to stakeholders when those investments succeed. In the pharmaceutical industry, patients should also have representations on corporate boards.
- In addition, we propose a sixth reform: to create stringent oversight mechanisms for intellectual-property rights in the pharmaceutical industry—recognizing that these rights are privileges granted by society to particular companies.

Reform for a new, more inclusive global health architecture:

The current global health architecture fragmented into specific disease areas of interest does not help to address the growing health and access needs in LMICs (Kerry, 2026). These needs, as we show in this paper, are only set to worsen if we do not address our model of pharmaceutical innovation, production, access and pricing. We therefore propose a rethink of the current global health architecture to create a PVC-based pharmaceutical ecosystem globally. This agenda means that, in addition to aligning current agencies with regional or national strategic decision making, and streamlining for impact, there is a need to consider the close relationship between innovation, production, supply chains, and access. Targeting pharmaceutical innovation and supply chain restructuring as a national priority in today's increasingly geopolitical world, while leaving the global community to tackle the fallouts of these changes is not a tenable solution to safeguard global public health. We propose the following six guiding principles for consideration:

- First, reset global health prioritization of areas needing critical interventions with a science-based articulation of global, regional, and national health needs, with adequate participation from the Global South.
- Second, support domestic manufacturing and capacity creation in the Global South by building capabilities among scientists and companies across all products, especially those who are developing innovative products or processes on site, as a matter of explicit global health priority. Proximity of personnel and scientists to specific diseases is an indispensable asset to the global community, which should be rewarded and promoted.
- Third, build consensus around a set of global principles for philanthropic financing for global health, which, while recognizing the important role of philanthropic organizations, also could address any potential conflict of interest and enable the engagement of such financing to build a multilateral global health agenda that reflects the needs of all countries.
- Fourth, promote enhanced scrutiny of the composition of actors in key decision-making processes at the global level to prevent agenda influences.
- Fifth, shift the grantmaking/financing focus from institutions in the Global North to empowering those in the Global South, including primarily focusing on creation of PVC-principled enterprises, research, and clinical capacity in the Global South.

- Sixth, revisit the global health architecture with a view to assess mandates, performance, and financing of agencies to fit global health priorities.

The principles we propose here are not meant to be exhaustive but rather are intended to facilitate a rethink of why we need to reform global health. We believe, in addition, that there is a strong case for regional coalitions for health sovereignty that can promote a more coordinated, and equitable, say for all regions in global health diplomacy in the future.

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APPENDIX

Short Name	Institution
AFRICACDC	Africa Centres for Disease Control and Prevention
AMF	Access to Medicine Foundation
APTF	African Pharmaceutical Technology Foundation
ASEAN	Association of Southeast Asian Nations
AUDA-NEPAD	African Union Development Agency-New Partnership for Africa's Development
BMGF	Bill & Melinda Gates Foundation
CEPI	Coalition for Epidemic Preparedness Innovations
CNHC	China's National Health Commission
DNDi	Drugs for Neglected Diseases initiative
EMA	European Medicines Agency
GAVI	Gavi, the Vaccine Alliance
GHSC-PSM	Global Health Supply Chain Program-Procurement and Supply Management
GHTC	Global Health Technologies Coalition
IAVI	International AIDS Vaccine Initiative
IMHFW	India's Ministry of Health and Family Welfare
IVI	International Vaccine Institute
JAMED	Japan Agency for Medical Research and Development
KEI	Knowledge Ecology International
KOFIH	Korea Foundation for International Healthcare
MMV	Medicines for Malaria Venture
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières (Doctors Without Borders)
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
PFSCM	Partnership for Supply Chain Management
ROCKEFELLER	Rockefeller Foundation
SouthCenter	South Centre
TBA	TB Alliance
TWN	Third World Network
UN	United Nations
UNICEF	United Nations International Children's Emergency Fund
UNITAID	UNITAID
USCDC	Centers for Disease Control and Prevention (USA)
USIAD	United States Agency for International Development
USNIH	National Institutes of Health (USA)
VillageReach	VillageReach
WB	World Bank
WELLCOME	The Wellcome Trust
WHO	World Health Organization

WIPO	World Intellectual Property Organization
WTO	World Trade Organization