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From Financialization to Public Purpose for Health

Every system is perfectly designed to get the results it gets.

—ATTRIBUTED TO MULTIPLE PEOPLE, INCLUDING DONALD BERWICK (1996), FORMER HEAD OF THE US CENTERS FOR MEDICARE AND MEDICAID SERVICES[1]

The social history of our time is the result of a double movement: The one is the principle of economic liberalism, aiming at the establishment of a self-regulating market; the other is the principle of social protection aiming at the conservation of man and nature as well as productive organization.

—KARL POLANYI, *THE GREAT TRANSFORMATION*[2]

In March 2016, pharmaceutical-industry executives and lobbyists huddled in a Boston hotel conference room as they grappled with the rising public attention on drug prices. They were there to hear from a powerful group of people, the largest institutional shareholders of their companies—mutual funds, including Fidelity, T. Rowe Price, and Wellington Management. Leaders from these funds had come with a warning and a directive: the pharmaceutical industry needed to better defend the prices of its drugs. How should pharmaceutical companies mount this defense? By educating the public about the value of their medicines. Otherwise, these Wall Street leaders cautioned, the government would impose price caps. In covering the meeting, a Bloomberg journalist observed, "The drug industry, just as eager to bolster slumping biotech shares, appears receptive to the message."[3]

Gilead Sciences had already taken up this charge over the previous two years, arguing that the value of its sofosbuvir-based hepatitis C medicines—quantified as the economic value of future health and averted health care costs—justified their launch prices in the United States and other high- and even middle-income countries. These prices had triggered a significant crisis in treatment access in the US and across the world. Health systems had rationed care to only those with

advanced disease, leaving millions of patients without treatment for a deadly and infectious disease. And yet even amid this crisis and the highly contentious debate over the price of new medicines, the launch of curative medicines for hepatitis C had shifted the terms and focus of the struggle.

Though the focus on drug prices had yet to recede, many in the drug industry and public policy circles had heeded Gregg Alton's exhortation that "price is the wrong discussion. . . . Value should be the subject." Across the pharmaceutical sector, companies were adopting the frame of "value"—with many policymakers, public officials, and other health sector stakeholders also taking up this rationale for the prices of new medicines. Value became a common refrain with the launch of new medicines, from Novartis's $2.1 million treatment for a rare disease in infants, to Gilead's remdesivir treatment for COVID-19.[4]

This book has pursued an alternative course in considering the subjects of both price and value. Unprecedented drug prices are creating crises in treatment access for patients, and certain representations of value appear to be legitimating these ever-higher prices. Guided by sociological and political-economic scholarship on capitalism and biomedicine, I have investigated the practices and strategies of pricing and valuation intertwined with the making of sofosbuvir-based medicines. Rather than weigh existing justifications, this book offers a new etiology for high drug prices: *the financialization of biomedicine*. Over the last three chapters, I have traced the mechanisms of this political-economic system through the twists and turns of the development of sofosbuvir-based medicines—from the conversion of public science into financially valuable assets, to the extraction of capital through speculative bets, and onward to the influence of financial logics over health policy and trajectories of treatment access.

In this chapter, I apply the key findings from this analysis to answer the two central questions motivating the book. First, what is the influence of financialization on pricing and value in the drug development process? This descriptive inquiry provides insights to apply to the second question: how has financialization shaped the outcomes for public health and future innovation? Berwick's observation rings true here: the financialized system out of which sofosbuvir-based medicines emerged was *designed* to produce unprecedented drug prices as well as significant value extraction, all naturalized under the banner of "value."

Bringing in wider industry examples to complement the analysis of hepatitis C, the evidence here debunks key claims regarding price and value in drug development and reveals the deleterious impact of financialization on our current and future health. The prevailing financialized approaches to drug development and pricing have been met with rising public discontent and inspired calls for alternative systems of biomedical research. Heeding Polanyi's insight, that counter-movements play a critical role in shaping a social economy, the second half of the chapter considers what a drug development system that intentionally prioritizes access and affordability would look like, and how it might already be within our reach.

WHEN MEDICINES ARE FINANCIALIZED: MECHANISMS, MYSTIFICATIONS, AND OUTCOMES

Writing at the dawn of the biotechnology revolution, science and technology scholar Edward Yoxen described the emerging intersection of finance and genomics as a new kind of "technology controlled by capital . . . a specific mode of the appropriation of living nature—literally capitalizing life."[5] But this appropriation was not latent in "living nature"; it has been *made* by the political-economic system described in this book: the financialization of biomedicine. The primary strategy of this system is to extract financial value through speculation on health assets in stock markets. Hepatitis C and sofosbuvir-based treatments provide powerful examples of how this plays out for the development and pricing of new medicines. As the last three chapters described in detail, setting drug prices and extracting value in this financialized drug development process rested on capitalizing science, drugs, and health itself. After taking up the mechanisms by which financialization influences pricing and value, we will turn to its impacts, showing how access, future breakthroughs, and democratic governance all become jeopardized in the process.

Powered to be High: Prices Tethered to Financialization

When Gilead set the launch prices for its sofosbuvir-based medicines for hepatitis C, it was making a basic calculation. As the US Senate investigation shows, Gilead reckoned that health system buyers would be compelled to pay more per treatment course for a superior therapy. But this expectation was not Gilead's alone; it is central to the entire circulation of capital in the drug development process. From Pharmasset's early venture backers to Gilead Sciences' shareholders, financial actors used their position in the drug development process to collect speculative gains based on this anticipation—in time horizons far shorter than the decade-plus time it took to develop sofosbuvir-based medicines. Rather than being tied to some tangible cost of research or production, pricing was almost entirely tethered to financial market expectations. Three mechanisms making up financialized drug development illuminate this link: capitalizing collectively produced knowledge into financial assets through patents; capitalizing drugs via short-term bets on growth in financial markets; and capitalizing health by compelling health systems to buy medicines at "value-based" prices.

First, the entire speculative process of drug development rests on the transformation of collectively developed knowledge into monetized assets. Long-term public investments supported the development of the nucleoside base for sofosbuvir. Later, Pharmasset's scientists turned to the publicly developed "prodrug" strategy to allow one of the company's existing compounds to better attack the hepatitis C virus. In granting Pharmasset its first patents for the compound in 2008, the US government converted this cumulative knowledge into an intangible asset with specific political-legal properties.

Patents are popularly conceptualized as a legal contract governing an exchange between an inventor and society, particularly the potential users of a given unit of knowledge. In the realm of drug development, patents are supposed to be a way for drug companies to "recoup" the costs of R&D. In a US Senate hearing on drug pricing, for example, senator Jon Cornyn voiced the commonly held view: "I support drug companies' recovering a profit on their R&D of innovative drugs."[6] The rationale of the patent, by this view, refers to what Sunder Rajan has called "the figure of the inventor-industrialist"—risk-taking drug companies that are positioned as the "inventors" of medicines.[7]

As I have shown, this conception is at odds with how financialized drug development actually operates. Patents allow knowledge to be repackaged into intangible assets, giving their owners specific control, such as the power to appropriate value or to transfer ownership. This control takes on financial meaning in the speculative markets in which these intangible assets are the objects of valuation and transaction. Through a relay race of financial actors, invention itself then comes to be about, in the words of Sunder Rajan, "the production of capitalized value rather than the production of the product itself."[8] In other words, patents become disconnected from the sources of their original innovative labor, and instead are transformed into financial assets in the circulation of capital.

This dynamic is connected to the observation made by industrial economist F. M. Scherer in a 2004 *New England Journal of Medicine* article on the role of patents in confounding debates over R&D costs.[9] In practice, he argued, patents in contemporary drug development *do not* function as vehicles to recuperate R&D costs; they are a lure for speculative capital. Given this reality, it becomes easier to see why the pharmaceutical industry has so fiercely resisted attempts at greater transparency into their R&D costs.

As the sofosbuvir case shows, at no point in the "relay race" are prices reflective of these costs. Though Pharmasset had spent $62.4 million on sofosbuvir and $271 million *in total* on R&D over its existence as a company, the company was valued in the billions—mostly driven by the asset that would eventually become sofosbuvir. Gilead's $11 billion bet on Pharmasset in 2011 was almost *three times as large* as Gilead's $3.96 billion in R&D costs *for the previous four years combined* (2008–2011). When the Senate later asked Gilead to enumerate its R&D investments in sofosbuvir-based regimens, Gilead gave a figure of $880.4 million. Even the R&D costs for *all* of its drugs during this time—over $4 billion—pale in comparison to the over $46 billion Gilead made on its sofosbuvir-based treatments in the *first three years*. Patents, in this system, are severed from logics of invention and production and instead tethered to the valuations that are possible in speculative financial markets.

This leads into the second mechanism: structural changes in the economy have shifted how capital circulates in drug development, from R&D-focused businesses to a relay race of economic actors betting on drug assets in financial markets. As

William Lazonick has shown in his work on maximizing shareholder value, gone is the era in which companies "retain and reinvest" their capital in their own R&D process.[10] As a consequence of a series of regulatory changes in financial markets and executive compensation beginning in the 1970s, business strategy has become increasingly oriented toward distributing earnings to financial actors that are external to the firm, from venture capitalists to shareholders in stock markets. For these financial actors, value comes less from the *profitability* of actual drugs, and more from trading on the anticipation of future *growth* in profitability. For pharmaceutical companies, this growth expectation usually hovers in the low double digits, just above what financial actors can expect to garner from the stock market otherwise. This produces a set of structural conditions that are inextricable from the drug pricing outcomes we witnessed with hepatitis C.

For large pharmaceutical companies like Gilead Sciences, with established products and revenue, striving for growth at the 10% clip (or more) that shareholders in financial markets expect means a near-continual hunt for new revenue streams. And, as Sunder Rajan has shown, this leads to an array of problematic strategies, from continual drug price increases to attempts to lengthen patents on existing medicines.[11] In the absence of sufficient growth, for example, Gilead turned to these strategies in its HIV business, pursuing annual price hikes as well as new patents for their treatments. Across the industry, price hikes are now almost a January ritual. At the beginning of 2019, the *Wall Street Journal* reported that pharmaceutical companies had hiked the prices of over 100 drugs by an average of 6.3%, with another round of increases expected in the second half of the year.[12] The practice is so baked into the business model that some companies have even taken it as a badge of honor to keep price increases *under* 10% per year. Then-CEO of Allergan, Brett Saunders, for example, said that he had limited price increases to under 10% per year as part of a "social contract" with patients.[13] The company later stuck to its pledge—by setting most of its price hikes at between 9% and 9.5%.

But this hunt for short-term growth also creates another problem: it reduces companies' appetite for making the long-run and risk-laden investments needed to create breakthrough medicines. Instead, large pharmaceutical companies prioritize maximizing growth for shareholders. To do that while mitigating risk, these businesses position themselves less as life sciences companies developing critical medical breakthroughs, and more as *acquisition specialists*—betting on the flow of capital in the drug development process by purchasing drug assets with the potential to bring in significant revenues. Gilead's pursuit of Pharmasset exemplifies this dynamic. Despite annual profitability of 20–30% in the 2009–2011 period, Gilead's share value *plateaued* on a perception of limited growth prospects.[14] Without the internal research pipeline to generate new growth, Gilead bet $11 billion on Pharmasset—with the anticipation that sofosbuvir-based medicines could generate many more billions in revenue growth.

On the other hand, for the smaller pharmaceutical and biotechnology ventures like Pharmasset, that often have no products or revenue, the *potential* of future growth is the lure for finance capitalists. In the summer of 2011 Pharmasset would come to be valued at over $4 billion, despite having no approved products, no sales, and having lost $330 million over its twelve-year existence.[15] This valuation was entirely based on its hepatitis C drug assets, which were anticipated to become big sellers once approved. Hepatitis C medicines in use at the time already cost upwards of $50,000. Newer treatments were expected to fetch even higher prices, and have more eligible patients. Yet the capital such valuations helped lure was not meant to bring the treatment across the finish line. Rather, for Pharmasset's financial backers, these valuations were an opportunity to make speculative bets with an end in mind—either through an IPO, a stock trade, or acquisition. Given this short-term dynamic, a small biotechnology company like Pharmasset is often seen less as a durable business and more as a *disposable* one, designed to be "exited" by its financial backers and ultimately bought out. Pharmasset, the epitome of such a business, was started with the explicit purpose—as signaled by its very name—of being a vehicle to develop assets for larger pharmaceutical companies.

Finally, financialized capital in drug development is predicated on a third key feature: the power of drug companies to capitalize health itself. The chain of speculative capital, from a small venture-backed firm to a large pharmaceutical business traded on the stock market, operates on the expectation that one day in the future buyers will be willing to pay more for better health outcomes. This expectation, in turn, rests on the power of businesses to transform predictions of future prices into a realized outcome. In other words, it is less that health systems will be *willing* to buy medicines at a given price, and more that they can be *compelled* to do so.

The power of pharmaceutical companies is thus contingent on their structural position, which lets them maintain patents and charge prices based on what the "market will bear"—and thereby is also vulnerable to political contestation and social resistance. The struggle over Gilead's pricing strategy in the three years after the launch of sofosbuvir-based medicines vividly illustrates this dynamic. In its pursuit of the growth expected by financial markets, Gilead took a territorially targeted approach. With the power of its patents, the company charged what it deemed "value prices" in financially lucrative countries, particularly in the US but also across Europe. It then licensed access to its sofosbuvir assets to low-income countries that could not have afforded anything near the "value prices" being charged elsewhere, but also used its control over patents to exclude dozens of middle-income countries from the license. Gilead's "value pricing" in high- and middle-income countries yielded significant treatment rationing—and capital accumulation. Yet this strategy, which relied on blatantly testing the upper limits of what societies could tolerate, was in turn met with resistance, as exemplified

by civil society responses—notably in the form of patent opposition—as well as governments' use of their negotiating power. Along with the entry of corporate competitors, this resistance opened spaces for public health programs in which pricing and value were more tethered to access and care, rather than the growth logics and imperatives of financialized capital.

Anticipating this deeply contentious terrain of drug pricing, Gilead tried to deploy not only its coercive political and market power, made possible by patent controls, but also a hegemonic conception of "value" that could satisfy both Wall Street and health policy elites. Through a moral-economic discourse, Gilead and the pharmaceutical lobby argued that it was a kind of duty for health systems to pay more now, to secure the economic value of better health in the future. This discourse attempted to shift the responsibility to governments—not to reduce drug prices, but to value the lives of hepatitis C patients by paying the prices Gilead was naming. To buttress this discourse, Gilead also drew on a set of valuation practices from clinical medicine, health economics, and epidemiology that quantified this future economic value of health and deemed sofosbuvir's price to indeed be "cost-effective" and "value-based." These valuation practices are viewed by many public and health policy experts as a rational way for public health systems to weigh how to most effectively allocate resources, so that more money goes to medicines with greater evidence of benefit. However, by wielding this evidence in the public sphere, Gilead appropriated the rationality of such valuation practices and attempted to turn its high prices into a new "common sense."

The attempt to frame drug prices in terms of financial value, in turn, highlights a key observation by anthropologist Danya Glabau: "Price in the pharmaceutical industry today is a highly orchestrated accomplishment with no natural referent."[16] Even as business leaders, health policy experts, and public officials search for such a natural referent—citing the costs of research or the quantified value of health—we see that the pricing of sofosbuvir-based medicines was in reality the orchestrated outcome of a financialized drug development process. The absence of some underlying fact that might serve as a natural referent is part of what makes drug pricing so hotly contested and why questions of power in its various forms must continue to be central to understanding the dominance and potential vulnerability of prevailing systems. Without political contestation, and short of alternative models of R&D financing, drug prices become tethered to the structural power and expectations of shareholders and financial markets. "Value," in this narrative of "value pricing," buttresses this structural power; in the process, this narrative elides the way value is created and extracted in contemporary drug development. Confronting these omissions reveals the possibility and importance of conceptualizing value in a different way, one that makes visible the pitfalls of the hegemonic view and legitimatizes new forms of power and models of biomedical innovation.

The Dynamic of Value: Collective Value Creation, Public Value, and Value Extraction

After the launch of Novartis's $2.1 million Zolgensma treatment, John Arnold, a hedge fund manager turned philanthropist and drug-pricing activist, took to Twitter. "Successive therapies," he wrote, "should be better, which will be used to justify even higher prices. But certainly there must be a price that is too high. 5 mil? 20 mil? 100 mil?"[17] In asking this question, Arnold was pointing out the basic challenge of "value-based" assessments under the conditions of financialized capital: each increase in drug prices sets the floor for the price of the next treatment, a dynamic which is used as a lure for speculative capitalists.

This phenomenon is not limited to hepatitis C. A group of neurologists found, for example, that while the first-generation multiple sclerosis drugs of the 1990s were priced between $8,000 and $10,000, those treatments now are priced north of $60,000.[18] In a *Wall Street Journal* piece on this study, one of the main authors observed that "These companies didn't have to price them at a lower level, because the prices for the older drugs were steadily being increased. What they're doing is feeding off each other in terms of how the prices are set."[19] The primary justification for these increases? The better clinical outcomes observed with the newer drugs.

Over time, financialization can turn the basic rationale of prevailing value assessments of treatments into almost a kind of absurdity. What would the "value-based" price have been, we might ask, for a polio vaccine? Within a decade, Arnold wonders, will we be comparing treatments with prices in the tens or hundreds of millions? This dystopic possibility signals the pragmatic and moral pitfalls of such frames of value, in that they normalize an upward spiral of prices, thrusting financial, ethical, and bodily challenges onto health systems, physicians, and patients.

In her book *The Value of Everything*, Mariana Mazzucato puts this kind of value thinking in a much larger historical context within the field of economics. She argues that at the core of economics, as conceptualized by classical thinkers like Adam Smith and David Ricardo, was a theory of value that was tied to the dynamics of production and the division of labor. In contemporary economics, however, value has become narrowly defined as the preferences of economic agents, who signal their preferences with prices in markets. Thus "price has become the indicator of value: so long as a good is bought and sold in the market, it must have value."[20] What drops from view, however, is a much more dynamic theory of value which was once at the heart of economic thinking—a political-economic analysis of how goods are actually made and produced.

Mazzucato revives and updates this theory for contemporary capitalism. She formulates a way of analyzing value as a dynamic entity that is central to the sofosbuvir story: both in terms of *value creation* as a collective process among public and private actors, as well as the *value extraction* that occurs due to financialization. Value, in this conceptualization, is not a static entity, but rather involves

questions of how value is created, shared, and distributed in the economy. This dynamic concept of value offers a counterpoint to prevailing discourses that legitimize significant value extraction under the banner of "value." "Returning value" to shareholders, and businesses as "value creators," are popular turns of phrases that pervade our thinking and direct the attention of policymakers. Thus, Mazzucato writes, "We have made it easier for some to call themselves value creators and in the process extract value."[21] In addition to unpacking the way financialization impacts drug prices, part of my empirical task was to cut through this hegemonic discourse and instead lay out the dynamic creation and distribution of value.

In Mazzucato's formulation, value is *co-created* by multiple kinds of actors, in public agencies, businesses, and civil society. A critical feature of studying value creation is the question, *For what ends?* In other words, innovation by definition has not only a rate but also a *direction*: potential new outcomes that are made possible through a novel product, market, or service. In the realm of drug development, the direction is better health through medical advances. But the hepatitis C case shows that public investments are critical to shaping this direction across the drug development process. The most prominent example is the public financing of the replicon, which transformed the possibilities of hepatitis C drug development and enabled the discovery of compounds which eliminated the virus.

To be sure, private business also created value in the sofosbuvir drug development process. However, our challenge is understanding how this private value creation occurs. Pharmasset's initial venture capitalists and the public shareholders involved in the IPO provided risk capital that enabled the business to further develop hepatitis C compounds. Gilead's pursuit of Pharmasset, in turn, required a major speculative bet and further private investments to create a curative regimen. Competing companies, like AbbVie and Vertex, also spent significant sums on hepatitis C clinical trials.

But these investments only came *after* and *alongside* critical public investments. Pharmasset, for example, was a company built on decades of public investments in nucleoside science with roots in government-funded HIV research. In its early launch phases, the company also received direct grants from the US government through the SBIR program. Later, when scientists at Pharmasset sought to improve their hepatitis C compounds, they relied on prodrug techniques—knowledge available in the public domain and the outcome of publicly financed science in the US and Europe. Through these developments, along with the replicon, the public sector co-created the market for potential hepatitis C investment and shaped the direction of this investment toward realizing potential curative medicines.

While the public sector plays this critical role in value creation, we lack policy and economic thinking that accounts for it. A conception of what Mazzucato calls "public value" would help consider and measure progress toward social goals that are pursued through an interaction between public and private actors.[22] The state, in this configuration, would see as part of its charge not only financing innovation

but also fostering a set of relationships that allow collective value creation to be directed toward these social goals—such as the elimination of an infectious disease and reinvestment of a large share of profits back into research, wages, and worker training. Prevailing policy thinking does not flow from this view. Instead, the state is relegated to the role of "fixing market failures"—such as financing "basic science"—with almost any other action deemed market "interventionism." Ironically, such pronouncements occur even as private corporations lobby governments for frequent intervention on their behalf, such as ironclad government protections for patents.[23] This setup leads to significant government failures in stewarding public value (including value that the state helps create) toward positive social outcomes. NIH, for example, does not take a stake in the companies it helps develop, nor does it garner significant royalties. The US tax code routinely allows companies to avoid taxes through loopholes, often by offshoring intellectual property that public investment helped create. The US intellectual property system grants broad patent protections, even for products that resulted from significant public investment. These examples encourage us to also pay attention, then, to how the benefits that emerge from innovation are distributed. In other words, a theory of public value needs to account for both the creation of value and how it may or may not be shared.

Under the current conceptions of "value," financialized drug development can lead to massive value extraction. Take the hepatitis C case. Between just 2014 and 2016, Gilead accumulated $46 billion in revenue from sofosbuvir, and distributed $30.7 billion to shareholders in the form of buybacks and dividends. Yet these shareholders were *not* the primary source of the risk capital in Gilead's investments in the drug development process and were even less crucial when taking the full pipeline of development into consideration. In fact, the accumulated capital for Gilead's $11 billion bet on Pharmasset came in large part from prior sales, not shareholder investment.

The flow of capital to Gilead's shareholders can best be understood through the economic concept of *rent-seeking*, in which a group or individual with special privileges (such as intellectual property claims or stock ownership) can extract a large share of wealth that would have been produced without their input.[24] Yet this extractive mode of capitalism is not unique to Gilead. Between 2008 and 2017, Lazonick found that the largest pharmaceutical companies spent *more than 100%* of their combined profits on payouts to shareholders.[25] This structure of value extraction echoes Mazzucato and Lazonick's reflection on inequality in contemporary capitalism:

> Although risk-taking has become more collective . . . the reward system has become dominated by individuals who, inserting themselves strategically between the business organization and the product market or a financial market, and especially the stock market, lay claim to a disproportionate share of the rewards of the innovation process.[26]

Beside financial actors on Wall Street, an important example of individuals occupying this strategic position are the executives of pharmaceutical companies, who—as major shareholders—garner earnings increasingly out of balance with their role in the drug development process. For Gilead's five leading executives, this meant collecting over $1 billion in earnings in the three years after the launch of sofosbuvir-based medicines. Making executives into shareholders with pivotal stakes in a company's share price has been a critical mechanism for embedding the ideology of "maximizing shareholder value" into the operations of the economy.

But this dogma of maximizing shareholder value has always itself been built on a set of economic, legal, and business myths. First, defenders of financialized drug development will claim that given the importance of the stock market for Americans' pensions, higher share prices (made possible by higher drug prices) end up flowing back to people. But such a claim runs up against the facts of unequal and diminished stock ownership—in 2019, for example, the top 10% of Americans controlled 84% of all of Wall Street's stock value, while the bottom 50% owned only 1%.[27] Meanwhile, many older citizens, even those with pensions invested in the stock market, struggle to afford medications.

Second, the legal scholar Lynn Stout, in her book *The Shareholder Value Myth*, has uncovered the ways in which corporate leaders do *not*, as is often claimed, have some fiduciary responsibility to "maximize shareholder value."[28] Reviewing case history, she shows that courts have *rarely* held corporate boards of directors liable for this purpose. Rather than being the "owners" of a company, and thus entitled to corporate earnings, Stout shows that shareholders are engaged in contractual relationships with corporations—a subset of many such relationships that corporations must navigate, such as with suppliers, buyers, and workers.

Finally, business scholar William Lazonick has demonstrated that investments in workers and knowledge creation—through wages, training, and R&D—create the conditions for long-term value creation within businesses. The irony of the ideology of maximizing shareholder value, Lazonick argues, is that the "shareholders held up as the only risk bearers do not typically invest in the value-creating capabilities of corporations at all."[29] Putting the perils of shareholder primacy in blunt terms, he says that maximizing shareholder value is "a theory of value extraction without a theory of value creation."[30] Indeed, the commitment to this dogma, and the system of drug development underpinned by it, has led to systemic crises.

The Triple Crisis of Financialization: Jeopardizing Access, Future Breakthroughs, and Public Governance

At the 2014 gathering of the American Society of Health Economists in Los Angeles, the topic *du jour*, particularly for health economists, was sofosbuvir-based treatments.[31] Dana Goldman, a health economist at USC, echoed a common view among his colleagues: "We'd love for pharmaceutical companies to come up with a treatment that cures diabetes rather than just treats it. I want to pay them enough

so it's possible they'll start working on cures rather than treatments." Lacking an analysis of financialization, Goldman subscribed to the view that rewarding the innovation system behind sofosbuvir-based treatments could incentivize more future cures. But the evidence from the sofosbuvir case belies this view. Instead, the financialization of biomedicine poses a three-fold threat. First, financial markets *penalize* the development of curative breakthroughs, even if prices are set high, because by curing people, these medicines can prevent ongoing revenue *growth*. Second, the occasional breakthroughs that *are* produced are priced at levels that pose an affordability challenge to patients and health systems. And these are intertwined with a third threat: the withering of democratic governance.

A 2018 report from Goldman Sachs, "The Genome Revolution," illuminates the threat that financialization poses to future breakthroughs. In the report, Goldman's analysts considered the potential for "one-shot cures" one of the "most attractive aspects" of medicines made via new gene-editing technologies.[32] But the author, Goldman's Salveen Richter, added a note of caution: "Is curing patients a sustainable business model?"

He had an example in mind. "GILD is a case in point," Richter wrote, using Gilead's stock-ticker abbreviation, "where the success of its hepatitis C franchise has gradually decreased the available pool of treatable patients." Though the company had made over $46 billion in revenue in the first three years of sales, Wall Street treated it like a transient sugar rush, because sales *growth* slowed and then plummeted.[33] After a peak near $120 per share in 2015, by early 2017 Gilead's market value had dropped by almost half.[34] Contrary to hopes that its high drug prices would enable the company to invest in further curative innovation, Gilead stockpiled money to acquire future treatments, while it doubled down on cornering patent protections and raising the prices of their HIV drugs.

In *Drugs for Life*, Joseph Dumit captures this dilemma. "In too many drug studies," he writes, "cures get in the way of repeat revenue."[35] A cure for HIV, for example—a medical breakthrough that could simplify treatment for millions of people around the world—would, over time, decimate a key earnings stream for Gilead. Better than cures, for the financial valuation of a publicly traded company, are recurring treatments for chronic pathologies—like lifelong treatment for HIV. "Mitigator" treatments can bring in the kind of recurring revenue and growing accumulation expected by shareholders. A *Bloomberg Business* story on Gilead's tribulations with hepatitis C captured Dumit's view: "Wall Street wants the best patents, not the best drugs."[36] The best patents, in turn, are financial assets with the most durable growth potential—which curative drugs do not provide.

In addition to *penalizing* curative medicines as an obstacle to future growth, this financialized model threatens breakthrough treatments in another way: it disincentivizes and undercuts long-run investments. As we have seen, to maximize shareholder returns, pharmaceutical businesses direct significant portions of their capital to shareholders, instead of making long-run investments in research.

And for the capital businesses do reinvest internally, a priority is placed on late-stage clinical trials, often of medicines surer to meet regulatory approval. This has produced a raft of "me-too" medicines, as businesses pursue lucrative markets by making drugs that are similar to existing treatments or represent an incremental advance.[37] To be sure, drug companies also use their stockpiled capital to speculate and acquire promising compounds. Occasionally, one of these compounds will end up being a breakthrough treatment, as sofosbuvir did. But when this financialized process does produce occasional breakthroughs, they are priced at levels that represent a second crisis: affordable access to medicines.

High prices for new medicines are rationalized as reflecting the "value" of better future health. But what they instead represent is the power of pharmaceutical companies to use their intellectual property protections to price their products at the upper bounds of what health systems can be compelled to pay. These prices are intertwined with a financialized drug development system in which expectation of higher prices for drug assets is the primary fuel for speculative capitalists.

With each progression in treatment setting the pricing floor for the next one, however, even a "value-based" price for a new medicine presents fiscal challenges for health systems. The leaders of these health systems are encouraged to "think like investors," as Birch and Muniesa put it, because paying for a given treatment *now* may optimize a "return on investment" in terms of savings and quality-adjusted life years *later*.[38] But the leaders of public health systems have a different job from Wall Street investors. When large numbers of patients stand to benefit from a high-priced medicine, as in the case of sofosbuvir, officials either have to engage in a political process to find significant new funding, use legal measures to lower the price, or make fraught ethical decisions about who can get access. Meanwhile patients' lives are left hanging in the balance.

The health systems in high-income areas, such as the US and Europe, that paid Gilead's "value prices" rationed treatment and delayed the public health planning that might have been possible if the treatments had been more affordable.[39] In countries and health systems like Australia's that took a bolder political stance toward Gilead and negotiated prices that would permit greater access, this planning began in earnest. In low- and middle-income countries, access to sofosbuvir depended on Gilead's "benevolence" in including countries in licensing agreements that enabled generic production and pricing of medicines closer to their manufacturing cost. Middle-income countries like Brazil and Ukraine were initially excluded from this licensing, so their health systems were essentially barred initially from deploying public health programs aimed at widespread treatment of hepatitis C.

To be sure, the pursuit of a lucrative market drew in competitors, as observed with AbbVie's successful entry into hepatitis C. With Gilead and Abbvie competing in an oligopoly market, lower list prices (in the range of $20,000–30,000) helped open up access in many high-income countries. Yet such price competition often

does not occur, even with multiple treatment options. Gilead dropped the price of its hepatitis C medicines, but continued with annualized price hikes on its HIV treatments—even with multiple competing HIV treatment manufacturers. This dynamic may reflect the peculiar political-economic features of a curative treatment, further illustrating the growth and accumulation logics of financialized biomedicine. One hypothesis might be that the political-economic dynamics of a curative treatment—in which Wall Street did not see long-term financial growth potential—led companies to engage in price competition (with prices still more than twenty times the cost of production) to pursue whatever sales and accumulation they could within a finite market. With "chronic treatment" assets like diabetes, insulin, or HIV medicines, drug companies have sought long-term financial accumulation and used their intellectual property protections to keep prices high for the life of their patent. In addition to Gilead's HIV price increases, for example, a 2021 paper in *JAMA* found "lock-step" price increases by manufacturers of specific classes of diabetes and anticoagulant treatments even with multiple competitors.[40]

This crisis of access and affordability is not limited to medicines for diseases affecting large populations. If drug prices continue at their current pace, new medicines even for smaller patient populations will represent a growing challenge. New "million-dollar" drugs are beginning to receive FDA approval on the basis that they present significant benefits for populations that previously had few viable options. Novartis's $2.1 million treatment for spinal muscular atrophy, Zolgensma, is one example. Some 400 gene therapies are currently in clinical trials. If even a fraction of these are approved and then priced based on the purported "value" they provide, they may drive rising insurance premiums and struggles for access in the US and around the world.[41]

The story of cancer drugs provides a preview. The mean launch price for new cancer treatments approved in 2018 was $150,000 in the US; all of them were over $100,000.[42] In low- and middle-income countries, cancer drugs are routinely priced at a fraction of the US prices but still many times the median wage in a given country. Xtandi, for example, a breakthrough prostate cancer treatment developed with major public investments and priced at $140,000 in the US, was priced at $65,000 in India, or 40 times the annual income of the average person in that country.[43] The consequences of the prices in the US are also staggering. Twenty-seven percent of insured adult cancer patients reported medication nonadherence due to cost.[44] Forty-two percent of insured cancer patients report a significant or catastrophic financial burden.[45] Oncologists have coined a phrase for this grave comorbid condition in their patients: "financial toxicity."[46]

These two crises of financialization—penalizing investment in curative medicines and making medicines unaffordable—are intertwined with a third one: the withering of public governance. With their large stockpiles of accumulated capital, pharmaceutical companies can mobilize significant political power by financially supporting political campaigns, and also through the direct influence of

corporate lobbyists on the policymaking process. But the interests of financialized capital also operate in a more subtle way, as I described earlier, by monopolizing the epistemic categories in which political struggles are conceptualized. The industry, backed by Wall Street, trumpets concepts like "risk" and "value" through marketing campaigns and also in scholarly discourses in academic fora. We saw this with hepatitis C, as many policy experts and academics came to view the $90,000 price point as a justified—and even morally good—outcome. These discourses gain their power, in part, through elision—for example, by keeping the scale of public investment and private value extraction out of view.

Through these strategies, pharmaceutical businesses attempt to make a given political-economic system—financialized drug development—into a naturalized system, free from democratic accountability to citizens and unburdened by public imaginations of alternative possible futures. Many scholars have warned of the danger of public goals being captured by private purpose; in drug development, we see this purpose being not only privatized but financialized.[47] This financial capture operates in at least two directions. On the one hand, it can the dominate the goals for which biomedical innovation might otherwise aim. We observe this, for example, in the way Gilead's "value pricing" strategy led to rationing in certain territories rather than the public health programs that materialized in others. On the other hand, this capture works by taking advantage of some of the internal tensions of the state to activate certain versions of public action on behalf of financialized capital while suppressing and denaturalizing others that could have been taken on behalf of citizens and patients. This is exemplified by the ongoing reluctance of the US government, for example, to curb intellectual property protections—even amid a global pandemic—for fear of blunting private incentives to commercialize publicly funded research.

In this conception of a multifaceted state, however, lies the seeds of alternative possibilities—a chance to imagine and mobilize a different version of what people do together through their government and publicly sanctioned courts of law. The struggle over access to treatment for hepatitis C indicated the willingness and even momentum for such action. Multiple groups—from the G7 to the European Union to the United Nations—recognized in the wake of hepatitis C that the prevailing order that produces such high drug prices needs to change. Civil society groups directly challenged patents on collectively and cumulatively produced knowledge and won in several legal arenas. Public authorities negotiated new types of deals, as in Australia and in certain US states. And despite the failure to enact such lessons in the global response to COVID-19, the massive government investments in vaccines to fight the pandemic have the potential to accelerate a push for new models of biomedical research. Public purpose, rather than financialized purpose, is within our imaginative *and* real-world reach.

TOWARD A PUBLIC-PURPOSE SYSTEM

A transition to a different model of biomedical R&D is possible—a model intentionally designed for equitable and affordable access *and* investment toward the future medicines we need. The nucleus of such a vision can be found in the struggles over the US R&D system after World War II. At the heart of these struggles was the role of government in financing and governing science and technology. Reviving and updating this lost vision can offer a guide for where we go next.

As the country sought to win World War II and to build the economy that would follow, policymakers debated the federal government's role in innovation. In a 2020 piece titled "Whose Drugs are These?" technology scholar Bhaven Sampat chronicles two competing visions that emerged from these debates, each championed by significant figures in science policy at the time.[48] Harvey Kilgore, West Virginia's powerful senator and a New Deal–era Democrat, proposed an ambitious government role: public financing across the early and applied stages of R&D, and a patent system that would protect these investments from the threat of monopoly power. Kilgore feared that without major public investments and coordination, private corporations would fail to address key problems at the speed required; he also feared that monopolists would abuse the patent system. At stake, in Kilgore's view, was the nation's technological competitiveness, as well as whether new technologies would be used in the public interest.

Yet Kilgore's legislative push in the early and mid-1940s was strongly opposed by policy leaders as well as industry and trade groups, all of whom feared that the government would crowd out and repel private investment. One of Kilgore's primary rivals would be a better-remembered figure in postwar science and technology policy: Vannevar Bush, FDR's chief science advisor and head of the wartime Office of Scientific Research and Development. He advocated a position that ultimately won out: the government would finance "basic research," with patents stimulating industry to do the needed "applied" research of turning science into usable products. Bush's primary fear was that, without profit opportunities for private industry, the massive new government investments in science would fail to be commercialized into technologies. Public policy, in his view, should solve this "commercialization problem" by providing incentives for private industry to take up the work.

In the subsequent decades, US science and technology policy has almost entirely heeded Bush's call for commercialization while ignoring Kilgore's prescient warnings against private and monopoly power. Yet the *way* this knowledge has been commercialized—increasingly under the conditions of financialized capital—has produced and exacerbated another problem: unaffordable medicines. This problem is one reason for the rising public discontent with the pharmaceutical industry, with polling in the US showing the worst favorability of any industry.[49] Reforming

this system has posed a significant challenge. The pharmaceutical lobby is among the most powerful in national capitals around the world, and particularly in Washington, DC. Defenders of the current system meet any drug pricing regulation with the claim that such moves would cause drug development to implode. After House Democrats in Congress proposed a reform bill in 2019, for example, the trade group Pharmaceutical Research and Manufacturers of America warned that a "nuclear winter" would befall the sector and endanger future medicines.[50]

Such claims are too strong. The pharmaceutical industry is significantly more profitable than other major industries, and lower prices would still leave the sector in a strong financial position.[51] But as I have shown, it is also plausible that in a financialized system powered by high prices, such regulations—without any other changes—would reduce some amount of speculative capital from entering the sector. Given the scale of the current drug affordability crisis, this trade-off may well be worth it. Consider the House bill proposed in 2019, which would give the US government negotiating power over as many as 250 high-cost brand drugs using benchmarks for drug prices in other countries.[52] The Congressional Budget Office estimated this policy would save Medicare $345 billion between 2023 and 2029, but would also result in perhaps eight to fifteen fewer new drugs over the next ten years.[53] This calculation assumes a static government which does not expand its investments in public R&D. Yet policies that only target drug prices after a medicine has launched would fail to address the larger systemic problem: the way medicines are financialized.

Kilgore's vision points to a path out of this financialized quagmire: a *public-purpose* system, in which government explicitly finances technology development and also governs the fair distribution of the rewards that flow from these investments. His 1942 Technology Mobilization Act, for example, called for the creation of a public innovation agency to lead such efforts. Contemporary activists and policy entrepreneurs offer a vision that follows in Kilgore's spirit, calling for a "public option" for drug development. In this alternative to a financialized trajectory, a public-option model would position the government to take a "full-cycle" approach to developing drugs, including financing clinical trials, and ensure they are sold at a price closer to their manufacturing cost. This public enterprise, in turn, would introduce valuable competition into the prevailing financialized model of biomedical R&D—with key governance lessons that could steer this prevailing model toward public purpose.

A Public Option for Medicines

Imagine the year 2030. Not long ago, a federal Health Innovation Institute was launched with the express intent to translate scientific advances into usable and affordable treatments for patients. The program began as a pilot soon after the end of the COVID-19 pandemic. The government's significant investments in vaccines, including clinical trials and manufacturing capacity, had proven to the public and

policymakers that an entrepreneurial state was capable of taking on sizable risks and accelerating science at a pace and in a direction that private industry alone could not have managed.

Instead of paying for high-priced medicines whose benefits flow to shareholders, the institute invests money in early and late-stage clinical trials, currently the most expensive part of R&D and the *raison d'être* for many large pharmaceutical businesses. The institute conducts clinical trials in various ways, from partnering with private companies through prizes and grants, to running the trials itself. Having taken on the risks of this process, the institute then ensures that treatments are priced in a way that guarantees a modest profit over and above the cost of making and distributing the product—either through public manufacturing corporations or through licensing to private manufacturers. In working with private manufacturers, the institute keeps its intellectual property in the public domain. Any royalties made in the process are reinvested in the institute, providing a sustainable stream of financing to complement other tax revenues.

Such a scenario is not far-fetched. It would offer a kind of "public option," as described by Sitaraman and Alstott, in which governments develop publicly financed alternatives that coexist alongside private businesses but operate with explicit public-purpose aims.[54] Public options have long been the practice in many other familiar arenas, including public libraries and the US Postal Service. In the realm of drug development, iterations of this idea have been proposed by various groups and scholars, from economist Amitabh Chandra's call for a "NASA for drug development," to the Democracy Collaborative's "public pharmaceutical sector" strategy.[55]

To be sure, there are thorny issues that would need working out—including which therapeutic and disease areas to direct investment to, the institute's organizational setup, and questions about global collaboration and access. For its first experiments, this institute might attend to areas where private innovation has failed to meet a significant health need, such as vaccines for future pandemics, new antimicrobials, or treatments for Alzheimer's disease. It could also focus on treatments where drug prices are creating acute crises—such as insulin, whose price has tripled over the past decade and led one in four people with diabetes in the US to ration or outright skip doses.[56] The institute could spearhead the development of a new insulin technology, or it could work with generic manufacturers to rapidly mobilize public production to bring patients an urgently needed affordable option. (In a preview of such an approach at the state level, in 2022 California announced a $100 million plan for public development and manufacturing of low-cost insulin products).[57] The institute could be an independent agency and draw on the expertise of other public agencies, such as DARPA and ARPA-E, that have experience in effectively managing high-uncertainty projects.[58] Though President Biden proposed an agency modeled on DARPA focused on biomedical innovation (called ARPA-H) as part of his Build Back Better agenda, whether it would operate with the principles enumerated here is an open question.[59]

On issues of global concern, such as antibiotic research, the institute could help spearhead international efforts in collaboration with other governments. Such endeavors can take inspiration from precedents like the International Space Station, which receives $3–4 billion annually from NASA and is part of a $150 billion international investment.[60] Intellectual property that arises from such investments could go toward international patent pools, like the UN-backed Medicines Patent Pool, and thereby be licensed to manufacturers around the world. This would build regional manufacturing capacity while avoiding the sharply divergent trajectories in treatment access observed with hepatitis C, and even more prominently with HIV treatments and COVID-19 vaccines. Countries could in turn tailor public health programs to their populations soon after the launch of a new technology, rather than waiting for years.

This public option would present its own challenges, including financing and maintaining political independence. Yet the benefits would far outweigh—and could even directly address—these risks. Any complaint about the price tag of this public option, for example, would need to consider current public spending on prescription drugs. The US government spent about $130 billion in public funds on prescriptions in 2015, which covered 43% of all drug spending in the country.[61] Spending even a *fraction* of this $130 billion on technology development (NIH's budget in 2020 was north of $40 billion) would yield significant savings and would allow new investment to address unmet health needs that today's financialized model neglects. And concerns over political gaming and influence over the agency and innovation policy would have to be weighed against the sheer scale of private influence that today corrodes public trust in both the political system and the pharmaceutical industry.

In sum, a public option is the most systemic way to address the many negative consequences of financialization. Rather than pursuing a variety of piecemeal reforms that could be rolled back, this strategy would develop durable public capabilities and be part of a renewed US industrial policy. To be sure, the prevailing model of financialized drug development and pricing would remain even with a public option. But the public option offers another opportunity: a proof of concept for the key principles that should undergird all biomedical R&D: mission-oriented innovation, socialized risks and rewards, collective learning and intelligence, and equitable access. With this competing public-option model, government policy could be used to steer the wider and currently financialized system toward public purpose.

Mission-Oriented R&D

Innovation has not just a rate but also a direction—the social outcomes that are made possible by new products, markets, or services. In the realm of biomedical R&D, such directions are new treatments that address significant unmet health needs. Yet the present financialized model still privileges "me-too" medicines and

therapeutic areas that are highly profitable while penalizing the development of curative medicines (as seen in the aftermath of sofosbuvir) and other treatments for conditions with low financial value. The public option would instead be clearly geared toward what Mazzucato has called a "mission-oriented" approach, in which a publicly funded innovation institute would collaborate with other public and private actors to take on important unmet health needs.[62] But governments can and should use this approach to shape the direction of the wider biomedical R&D system.

Rather than leaving the directions of innovation to be set by commercial interests, public organizations should take an active role, along with civil society and business. For example, in the US such directions could include addressing racial health inequities by taking on conditions like sickle cell disease and breast cancer. Across many industrialized countries, aging and dementia-related diseases and cancers present major public health threats. Globally, future pandemic disease and growing antibiotic resistance loom as challenges that require proactive public investments.[63] Setting these as purpose-led missions can create entirely new technological horizons while also addressing crucial health needs for patients. These missions would be defined with the goal of not only producing new technologies but also ensuring their widest and most equitable deployment for health.

Policymakers can use multiple tools to steer the hybrid public–private model of biomedical research toward such missions. In selecting potential directions, governments can help set ambitious but reachable goals that attract and coordinate investment. Governments can also provide financing through prizes and loans, using them to attract bottom-up innovation. But for such a configuration to succeed in realizing social goals, public policies would also need to ensure that the fruits of public investments are mobilized for these goals. This would require rethinking our prevailing approach to the distribution of risks and rewards in the innovation process.

Socializing Risks and Rewards

The existing system allows private shareholders, particularly of large pharmaceutical companies, to take the lion's share of the rewards from drug development, though they are far from being the primary risk-takers. Instead, the public pays twice, both for the significant investments made in the most uncertain stages of research, *and* for the high prices charged by companies at the end of the process. In this scenario, the risks of innovation are socialized (with significant public risk taking), but the rewards are privatized (accumulated by financial actors). The public-option strategy addresses this directly, by socializing the risk through investments across the technology development process, but also sharing in the rewards, through manufacturing drugs at generic prices and reinvesting any royalties that come out of the process.

This general principle can guide policy more broadly. First, governments should seek a more direct return on public investments by setting clear and

transparent conditions to ensure that technologies are used to fulfill public purposes. In the COVID-19 vaccine rollout, for example, the US and European governments failed on this crucial front. Even with significant government investments, US and EU contracts lacked basic mechanisms to protect government-funded intellectual property, guarantee delivery timelines, or prevent future price-gouging.[64] Governments could also earn direct returns via royalties and equity stakes in businesses in which they invest, though there would have to be a way to guard against the public sector adopting the same short-term and growth-oriented financial interests as Wall Street shareholders.

Second, policymakers should enact corporate governance reforms that limit disproportionate extraction of rewards by Wall Street. They can follow in the tradition of the COVID-19 legislation passed by Congress in the spring of 2020, in which the CARES Act banned companies benefiting from the bill from buying back shares.[65] Buybacks were illegal until 1982; given their role in share price manipulation and significant value extraction, they can and should be significantly limited through legislation and rulemaking. Furthermore, policymakers can reform executive-compensation rules and limit the role of share ownership in compensation packages. Senator Elizabeth Warren's proposed Accountable Capitalism Act, for example, would prohibit executives and directors of US corporations from selling their shares within five years of receiving them, or within three years of a company stock buyback, limiting the gains from short-term speculative activity.[66]

On their own, these steps regarding buybacks and executive compensation would not solve the problem of financialization. But they would be important initial steps away from the era of maximizing shareholder value. This desire has even been endorsed by corporate leaders, as exemplified by a 2019 statement by the Business Roundtable, which broke long-held orthodoxy by holding that providing value to *stakeholders* (such as communities, customers, and employees), rather than only shareholders, should be a core aim of business.[67] Yet whether a more stakeholder-oriented version of capitalism emerges will turn less on the statements of CEOs and more on whether voters urge, and political leaders craft, a new set of rules for the economy.

Learning and Collective Intelligence

One set of rules we need to consider is those that govern how we share knowledge to accelerate and direct innovation toward social goals. For example, what if a global network of scientists and medical experts could collaborate to develop and update a vaccine for an emerging strain of a contagious virus and then share this knowledge with companies and countries around the world? This is precisely the purpose of the World Health Organization's Global Influenza Surveillance and Response System.[68] For the past five decades, this network of experts and laboratories spanning 110 countries has developed the annual flu vaccine. Funded

almost entirely by governments (with some foundation support), this system is a prime example of the power of "open science."

Whereas the financialized system is organized around patents, which allow their owners to package and control biomedical knowledge as financial assets, open science models privilege shared learning and collective intelligence. If research data and processes are available under terms that enable reuse, redistribution, and reproduction, scientists can use the collective intelligence of the knowledge commons to learn from failures, successes, and unexpected outcomes. An emphasis on open science methods could more efficiently accelerate knowledge production and potentially address the declining rate of productivity observed today in the private pharmaceutical industry, with fewer approved treatments approved per billion dollars spent on R&D over the past two decades.[69]

The public option could model these open science principles. The Democracy Collaborative has suggested, for example, that an innovation institute could be chartered in a way to ensure that its inventions are patented, so that private companies do not use them to raise prices; these patents could also be maintained in a pool and licensed to companies and third parties.[70] The institute would also begin discretionary sharing of its preclinical and clinical trial data. Such data sharing would reduce redundancy, allow researchers to replicate findings, assess drugs for preliminary safety concerns, and speed the development of new treatments.

Outside of this public option, patents would still play a role in the biomedical R&D toolkit, but they could be modernized to encourage innovation and public-purpose use. Public patent policy would require a paradigm shift: to receive a patent, the applicant should have to show they have invented something substantially better, thereby incentivizing true breakthroughs and promoting competition. I-MAK has found, for example, that in 2017, on average, *each* of the twelve best-selling medicines had 125 patents. Many of these are for slight variations in manufacturing processes.[71] Such "patent thickets" stifle competition and have attracted bipartisan concern in the US Congress.[72] Rather than raising barriers to generic production, policymakers need to raise the bar for patents. For such a reform to stick, patent-granting offices would need to be funded differently. Funding for the US Patent and Trademark Office, for example, is based on the number of patents it grants, which incentivizes lax patenting standards and less competitive markets.

Another area of reform would center on university licensing policies, via which private companies are often given ownership of publicly funded knowledge without public protections on future use and accessibility. Universities Allied for Essential Medicines is a group that has long fought for fair licensing rules between universities and private pharmaceutical companies, beginning with a battle to convince Yale and Bristol Myers Squibb to permit generic production of a Yale-discovered HIV/AIDS drug—a move that led to significant price reductions in sub-Saharan Africa. Efforts like this will continue to be vital, as transformative, publicly funded tools such as the gene-editing technology CRISPR are developed at universities

across the world and commercialized by private companies for various health conditions and indications. A move toward "socially responsible licensing," such as the one spearheaded by Dutch university medical centers in 2019, can serve as a guide.

Equitable and Affordable Global Access

As the main buyers of medicines in the world, governments hold significant power to negotiate more affordable and equitable access to treatments. The public option would demonstrate this power in its fullest form, by protecting patents from being used in a financialized system and working with public or private corporations to offer new medicines at near the cost of production. While initially many if not most drugs would still be developed outside the public option, this strategy would bolster government efforts to negotiate better deals with industry, in part by providing a more visible role for the public sector in the value-creation process.

To improve access to key health technologies in low-income and many middle-income countries, US and European governments would need to promote and even mandate—particularly in health emergencies—the pooling of intellectual property and licensing to generic manufactures in these countries. Without this licensing, countries could be left with the option of unilaterally issuing a "compulsory license" to a generic manufacturer, which allows a government to override a patent holder's protections when there is a public interest in doing so.[73] Malaysia notably used this approach for hepatitis C, when it issued a compulsory license for sofosbuvir in 2017. This echoed Thailand's move in 2007, when authorities there rejected Merck's and Abbott's prices for antiretrovirals and instead approved generic versions from India, saving more than 50%. As observed with COVID-19 vaccines but also with hepatitis C remedies, the failure to take such measures sustains sharp inequities in access. In response to the absence of licensing for COVID-19 technologies, a promising and emergent strategy has been the creation of technology hubs in countries like South Africa and Brazil that are pursuing the development and manufacturing of vaccines and treatments.[74] While such efforts face challenges over intellectual property, their success could bolster local and regional innovation and production capacity outside North America and Europe and make technologies more widely accessible to low- and middle-income countries.

In high-income countries, value assessments like the ones performed by ICER and NICE would play an important role, since governments need to decide how best to spend their money on existing and new medicines. Yet such assessments would need to be differentiated from the "value" narrative advanced by the industry, which involves pushing the upper bounds of what governments and health systems might be compelled to pay even for diseases with large numbers of patients (as in the case of hepatitis C). Formal value assessments by public bodies would need to weigh incentives for private investments in drug development against the impacts of drug prices on public budgets and their consequences for treatment

access.[75] Canada, for example, announced new policy in 2019 in which public health systems would pay for new drugs based on value-based assessments but also require discounts for additional units of drugs sold past certain thresholds of market size. This policy reduces the possibility of delays in access to treatment due to fiscal pressures for otherwise high-priced health technologies that may benefit large patient populations.[76]

Such valuation assessments could also consider the public role in the value-creation process—and potentially even the extent to which a given manufacturer engages in value-extracting activities, like share buybacks. This can create the space for more robust deliberation between governments and drug companies, leading to prices and deals that are anchored in health rather than a narrow conception of value flowing to private shareholders.

When formal assessments and negotiations fail to address an access challenge, governments should pursue alternatives. The US can take a page from the licensing strategies of low-income countries. Though the US government has not used licensing as a strategy for drug pricing reductions, representative Lloyd Doggett (D-TX) has developed legislation calling for "competitive licenses" to be issued to generic companies when pharmaceutical companies fail to negotiate affordable prices with public health systems.[77] This discursive turn is welcome particularly in the American context, given that the creation of competitive markets is an aim those of differing political orientations often share, at least rhetorically.

Finally, if public officials are not prepared to take action on drug prices or patents, then they should be prepared for the fall-out for failing to cover the price of new medicines, particularly for those that can benefit marginalized populations that rely on public insurance for access. The response chosen too often early in the story of sofosbuvir-based medicines—of restricting access based on criteria with little medical basis—injures patients and harms public health.

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In his seminal work *The Great Transformation*, the Austro-Hungarian economic historian Karl Polanyi argued that market societies comprise two opposing movements—what Polanyi scholar Fred Block calls a "*laissez-faire* movement to expand the scope of the market" and a "protective countermovement" that resists the "dis-embedding of the economy."[78,79] Laissez-faire movements defend a supposed "self-regulating market," free from the rules of public governance, in which the price mechanism automatically adjusts supply and demand. In Polanyi's analysis, such a pursuit is both dangerous and mythical, because the economy is embedded in social relations and politics—processes which depend on trust, deliberation, and contracts. "The idea of a self-adjusting market implied a stark utopia," he wrote—its existence contrary to the "human and natural substance of society."

Polanyi's insights are useful as we contemplate financialized drug development and what an adequate social response might be. Share prices and drug prices are

used as metrics of efficiency, growth, and value; these are in turn used for the allocation of capital. To grease the flow of capital, the same defenders of "free markets" want governments to protect broad patent monopolies. This occurs even though public systems finance the creation of pivotal knowledge, and then are the primary buyers of high-priced medicines. Across the world, counter-movements are calling for alternative directions, in which biomedical R&D is "re-embedded" in human health and public purpose.

The politics of such efforts must consider, however, that the state—far from being outside questions of markets, drug pricing, and value—is deeply intertwined with the creation and design of the political-economic structures that shape biomedical R&D. In harkening back to the lessons of Polanyi's economic history, Block writes, "Real market societies *need* the state to play an active role. . . . It cannot be reduced to some kind of technical or administrative function."[80] The public-purpose system I have outlined in this chapter offers one possibility for such a role—a kind of blueprint some social movements are already employing in their quest for a fairer drug development system.