Introduction

The Politics of Drug Pricing and the Value of a Cure

How much should a miracle drug cost?
—*BLOOMBERG BUSINESSWEEK* COVER STORY, JUNE 2015

Price is the wrong discussion. . . . Value should be the subject.
—GREGG ALTON, FORMER GILEAD SCIENCES EXECUTIVE[1]

It is not prices that determine everything, but everything that determines prices.
—PIERRE BOURDIEU[2]

By the mid-2000s, hepatitis C had infected approximately four million people in the US and some 70 million across the world.[3] Spread through the blood, the virus elicits a reaction from the body's immune system that scars liver tissue over the course of years.[4] While many people with the virus do not feel any symptoms, a significant minority fall ill with the progression of liver disease, and some die from liver failure.[5] The treatments at that time involved interferon, a drug with limited effectiveness and noxious side effects, akin to cancer chemotherapy. Even when patients knew their diagnosis, most avoided the treatment. In this pre-COVID-19 world, hepatitis C would become the leading infectious killer in the United States, killing more people in 2014—about 20,000—than all other infectious diseases combined; it would also claim the lives of nearly 400,000 people globally in 2016.[6]

Yet a new drug, launched in December 2013, heralded relief from this suffering. The pharmaceutical company Gilead Sciences received approval from the US Food and Drug Administration (FDA) for sofosbuvir, which had produced sterling results in clinical trials. Recognizing sofosbuvir's promise back in 2011, Gilead had bought Pharmasset, the government- and venture-backed company that had developed the compound, for $11 billion—at that time the largest

acquisition price in biotechnology history. After phase III trials, a combination treatment pairing sofosbuvir with one of Gilead's compounds showed cure rates north of 90% and would receive FDA approval in 2014, just ten months after sofosbuvir itself.

Yet the jubilation for science was quickly met with contention following Gilead's next move: the US launch price of the sofosbuvir-based treatment was near $90,000. From the company's view, the price was reasonable—only incrementally higher than previous hepatitis C treatments, which exceeded $70,000 but offered far lower cure rates from longer and more toxic regimens.[7] While the drug was estimated to cost only about $100 per treatment course to manufacture, Gilead also viewed its price as representing a reward for the billions the company had spent buying Pharmasset and bringing the treatment through the final stage of clinical trials.[8] For health systems with tens of thousands of hepatitis C patients who could benefit from this better treatment, however, the price was a serious problem.[9] The health of patients hung in the balance.

The US case highlights a struggle that played out across the world between health systems and Gilead, particularly in high- and middle-income countries. In response to Gilead's prices, US state-run Medicaid programs instituted "eligibility requirements" that limited the treatments to those in the most advanced stages of disease.[10] Patients faced delays and denials. Even until 2018, for example, the Medicaid program in Texas was denying most patients' treatment requests, though the state was estimated to have over 500,000 patients with hepatitis C. Through Medicare, the publicly financed insurer for people over the age of 65, thousands of older patients were receiving the treatment. But without the ability to negotiate drug prices with companies, Medicare officials worried that the treatment—and other highly priced breakthroughs in the future—would strain the federal budget.[11] The Finance Committee of the US Senate, one of the most powerful stewards of budgets and costs in the healthcare system, paid close attention to what was unfolding with hepatitis C treatment. In July 2014, the committee launched a bipartisan investigation into Gilead Sciences and its hepatitis C pricing strategy.[12] Citing the cost of the treatment to the overall US health system and concerns over treatment restrictions, Senators Wyden and Grassley sought answers from the company on the rationale it used to set its prices for hepatitis C treatments.

In the summer of 2015, during my field research into the debate that was raging over hepatitis C drug pricing, I found myself in a policy meeting in Washington, DC, observing physicians, representatives of federal health agencies, and patient advocacy groups as they deliberated over how to realize the potential of these curative therapies.[13] Though many were concerned by the high prices charged by Gilead, they also worried that all this focus on the price was shifting attention away from the value and efficacy of the drugs.

Since their launch, the medicines had been dubbed the "$1,000-a-day pill" in the popular press. CBS's *Evening News* ran multiple prime-time stories on hepatitis C that centered on the treatment's price.[14] Even *Bloomberg Businessweek* had featured the price of these treatments on their cover earlier in the summer, with the headline, "How much should a miracle drug cost?"[15] In the view of many physicians and public health experts who had long worked on hepatitis C, this media coverage, alongside the ongoing political consternation, was diverting attention from the extraordinary potential for these new treatments to cure disease. After the decades-long wait for better treatment options for patients with hepatitis C, the attention on price was wearing thin.

Rising to address the meeting, one public health official seemed to have a rejoinder to the question posed by Bloomberg's cover story. "These drugs are of high value," they said. Citing a recent study, this person insisted, "They could cost up to $1.4 million and they would still be cost-effective!" While this official did not think the prices *should* be in the millions, they believed high prices could be justified given their curative potential. It was up to health systems to pay. I would hear this refrain—that the "value" of these medicines justified their price—throughout my research into the development and pricing of hepatitis C treatments.

From this view, health systems would be wise to pay for treatments, even at prices they might deem high, because the medicines represented a significant advance from the previous standard of care and could save the health system billions in averted hospitalizations and transplants. This position echoed the views of a powerful player in the debate. In the 2015 story accompanying the *Bloomberg Businessweek* cover, Gilead's senior executive Gregg Alton said that "price is the wrong discussion." Instead, he urged, "value should be the subject."[16]

I take a different view. We *do* need to tackle price. Prices for new medicines are reaching unprecedented levels, and creating a crisis for health systems and patients. We must get to the bottom of why this is happening. Yet questions of value—what value is, who creates it, and how it flows in our economy—are also crucial. As I witnessed first-hand in the debates over hepatitis C, particular narratives of value were used to justify higher drug prices while obscuring the dynamic way value is created and extracted in contemporary drug development.

This book thus pursues the subjects of both price and value. But rather than take up the conventional wisdom urged by Alton—that prices simply represent the value of health improvements developed by industry—I took a different approach. I examined history, tracing the dynamics of drug pricing and the notions of value underpinning the development process behind sofosbuvir-based treatments. An illuminating but underappreciated explanation emerged: the reach of finance into drug development and public health. Even as contention over drug pricing

has intensified, however, the role of financial logics and actors has been largely obscured from public view. Instead, the struggle over rising drug prices has been dominated by industry arguments about "risk" and "value." We turn to these prevailing arguments next.

RISK, VALUE, AND THE POLITICS OF JUSTIFICATION IN THE DRUG AFFORDABILITY CRISIS

In their first two years, sofosbuvir-based medicines brought Gilead Sciences nearly $46 billion in revenue, making it the most profitable drug launch in history.[17] By then, hepatitis C treatments had become part of a growing political battle over the rising prices of prescription drugs. Industry observers and health policy analysts warned that hepatitis C medicines were just our first glimpse of a wave of new drugs with unprecedented prices coming in the next decade or so.[18] In this future dystopia, drug prices ranging from $100,000 into many millions would be the new norm. Indeed, that future is already here, with many cancer therapies priced in the hundreds of thousands, and a treatment for infants with a rare muscular disease priced by Novartis at $2.6 million in 2019.

Such drug launches spawned an intensifying crisis in drug affordability and access for health systems and patients around the world. In low-income countries, many medications were inaccessible due to the intellectual property protections that allowed multinational drug companies to charge monopoly prices. Gleevec, a cancer medication, exemplified this crisis: its manufacturer, Novartis, had charged $2,200 for one month's treatment in India, before the country's Supreme Court struck down its patent claims.[19] Even high-income countries with publicly financed health systems struggled to cover new drugs for conditions like cancer, cystic fibrosis, and hepatitis C.

In the United States, with its private insurance system, high drug prices were being passed onto patients in the form of rising copayments and premiums, and a growing number of patients were having to choose between prescriptions and other expenses, like rent and food. One survey showed, for example, that three in ten patients had not taken their prescribed medications in the prior twelve months due to cost.[20] Such prices also disproportionately affect the health of racial and ethnic minorities, with Black and Latinx people more likely to ration medicine due to cost—and thereby suffer complications of chronic conditions.[21] These grim consequences led to growing calls for drug pricing reform in the US and around the world.[22]

Yet accompanying the political struggle over high drug prices has been another debate: the arguments used to justify them. This debate has formed around two central arguments used by the pharmaceutical industry. First, drug companies argue that high drug prices are a reward for the enormous costs of research and development (R&D) and the risks these investments entail; second, drug companies,

à la Gregg Alton's exhortation, defend high drug prices by pointing to the economic value of future health produced through innovative treatments.

Let us start with the first rationale. For decades, the industry has argued that the price of new drugs needs to be put in the context of the soaring costs of R&D. Since the early 1990s, the pharmaceutical industry has supported a group of economists at the Tufts Center for Drug Development who generate data to buttress this view.[23] They find that the average cost of developing a drug has escalated over the past three decades, from $231 million in 1991, to $802 million in 2003, to $2.6 billion in 2014.[24] These estimates are based in part on assumptions about the long time horizons, high rates of failure, and opportunity costs involved with drug development.

This industry argument is strongly linked to their advocacy of intellectual property protections, since patents give drug companies the pricing power they can then use, by their view, to finance risk-laden R&D. In the popular rhetoric and even legal discourses used in these debates by many policymakers, business executives, and scholars, patents are often viewed as governing a "fair exchange."[25] In this transaction, customers access the inventor's product in exchange for the investor's recouping the cost of developing that product, plus some profits to reinvest in further research.

Yet critics have argued that the industry's figures are likely grossly inflated. In interpreting the 2004 Tufts study that reported $802 million per drug developed, for example, Light and Warburton used a different set of assumptions and independent data to give an estimate approximately 25 percent of the original: $180–231 million per approved compound.[26] Based on this and similar studies, critics claim that the high prices are not reflective of R&D investments and instead represent the industry's abuse of the monopoly power granted to companies via patents.

In recent years, as this argument has come under greater public scrutiny, the pharmaceutical sector has advanced a second rationale: that prices reflect the "value" they bring to health systems and society. This narrative relies on an alluring logic: "consumers" are willing to pay more for better health outcomes, and such payment will direct innovation toward producing more "high-value" therapies. More than a decade ago, health industry consultants described this shift toward a "value-based pricing strategy" as follows: "In essence, the fundamental pricing question has shifted from 'what price do we need to charge to cover our costs and make a good return?' to 'given market perceptions of value, which products can we profitability produce?'"[27] In the case of health, however, the "market" is not typically individual patients. With prices for patent-protected medicines many times the median wage of individuals, "value" is perceived through the eyes of the primary buyers: public health systems, and in the US, private insurers.

But "value" has multiple interpretations in the arena of pharmaceuticals, with significant differences between insurers and public health systems in the US and Europe. In Europe, national health systems assess value by making a comparative

analysis between a new medication and the existing standard of care. Through "cost-effectiveness research," health systems weigh whether a new therapy adds enough benefit, in "quality-adjusted life years," for its incremental cost.[28] Manufacturers aim to price drugs within the ranges health systems are willing to pay for this additional benefit. This method of "health technology assessment" is used widely across Europe, most notably with the UK and its National Institute for Clinical Excellence (NICE). Value assessments have important merits that I discuss in chapter 4 and have been proposed by progressive reformers in the US as part of the solution to the drug pricing crisis. Yet even these European bodies have come under increasing pressure from the rising prices for new treatments, especially those that might benefit large patient populations.

In the more fragmented US system, however, with both public and private payers, pharmaceutical companies have typically been more resistant to any formal process of value determination.[29] The rising influence of the Boston-based Institute for Clinical and Economic Review and its value-assessment reports for new drugs—modeled in part on the British NICE—have many health policy experts calling for value assessment to be part of any prescription drug pricing reforms in the US.[30] But fearing that such a process will lead to pricing caps, the industry has used its lobbying power in Washington to thwart such efforts. Without institutional or legal mechanisms for assessing the benefits and prices of new medicines before approval, considerations about value center on the upper bounds of drug prices that a health system may be able to bear. These considerations of "value" are shaped by industry lobbying and marketing.

For example, one of the leading interpretations of value advocated by industry, which has migrated into mainstream policy debates, is that value is about both cost-effectiveness *and the savings* particular treatment outcomes can bring for health system payers by averting downstream disease. A fact sheet produced by Pharmaceutical Research and Manufacturers of America highlights this framing, claiming that "every additional dollar spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes and high cholesterol generated $3 to $10 in savings on emergency room visits and in patient hospitalizations."[31] According to industry leaders and even many policy experts, paying higher prices now could create "public health value" for the future—such as averted liver transplants and hospitalizations in the case of hepatitis C. Media headlines like "These Drugs Cost $84,000—and That's a Good Deal," on the typically progressive policy-focused site *Vox*, capture the attractiveness of this position.[32]

Both explanations for these unprecedented drug prices—the expensive risks of R&D and the economic value of therapeutic advances—assume that prices correlate with some underlying objective sum. Yet both abstract questions of pricing and value away from the actual contexts in which drug development occurs. Neither approach, for example, could make sense of Gilead's $11 billion acquisition of Pharmasset. Was this a research cost? The public health value of a potential cure?

Or an artifact of financial market speculation? Even if both prevailing rationales correctly explained the reasons for rising drug prices, they have troubling normative implications. For example, if R&D costs are indeed increasing, is this a justification for ever-higher prices, or more a troubling sign of the extent of waste and inefficiency in the patent-driven system of drug development, as some have claimed?[33] The "value" argument is also vexing—it would mean that some of the most vital drugs for patients and public health should by definition cost the most for health systems and patients, regardless of consequences for access.

Rather than explanations of why drug prices have come to be what they are, I see these rationales as attempts to justify the industry's power over intellectual property and pricing. My investigation into drug pricing instead seeks to illuminate the social mechanisms that produce drug prices in the contemporary political economy. To pursue this understanding, I examined the existing critiques of the pharmaceutical industry for insights. I found important lessons, but also glaring blind spots.

DIAGNOSTIC BLIND SPOTS IN THE PRICE OF A CURE

I first learned of the heated debate over hepatitis C and drug prices soon after the launch of the initial sofosbuvir-based treatments in December 2013. At the time, I was in the early stages of a doctoral program at the University of Cambridge, where I was studying sociology and political economy. My doctoral studies took place in between medical training at Northwestern University in Chicago. The delays and denials of care I was learning about with hepatitis C went against the very purpose with which I was pursuing medicine.

As a medical student, I had taken the Physician's Pledge, a modern-day version of the Hippocratic Oath which begins by stating that "the health and well-being of my patient will be my first consideration."[34] For me, at least part of practicing this pledge meant using available life-preserving technologies, like new medicines, to treat illness and take care of the vulnerable. But those taking care of patients with hepatitis C often faced a quandary. Two clinicians in the US's Indian Health Service put it well in *JAMA*: "Earlier treatment can prevent advanced liver disease, but late-stage liver disease is needed to qualify for treatment. For a clinician, explaining this circular logic to a patient can be frustrating for both parties."[35] Thousands of encounters like this one—with physicians having to explain to patients why getting treated would not be possible at the time—occurred across the US and the world.

The pledge that we take as doctors sets out an ideal. Yet by itself, medical anthropologist Danya Glabau writes, this ideal "falls short in describing the real state of things in the world, or how to fix them."[36] Caught between the ideal to which I had pledged and the material realities that patients faced, I searched for explanations. And here I was struck by the plain inadequacy of the ongoing attempts to dissect

high drug prices. When the Finance Committee completed its 18-month investigation into Gilead's hepatitis C pricing, the headline of the final report flashed across their website: "Wyden-Grassley Sovaldi Investigation Finds Revenue-Driven Pricing Strategy behind Hepatitis Drug."[37] The headline fell flat not because the charge made by the committee was not true, but because of how little it explained.

At a conference on hepatitis C a week after the release of the Senate report, I listened as one of the conference leaders, a physician and liver specialist, referred to the report with resignation: "This is just how capitalism works."[38] For some, like this physician, the contradiction between the ideal of care and the reality of drug prices needed simply to be accepted as a byproduct of the natural laws of our prevailing economic system. Yet this physician's acceptance exposed a stark blindness. "Capitalism" is an economic system created by people, organizations and institutions—not simply handed down from above. Furthermore, it is not a monolith but has various incarnations across time and space. What interested me were the specific institutional and political factors that shaped the particular incarnation of capitalism from which sofosbuvir and its price emerged.

Several incisive critiques of the pharmaceutical industry have advanced an important and by now accepted explanation for the drug pricing outcomes we see: the enormous political and economic influence of these companies. In her 2005 book, *The Truth about the Drug Companies: How They Deceive Us and What to Do about It*, Marcia Angell, a former editor of the *New England Journal of Medicine*, offered a trenchant analysis of the influence of the pharmaceutical industry in using patents to charge high prices—and spending more money on marketing than on R&D.[39] In *The $800 Million Pill*, Merrill Goozner debunked the industry's myths about R&D costs and described instead how many of our most significant medicines have come through public investment.[40] On the specific question of sofosbuvir-based treatments, the economist Jeff Sachs concluded in a piece titled "Gilead's Greed that Kills" that the US government needed to tame the company's "untrammeled corporate greed and the monopoly power."[41] These critiques bring into view a core dynamic that is fundamental to any discussion of drug prices: power.

Identifying the power of the pharmaceutical industry is important. But to understand how we have arrived at our current predicament of drug pricing requires a more complex dissection of power. This dissection involves situating the most obvious rationale for the actions of drug companies—profit maximization—in the wider social and political-economic context that shapes drug pricing outcomes. To be sure, part of this is the overt power companies can exercise through government-granted patents. Yet as I was observing in the arguments over the "value" of hepatitis C medicines, this power also functions through forming categories of thinking and frames for debate used by authorities across an array of elite fields like medicine and public policy. This evokes an array of questions. For example, what are the institutions of power that influence drug companies? And

how does this power influence drug development and public health? Mapping the machinations of the industry is a critical empirical and political task for challenging the status quo, but by itself it does not give us the systemic analysis we need for envisioning and enacting new possibilities.

THE MISSING DIAGNOSIS: FINANCIALIZATION

To share an initial set of findings from my research into the systems that had shaped Gilead's sofosbuvir strategy, in July 2016 I coauthored a short article for the *British Medical Journal*.[42] Within forty-eight hours, Gilead's executive vice president, Gregg Alton, countered with a post on the *BMJ*'s website listing a set of counter-arguments.[43] Unsurprisingly, Alton noted the risk Gilead and the wider pharmaceutical industry had undertaken on hepatitis C research and the significant value sofosbuvir-based medicines offered to society. (We later responded, using some of the evidence laid out in this book.[44]) This public counter—a post in response to a journal article—was an unusual move. Maybe, in pulling back the curtain on drug development and pricing, I had struck a nerve.

In my emerging analysis, I was coming to understand that the etiology of these unprecedented drug prices had a name: *financialization*. As elucidated by economic historians and sociologists, financialization is the growing influence of the financial sector and its imperatives over our economy and, in turn, our society.[45] In this analysis, since the 1970s the financial sector, rather than being a productive engine for investment, as it was in the postwar era, has increasingly contorted our economy around share prices, quick returns, and speculative boom-and-bust cycles, as witnessed with the 2008 global financial crash.

This book argues that the logics and institutions of finance reign supreme far beyond the financial industry; they have come to dominate how pharmaceutical businesses operate and how we price and value new medicines. Understanding this phenomenon is key to explaining why Gilead paid billions to buy a promising compound, for example, or why a medicine priced at nearly $100,000 could be argued by the industry and by many health economists to be a "good value" for society. How did finance come to have this power, and how might this analysis apply to new medicines?

Finance is, of course, critical to innovation. Writing in the first half of the twentieth century, the Austrian economist Joseph Schumpeter recognized that the new industries and technologies had not materialized on their own.[46] Their creation required credit, which provided entrepreneurs with capital for the experimentation, failure, and learning needed for innovation. He understood the source of this credit to be banks, which he called the "headquarters of capitalism." Alongside banks, however, another major source of capital for innovation existed during the postwar economic boom: the retained capital of large industrial companies. Companies like Xerox, AT&T, and IBM reinvested their earnings in large innovation

laboratories to pursue the development of new markets and products.[47] But then this dynamic changed. As the financial sector grew in the 1970s and 1980s, with budding actors such as new stock exchanges and hedge funds emerging alongside banks, the sector became less and less about long-term investing in innovation and manufacturing and more about financial products geared to short-term gains. Businesses, ranging from General Electric to Pfizer, followed suit.

At least three shifts have been implicated in the rising power of finance. First, as sociologist Gretta Krippner documented in her book *Capitalizing on Crisis*, a series of political decisions that began in the 1960s and continued into the 1980s transferred power from the government to financial markets.[48] After a significant postwar boom, US policymakers were confronted with how to allocate increasingly scarce resources in the face of slowing growth and rising inflation. Instead of making these decisions themselves, however, they increasingly decided to grant power to what they deemed "depoliticized" financial markets by deregulating interest rates and foreign capital flows to make capital less scarce. This expanded the role and ultimately the size of financial market actors in allocating capital across the economy, from homeowner loans to municipal infrastructure. The launch of the 401(k) system and Reagan-era rollbacks of financial-sector rules accelerated the power and place of financial markets in our economy.

Second, the growing power of financial markets led to an explosion in financial speculation, with "institutional investors" like pension and mutual funds exercising newfound muscle in financial markets. In the deregulated market, financial actors like banks also turned from the traditional role of taking deposits and making loans to the widespread use of "securitization," which meant turning loans into financial products which could then be packaged and traded in financial markets.[49] The prices of these "securities" were subject to the speculative whims of financial markets, in which forecasts of future earnings drove value and provided the basis on which traders could gain returns.[50] Yet this casino-like betting game could also result in boom-and-bust cycles of speculative markets, as epitomized by the global financial crisis in 2008.

Third, as stock markets turned into a paramount force in the economy, "maximizing shareholder value" became the reigning ideology of corporate governance and business strategy.[51] As Gerald Davis described in his book *Managed by Markets: How Finance Reshaped America*, this ideology focused corporations on strategies aimed at meeting financial market expectations instead of making investments in goods and services.[52] Companies increasingly pursued financial maneuvers, like leveraging acquisitions and borrowing money, to generate short-term growth. To hit Wall Street's double-digit growth expectations, for example, General Electric expanded its consumer lending and financial services businesses at a pace that outstripped its investments in making innovative electrical products. A GE executive later remarked, "We had to decide whether we wanted to be a tech company that solves the world's big problems or a finance company that makes a few things."[53]

I contend in this book that the development of medicines is far from immune to such forces and has also become deeply entwined with the rising influence of finance. Though largely overlooked in controversies over access to medicines, emerging political economy scholarship has begun to illustrate how finance has structured the pharmaceutical industry, making it more short-term and extractive.

In his 2006 book *Science Business*, for example, business scholar Gary Pisano documented how the emerging biotechnology sector of the 1980s and onward focused on monetizing intellectual property in financial markets to draw in capital, rather than using firms' own retained capital for research. But only a few businesses (like Biogen, Amgen, and Genentech) have been successful in this model; Pisano argues that the short-term makeup of much of the speculative capital behind new ventures is ill-suited for the long-term, uncertain work of converting complex science into usable treatments.[54]

William Lazonick and colleagues have focused on the effect of stock-market-driven imperatives on pharmaceutical research and development. In one paper, for example, they showed that drug companies increasingly downsize early-stage research deemed too risky, and instead distribute large sums of capital to shareholders to "maximize shareholder value."[55] Lazonick and others have also explored how biotechnology companies come to be valued in the tens and hundreds of millions—even billions—without ever having developed a therapeutic product. Such "productless IPOs" are traded on stock markets based on their speculative potential, rather than any products or revenues.[56] This structure of speculation lets financial actors trade on share price and derive financial gains.

While this scholarship provides a helpful orientation to how financial-sector imperatives can shape business strategy, it has largely "black-boxed" questions of drug pricing and value by focusing on macro sector-level data rather than the political economy of particular businesses and medicines. We need further research that interrogates the relationship between financialization and specific drug pricing outcomes and orientations of value. *Capitalizing a Cure* helps close this gap by tracing how organizational strategies and practices linked to financialization unfolded in the case of sofosbuvir-based medicines. Pursuing this account, in turn, demanded dusting off a set of analytical tools long pioneered in political economy, economic sociology, and science and technology studies, but little used in the world of public policy.

OPENING THE BLACK BOX OF PRICE AND VALUE: CAPITAL, ASSETS, AND POWER

A 2015 profile in *Fast Company*, "How Drug Company Gilead Sciences Outpaces Its Competitors—and Common Diseases," honored Gilead as one of the most innovative companies in the world.[57] "It can take up to 15 years to bring a drug to market," the piece said—"Gilead did it in two." Ignoring the fifteen-plus-year

drug development process, which involved crucial public investments, the article gave *Fast Company*'s readers a portrait of a lone, risk-taking company. The prices it can charge are cast as a commensurate reward. In the economic thinking that underlies such portraits, the power of contemporary business is the product of a "knowledge-based economy," in which novel technologies (information, digital, genomic) help solo entrepreneurs and pioneering businesses create newfound productivity and innovation. Yet an alternative view has also endured in economic thinking: that production is not an atomized activity but a social process.

In the early twentieth century, the economist Thorstein Veblen was also witnessing rapid economic change, with the emergence of industrial giants in railways, steel, and soon oil and automobiles. To many of Veblen's colleagues in economics, the power of these new corporations could be explained by new forms of technological productivity—as in many analyses of the contemporary knowledge economy.[58] In Veblen's view, however, economic power was not intrinsic to any technology or corporation. Instead, the power of new businesses rested in the means by which these businesses could control industrial knowledge within a community in an effort to accumulate capital. Veblen was concerned with *capitalization*, or the conversion of knowledge into something with future financial value. For Veblen and a line of subsequent scholars, control over industrial knowledge is not a given feature of an economy. Rather, this control is *made* by dominant economic actors through a set of social strategies and practices.

Alongside this work to dissect capital in a Veblenian tradition, contemporary scholars of biomedicine and innovation offer a lens into these control strategies in the specific realm of drug development—from the ways in which collectively developed science is turned into financial assets, to the way health itself comes to be valued in financial terms. Taking a lead from Veblen, I draw on this scholarship to glean three critical insights that help lift the cover off the black box of drug pricing and value.[59]

Innovation, Entrepreneurial States, and Capital as Control over Assets

First, Veblen conceived of economic production as a social process *derived from an array of assets in a community*. Assets can be tangible, such as material technologies, or intangible, such as knowledge. Capital, in this view, derives from the ownership and control over groupings of tangible *and intangible* assets by powerful economic actors within a given community.[60] In the context of pharmaceutical development, for example, intangible assets are things like intellectual property in the form of drug patents. In turn, the logics of pricing and value in drug development are intimately tied to the way this knowledge is produced and made financially valuable.

Akin to Veblen's concept of economic production arising in a "community," contemporary heterodox economists Lazonick and Mazzucato have described

the innovation processes that generate and make use of knowledge as "collective, cumulative, and uncertain."[61] Let us take uncertainty first. Taking risks for the possibility of financial reward is central to value creation in the economy. But while businesses typically take risks by making bets with a knowledge of probabilities, as in a lottery, innovation requires confrontation with "Knightean uncertainty." Named after the economist Frank Knight, this kind of uncertainty involves situations where the odds of any rewards are *unknowable* beforehand.[62] Building the complex technical base behind biotechnology and genomics, for example, required long-term public investments in science before profitable products could ever be developed.[63] Confronting this uncertainty is not the work of solo actors.

The *collective* nature of innovative labor is a second defining feature of innovation processes. This labor depends on multiple public and private organizational actors—from universities to financial institutions, workers to government agencies.[64] In this collective activity of innovation, public-sector organizations are critical.[65] As shown by economist Mariana Mazzucato in her book *The Entrepreneurial State*, the patient, long-term capital of the public sector—particularly in the US, but across many countries—has been pivotal in managing the uncertainty involved in developing products, from mobile phones to pharmaceuticals to renewable energy. In Mazzucato's view, this investment does not crowd out private-sector actors; rather, the state's significant technology investments "dynamize in" private capital. These public investments, in turn, allow governments to take on "technological frontiers," where overcoming radical uncertainty and technical hurdles can translate to entirely new discoveries and unforeseen business opportunities.[66] For example, this risk-taking capital has produced new general-purpose technologies (e.g., semiconductors, the Internet, gene-editing technology) from which whole new sectors of the economy (such as biotechnology) have been born.

The collective nature of innovation is also critical to the third defining feature of innovation processes: they are *cumulative*. What organizations and fields learned yesterday becomes the starting point for what can be learned today, and tomorrow. The stages of biomedical innovation, for example—which are typically expressed as basic science, preclinical research, and then Phase I through Phase III trials—illustrate this cumulative quality. This reality creates a need for committed finance across an innovation process, so that knowledge can ultimately be translated into products and markets.

This *uncertain, collective*, and *cumulative* process, then, creates a community of knowledge that can be turned into assets. In Veblen's view, economic value—in the form of capital—materializes when certain actors are able to control intangible assets (like knowledge) and tangible assets (like drugs or factories) and turn them to their advantage.[67] While assets are not a new economic phenomenon, as illustrated by Veblen's work in the early twentieth century, what is important to

understand is how contemporary pharmaceutical businesses gain and maintain control over assets. In investigating this process, science and technology scholar Kean Birch has observed that knowledge has become a pivotal "intangible asset" through various forms of political-legal rules regarding intellectual property.[68] These rules enable socially produced and often publicly funded knowledge, for example, to become "enclosed" by a single private actor. Beyond such initial acts of enclosure, private actors engage in an array of legal and financial strategies to protect and expand their control over assets. Maintaining the boundaries of asset ownership can be a fraught endeavor, however, as illustrated by the tens of millions of dollars pharmaceutical companies spend on litigation against each other in intellectual property disputes with billions at stake.[69] Assets, in other words, are constructs of the law, and the underlying politics of intellectual property.

Furthermore, Birch argues that rather than studying commodification (a preoccupation he charges fellow social scientists with) we should examine *assetization*: the transformation of something (e.g., knowledge) into a revenue-generating and tradable resource.[70] While commodities are objects that gain their value through *exchange*, Birch argues, assets gain their value through *ownership* and entail a different array of social strategies of valuation. For example, while rising demand tends to push *down* commodity prices over time as more producers are incentivized to enter a market, assets become *more expensive* as demand rises as they are more difficult to replicate, inherently or legally (via politically constituted ownership protections). Thus, the stakes over intellectual property are so high in drug development because assets have a crucial and distinctive economic meaning: knowledge is transformed into property that may yield a future income stream.[71] Control over assets, in other words, also depends on control over the future—a future with uncertain financial promise. To appreciate these financial implications, we lean on a second crucial insight.

Capitalization as Quantified and Future-Oriented Control

Veblen defined capital as a *quantified, future-oriented* form of control over assets: the value of assets is based on the expected future stream of earnings that can be derived from owning them.[72] To value these streams of earnings, business and financial actors use *capitalization* exercises in which future earnings are translated into a present value to guide decisions over capital allocation.[73] Furthermore, businesses not only anticipate capital in terms of future streams of earnings, but also in terms of whether assets will generate an *advantage* over their competitors.[74] In other words, capitalists do not pursue accumulation by some absolute register of "maximizing profits" but in *comparison* to competing businesses, sectors, and the stock market.

This dynamic of quantified and future-oriented control has been further shaped by the emergence of "maximizing shareholder value" as an ideology governing corporate strategy. From the 1970s onward, shareholders, not managers of businesses, were deemed to be more efficient allocators of capital in the economy. Scholars in law, economics, and finance advanced the notion that shareholders

could use a singular metric—share price—to direct capital toward higher-growth companies and sectors. Pharmaceutical companies came to be assessed not on their current profitability but on their potential to deliver *growth* in profits to shareholders. Echoing Veblen's observation of differential accumulation, this shareholder-oriented growth is expected to be faster than what investors and traders could make in the stock market.

"Maximizing shareholder value," in turn, has influenced business strategy across the drug development process. I particularly draw on anthropologist Kaushik Sunder Rajan's 2017 book, *Pharmocracy*, in which he elucidates the structural vulnerabilities that such speculative, future-oriented growth logics create for pharmaceutical businesses.[75] The structural force of financialized capital has configured drug companies, Sunder Rajan argues, to pursue short-term strategies to acquire growth by buying promising drug assets—a phenomenon I investigate in chapter 2 in the context of Gilead Sciences.

Such acquisitions are one of the many examples within contemporary drug development in which economic actors perform capitalization exercises—exercises that in turn serve as important windows for social analysis. Traders on Wall Street, for example, weigh what the latest clinical trial results might mean for their day's bets. A small biotechnology company, with no products or sales, considers what a promising compound might be worth to another company. These predictions call to attention the sociologist Jens Beckert's insight that actors' perceptions of the future need to take center stage in our understanding of economic action—"not only 'history matters,' but also the 'future matters.'"[76] Beckert reminds us that forecasts of the future are always contingent on what might happen in a web of social relations, which is why "capitalist competition is essentially a battle to establish and alter expectations." This battle leads to the third key insight.

Capitalization as Power and Hegemony

The two prior insights—that capital can be understood as the ownership and control over assets within a community *and* as a quantified, future-oriented form of control—converge on a third observation: *capitalization exercises reveal relations of power in society*. As several contemporary scholars have argued, methods of capitalization are far from simple pricing operations in a "natural" market.[77] Instead, as Nitzan and Bichler have detailed, capitalization exercises translate the roiling and complex interactions between capitalists and other social arenas into contingent forecasts of the future.[78] In the arena of drug development, for example, pharmaceutical companies' forecasts depend on the prices they anticipate being able to charge health systems and payers. This anticipation, in turn, relies on the relations of power between these companies and the various actors that shape drug pricing policy. As I describe at several points in the book, one way this power is readily visible is in their lobbying of government officials. But analyzing the sofosbuvir case also requires understanding a different kind of power. One of the particularly salient and puzzling features of the case is how the prices of sofosbuvir-based

medicines were justified not only by the industry but also by many policy experts, who deemed them "value-based." The concept of "value" became the dominant lens through which most other discussions of the treatments were filtered.

In unpacking the influence of this logic in the debate over drug pricing, I call on Sunder Rajan's application of the concept of *hegemony* (drawing on social scientist Antonio Gramsci) to the modern pharmaceutical industry. Hegemony, in Sunder Rajan's reading, describes not a straightforward relationship of coercive dominance but the power to establish a new "common sense" within a society at a given time. The new common sense, in this case, centered on the notion that a high price for a cure represented its value to society.[79]

In pursuing a hegemony over value, part of Gilead's strategy involved mobilizing certain epistemic practices that are used by health policy experts and public officials to "value" new treatments and most effectively allocate public budgets. Sociologist Joseph Dumit's book *Drugs for Life*, in which he uncovers a critical set of such epistemic practices, is a useful starting point for this analysis. In his tracing of postwar American biomedicine, Dumit describes a series of innovations in clinical medicine that have changed the locus of financial value in modern biomedicine. Instead of only treating "felt illness," using medicines to make sick people feel better, we now also treat "statistical illness," using medicines to reduce the risk of downstream morbidity and mortality. This potential to reduce future disease risk, in turn, has been converted into a tractable source of revenues for drug companies through the production of long-term treatments for conditions like diabetes and hypertension.

Building on Dumit's analysis, I investigate the emergence of pharmacoeconomic methods of valuing the future benefits of such medicines in financial and population-level terms. Health systems and manufacturers use cost-effectiveness studies to determine whether a medicine is good "value for money." Public health modelers calculate the "prevention value" of new medicines. Health, in this framing, is an asset whose economic value can be measured through statistical methods. Public health officials and health policy experts, in turn, increasingly use these valuation practices to "rationally" allocate budgets to the treatments with the most economic value. While many of these methods have important uses, what is crucial to unpack is how a financialized drug development process can motivate drug companies like Gilead to appropriate the ostensible rationality of these practices to justify their prices.

Gilead's position that high prices reflected the value of a cure, in turn, engendered a deeply contested politics of drug pricing. Some health systems responded by restricting access to a life-saving cure; others challenged the company's intellectual property and bargained for lower prices. Sunder Rajan's reading of hegemony as a dynamic, fluid form—one that is open to challenge—is thus also important to consider. Such a reading brings to the fore John Kenneth Galbraith's concept of *countervailing power*. In a 1952 book on the topic, Galbraith argued that the economy was not an even playing field, as imagined by neoclassical

economists.[80] Rather, some actors, such as big corporations, are able to gain and expand power, with attendant negative social and economic consequences. The only way to restore balance or change the dominant position is for other organizations to exercise countervailing power. This could be another company, but it could also be government, unions, or social movements. In the arena of drug pricing, the role of governments is pivotal as they are the main rule-makers (over intellectual property, regulatory approval, pricing regulation) and the main buyers of medicines. Civil society organizations also play an important role by challenging drug companies in different arenas of struggle, whether through pressuring governments to act or directly challenging intellectual property claims in courts. A crucial subject of investigation, then, is the extent to which the countervailing powers are activated and mobilized and how this shapes outcomes like drug prices and access to treatment.

Summing Up: Three Analytics for Capital and Finance in Biomedicine

Taking these literatures together, what can we learn for an investigation of drug pricing? Three key analytics can guide our study of drug pricing and debates over value.

The first analytic involves knowledge labor. Knowledge production in biomedicine is an uncertain, cumulative, and collective process entailing significant investments by governments, which also play a critical role in setting the political-legal rules (e.g., patents) that govern how knowledge can be translated into capital via relationships of ownership and control.

The second analytic involves financial value. Capital is a quantified and future-oriented form of control used to pursue advantage, with assets valued based on the expected stream of future earnings—a process shaped by shareholder-oriented corporate governance.

The third analytic involves power. The capitalization exercises at the heart of business strategy reveal the broader relations of power at stake in a community—including hegemonic positions but also potential countervailing powers that are engaged in social struggle.

As we examine the ways finance influenced the pricing and valuation of sofosbuvir-based medicines, I link these three analytics of capital to my particular orientation to studying drug prices, value, and financialization in this case.

A SOCIOLOGICAL ACCOUNT: THE CASE OF SOFOSBUVIR-BASED TREATMENTS

The sofosbuvir-based treatments for hepatitis C are well suited for an investigation of price and value. These treatments were launched as breakthrough therapies for an infectious disease affecting large numbers of patients, but they were also highly

priced products that challenged health systems and led to a significant political struggle. This combination makes these treatments a paradigmatic example in health policy discussions related to drug pricing and biomedical innovation. In the primary public drug pricing forum organized by the Obama administration, for example, sofosbuvir was cited repeatedly.[81] As the most profitable drug launch in history (at the time) and also a major advance for public health, these treatments were held up as a study in how innovation should work—and also how our current systems of innovation are broken. This consternation played out in full public view, ranging from the significant news coverage detailed earlier in this chapter to the launch of a Senate investigation.

This outsize influence in the public debate makes sofosbuvir a particularly salient case. My interest draws inspiration from the anthropologist Marcell Mauss, who wrote that certain cases have "an excessiveness which allows us to better perceive the facts than in those places where, although no less essential, they still remain small scaled and involuted."[82] The political conflict that accompanied sofosbuvir's pricing generated a large array of publicly available evidence—including fifteen-hundred-plus pages of internal corporate documents reproduced in the Senate report. With the broad array of evidence in this case, lessons abound about how we as a society might consider making, pricing, and valuing future breakthrough therapies.

Research Questions and Concepts of Financialization, Price, and Value

To unearth these lessons, I pursued two central questions. First, what is the influence of financialization on pricing and value in the process of biomedical innovation? This assessment of pricing and value, in turn, motivates my second question: how does financialization shape outcomes for public health and future innovation? I pursued the answers to these questions with specific concepts of financialization, pricing, and value in mind.

First, financialization here refers to a political-economic system in which the structural power of the financial sector and its logics influence biomedical innovation. Rather than offer an *a priori* definition of financialization in the realm of biomedical innovation, I traced the relationships between the financial sector and the organizational strategy of pharmaceutical businesses. I then synthesized my findings to offer a more composite description of how this political-economic system operates (chapter 4).

Second, I viewed drug prices as products of specific social trajectories that are in turn results of prior business strategies and social struggles. For example, I situated sofosbuvir-based prices in the context of the prices of previous hepatitis C medicines. I also analyzed the ways in which financial actors anticipated future prices for hepatitis C assets (and ultimately sofosbuvir) throughout the drug development process. This allows me to best account for the precise launch prices

charged by Gilead in the US as well as other major markets. My research also carries onward from the launch by looking at how health systems responded to Gilead and the subsequent prices and deals that emerged.

Third, throughout the study I considered value in two ways: in terms of the valuation practices economic actors use in a particular moment, and also in terms of the "flow" of value that materializes across an innovation process. Drawing on Veblen and work on capitalization, I delve into how sofosbuvir-based medicines are valued by financial markets throughout the innovation process in terms of their potential for future accumulation. I also trace how this future- and growth-oriented view of value colonizes representations of value in public health policy, as Gilead drew on a set of moral-economic discourses as well as valuation practices to buttress their view that high prices are a reflection of the value of future health. But in making these claims about value, Gilead and the pharmaceutical industry—as well as the many policy experts that aligned with this view—made crucial omissions that required a deeper analysis.

Here I juxtapose the narrow representation of value adopted by dominant economic actors with the systemic and dynamic view offered by Mariana Mazzucato in her 2018 book *The Value of Everything*. In her conception, the key questions in defining economic value are how "outputs are produced, how they are shared across an economy (distribution), and what is done with the earnings that are created from their production (reinvestment)."[83] Value, in other words, is not just the price that a buyer is willing (or often forced, in the case of medicines) to pay—it is dynamic. Innovation thus involves processes of what Mazzucato calls *value creation* (i.e., how new, higher-quality products are created) and *value extraction* (i.e., how the rewards from this creation are distributed in the economy and society). Fundamental to our understanding of value is thus also the role of public investment in drug development, as well as what Gilead did with the money it collected from sofosbuvir-based medicines. For many observers, the production of a curative therapy was in itself a signal achievement, indicating the effectiveness of existing innovation models. Rather than stopping with the launch of the treatments, however, I trace the innovation process forward to study treatment access for patients, as well as Gilead's decisions in financial markets after the launch of sofosbuvir-based medicines. These data complicate simple stories of valorization and allow us to consider the tensions that plague financialized drug development.

Building a Sociological Account

To answer the two central research questions, I developed a sociological account of the pricing and valuation of sofosbuvir-based treatments. Much like a clinician combining patient history with quantitative lab data to make a clinical diagnosis, I take "account" as a double entendre *à la* Stark: a set of *numbers* (such as R&D investments, revenues, shareholder payouts, and patients treated), as well as a

narrative of the innovation process.[84] Each gave the other context. This account was sociological because I took a processual view of the developments that underpinned the creation and deployment of these treatments. This involved tracing the social process from the key scientific steps that made sofosbuvir-based treatments possible all the way to the treatment-access struggles that ensued from their launch. Studying this process, in turn, involved interrogating the relationships of power between multiple public, business, and financial actors—not just the work of one drug company.

I generated this sociological account in a provisional and iterative manner, toggling between the theoretical frames described in this chapter and the data I collected. A primary methodological tactic I employed in collecting and interpreting these data was to rely on documentary evidence as my primary type of source (see the appendix for an overview of my data sources). While I interviewed business leaders and financial analysts along with scientists and public health officials, no interviews are cited in the account. In relying on documentary evidence such as earnings-call transcripts, media accounts, and corporate documents, my research illustrates that much of what I critique about financialized drug development is already said openly, in public and in reports, by capitalists themselves. This book thus follows in the tradition laid out by Joseph Dumit, who wrote that "exposé alone is not critique; one must show how the system reinforces the worst tendencies despite being conscious of them."[85] In building an account of sofosbuvir medicines, my aim is to show how these worst tendencies (such as ongoing double-digit revenue growth and the scale of shareholder value extraction) have become naturalized and assimilated into the current system—and why we should find this less tolerable and more in need of change than many will argue.

To be sure, employing such a method to studying a single drug meant that I had to draw certain boundaries around the account. First, in focusing on sofosbuvir, I could not cover the dozens of compounds that drug companies pursued but that failed in clinical development—for hepatitis C and otherwise. Some analysts, and certainly industry allies, may fret that this underplays the role of private drug development. To provide greater context to private-sector efforts, I included available quantitative data on Pharmasset and Gilead's R&D costs beyond sofosbuvir during the times in which they made their biggest bets on hepatitis C. But the larger point I make in the book is that the exercise of summing up development costs in a financialized model of drug development reveals how drug prices bear no relationship to the division and costs of innovative labor and instead become tethered to speculative stock market expectations.

A second boundary: because I focus on US-based companies in Pharmasset and Gilead, my analysis centers largely on the American case of financialized biomedicine. While the financialization of pharmaceutical corporations may have important geographic variation based on the location of headquarters—an empirical question and potential direction of further research—I link this US-focused

analysis to global consequences for treatment access. Given the enormous role that US-based public investments and private pharmaceutical corporations play in the global landscape of R&D and access to health technologies, this lens provides useful policy insights and can also generate questions regarding pharmaceutical companies in different geographic settings.

A third decision I made relates to my analysis of actors within the financial system. Instead of dissecting each individual actor, I examined groups of them—such as venture capitalists, institutional shareholders, and corporate executives—and their function within the drug development process. To be sure, each of these groups of actors has some internal variation: for example, two venture capital funds may take different approaches to risk tolerance or duration of investment. While a different book or research agenda may look at each of these groups and their influence on drug development, my emphasis was to trace the innovation process and the ways multiple groups of financial actors intersect with the process to shape individual corporations like Pharmasset and Gilead. In describing each group of financial actors (in chapter 2), I pointed to the range of possibilities typically available to them and how their strategies played out in this specific case. Mindful of these choices in my investigation, the sociological account that emerges faithfully answers the two research questions I set out to answer.

CHAPTER OUTLINES

The next three chapters follow the role of financialization in the innovation process that led to curative sofosbuvir-based therapies for hepatitis C. This sociological account starts in chapter 1, "Capitalizing Science," which chronicles the creation and of publicly funded research and its conversion into financial assets. At the center of this tale is the launch and evolution of Pharmasset, a company that emerged from publicly funded research at Emory University to develop the key curative compound for hepatitis C, sofosbuvir. Drawing on political-economic scholarship on assets and speculation, I show how the presence of financial markets as well as forecasts of growing drug prices and market valuations created opportunities for investors and traders to make significant returns in periods far shorter than the time it takes to develop a new medicine. This chapter ends in 2011 with Pharmasset's executives, now with a promising compound for hepatitis C in hand, searching for a suitor.

Chapter 2, "Capitalizing Drugs," investigates the extractive strategies that drive larger pharmaceutical companies as they hunt for growth to feed their shareholders. By documenting the history of Gilead—the eventual manufacturer of sofosbuvir-based treatments—this chapter unpacks how "maximizing shareholder value" has shifted the focus of drug companies away from life sciences research and toward the acquisition of promising and lucrative compounds. The focal point of this chapter is Gilead's $11 billion acquisition of Pharmasset in 2011. The chapter

than traces how Gilead used the lion's share of its hepatitis C profits to distribute capital to shareholders and stockpile it for future acquisitions. This financially extractive model, however, would depend on the deeply contentious question of the prices drug companies charge health systems for medicines.

The closing act in the story is chapter 3, "Capitalizing Health," which begins with Gilead setting its prices and follows the role of financialization in shaping struggles for access to treatment in the US and around the world. The chapter documents Gilead's "value pricing" strategy, whereby in high- and middle- income countries the company based its pricing of sofosbuvir-based treatments on its expectation that health systems would be compelled to pay more for a better treatment. To execute this strategy, Gilead sought to establish a *hegemony of value*, in which paying more for the value of future health could be held up as a commonsensical idea accepted by policymakers, academics, and public officials. Even as this strategy generated significant political contestation in the face of mammoth financial accumulation, the chapter ends with Gilead turning to yet another cycle of financial maneuvers involving drug price hikes and acquisitions because of a staggering dynamic in financialized capitalism: Wall Street soured on sofosbuvir-based medicines because, as curative drugs, they *eliminated the very market for growth* on which their value as assets rested.

Chapter 4, "From Financialization to Public Purpose for Health," synthesizes the influence of financialization on the pricing and value of new medicines for hepatitis C and builds momentum for alternative directions. Equipped with the evidence from sofosbuvir-based treatments presented over the previous three chapters and drawing on wider industry data, I detail how drug prices have become fastened to the expectations of extractive financial markets. This financialized system of drug development produces a triple crisis: for access, for future curative breakthroughs, and for democratic governance. To craft a pathway toward equitable and affordable access, I lay out a "public-purpose" system for biomedical innovation. Such a system would involve enacting a public option for drug development and adopting a set of principles that would steer the wider system toward intentionally prioritizing access and investment in medicines that address the unmet health needs of patients and populations. A concluding chapter foregrounds financialized biomedical research amid COVID-19 and considers the possibilities and hurdles for a transition to a world in which science can be put more fully and equitably in the service of human health.