KAUSHIK SUNDER RAJAN

Pharmocracy

Value, Politics & Knowledge in Global Biomedicine

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INTRODUCTION

Value, Politics, and Knowledge in the Pharmocracy

SAN DIEGO, 2008—I was at a life science investment conference devoted to investment opportunities in India and China organized by Burrill and Co., one of the world's leading life science investment funds. Important figures in the Indian biotechnology and pharmaceutical industries were in attendance. The focus of the conference concerned innovation in Indian biomedicine: the need for it, and the lack of it. One speaker was explicit that the biggest challenge to India becoming "innovative" was that it is a democracy. According to her, this led to a "democratic lag." The contrast was drawn to China, which happily could just foist innovation upon its population.

As I listened, I considered the market contradictions that emerged in this conversation. There was talk about the importance of India making novel therapeutics rather than focusing on the prevalent model of reverse engineering generic versions of drugs already on the market, but there was no discussion of how these novelties would be priced to be affordable to the Indian population. There was talk about building global partnerships with multinational drug companies to foster innovative capabilities among Indian companies, but no explanation of the nature of a partnership with powerful entities who are your direct competitors, in a global playing field that is anything but level. And no reflection on how it was possible to talk about innovation without talking about universities. Pricing strategies, competitive

landscapes, and enabling technologies are all fundamental market issues that were being elided, in the name of an innovation that was out there, all powerful, all ready to bestow its enormous benefits upon an ignorant, suspicious, or resistant population.

It was repeatedly emphasized by the investors at the meeting that this innovation was necessary to help the rural poor.

BHOPAL, 2011—Santosh was living in the slums near Qazi Camp in Bhopal. He was fourteen when I met him. His entire life had been lived in the aftermath of December 3, 1984: the night when Bhopal became the focus of global attention because of the deadly leak of methyl isocyanate from a factory owned by the chemical company Union Carbide. I met Santosh at a meeting of gas survivors planning a *rail roko*, an agitation that would involve their lying on railway tracks to stop trains going through Bhopal, to mark the twenty-eighth anniversary of the disaster. Many of the people at the meeting were women in their eighties, who were explaining to others the bodily techniques of lying on railway tracks: how to hold hands together, how to become flaccid when the police came so that they would find it difficult to lift the protesters, how to come back to the tracks once removed, how to congregate. After the meeting, Santosh and I walked as we talked. There was a lake nearby. It was bright green, toxic sludge. Santosh said that no water that the slum dwellers drink is untainted by chemicals and poison; all the water that their animals drink is poison.

In 2010 and 2011, the Central Drugs Standard Control Organisation of India (CDSCO) conducted site inspections of the Bhopal Memorial Hospital and Research Centre to audit three clinical trials that had been conducted there from 2004 to 2008. The hospital was set up in 2004 as part of the 1989 Indian Supreme Court settlement of the 1984 Union Carbide gas tragedy in Bhopal as a tertiary care hospital that would provide free care to gas victims. Since its establishment, it has morphed into a two-tiered hospital. While it still provides free care to victims, it is also a for-profit hospital that makes money by charging private patients who are not designated as victims. The CDSCO reports created a furor, because they suggested that victims of the Bhopal gas tragedy, who had since 1984 been denied any kind of justice or rudimentary provisions for health care, had now been made experimental subjects in clinical trials in the very hospital that had been set up as part of a court settlement to care for them. Furthermore, these were global clinical trials, sponsored by American biotechnology or pharmaceutical companies.

Hence there was a sense not just of violation, but of continued violation by multinational corporate interests.

One resident of the slums told me that he does not go to the hospital anymore, because "they do trials there, and we come out dead."[1] Satinath Sarangi, who runs a free clinic in the slums for the gas victims, subsequently described this to me as a continuation of the "circle of poison" that started with chemical companies and continues to be propagated by pharmaceutical companies.[2] He reminded me that a pharmaceutical company is just another kind of chemical company. Santosh told me, as our conversation continued, that he wants to become a biologist when he grows up, because he wants to do research that can improve the health of people like his who live in the slums.

BOMBAY, 2008—I was talking to Yusuf Hamied, the chairman of Cipla, India's oldest surviving pharmaceutical company. I asked him about the impact of World Trade Organization (WTO)-imposed patent regimes on access to medicines in India. His response: "What a silly question, Professor Sunder Rajan. What we are witnessing is selective genocide."[3]

Representations of Health

It is an obvious truism that there are investments in health across social positions. These investments are variously monetary, bodily, and affective. But what health might mean, how health might be achieved, and what imaginations of social relations and relations of production underlie various conceptions of health differs depending on institutional location, social hierarchy, and power relations. Clinical trials are thought of as benefiting humanity even as they are considered scandalous; hospitals are seen as spaces of cure but also in certain situations as spaces of death; intellectual property rights are argued for as necessary for innovation even as they are decried as being genocidal.

This book seeks to understand the political economy of health in contemporary India as it operates in relation to global biomedicine. It concerns emergent biomedical regimes of experimentation on the one hand, and therapeutic production, circulation, and access on the other. These regimes are operating in political economic environments that are highly capitalized, albeit through different mechanisms, business models, and industrial forms. In turn, these capitalized political economies foreground forms of biomedicine

that focus on pharmaceutical production, access, and consumption, rendering forms of care that are not so commodity- and artifact-driven less visible as a matter of policy or political concern. This capitalization operates at national and global scales, and is not without contestation. Arguments and considerations pertaining to value—both market value and ethical value—come to be front and center in these politics.

Further, the politics at stake is a representative politics, one whose forms and spaces are emergent and contingent, but that nonetheless operate within and in relation to structures of power and modes of production that are enduring. With their invocations about helping India's rural poor, the investors at the Burrill conference in San Diego were not shy about taking on the role of representatives promoting public health—just as Satinath Sarangi has been doing by providing free care for gas victims through his clinic in Qazi Camp in Bhopal, even as he has been at the forefront of the more than three-decade struggle for justice for the victims; as Yusuf Hamied has been doing, as a vanguard nationalist industrial leader who was one of the pioneers of the Indian pharmaceutical industry as a nationally viable industry that could reverse engineer generic versions of drugs to sell in domestic markets at competitive cost, and who in the early 2000s became a major player in global politics of access to essential medicines by selling generic antiretrovirals in African markets at a fraction of the price that Euro-American companies were selling their patented medications. Indeed, even as Santosh was aspiring to do, in his hopes of becoming a biologist who could contribute to the health of the people of his community.

And so, the democracy that investors at the Burrill conference lamented is neither an abstract philosophical concept nor simply a formal macropolitical exercise in choosing leaders; nor even just an expression of popular or community sentiment. Rather, it speaks to particular kinds of representative relationships: individuals and institutions acting on behalf of the marginalized, the vulnerable, or the disenfranchised in the cause of a more public health. But they suggest radically different conceptions of how health, value, and politics might be conceptualized, in and of themselves and in relation to one another.

While I was in Bhopal conducting research on clinical trials conducted on gas victims, I interviewed an oncologist who was at the time running trials on forty cancer patients, many of whom were gas victims. We were sitting in his outpatient office. He pointed to an old man sitting hunched next to me and said, "Look at him. He is a gas victim. He has stage IV pancreatic cancer. Either I enroll him in a clinical trial to give him experimental medication, or

he dies."[4] The image of that scene has stayed with me, of a man whose only chance of living was to be on experimental medication. But what I remember most is not the man himself, but rather the pointing finger of the doctor—directed at a dying man sitting in front of him, as he talked about that man to a stranger in English, a language he could not understand. He was pointing not just to a dying man, but to the situation of treating gas victims as their tissues turned malignant, in a context that has been marked by a failure of both health care and the law for over three decades. The doctor was engaging simultaneously in experimentation, therapeutic intervention, and representation, even as he was involved in a deeply politicized situation that had already been rendered scandalous.

How do we think about value that emerges here, in such spaces and through such relationships? How do we think about the politics that emerges here? How do we think about the health that emerges here? How do we think about the democracy that emerges here? I ask such questions by following ways in which health, value, and politics are constituted globally, in and through speculative metrics of value established on Wall Street, or pharmaceutical corporate lobbies in Washington, DC, or through local, national, and global civil society advocacy around health issues as they play out in high courts in India, in the calculations of brokers in clinical research located in Seattle and Hyderabad, North Carolina, and Northern Andhra Pradesh, in the investments of Indian capitalists with nationalist inheritances attempting to be global health players, in trade negotiations happening behind closed doors within bilateral and multilateral forums, in the pages of public health journals, or in legislative debates in the Indian Parliament. These are questions of pharmocracy.

Pharmocracy

In early 2005, the Indian government passed two consequential pieces of legislation for the pharmaceutical sector. Both involved bringing national laws in line with global regulatory frameworks, a process referred to as harmonization. One involved an amendment to Schedule Y of India's Drugs and Cosmetics Rules of 1945, in order to harmonize guidelines for the conduct of clinical trials with those mandated by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the purpose being safe, efficient, and ethical processes for the testing, approval, and registration of drugs for market. The second change was to India's patent laws to make them compliant with the mandates

of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, enshrined under the aegis of the World Trade Organization (WTO), which would involve a radical amendment of India's 1970 Patent Act. These "global" frameworks were both Euro-American ones, and the term *harmonization* suggests their normative value and benevolent nature.

This book argues as its point of departure that in fact such policy moves are not about harmony as much as they are about hegemony. *Pharmocracy* is a term I coin to refer to the global regime of hegemony of the multinational pharmaceutical industry. It describes the ways in which the Euro-American research and development (R&D)-driven pharmaceutical industry operates to institute forms of governance across the world that are beneficial to its own interests. I argue that the global harmonization of clinical trials and intellectual property regimes must be understood in terms of this expansion of multinational corporate hegemony. Third World national regulations are now being instituted to facilitate First World corporate interests. This has consequences for state policy, industrial competitiveness, and public health that materialize in specific ways in different national contexts.

The policies that India implemented in 2005 could be interpreted in radically different ways. An interpretation that emphasizes the harmonic aspects of these policies would highlight their social benefit. After all, a strong regulatory environment for the conduct of clinical trials is one that would provide adequate protections to individuals subject to potentially risky biomedical experimentation. Equally, an environment that strongly protects intellectual property is seen as a spur to innovation, providing monopolistic protections that are essential to incentivize the high-risk, capital-intensive venture that novel drug development is.[5] Meanwhile, an interpretation that focuses on the hegemonic aspects of these changes would recognize the perversity of synchronous legislation that constructs India as a global hub of clinical experimentation at the same time as it renders access to medicines potentially more difficult.

What are the logics, forces, and relations of production that allow us to make sense of this hegemony that is naturalized as harmony? This could simply be seen as the naked exercise of power by corporations with global reach and influence, cynically manufacturing ethical justifications for their profit-driven actions. But that still begs the question: Where does their power come from? Through what kinds of institutional and political mechanisms does it act? And how is it naturalized, such that it can be portrayed as the story of an industry pushing for more innovation and acting with ethical conscious-

ness? Answering these questions involves understanding the nuanced notion of power represented by the idea of hegemony.

As Antonio Gramsci emphasized, hegemony does not imply a simple relationship of coercive dominance.[6] Rather, it involves a contestation for the "common-sense" of a society at a given moment in time. Gramsci uses "common-sense" to allude to naturalized sensibilities about politics, economy, and culture that prevail within social formations under given historical situations. These sensibilities develop within the context of prevalent modes and relations of production, of structures of political economy. Following Gramsci, it is worth asking: What are the structures, situations, and sensibilities that give shape to this moment of policy harmonization in India? Whose norms are being established, at whose expense? Within what kinds of power hierarchies do these policies operate? Through what regimes of governance are they instantiated? And what might that tell us about global pharmaceutical production, circulation, and consumption today?

Acknowledging the power of the multinational pharmaceutical industry is important, but understanding its hegemony involves moving beyond simple explanations grounded in a purely cynical reasoning of their actions. To be sure, pharmaceutical corporations—and not just large Euro-American ones but also smaller, nationally located, Global Southern ones—are strategic actors involved in profit maximization, influencing state regulation, and manipulating public perception to their advantage. Mapping their machinations is an essential empirical and political task. But pharmocracy is constituted in more complex ways than merely rational, strategic, or cynical action on the part of corporate actors. I argue that we must additionally understand the mechanisms by which health gets appropriated by capital, in order to instantiate forms of political economic value that are dictated by logics of capital; how these logics of capital materialize through regimes of governance; and how they are contested and rendered political. In the process, the notion of health itself as it gets constituted in relation to emergent forms of experimentation and therapy comes to be at stake. Health is no longer just an embodied, subjective, experiential state of well-being or disease; it can be abstracted and grown, made valuable to capitalist interests.

One part of the task of understanding pharmocracy then is to elucidate the political economy of the appropriation of health by capital. At stake here is a conceptualization of value. The complementary part of this task is to recognize that logics of capital are not seamless. They materialize differently in different places and times through different forms of capitalism and often

consequent to deep contestation. At stake here is a conceptualization of politics. Undergirding and articulating forms of and relations between value and politics are ways of knowing, and questions of what kinds of authorities are vested in particular ways of knowing. At stake here is a conceptualization of knowledge in its interactions with value and politics. These conceptualizations cannot occur in the abstract. They have to emerge out of concrete empirical substance: historical trajectories, critical events, institutional structures, political economic formations. The moment of synchronous policy harmonization in relation to experimentation and therapeutic access in 2005 in India provides a useful starting point in this regard because it reflects major shifts in the political economy of global biomedicine happening along two tracks.

One concerns the harmonization of the regulation of clinical trials, which are required to certify a new drug molecule as safe and efficacious for the market.[7] This set of practices serves in its rationale as a regulatory watchdog to prevent the market from being flooded with unsafe or spurious medication.[8] In the United States, the clinical trials procedure is an elaborate one, conducted in a number of stages and contributing to the immense time, risk, and expense of the drug development process. First, there is preclinical toxicological testing of a potential new drug molecule. This is usually performed on animals, in order to determine whether the molecule being tested is safe enough to put into a living system. The second stage is dosage studies, designed to come up with a metric for the dose of the drug to be administered. Predictably, the efficacy of a drug increases with its dose, but so too does its toxicity; the aim is therefore to find an optimum range within which efficacy is maximized without too greatly compromising safety.

If the drug is too toxic when tried on animals, the trial will not proceed any further, but if acceptable dose ranges can be determined, the third stage is a three-phase trial in humans. Phase 1 trials are conducted on a small number of healthy volunteers to test the drug's basic safety, since drugs that seem safe in animals may still show adverse effects in humans. Phase 2, which serves as a bridge, involves larger, scaled-up efficacy and safety trials on as many as a few hundred subjects, who may be either patients or healthy individuals. Phase 3 involves large-scale randomized trials on several thousand people, usually patients suffering from the ailment for which the therapy has been developed. These trials are frequently coordinated across multiple centers, increasingly on a global scale.

The sponsors for trials are generally biotechnology or pharmaceutical companies, since drug development in the United States and most other parts

of the world is undertaken largely by the private sector. Universities and publicly funded laboratories play a major role in the early stages of discovery—the identification of potential lead molecules and the conduct of preclinical tests—but the institutional structure of drug development is such that they increasingly license promising molecules to corporations that take them through clinical trials. These later stages of drug development have come to be significantly privatized over the past forty years. According to the Healthcare Financial Management Association's newsletter, "[In the late 1970s], 80 per cent of clinical research trials were conducted through academic medical centers. In 1998, estimates indicated the number of [these] centres as investigator sites had dropped to less than half" (Jones and Zuckerman 2007). This means that the biomedical and experimental rationales for clinical trials are entwined with the market value these companies see in the drugs that eventually get developed, and with the market risk that attends the drug development process. The increasing complexity of clinical trials over this period has however meant that it has been difficult for pharmaceutical companies themselves to manage them, leading to the emergence of an entirely new sector devoted to the management and administration of clinical trials. These companies, known as clinical research organizations (CROs), are now an integral part of the overall biomedical economy.[9]

This is the context in which to situate the ICH as a multilateral institutional framework to govern the global conduct of clinical trials. It was initially established in 1990 as a conference between pharmaceutical regulatory authorities in the United States, Europe, and Japan to devise uniform guidelines for the conduct of clinical trials and their evaluation for drug approval to market.[10] While this was an attempt to ensure ethical clinical trials conducted in accordance with what is known as good clinical practice, it must also be seen in the light of this broader emergent trajectory of the privatization and globalization of trials and the concomitant actual and potential expansion of pharmaceutical markets for the Euro-American industry.

The second track along which major shifts toward harmonization/hegemony in global biomedicine has occurred concerns the regulation of intellectual property rights, specifically drug patents. Current regimes that govern patenting pharmaceuticals emerged out of structures involved in the regulation of global trade, specifically the General Agreements on Tariffs and Trade (GATT), a post–World War II multilateral agreement. Seven rounds of negotiations under GATT occurred between 1949 and 1979. The eighth round (referred to as the Uruguay Round) commenced in 1986 in Punta del Este, Uruguay. It included 123 countries and deliberations continued for the next

eight years, leading eventually to the establishment of a new multilateral regulatory organization for global trade, the WTO, in 1995. The Uruguay Round departed from all previous rounds by bringing intellectual property into the purview of free trade negotiations for the first time. This was enshrined in the TRIPS agreement. Hence, while it is a trade regulatory authority, the WTO's significance lies in its power to enforce uniformity in intellectual property regimes across its member nations.

At its simplest, TRIPS enforces regimes that approximate those already prevalent in the United States and Europe. In the case of pharmaceuticals, this entails the establishment of product patent regimes by all member nations of the WTO. Before becoming a signatory to TRIPS, India operated under a Patent Act passed in 1970 that allowed only process and not product patents on pharmaceuticals. This meant that one could not patent a drug molecule itself, only its method of manufacture. This was a spur to India's local drug industry, which developed expertise in reverse engineering generic versions of medications patented in the West. It also led to a market terrain that allowed for free market competition in drugs, as opposed to the monopolistic terrain of patented medication prevalent in the West. Consequently, drug prices in India since the 1970s have been among the lowest in the world (Chaudhuri 2005, 53–58). Under TRIPS, India had to relinquish its process patent regime and replace it with one that allowed patents on drug molecules. It also had to extend the duration of patent validity, from seven years as stipulated in its 1970 Act to twenty years, the same period as exists in the United States. The new patent laws therefore instituted patent monopolies of the sort prevalent in the United States and Europe. As a less developed country, India was allowed a ten-year transition period to modify its laws. This meant that Indian laws had to be TRIPS compliant by 2005, by which time any drug developed after 1995 would qualify for a twenty-year product patent in India. Any drug developed before 1995 would however still only be eligible for a process patent as under the 1970 Act.

This new patent regime, enshrined in law in 2005, would have implications for India's largely generic drug industry. But there was also concern about its implications for drug prices in India, which over the previous three decades were largely controlled through free market competition. Like the United States (but unlike most European countries, or indeed most other countries in the world), India does not have a system of nationalized therapeutic access except for central government and defense employees, and its state regulatory mechanisms for controlling drug prices have proven inconsistent. Hence, the control of drug prices in India since the 1970s, while

extremely successful, has almost entirely been a function of free market competition in generic drugs. Meanwhile, TRIPS compliance on India's part would have potentially beneficial implications for that section of the global pharmaceutical industry that depends upon patent medications for revenue generation. This includes companies that are mostly Euro-American and multinational and that have based their business models on R&D into novel therapeutics (and are therefore referred to as R&D-based companies). Indeed, this industry lobbied powerfully to ensure that intellectual property would come under the purview of Uruguay Round negotiations in the first place.[11]

The trajectories of harmonization/hegemony that resulted in the legislative changes in India in early 2005 therefore concern two simultaneous movements of global agreement and compliance, those of ethical regimes on the one hand and of intellectual property regimes on the other. The harmonization of clinical trials regulation facilitates the outsourcing of trials away from the United States and western Europe to parts of the world where they are cheaper to perform. Meanwhile, the 1970 Indian Patent Act, in allowing for a strong national pharmaceutical industry, squeezed the multinational industry out of the country; but now the multinational, R&D-driven industry can enjoy monopoly protection on its patented medication in India, which emerges as a potentially lucrative market to return to (albeit with limits, as I elaborate in chapter 1). Thus the legislations of 2005 allow experiments to travel (to use Adriana Petryna's [2009] phrase), even as they allow patented medications to travel.

The harmonization of clinical trials and intellectual property regimes are both a function of logics of global capital touching down in India. However, the contestations around the kinds of hegemony they represent would come to develop through different forms of politics, within distinct institutional spaces and adopting different discursive modalities running in parallel. Issues concerning clinical trials have been rendered political largely by means of publicity around the ethical imperatives underlying the proper conduct of trials and the often scandalous failure to conform to such ethics. Those concerning access to medicines meanwhile have been significantly judicialized, such that the constitution of the political has tended to happen largely in and through the courts.[12] I am interested in each of these biomedical domains and political trajectories in their own right, but also in their confluence, which sees the opening of borders for clinical experimentation at the very moment that access to essential medicines has become potentially more difficult through the institution of monopolistic patent regimes. It is in thinking about these two domains together that one can conceptualize broader

structures of global pharmaceutical political economy. What interests me is precisely the fact that in the same place (India), at the same time (the 2000s), in the same industrial sector (concerning pharmaceuticals and health), one can have such different trajectories of political contestation, which intersect and interact with globally hegemonic movements in political economy.

This is the empirical conundrum that allows me to enter into a further discussion of how I conceptualize the emergent phenomenon of pharmocracy. This is a complex phenomenon, operating across scales, locales, histories, and events. I do not wish to present a simplified picture of this phenomenon for the sake of analytical clarity; but I also do not want to allude to the massive complexity of this phenomenon without a concerted attempt to unpack it.[13] This will necessarily be partial, following certain threads that I feel are significant, and focusing largely on Indian events and circumstances. But through a multiplicity of such partial perspectives, juxtaposed and set in historical, geographical, epistemic, and sectoral relationship to one another, I hope to generate elements of a broader and more comprehensive structural elucidation of contemporary biomedicine, contemporary capital, contemporary globalization, and contemporary Indian politics.

I enter into an empirically grounded analysis of pharmocracy through the case: significant events in India that have structured terrains of global biomedicine even as they highlight elements of that terrain. The two cases that are central to this book concern clinical studies of vaccines against human papilloma virus (HPV) infection conducted in the Indian states of Andhra Pradesh and Gujarat (the focus of chapter 2), and patent disputes in India around an anticancer drug, Gleevec, developed by the Swiss pharmaceutical company Novartis for the treatment of chronic myelogenous leukemia (the focus of chapter 3). Alongside that, I unpack the critical concepts of value, politics, and knowledge, to show how complex and multifaceted each one is. I next elaborate these two parallel routes through which I elucidate elements of pharmocracy as they have materialized in contemporary India.

Elements of Pharmocracy (1): A Tale of Two Trials

The year 2005 saw the coincidence of critical pieces of legislation being passed in India in the domains of clinical trials and intellectual property rights respectively. These changes must be located within larger trajectories and contexts of global harmonization/hegemony that facilitate capital flows. How does one think of the relationship between these *longue durée* institutional reconfigurations and the particularity of a legislative event? Or more

simply: how might we see structures of pharmocracy through the lens of these esoteric and coincidental regulatory moments?

One way I do so is by focusing on two significant events that played out over a longer time horizon (months and years) rather than a single moment of policy formulation. The first event concerns a scandal that erupted consequent to the death in 2010 of seven teenage girls who had been enrolled in a clinical study of vaccines against HPV, developed by the American multinational company Merck (whose vaccine was called Gardasil) and the British multinational GlaxoSmithKline (which developed a comparable counterpart, Cervarix). The second concerns the Indian Patent Office's denial in 2005 of a patent on the anticancer drug Gleevec, developed by the Swiss multinational pharmaceutical company Novartis, and the long judicial appeals and judgments that followed in Indian courts.[14] The former case exemplifies the politicization of clinical trials in India through public scandal, while the latter exemplifies the judicialized politicization of intellectual property rights and issues concerning access to essential medicines.

The scandal of the deaths of seven girls in the HPV studies unfolded as follows. The new vaccines were considered revolutionary advances in the prevention of cervical cancer, for which HPV is a primary causal agent.[15] Phase 3 clinical trials for these vaccines had already been conducted (though never in India), so these were not studies to demonstrate the safety and efficacy of the vaccines. Rather, they were demonstration studies being conducted by the Seattle-based Program for Appropriate Technology in Health (PATH), a global health nonprofit whose major donor is the Bill and Melinda Gates Foundation, in collaboration with the Indian Council of Medical Research (ICMR), which is the apex public body for the formulation, coordination, and regulation of biomedical research in India. The purpose of the studies was to consider inclusion of these vaccines in India's national immunization program. It could not eventually be established that the girls had died because of the vaccines, but the controversy that arose subsequent to the deaths provided an impetus for civil society mobilization against unethical clinical trials in India.

The second case I discuss relates to Gleevec, a revolutionary treatment for chronic myeloid leukemia. It directly targets the protein *bcr-abl*, known to cause the cancer. Therefore it provides a more targeted, less dangerous therapy than the possibilities that had existed earlier (either treatment with interferon or bone marrow transplantation). In this regard, Gleevec provides one of the earliest examples of rational anticancer therapy that directly addresses the cause of the disease and not just the symptoms of out-of-control cell

division.[16] The basis of the Gleevec patent denial in India was a public health flexibility incorporated into the amended, WTO-compliant 2005 Patent Act, which prevented what is known as pharmaceutical evergreening. Evergreening is a common practice in the United States and Europe, whereby a patent holder on a drug modifies it slightly as it approaches the end of its patent term and claims a new twenty-year product patent for the new drug that is thus produced. The Indian legislation by contrast included a provision under Section 3(d) that prevented a patent on a modification of an already known substance unless it conferred significantly enhanced efficacy on the prior molecule. The core molecule that would subsequently be developed by Novartis, imatinib, was patented in the United States and Canada in 1993. A crystalline salt isoform of this molecule, β-imatinib mesylate, was the subsequent marketed iteration of this molecule for which patent protection was being sought in India. It was determined that this was not a new molecule, simply a modification of an existing patented molecule, which came under the purview of the 1970 Act since it had already been patented prior to 1995 and hence was not eligible for a product patent. Novartis disputed this denial by embarking upon a seven-year legal battle, first in the Madras High Court (2006–2007) and then in the Indian Supreme Court (2009–2013). It lost both cases and the denial of the Gleevec patent stands in India.

What was at stake in the legal adjudication of the Gleevec patent was not just the patentability of a single drug, but the very question of how the new Indian patent legislation would be interpreted, especially as intellectual property rights had to be balanced against considerations of public health. The 2005 Act came to be rendered an interpretive matter, even as the politics of intellectual property and access to essential medicines came to be judicialized. Indeed, subsequent to Gleevec becoming a subject of legal contestation, a slew of drugs have had their patent status questioned in India through judicial and quasi-judicial appellate procedures. The law has provided a terrain by which intellectual property rights have become politically contestable. Meanwhile, following the HPV vaccine controversy, the capacity building for global clinical trials that had been envisaged in the 2005 Schedule Y amendments has come to be mired in controversy and scandal, as further cases of possibly unethical clinical studies have come to light and the general absence of adequate regulation of experimentation on human subjects has been questioned. This controversy has become a nodal point around which the conduct of clinical trials in India more generally has come to be politicized, largely through the register of public scandal. At the same time, the gendered dimensions of biomedical intervention came to be especially evident

through this case, as connections were explicated between emergent regimes of clinical research and longer histories of reproductive politics.[17]

Just as the ways in which the two cases have become politically contested have been different, so too has the configuration of actors involved in each.[18] The Gleevec case saw Novartis pitted against a host of Indian pharmaceutical companies that had started manufacturing generic versions of the drug; the patient group Cancer Patients Aid Association (CPAA), which was involved in procuring generic medication and subsidizing its availability to poor cancer patients; an Indian legal advocacy group, Lawyers Collective, which represented CPAA throughout the legal trajectory of Gleevec; and the Access to Medicines and Treatment Campaign of Médicins sans Frontières (MSF), which had been established with Nobel Peace Prize money in 1999 and emerged as a major global advocate for affordable medication. These legal actors were joined by other civil society actors, especially HIV-AIDS groups in India and global civil society groups involved in battles around access to knowledge and access to medicines, in the terrain of popular and policy advocacy around Gleevec.

Meanwhile, mobilization against the HPV vaccine studies was initially orchestrated by feminist groups, including the All India Democratic Women's Association, which is affiliated with the Communist Party of India (Marxist), and Sama, an advocacy group for women and health based in Delhi. They joined together with medical ethicists, people's health movements, and advocates concerned with the proper regulation of scientific and medical activities in India. It was less clear in this case who the adversaries were: even though the vaccines in question belonged to Merck and GlaxoSmithKline, their responsibility for the studies seemed to have been outsourced along with the vaccine itself. Questions were asked of PATH, which was notably absent in answering any of them. Much of the immediate ire therefore ended up being directed at the Indian state, specifically the ICMR. If the Gleevec case targeted the multinational corporation as the hegemonic global capitalist adversary, the HPV case showed how difficult identifying such an adversary could be in situations where global capital flowed through dispersed and multiply outsourced brokerage economies operating under the sign of public-private partnerships.

I elaborate upon the controversy surrounding the HPV studies in chapter 2 and upon the Gleevec case in chapter 3. These speak to two distinct meanings of *trial*, one biomedical and the other legal. The first is concerned with movements of pharmaceutical clinical trials and concomitant politics consequent to their progressive privatization and globalization, while the second refers

to the judicialization of pharmaceutical politics, which describes the playing out of politics of access to essential medicines in the courts (see Biehl and Petryna 2011).[19] I situate these in relation to a third, everyday use of *trial* to describe any kind of problem, difficulty, or trouble, in the sense of the structure of constitutive crisis under which both the Euro-American R&D-driven pharmaceutical industry and the Indian generic industry operate. Taken together, the HPV and Gleevec cases become emblematic of and signify a broader political terrain in their own right, and are therefore events that function beyond themselves.[20] They demand conceptualization that goes beyond just pointing to the contingency of their own happening, and allow for a thicker insight into the structural trajectories informing the legislative moment of 2005 while also signifying this moment as a site for the theorization of value, politics, and knowledge. But what do these terms mean, and what are these structural trajectories? I next discuss how I analyze value, politics, and knowledge in this book. This involves disaggregating them into multiple registers through which they operate, and thinking about the articulations and contradictions between these registers.

Elements of Pharmocracy (2): Theorizing Value, Politics, and Knowledge

This book traces the hegemonic structures and operations of pharmocracy. One of the nuances of Gramsci's notion of hegemony is that while it refers to a state of (naturalized or legitimated) domination, it is fluid. Hegemonies can be established, contested, overturned, or reconfigured. Battles over hegemony constitute politics, while politics comes to be the means of establishing hegemony. I argue that the establishment of regimes of value becomes a means through which hegemonies can be naturalized or reconfigured, such that value itself becomes the ground upon which further politics plays out. Value and politics become mutually constituting and reinforcing. Further, questions of knowledge often come to be at stake or mediate various articulations of value and politics. Yet none of value, politics, or knowledge is a singular thing, and each requires disaggregation and conceptualization in its own right.

Certain elements of value, politics, and knowledge have emerged as constitutive to contemporary global biomedical economies as they have materialized in India. I consider value in four registers: as an abstraction that has material consequences; as surplus value for capital; in terms of norms and ethics; and as an antinomy, something that is in contradictory relationship

to itself. This in turn leads me to think of five sites through which value in all of its registers comes to be explicitly articulated through and as politics: (1) the speculative value of financial capital (chapter 1); (2) the bioethical value that underlies the establishment of good clinical practice for biomedical experimentation (chapter 2); (3) the constitutional values that underlie modes of judicial interpretations of intellectual property law in India (chapter 3); (4) philanthropic values that rationalize corporate monopoly (chapters 4); and (5) postcolonial values that contest Euro-American corporate and state hegemony through both market and state intervention (chapter 5).

Additionally, I consider politics in terms of six emergent forms of and spaces for representation:

1 the conjuncture of policy harmonization as creating openings for flows of global capital and for political mobilizations of global civil society around access to essential medicines and against unethical clinical trials (as summarized in this chapter and elaborated through the HPV and Gleevec cases in chapters 2 and 3);
2 logics of financialized capital and the spaces of crisis that they create, leading to structural contradictions requiring political reconfiguration of multiple sorts, including more intense forms and strategies of financialization (chapter 1);
3 civil society advocacy as activated and mobilized through scandal (chapter 2);
4 judicialization and the fight to make patents incentivize the public good (chapter 3);
5 competing forms of social responsibility, as articulated through corporate philanthropy and as demanded of the state (chapter 4); and
6 corporate alliance making with civil society groups for access to medicines in the context of imperialist geopolitics (chapter 5).

Some of these political forms establish hegemonic modes and relations of production, while others contest this hegemony.

Finally, I think through the ways in which articulations between value and politics are mediated by knowledge, which itself is neither pure nor static. Rather, knowledge gets appropriated into different domains and to various ends, rendered instrumental, serviceable, or commodified as it moves across domains and geographies. In other words, knowledge can be mobilized in a variety of ways to configure value, politics, and their relationships; in the

process, forms of knowledge can themselves be coproduced with those of value and politics. Some of the manifestations and mobilizations of knowledge that concern me the most in this book are

1 the actual kinds of scientific and medical knowledge required in drug discovery and development, ranging from the organic synthetic chemistry required in much small-molecule drug manufacture to the pharmacological knowledge that goes into establishing drug dosage, the clinical knowledge involved in establishing safety and efficacy profiles in clinical trials, and the knowledge of cellular and molecular mechanism required in ventures of rational drug development of which Gleevec is exemplary;
2 the epidemiological knowledge that underlies public health interventions, or broader population-based targeting of therapeutic markets;
3 various kinds of anticipatory knowledge that operate in different domains, ranging from financial markets to clinical research to patent law; and
4 knowledge as process and strategy of making meaning, modalities of reasoning and interpretation that operate in particular situations or domains with more or less authority.

But further, knowledge matters not just when it explicitly becomes valuable or political (or renders particular articulations of value and politics), but also when value and politics manifest through erasing, silencing, or obscuring knowledge, or in situations in which knowledge operates through uncertainty or indeterminacy.

What results, then, is a more complex, elaborated, and differentiated structure of pharmocracy, something that looks like figure 1.1.

Value

The most important abstraction that this book is concerned with is value. In order to elaborate how I think about value, I find it particularly useful to turn to the way in which Karl Marx analytically conceptualized it in relation to labor and capital. Marx insisted that any proper understanding of capital has to come from beginning the analysis with the question of value.[21] And for capital, value has no meaning unless it is surplus value. For money to be capital, it must have the potential for generating surplus within it as it circulates in processes of commodity exchange. In relation to the situation of European (especially English) industrial capitalism that Marx was writing

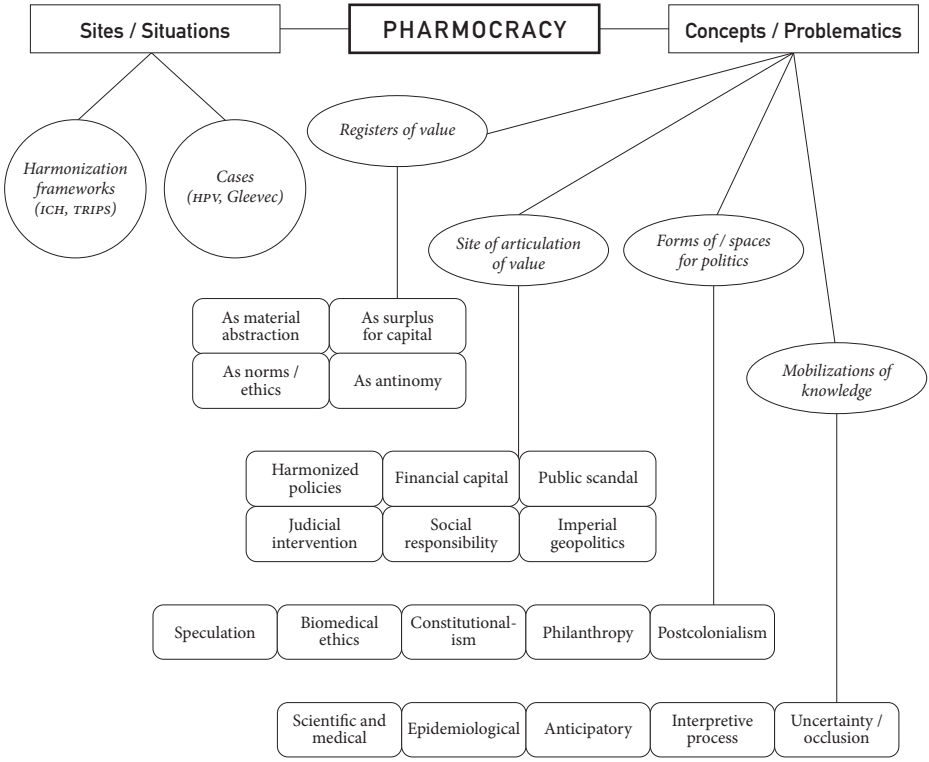

FIGURE I.1

about, this potential comes from what he called labor power—the potential for the worker to generate more labor than that rendered adequate by wage. The question of whether and to what extent the labor theory of value is applicable to all places and times is of less interest to me than the methodological insight it provides into an analysis of how capital generates value through an exploitation of bodily potential, even as the generation of value becomes an end in itself.[22] Further, value is that which allows the commodity, which is always the product of specific and concrete human labor, to figure as abstract labor. At the core of Marx's critique of political economy is his insistence that value is an abstraction device.

Therefore, on the one hand, value is simply an attribute (something that a commodity has: its utility, its beauty, its ability to be worn or eaten; something that money has: its ability to circulate itself, to mediate and measure other kinds of circulations, to quantitatively express circulation itself). But on the other hand, value itself performs the various materializations and

abstractions of those things that it is simply supposed to represent. To quote Marx:

> In the circulation M-C-M both the money and the commodity function only as different modes of existence of value itself, the money as its general mode of existence, the commodity as its particular or, so to speak, disguised mode. It is constantly changing from one form into the other, without becoming lost in this movement; it thus becomes transformed into an *automatic subject*. If we pin down the specific forms of appearance assumed in turn by *self-valorizing value* in the course of *its life*, we reach the following elucidation: capital is money, capital is commodities. In truth, however, *value is the subject [i.e., the independently acting agent]* of a process in which, while constantly assuming the form of money and commodities, it . . . *valorizes itself independently*. For the movement in the course of which it adds surplus-value is its own movement, its valorization is therefore self-valorization. . . . *By virtue of being value, it has acquired the occult ability to add value to itself.* (Marx [1976] 1867, 255, emphases added)[23]

This definition of capital in terms of self-valorizing value is significant, but is not the point at which Marx's explanation runs out. Rather it signifies, in Spivak's terms, "the possibility of an indeterminacy" (1985, 78). The ability to "add value to itself" is precisely that which renders capitalist value appropriative—of labor (turning it into surplus), but also, in other situations, of health (turning it into surplus), or of ethics (turning it into surplus). It is also that which renders the generation of capitalist value political, a politics that plays out through both the consolidation and the contestation of modes and relations of power and production. Hence an ethnographic elucidation of these relations and of their consolidation and contestation allows us to work backward toward a conceptualization of the capitalist value form itself.

How does this relate to health? The most literal answer to this question has been provided by Joseph Dumit (2012a, 2012b), who developed the notion of surplus health as an analogy to Marxian surplus labor.[24] This refers to the market value that pharmaceutical capital gains from the potential for future illness of those who might one day consume drugs, which includes anyone with the buying power to constitute a market for therapeutics and crucially excludes those without. Empirically, Dumit (2012a) studied the growth of pharmaceutical marketing in the United States in the second half of the twentieth century and its imbrication with the growth of clinical trials, a trajectory that has resulted in the progressive growth of prescription rates

in the country with no signs of stopping. Analytically, he substituted Marxian labor-related keywords with health-related keywords in volume 1 of *Capital* (Dumit 2012b).[25] In the process, Dumit generated a "health theory of value" that is literally analogous to Marxian labor theory, showing how value creates health that is appropriate to and appropriable by capital, alienated from embodied healthiness. Value thus is that which allows the symptom, which is always the product of specific and concrete human health, to figure as abstract health.[26] Even as health itself comes to be at stake, so too does labor, as biomedical economies engender both multiplications and divisions of labor, seen especially in the various proliferations and dislocations of experimental subjectivity in clinical trials.[27]

There is a further tangle here, because value is never just about surplus; it also refers to the ethical and the normative. Often, pharmaceutical corporate capital is contested by taking recourse to seemingly opposed value systems grounded in ethics and morality: for instance, by an insistence on the ethical conduct of clinical trials and human-subject experimentation based on principles of good clinical practice; or by demands for equitable and broad access to essential medicines for people who do not have the purchasing capacity to buy them on the market; or by attempts to hold states accountable to their responsibility to ensure the health and care of their populations. In other words, one could envisage a value that is not just defining of capital but (in its ethical registers) also an alternative normative framework to capital. And yet corporations are perfectly capable of enfolding these concerns into their own value-generating enterprises.[28] Hence, these latter forms of value are never entirely outside the fold of capital but are always appropriable by it. Ethics can be potentially opposed to surplus value but also deeply tangled within its logics.

There are enmeshed conceptual relationships between the ethical and the norm as well, given that the norm also inflects in two ways, implying either the normative or the normal (Hacking 1990). To the extent that the normal is normative in a given situation, ethics is the norm; to the extent that the normal falls short of the normative in a given situation, ethics is precisely not the norm but an improvement upon it. And so, the ethical can come to be the grounds for political contestation around the norm itself. One saw this transpire in the Gleevec case, as Novartis's lawyers argued for the product patent, among other things, on grounds that this drug was patented in forty other countries. Hence, they claimed that granting a patent on the drug was the normal thing to do, and that the Indian Patent Office's denial was unethical, preventing as it did a legitimate monopoly that had already been established

in other jurisdictional contexts. The opposition, on the other hand, argued for an ethics based in normativity, claiming that what was normal had no bearing on what was appropriate, which was adhering to the standard of invention as established under Indian law with its public health flexibilities that prevented pharmaceutical evergreening. If the former position established the authority of the norm by taking recourse to a patent claim that had already been held valid in multiple other contexts, then the latter did so by taking recourse to legislative history that rendered the normative constitutional ordering of how invention was to be understood in India as a higher standard to be met than normal standards of patentability prevalent in other countries.

What is at stake, through and through, are the antinomies of value in its multiple registers. An antinomy is a contradiction between two beliefs or conclusions that are in themselves reasonable. Resolution or consensus is often impossible; what is at stake is living within the mutual incompatibility. Value, in the contested, conjoined, multiply jointed senses of market/surplus value and ethical/normative value, precisely because of its inherent indeterminacy, constitutes the terrain of politics. My investments therefore do not lie in defining what value really is, and certainly do not correspond in any straightforward way to what people say or believe value really is. I am not interested in finding an ontology of value that manages a transhistorical reconciliation of its contradictory manifestations, nor am I attempting an elucidation of cosmologies of value that describe the ways in which actors resolve these contradictions for themselves.[29] Rather, I stay attentive to the articulations and antinomies of value as it is rendered political.

Politics

Without a doubt, global pharmaceutical politics has come to be deeply contested, often with polarized positions around a range of issues. I have already introduced the polarization around global harmonization, which is projected as being about ethics and innovation by its cheerleaders and about the hegemony of multinational corporate capital by its detractors. But beyond this, there are all sorts of situated alliances across adversarial positions, just as there are major disagreements among actors who are otherwise in positions of structural solidarity.

Even among those who oppose the appropriation of health by capital, there is a range of different positions. There are those who respond to the problem of unethical clinical trials by adopting an antiscience position toward clinical research, while others insist upon the importance of clinical research for

public health even as they oppose the ways in which it has been institutionalized; there are those who decry the conduct of clinical research on the poor and vulnerable, just as others believe that any genuinely progressive public health practice must include research on more marginal populations within its ambit; there are those who believe that civil society has the right and the responsibility to shape public health agendas, while others who believe in the paramount importance of scientific autonomy free from such dictation; there are those who believe that access to medicines cannot be achieved without a pragmatic engagement with the multinational pharmaceutical industry, including the provision of incentives, while others insist that genuine transformation in political economies of health cannot happen as long as one is wedded to privileging the institutional capacities of the most powerful corporate players; there are huge disagreements around specific mechanisms of enabling access, or around the relationship between pharmaceutical access and primary health infrastructure development.

Of course, there are deep divisions among capitalist interests as well, especially between Euro-American innovator industries involved in R&D and Indian companies who have primarily been involved in reverse engineering generic drugs; but even those divisions are fluid as Indian companies strategically align themselves in certain instances with multinational pharmaceutical corporations, just as the latter seek out national generic competitors as potential targets of acquisition. Different kinds of clinical trials brokers act in concert when it comes to driving regulatory harmonization even as they compete with each other to construct market terrains according to their perception of strategic interest.

The state too is an inherently conflicted actor. If capital is defined by its incessant drive toward surplus, then the state in its liberal democratic form is caught within its own fundamental antinomy, accountable both to the interests of local, national, and global capital on the one hand and on the other to its citizens. What this division means and how its different representative functions get activated becomes an important empirical question.[30] Political orientation toward the state on the part of both corporate and civil society interests is immediate and constant, in a context in which what the state is, which arms of it are activated, and how it emerges as a differentiated entity that is often acting at odds with itself all come to be at stake and contested. This is so even—perhaps especially—as the place of the state as a primary institution of governance comes to be in question with the growth of parastatal, nongovernmental, multilateral, or corporate governance regimes.

Part of the task of conceptualizing politics then is empirical, tracking and mapping the content of heterogenous positions, strategic alliances, and situated articulations in relation to different biomedical domains. But further, this book focuses on different forms of and spaces for politics in the context of health. Similarly to my engagement with value, my attempt here is not to generate some authoritative definition of the political as much as it is to show the situated intersection and interaction of particular modalities of politics that emerge within certain economic and governance structures and out of specific historical conjunctures.

This book considers the constitution of the forms of and spaces for politics as health comes to be appropriated by capital. I think of constitution in two mutually reinforcing but opposing senses. The first is in terms of the ways in which these forms and spaces are constituted. This speaks to an active sense of constituting, of putting in place. Constituted entities are not static or given; they are almost by definition historically enacted, culturally endowed, in formation, even as they are emplaced and located. This is a concern with emergent forms of and spaces for politics (Fischer 1980, 2003). At the same time, there is a sense of the constitutional as related to the constitutive—that which is inherent to or defining of a political order. This refers to institutionalized codes, legal and normative, that get held up as defining prescribed codes of action and governance; taking the form perhaps of a Constitution (with a capital *C*), a foundational (often national-state) document that goes beyond prescription to signifying the ethos of "a people" (Ackerman 1991). But it could also imply constitution with a small *c*; the multiple sites of regulation and governance within which rules and norms come to be enshrined (Jasanoff 2003, 2011).

Hence, this book locates its analysis within a fundamental tension that exists between the variant trajectories of the materialization of value and the normative consolidation of the appropriation of health by capital; but also within the tension that exists between the content of a politics around health and the forms and spaces of its emergent and constitutive articulations, which are at once unsettled and deeply normed, constantly contested but also variously constrained and naturalized. What is at stake here is not simply the generation of a catalog of different emergent political forms, but rather the question of relationships between different constitutive and emergent forms of and spaces for politics. Which ones get activated, and which are suppressed, contested, and denaturalized? Which imaginaries fall out and lose salience? Which ones sediment to become the grounds upon which

naturalized assumptions get made?[31] Imbricated in these forms of and spaces for politics is a third register of the constitutional, referring to health, to the body and its overall well-being.[32]

If a conceptualization of value has implications for an understanding of the reconfigurations of health as it gets appropriated by global capital, then I argue that tracing these forms of and spaces for politics in the context of value-laden health is equally consequential for a conceptualization of democracy. It is useful to think here of two important modalities of theorizing the democratic. One considers it in terms of rational communicative action with the eventual goal of consensus, going beyond goal-directed strategic action for one's own benefit (for instance, Habermas 1984, 1985). Another conceptualizes it in more organic terms, as the expression of popular sentiments and actions that can never be completely constrained or represented by the macropolitical form of the state (for instance, Chatterjee 2004, 2011). My own stakes in the democratic go beyond both formulations. The Habermasian ideal of rational communicative action as the means and consensus as the ends of an ideal democratic situation is, certainly in an Indian context, an empirical absurdity, and Chatterjee provides a more productively realist formulation.[33] But there are empirical limits to this formulation as well, because it locates the site of the political outside formal structures of the law, outside corporatized modes and relations of production. Hence, the sites of the political come to be rendered outside structures of representative power or hegemonic modes of production. Chatterjee's theorization of democracy occurs largely within what he calls political society; capital itself, or law itself, or civil society itself, get evacuated of empirical and explanatory thickness.[34]

This book traces political struggles for ethical clinical trials or access to medicines that occur resolutely within civil society (and indeed, are involved in constructing domains of civil society across scales, as seen with global civil society movements for access to medicines); follows the law as it comes to be the site for the instantiation of judicial sensibilities that have cultural and historical specificity and resonance; and conceptualizes capital in its most corporatized, monopolized, financialized forms, containing its own sectoral, national, and situational sensibilities. Hence, it theorizes democracy not in terms of what Chatterjee calls the politics of the governed, but rather in terms of the politics of governance. Chatterjee locates democratic politics within the realm of popular reason; this book correspondingly does so within representative domains that see the constitution and contestation of public reason

(Jasanoff 2013). Representative politics are not just ideological constructs of liberal political philosophy; they speak to political forms and spaces that are central to the configuration of contemporary democracy in ways that demand empirical attention in their own right.[35]

Knowledge

Questions of value and politics, of global hegemonies and their contestations, often come to be at stake around questions of knowledge. When, how, and on whose terms does knowledge come to matter in the articulations of value and politics in global biomedicine? Biomedicine is, among other things, a knowledge-producing activity, even as it produces artifacts, institutional structures, and subjective states around something called health. The centrality of knowledge production to biomedical research and production has perhaps become more explicit throughout the second half of the twentieth century, through the growth of evidence-based medicine (Timmermans and Berg 2003). But knowledge practices are consequential not just internally to the practice of biomedicine. As part of its very rationale and practice, biomedicine interacts with regimes of value shaped by representative forms of politics. Clinical research for instance might be a constitutive part of the apparatus of evidence-based medicine, but it is equally and immediately also about the experimental subjection of humans (and animals) and therefore about the apparatus of ethical norms and regulatory frameworks under which such subjection can occur. Intellectual property is integral to many practices of drug discovery and development, increasingly globally, but it also concerns philosophical and legal questions of what constitutes invention and which jurisdictional frameworks apply in deciding the answers to such questions.

And so my interest in knowledge is not as something that can be purified and thought of in its own terms, but rather as something that is coproduced with and mobilized in relation to value and politics.[36] Sheila Jasanoff (2004) describes coproduction in terms of the mutually determining ways in which scientific knowledge and social order come to be produced. Following Jasanoff, my attempt is to understand the coproduction of knowledge with value and politics in a context in which health comes to be appropriated by capital in ways that put democracy at stake. One cannot think of knowledge in global biomedicine devoid of value and politics; one cannot contemplate the stakes of changing modes and relations of knowledge production in biomedicine without considering its stakes for democracy. Value and politics do not emerge, as it were, after the fact, but are conjoined with it.

I attend to such coproduction by looking at how knowledge comes to be mobilized across domains and geographies in global biomedicine. For instance, when the HPV vaccine, produced in the West, travels to India to be incorporated into its national immunization program on the basis of clinical trials that have been conducted in a number of countries but not in India, what kinds of knowledge about vaccine response or cervical cancer epidemiology are assumed to be portable across territorial and demographic contexts, and by whom? How and when are such assumptions naturalized or challenged? When Gleevec's patent denial is contested in India in spite of it being accepted largely without question in many other countries, what kinds of legal interpretations of invention come to operate in different jurisdictional and legislative contexts? Mobilizations of knowledge are not just transnational, but also operate across domains: of science, law, and policy; of laboratory, clinic, and public health; of experiment, therapy, and epidemiology; of university and industry; of manufacturing and financial capital. During such mobilizations, the representative function of knowledge is not consequent to some absolute truth-value, but rather is a result of its serviceability.[37]

As in my conceptualization of politics, I think here both with and against Michel Foucault, who has provided some of the most important theorizations of the relationship between knowledge and power throughout his work (but most explicitly in essays and interviews collected and published as *Power/Knowledge* [Foucault 1980]).[38] Through an analysis of knowledge, Foucault was able to open up different ways of conceptualizing power. Simply put, Foucault went beyond an analysis that simply read power and politics as ideological corruptions of the truth of science. He recast the question of the influence of power on truth into one that was about the "interweaving effects of power and knowledge" (Foucault 1980, 109). Thus, he was able to ask new questions about the nature of the practice of knowledge production itself, of how such practice was interwoven with the emergence of institutional forms and structures that would regulate social conduct. But Foucault's investment in the conceptualization of knowledge was as truth, especially as he articulated the problematic of Power/Knowledge.[39] How might other concerns with knowledge develop in relation to the situation of highly capitalized biomedicine? Specifically, I am interested in the question of knowledge as being a problem of translation across domains and locales.[40]

A concern with the translations and translocations of knowledge speaks directly to its articulations with value and politics. Which (and whose) representations mobilize knowledge, across which domains, and through what kinds of norms and authority? When (and in what ways) does knowledge

come to legitimize or be rendered legitimate by different regimes of value, such as those that promise capital accumulation and appreciation, or mandate ethical clinical practice, or activate foundational constitutional imaginaries, philanthropic ideals, or nationalist sentiments, and through which forms of and spaces for politics? Answering these questions involves attending to the kinds of work that count as valuable knowledge production in contemporary biomedicine—for instance, experimentation, innovation, anticipation, speculation, interpretation, or advocacy—and to the embodied representational forms that knowledge takes as it comes to be mobilized (of the innovator who promises therapies, the industrialist who promises economic growth and national self-sufficiency, the speculator who promises returns on investment, the volunteer who becomes the subject of clinical experimentation, the judge who promises an appropriate interpretation of the law, the activist who fights for social or distributive justice). This speaks both to the labor of biomedicine and to what Michael Fischer (2013) has called its peopling. At stake here is a knowledge-for-itself: all the immediately value-laden, representative political forms that knowledge takes in global biomedicine as it concerns experimentation, innovation, corporate strategy, financial speculation, technocratic expertise, legal interpretation, or civil society advocacy.[41]

This is directly relevant to understanding the ways in which hegemony operates. For Gramsci, understanding representation involved understanding the place of knowledge in culture, society, and politics in deeply situated ways.[42] Gramsci was interested in how the hegemonic organization of coercion and consent was a function of the intellectual authority of dominant groups, and conversely in what kinds of intellectual work were necessary to oppose and transform existing hegemonic orders. The work of knowledge that I trace operates in both directions: toward the consolidation and the contestation of capitalized health. But the kinds of knowledge practices involved in specific forms of hegemonic consolidation or contestation are extremely particular, located within historical, institutional, societal, cultural, and personal investments, and demand empirical attention. Even the question of who counts as a significant intellectual in a given situation becomes deeply fraught and consequential. For instance, I show how it is the financial analyst who disproportionately authorizes what constitutes innovation in the context of the Euro-American pharmaceutical industry (chapter 1), even as high court and Supreme Court judges do so in India (chapter 3); how technocratic clinical research brokers and feminist civil society advocates clash over what constitutes the definitions and priorities of public health, even as those

very questions are debated within disciplinary public health journals and forums (chapter 2). What is at stake is not just whose knowledge is right in some absolute, factual sense, but whose knowledge comes to count as valuable and authoritative, where, and through what kinds of mechanisms.

This book thinks through the situated trajectories of global pharmaceutical policy harmonization in India and the cases of HPV and Gleevec while analyzing the conceptual problematics of value, politics, and knowledge. Chapter 1, "Speculative Values: Pharmaceutical Crisis and Financialized Capital," explains the nature of speculative, financialized, multinational pharmaceutical capital. It focuses primarily on the logics that drive the Euro-American, R&D-driven pharmaceutical industry, to argue how an industry that is captured by capital is one that, structurally and constitutively, comes to be in crisis. I show how this crisis extends globally, implicating other national industries as well as consumers and patients in both the First World and the Third. Chapter 2, "Bioethical Values: HPV Vaccines, Public Scandal, and Experimental Subjectivity," elaborates a politics of civil society advocacy as it develops through the public scandal around the HPV vaccine studies. This raises questions not just about relationships between health, value, and politics, but also of the configuration of epidemiological knowledge and technocratic forms of governance within these relationships. Chapter 3, "Constitutional Values: The Trials of Gleevec and Judicialized Politics," illustrates judicialization as it is played out in the Indian courts. It elaborates the legal history of Gleevec in India between 2005 and 2013 to think about the place of the law and judicial governance in articulations of health, value, knowledge, and politics. Chapter 4, "Philanthropic Values: Corporate Social Responsibility and Monopoly in the Pharmocracy," offers a critique of monopoly capital. It describes the incorporation of ethical and normative commitments into the value-generating activities of the multinational R&D-driven pharmaceutical industry through discourses of innovation and materialized through practices of corporate social responsibility. I focus specifically on Novartis's drug donation program, the Gleevec International Patient Assistance Program, and the way in which it was established and run on the ground in India. In addition to imbrications of different registers of value (market and ethical), one sees here complex articulations of experimental and therapeutic biomedical economies. Chapter 5, "Postcolonial Values: Nationalist Industries in Pharmaceutical Empire," identifies Indian free market capitalism as it intersects with global geopolitical configurations and strategies. I provide an account of India's oldest surviving pharmaceutical company, Cipla, which has become a leading player in the opposition to WTO-mandated product

patent regimes and hence an ally of global civil society groups fighting for access to medicines. Cipla's history reveals a record of consistent action in its own market interests, and an attempt to define a market terrain in terms of those interests; but it also reflects certain explicit nationalist and (more recently) global humanitarian sentiments, in ways that open up questions about the postcolonial and ethical investments of these market actors. I then think through the global geopolitical landscape that structures these different ethical incorporations in antagonistic and power-laden ways. The conclusion is an attempt to think through the implications of this analysis for considering the future trajectories of politics engaging global biomedicine and global capital.

At the end of each chapter is a postscript that spells out the chapter's concerns to pharmocracy as a politically salient concept. It marks the site of questions concerning the nature of the political as it emerges in and through domains of health that are appropriated by global capital. These postscripts do not provide answers or explanations; they are meant as a reminder that the real challenge here—empirically, conceptually, and politically—is to remain attentive to how pharmocratic regimes put both health and democracy at stake.

Situating Pharmocracy

It is important to locate the analysis of pharmocracy in this book in relation to the specificities of place, history, and event that constitute its empirical substance. The task here is not to provide some sort of comprehensive explanation of what value or politics or knowledge is in some definitive sense as much as it is to multiply the situations from which its various articulations can be seen. Each situated perspective from which this book is written—of speculative, financialized, multinational pharmaceutical capital, of public scandal, of judicialization and the Indian courts, of monopoly capital, of Indian free market capitalism, and of global geopolitics—affords a locus for observing articulations of value, politics, and knowledge.[43]

This book is immediately concerned with a very particular situation in place and time, post-2005 India, in the domain of a specific industrial sector (pharmaceuticals), and with politics concerning health. On the face of it, the story that I am about to tell could be seen as one of a pharmaceutical industry acting and developing in the cause of more innovation and greater ethical consciousness. But it could equally be seen as one of the expanding domain of global capital and of multinational corporate hegemony, resulting

in new Third World national regulations that are called upon to facilitate First World corporate interests. Such expansion occurs at the expense of the world's poor, who become guinea pigs in clinical experiments even as they find it harder to access essential medication. The reality involves understanding these hegemonic movements in all their fullness, but also and at the same time the ways in which they are contested. Contemporary India is important in this regard. India occupies a central place in global pharmaceutical politics by virtue of its strong national generic industry, which has been an important source of affordable medication for the Global South over the past two decades. For instance, MSF procures 25 percent of its essential medicines for worldwide distribution and 75 percent of its antiretrovirals from India.[44]

In addition to situating India thus, it is important to situate the period that this book focuses on. Specifically, 2005 serves as an empirical entry point because the legislative events that took place that year signify broader transformations of pharmaceutical political economies. But more generally, the time at stake is the contemporary.[45] How do we situate these legislative moments and the political events that surround them in relation to a broader historical movement in the global pharmaceutical economy and in contemporary India? In order to address this conceptually and methodologically, I turn to Gramsci's notion of the conjuncture, as a conceptual and methodological framework within which to situate my analysis in this book.[46]

Gramsci discusses two kinds of historical movements in relation to one another: the "conjunctural," which "appear as occasional, immediate, almost accidental," and the "organic," which are "relatively permanent" (2000, 201). Conjunctures could most certainly be marked by significant events; indeed, in order for them to be recognized as conjunctures, they probably are. But Gramsci finds them significant not just as historical markers of some kind of epochal shift (as events that radically cause a separation between then and now), but as political ones: the conjuncture provides a terrain upon which politics plays out. This could be a politics that attempts to preserve existing forces and relations, or one that attempts to overturn them. When I say that India's becoming party to the WTO or its attempts to globally harmonize ethical regulatory regimes for clinical trials provides the conjuncture in which this book is written, it does not imply in any simple sense that these events in and of themselves allow for an epochal shift in pharmaceutical economies. What it means is that they are markers of a reconfiguration of the terrain of the political in relation to these economies. Whether we think about the operations of multinational pharmaceutical companies in India, Indian generics companies, or sick Indians who are also citizens and consumers, life

(and death), health (and illness), and the nature of markets, production and consumption come to be configured differently in a product patent regime than a process patent one, or in a liberalized clinical trials regime than in a more restrictive one.

The particular events in question, whether in relation to clinical trials or to intellectual property and access to medicines, were themselves contingent events. Nothing was predetermined about India becoming signatory to TRIPS. Indeed, there had been much civil society opposition to India's participation in the Uruguay Round of GATT negotiations in the early 1990s. But trade pressures from the United States, driven by the strength of the multinational pharmaceutical lobby in the U.S. government, coupled with the Indian government's strategic rationalizations that belonging to a multilateral free trade forum would be in the country's economic interests, held sway. Similarly, the political mobilization of CRO interests drove the liberalization of clinical trials regimes, which was hardly an obvious or predetermined movement. Yet elucidating the contingencies that underlie these conjunctural moments alone is insufficient. It remains to be asked at the level of empirical specificity: Why is it that these contingent conjunctures happened together? Why did they happen at a moment of the broader appropriation of various domains of health in India by global capital? And what is the relationship of these multiple, convergent (if contingent) events to the logics of capital and its institutional materialization in corporate strategies and global geopolitics?

For Gramsci, what was most important about the conjuncture was the way in which it always poses the question of its own relationship to the organic. The theoretical task, he suggests, is neither just the elucidation of the conjuncture (which ultimately privileges the contingent as an end in itself or, in Gramsci's terms, leads to "an exaggeration of the voluntarist and individual element" [2000, 202]), nor simply the elucidation of some fundamental organic movement as underlying the conjuncture (which leads to structural determinism). It is rather the determination of the relationship between the conjunctural and the organic.

For this, it is important to locate the conjuncture of pharmaceutical politics in India that I am marking in the context of a broader political economic conjuncture, within a broader trajectory of capitalization of the life sciences and of India. One has seen the progressive privatization of clinical trials since the 1970s alongside the capture of the multinational R&D-driven industry by speculative financial capital, a process I describe in detail in chapter 1. Concomitant to this has been India's transformation into a global market economy, a process initiated in earnest by the 1991 Congress Party–

led government and marked since by various forms of economic liberalization in the interests of global capital. One can see this manifest in relation to changing intellectual property regimes under the guise of free trade and of changing ethical regimes in the cause of good clinical practice. But these are just sectoral instantiations of broader movements of global capitalization in the Indian economy writ large, marked by the opening of markets to foreign investment; intense wealth generation among certain segments of the population in the context of widening inequality and wealth disparity; new kinds of urban-rural divides, along with new forms of sociological mobility (and immobility); the emergence of parallel private infrastructures for essential services such as health, water, and electricity for those who can afford it; and the apparent handing over of the reins of the state to the market.[47]

Yet this period has also been marked by populism of the representative Indian state in relation to the poor. This is different from the feudal populism of political patronage networks, which has existed throughout the history of independent India and which, as Partha Chatterjee (2008) has argued, is important for understanding the functioning of informal economies in India today. It is also different from the state socialist populism of the 1970s, marked by Indira Gandhi's *garibi hatao* (remove poverty) manifesto. Rather, it is deeply coupled to instruments of global capital. An example of this in relation to pharmaceutical economies is the National Rural Health Mission (NRHM), launched in 2005. This initiative has emerged alongside the building of institutional capacity for public health education and research that was previously lacking in India, but also alongside the establishment of global health as a central focus in American medical schools and public health curricula. Programs such as these are closely articulated to institutions of global expertise such as the Gates Foundation, operate with top-down imaginaries of public health, involve public-private partnerships, and are often deeply technocratic in their mind-set.

There are many symptoms of neoliberalism in these formations, but they emerge in the context of representative populism toward the poor as an object and target of state intervention.[48] The NRHM, for instance, happens at precisely the conjuncture that sees India liberalizing its clinical trials regimes and changing its patent regimes to become WTO compliant. But it also happens alongside or anticipates a host of other initiatives launched by the Congress government that was elected in 2004 (and continued in power, albeit with a different set of coalition partners, until 2014) that are similarly populist, and often hitched to rights: for instance, the right to food, right to education, right to employment, and right to information.[49] All of these in various

ways represent unfulfilled promises, but they have become important sites of political action. They signify not just the state's acknowledgment of obligations toward its citizens, but also represent modernist promissory notes that emerge out of a conjuncture of economic liberalization. What is at stake here is an understanding of history for the articulation of value and politics, "not the reconstruction of past history but the construction of present and future history" (Gramsci 2000, 202).

This understanding of history, in this book, is grounded in nine years of ethnographic fieldwork with a range of actors involved in various aspects of global biomedicine, pharmaceutical capital, and the politics of health. The research for this project started in early 2006 and involved following the burgeoning CRO industry in India, specifically its attempts to drive regulatory harmonization. This was where, it seemed, all the action was at the time. I was interested in following the intense conversation that was developing within the industry about the importance of developing an ethical infrastructure for the conduct of clinical trials; but the ethics in question was an instrumental and purely procedural one, concerned with good clinical practice and developing the apparatus for informed consent. I became interested in how this conversation around ethics was taking shape, not just for what was being said but also for what was not being said by the actors who were most powerfully involved in substantiating regulatory harmonization on the ground. Specifically, there was no regulatory conversation about whether drugs tested in India would be marketed in India, let alone be made available at affordable prices. The fact that this was happening at a time when actual access to medication could potentially become more difficult under the newly instituted product patent regime exacerbated the stakes of the issue. And so, what seemed as significant as the discourses of ethics that were being articulated were the discursive gaps that were at the heart of this articulation.[50]

I published a piece with this argument fairly early in the game, along with an op-ed in the *Indian Express* (K. Sunder Rajan 2007, 2008). Consequently and unsurprisingly, my access to CRO executives, who were initially very keen to talk to me, started drying up. By this time, my interests were in any case shifting to the question of access to medicines, a shift that followed naturally from attending to the discursive gap at the heart of the conversation on regulatory harmonization. If the CRO actors and clinical trials regulators were not talking about access to medicines, who was? I did not have far to look, since this was the very time when the politics around interpreting the 2005 Patent Act was at its height and becoming heavily judicialized through the Gleevec case. What was a discursive gap in one biomedical and regulatory domain was

a site of deep political contestation and thick discourse in another, at exactly the same time. Much of my fieldwork at this point shifted to following the trajectory of the Gleevec case, which involved following its contestation and resolution in the courts, but also tracking the strategies of the multinational, Euro-American pharmaceutical industry in response to this judicial politics, and having conversations with civil society advocates for access to essential medicines and members of the Indian generics industry who had formed alliances with these advocates. I assumed that the clinical trials side of the project was done and dusted, having raised certain questions that I had followed into new research. I thought I had moved on.

But in 2011, I was sucked back into it with a vengeance, as clinical trials became the subject of scandal in India. The specific event that precipitated this was the HPV vaccine study, which became the focal point of political mobilization around unethical clinical trials. At the same time, a slew of other such cases came to light. This included the trials conducted on victims of the Bhopal gas disaster, trials conducted in a hospital in Indore that apparently did not conform to standards of good clinical practice, and trials conducted in Ahmedabad on poor volunteers in the apparent absence of proper informed consent.[51] The specific events in each of these cases was different, but they all suggested that the capacity building undertaken in the mid-2000s to make India a global experimental hub had led to a proliferation of poorly regulated clinical trials. There was no way that the clinical trials issue was a past concern, either politically or for my research.

Hence, part of the structure of this research simply comes from having conducted it in many sites, a process of following significant actors and events around. But more substantially, it comes from thinking about two domains of biomedical politics, concerning clinical trials and intellectual property and access to medicines, together. On the one hand, the specific actors and events that I was tracing in these two domains were different. On the other hand, they were parts of structurally interrelated biomedical and political economies. What I came to be concerned with was the relationship between these two domains, which raised two inverse conceptual problems. The first involves understanding the problem of variance that presents itself here: how it is that similar logics of capital materialize in such different political trajectories, mobilizing different strategies and institutional mechanisms. The second involves understanding norms: how it is that in spite of obviously different and contingent materializations of politics in these different domains, one sees the consistent establishment of certain political economic trajectories and power hierarchies that lead to the progressive capitalization of health.

It is this conjoined relationship between historical variance in the context of structural norms, and conversely of historical normalization of biomedical political economy in the context of contingent variance, that provides the anthropological problem space of this book. It seeks to provoke conceptual and political questions concerning how value, politics, and knowledge come to be related to one another in contemporary global pharmaceutical economies in ways that put both health and democracy at stake.

CHAPTER ONE

Speculative Values

Pharmaceutical Crisis & Financialized Capital

Dialectics of an Industry

This chapter explores how logics of capital grounded in the generation of surplus lead to a structure of crisis in global pharmaceutical industries, leading to trials for the industry itself, for patients and consumers who constitute its markets, and for populations who are excluded from these markets. This is an analysis of the sectoral manifestations of logics of capital. It further explores how these logics operate within a trajectory of the progressive financialization of pharmaceutical corporate capital, especially in the United States. I show how this structure of crisis creates a terrain that allows for situations such as that seen in the conjuncture of the mid-2000s in India, when the country was being conceptualized as a global biomedical experimental hub at the same time that therapeutic access was becoming potentially more difficult under newly instituted product patent regimes (see introduction). This happens at the same time that places like the United States experience prescription maximization and therapeutic saturation among those segments of the population that are included within pharmaceutical markets (Dumit 2012a, 2012b; Petryna 2009).

Antonio Gramsci says of crisis that it "consists precisely in the fact that the old is dying and the new cannot be born; in this interregnum a great variety

of morbid symptoms appear" (Hoare and Nowell-Smith 1971, 276). I argue that the pharmaceutical industry is at present defined by a constitutive state of crisis. Crisis is a state that is simultaneously structural (a condition of the present) and exceptional (as being borne of the event).[1] In pharmaceutical politics, crisis manifests in both a humanitarian register and as something that is structurally endemic to capital. This analysis focuses on the latter, analyzing crisis as constitutive to capitalist modes and relations of production.[2]

My concerns in this chapter operate at multiple scales of analysis: first, to general conceptual questions concerning the logics of capital as they are grounded in imperatives to generate surplus; second, to the materialization of these logics in terrains of technoscientific capitalisms that are invested, quite literally, in the ideology of innovation; and third, to the specific sectoral logics of the pharmaceutical industry, as distinct from other kinds of high-technology, research and development (R&D)–focused industries. The most important distinction to note here concerns the specific scales and temporalities of capital investment in R&D-driven pharmaceutical development. The development of a new drug molecule involves enormous initial investment in drug discovery and development. Drug discovery is the process of finding potential target molecules that might have a useful (and marketable) therapeutic effect; this is in the United States largely underwritten by public money, especially through the funding of university-based biomedical research. Drug development involves taking potential therapeutic molecules through preclinical and clinical trials—which is an expensive and risky process, with no guarantee of success. Clinical trials have over the past four decades increasingly moved to the private sector, and this is a capital investment whose risk is largely borne by the R&D-driven pharmaceutical industry. This structure of enormous upfront capital investment into a process that might take over a decade to realize that investment, and whose realization is filled with risk and uncertainty, leads to sectoral specificities in the pharmaceutical industry.

In global pharmaceutical economies, there are at least three sets of actors that are simultaneously in crisis. The first is the multinational pharmaceutical industry, largely Euro-American, which is involved in R&D-based drug development. The second is patients, both in developed-country contexts such as the United States and in developing-country contexts such as India. And the third is national pharmaceutical industries such as the Indian, which is primarily a generic industry with expertise in reverse engineering drugs and selling them at a lower cost than patented medication, and deeply impacted in its business models by patent agreements mandated by the WTO.

Crisis itself, however, is polymorphic—it does not mean the same thing for each of these actors.[3]

Some of the factors that combine to configure the fundamentals of the market terrain that we now recognize in pharmaceutical development include the following: first, the development and growth of the Euro-American pharmaceutical industry, which began to focus on R&D-driven business models in the 1980s, leading to the development of blockbuster drugs that could earn over a billion dollars in annual revenue; second, the elaboration of a regulatory infrastructure in which larger and more complex clinical trials became essential before drugs could be approved for market; and third, the emergent possibilities of biopharmaceutical development (the development of complex biological molecules, as opposed to small organic chemical molecules as drugs), enabled by the growth of the entrepreneurial university, the interest taken in biotech by both private and public speculative markets, and intellectual property regimes that facilitate patenting. All of these were in place as constitutive elements of the drug development process by the end of the 1980s.

In the 1990s, further significant developments occurred. These include, in the United States, first, a restructuring of the regulatory process in ways that recognized the need for facilitating the approval of drugs to market in streamlined fashion;[4] second, the allowance of direct-to-consumer advertising by pharmaceutical companies; third, the release of a study by Tufts University's Center for the Study of Drug Development, which showed that the price of developing a new drug was on the order of $250 million, which made drug development costs a central part of the discussion in business and policy circles on the relationship of drug R&D to drug pricing (exacerbated by the estimation that only one in five drug candidates tends to make it through clinical trials to market; DiMasi et al. 1991);[5] and fourth, the growth of off-label use as a business model, which involves selling a drug for an indication other than that for which it was initially approved.[6] Along with these changes in the business models of pharmaceutical companies, the past thirty years have also seen the progressive movement of clinical trials into the private sector. In the mid- to late 1990s, trials started moving out of the United States to the rest of the world at a rapid rate (Petryna 2009).

By the turn of the twenty-first century, the contours of the pharmaceutical industry were as follows. This was a large industry that was extremely profitable. But these profits were built on the strength of a handful of blockbuster drugs, molecules that made in excess of a billion dollars a year. They offset the high rate of failure of drug candidates to make it through clinical trials (probably four drugs out of every five). Hence, this was an industry

whose profits, although huge, depended upon a large amount of money from a small number of compounds. The ability to make so much money from these compounds was secured through strong intellectual property protection. Three historical, institutional factors make this configuration a structure that is potentially ridden with crisis: the place of the pharmaceutical industry in the speculative marketplace, pipeline problems, and the patent cliff. I elaborate.

Most major R&D-driven pharmaceutical companies are publicly traded. This means that value for these companies is determined less by profit (how much money they actually make over the amount expended) than by growth (how much potential there is for future earnings over and above the present rate of earning, which can be translated into shareholder value). The financial community expects a pharmaceutical industry growth rate of 13 percent earnings per share (EPS) annually. The industry growth rate typically operates at 8–10 percent EPS, and between 2002 and 2012 showed an annualized return on equity of −1.2 percent, according to the New York Stock Exchange Arca Pharmaceutical Index.[7]

To reach the kinds of growth the stock market expects purely through the development of new therapeutics requires three to five new chemical entities to be approved each year. This is difficult to achieve. If only one in five drug candidates entering clinical trials makes it to market, then in order to generate three to five new chemical entities a year, the company needs a large pipeline of drugs entering clinical trials. The absence of a robust pipeline in the pharmaceutical industry exacerbates the crisis. The pharmaceutical industry has over the past two decades faced what is referred to as an innovation deficit, a concern that developed in the latter half of the 1990s.[8] This was likely a function of the fact that by this time many of the low-hanging fruit, natural products that could be developed as potential therapeutic molecules, had already been picked, and more sophisticated, targeted forms of drug discovery that could address mechanistic aspects of disease were seen as necessary. The structural relationship between the pharmaceutical industry and the speculative marketplace thus intensified a scientific crisis that had already been in existence.

In this situation, the one thing that has saved pharmaceutical companies is the handful of blockbuster drugs that make billions of dollars a year. The only way these drugs have been able to make so much money is through the monopoly afforded by the patent. Hence, intellectual property becomes the critical factor that allows value generation in this business model. This is where the phenomenon known in industry circles as the patent cliff becomes

such a potential source of crisis. Between 2009 and 2012, it was estimated that drugs representing over $74 billion in sales lost patent protection, and hence faced the prospect of competition from generic manufacturers (Deloitte 2009). This means that the pharmaceutical industry has been in crisis from both directions—the looming expiration of patent monopolies on currently profitable drugs; and the lack of an adequate pipeline of new drugs to replace those that start facing generic competition upon patent expiration. This led to the recognition on the part of the pharmaceutical industry of the importance of near-term revenue, and a resulting focus on mergers and acquisitions (M&A) rather than research and development (R&D). Hence, two tendencies are consequent to the structure within which the pharmaceutical industry operates. The first is monopolistic; the second is the tendency to consolidate through acquisitions.

The pressures from the financial markets that R&D-driven pharmaceutical companies inhabit in the context of their current pharmaceutical crises are indicated, for instance, in an article in the pharmaceutical industry newsletter *Pharmalot*. Titled "One More Reason That Lilly Must Do a Deal, Fast" (E. Silverman 2010), it cites figures that point to the crisis faced by the pharmaceutical company Eli Lilly (the makers, most famously, of Prozac), and arrives at the definitive conclusion—acquire or be acquired. Lilly is a big pharmaceutical company that at the time had a particularly anemic pipeline. They had had two major flops, including very poor sales performance of a blood thinner, Effient, and an Alzheimer's medication that was under development and failed to come to market. According to industry analysts, Lilly faced the steepest patent cliff of the big pharmaceutical companies. Another analyst was cited in this article as saying that Lilly's pipeline "still carries considerable risk. In our opinion, management must reconsider its long term strategy and will need to take short term actions."[9]

All the analysts cited in this piece who diagnose the crisis faced by companies like Lilly come from the financial sector—one from Sanford Bernstein, another from Leerink Swann, and a third from Deutsche Bank. In other words, on the one hand, there are actual events and figures—a failed clinical trial, poor sales performances, a certain amount of capital reserves ($5.1 billion in cash and equivalents at the end of the second quarter of 2010, according to the article). But there is also the interpretation of those events and figures through certain kinds of epistemology—in this case, financial risk. It is the financial analyst who assumes the role of the legitimate diagnostician when it comes to identifying the company's problems and its necessary solutions.

In the face of pipeline crises and patent cliffs, the logical response of the speculative marketplace is to push pharmaceutical companies toward M&A. The logic of this step is twofold. First, M&A potentially bolsters pipelines—instead of having to discover a drug candidate from scratch and take it all the way through drug development, companies could either in-license promising late-stage drug candidates from a smaller company that is looking for revenue, or they could acquire the smaller company altogether. This is often the mode of interaction of big pharmaceutical companies with biotech companies, which might have products in the pipeline but do not have the capital reserves or resources to take those products all the way to the market. Second, M&A reduces costs through streamlining, by consolidating projects and workforces in two companies.[10] This leads to the large number of layoffs and redundancies in the industry.

A Deloitte (2009) report on M&A in the life sciences (between pharmaceutical companies, or between pharmaceutical and biotech companies) cites figures that show the increasing trends toward such deals, and the increasing valuation of such deals. For instance, the median value of deals in which a pharmaceutical company acquired a biotech company rose from $80 million in 2000 to $400 million in 2008. There was a similar sort of increase in the median value of out-licensing deals (when a company licenses out a single molecule to a pharmaceutical company, rather than selling the entire company), from $25 million in 2000 to $230 million in 2008. The single largest factor responsible for these trends, it has been suggested, is the patent cliff and the threat of competition from generic manufacturers, which leads to a "laser-like focus on near-term revenue growth and profitability" (Deloitte 2009). What this means is less of a focus on R&D within the companies, especially early stage R&D, since such R&D implies commercial expenditure on projects that have no guarantee of resulting in the successful development of a therapeutic. Therefore, one sees the reinforcement of the very conditions that led to crisis in the first place: there is a pipeline crisis because there are not enough drug candidates coming into the pipeline. Yet the short-term focus on M&A as the way to mitigate that crisis (and as the way that is suggested by the speculative logics of financial markets) leads to a further inattention to R&D within companies, ensuring the continuing lack of an in-house pipeline. Indeed, a 2008 Deloitte survey of 360 senior pharmaceutical industry executives predicted that before 2020, most research and development would be conducted outside large life science companies.

Thus crisis is created by the coming together of a political economic structure of financialized capital that demands growth with an epistemology of

risk assessment through which crisis comes to be naturalized. This is a form of diagnosing and understanding crisis that does not question the institutional structure of financialization itself, just the growth and performance of industries operating within the structure. Consequent to this, there is a monopolistic tendency that is enforced through patent protection, which has consequences for drug access, especially (but not just) in the developing world. And there is a tendency toward consolidation through acquisitions, thereby increasingly turning the R&D-driven industry into an M&A-driven one. In the process, one sees a fundamental shift away from the R&D model that has defined the industry for much of the past two decades. Pharmaceutical industries, it could be argued, function less and less as discoverers of new therapy and more like investment banks themselves, controlling, regulating, and betting on the flow of capital.

Ramifications of the Structure of Pharmaceutical Crisis

I argue that the process of the appropriation of the pharmaceutical industry by logics of speculative, financial capital results in the separation of value from considerations of patient needs or good health. Indeed, the very definition of health comes to be at stake and reconfigured in this process. What one is seeing within pharmaceutical industry logics is the implicit understanding of health in terms of surplus health, where health itself becomes a potential source of value for capital (Dumit 2012a, 2012b; see introduction, this volume). Indeed, health has to be thus valuable if one is to even imagine making the kinds of speculative financial bets on it that one sees in this model of pharmaceutical development. This is because the bet that is made here is not one that has anything to do with healthiness or therapeutic efficacy; it is, rather, a bet on market size, market penetration, and the potential for market growth. It is a bet on therapeutic consumption—which, in order to be a source of surplus value, must by definition be potentially greater than the amount of therapeutic consumption required to maintain healthiness. This creates a structure of crisis for patients.

The innovation deficit that puts the pharmaceutical industry in crisis has been compensated for in the American context by a consumption surplus. This is because pharmaceutical companies need to grow their markets in order to create value for their investors. But they have been poor at growing markets by coming up with new drugs for new indications. Hence, American patients get imagined as consumers who can grow markets if they just consume more drugs, leading to Americans consuming more and more drugs

and to their becoming, in the language of clinical trials, "therapeutically saturated" (Petryna 2009; Dumit 2012a, 2012b). Given that drugs are fundamentally toxic molecules, this constant growth in drug consumption cannot possibly be harmless, even if it is often invisible (except when it manifests in dramatic crises such as in the case of Merck's blockbuster drug Vioxx, which had to be pulled from the market because of fatal side effects).

If one is considering an industry, such as the Euro-American, R&D-driven pharmaceutical industry, which operates within a value system that is fundamentally dependent on market growth, then one has to consider the various ways in which markets can be potentially grown. One way for a company to grow its market is to come out with a new therapeutic molecule—but this is time consuming, expensive, and risky and has not been as successful over the past decade as capital markets require. A second way is by expanding the indications for medications on the market through off-label use or reframing diseases as chronic or requiring prophylactic and preventive intervention, which is the mechanism of surplus health generation that Dumit has described in his work. This suggests a form of expanding therapeutic consumption that is not necessarily related to expanding the domains of treatment into new arenas, but is rather about expanding the domain of disease itself.[11] A third way in principle is to expand markets spatially, especially into emerging markets. This is harder to do for the pharmaceutical industry because of its concerns with protecting intellectual property (and this is where providing global security to companies' intellectual property through the WTO becomes important) and in maintaining control of their ability to set prices, which itself is limited in ways that I elaborate shortly. Therefore, including developing country populations within a global market calculus, while attractive, is variously constrained. However, value can be increased if the price of drug development is reduced. This is best achieved by reducing the cost of the clinical trials process through outsourcing the trials to the developing world. This does not require the developing world to be constituted as a market—one does not need to sell a drug in a country in which one tests a drug. I elaborate upon this logic with reference to India.

Clinical Trials

India has over the past forty years developed a thriving national pharmaceutical industry, built on the basis of a process patent regime, instituted in 1970, which did not allow patents on drug molecules but only on the process by which they could be manufactured. Unlike many developing (and indeed developed) country contexts, India never instituted a system of nationalized

access to medicines, or even a properly functioning system of government-imposed price controls on drugs. Hence, price regulation has largely been a function of the market. This means that the question of what kind of market is operational is critical.

India has become incorporated into the globalization of drug development in two ways since the mid-1990s. As described in the introduction, one concerns the globalization of clinical trials, and the second concerns the globalization of intellectual property regimes under the aegis of the WTO. This shift in patent regimes was happening at a time when one was seeing the emergence of a new industry segment in biomedicine—existing solely to conduct clinical trials, and operationalized by companies called clinical research organizations (CROs). As clinical trials have moved more and more into the private sector in the United States over the past three decades, these companies have come to constitute an autonomous sector within the drug development industry. Unlike that of the pharmaceutical companies, their locus of value lies not even in the valorized expansion of health but simply in the valorized expansion of pharmaceutical clinical trials. India is a potentially attractive destination for clinical trials because of the presence of low-cost, bioavailable experimental subject populations, combined with good quality medical infrastructure.

And so, logics of capital as they expand globally exclude certain populations from the therapeutic market but include them as experimental subjects in global pharmaceutical clinical trials (K. Sunder Rajan 2007). These are populations that are incorporated as labor in the process of biomedical value generation, but not as consumers. Hence, the very imagination of trial populations in India is merely as risked experimental subjects, without the implicit social contract of therapeutic access at the end of the day. Layered onto these structural logics are the historical conditions that lead to the possibility of the configuration of such merely risked experimental subjectivities in the first place. I have described in earlier work how the kinds of subjects who get recruited into especially early stage clinical trials on healthy volunteers in India are often those who are victims of other kinds of prior dispossession (K. Sunder Rajan 2005, 2007). (Examples include mill workers in Bombay who have lost their jobs because of the evisceration of the textile industry, or, more recently, diamond workers in Surat who are following similar trajectories of de-proletarianization leading to experimental subjectivity).

The clinical trials situation represents a constitutive condition of exclusion from the therapeutic market in order to be enrolled as experimental subjects for drugs that others consume. This reflects the fact that India has

cheap, bioavailable bodies.[12] But there is also the fact that India is a country with a burgeoning consumer class and constitutes an emerging market of enormous potential. In this register, there is a desire to include India in a global pharmaceutical market imaginary. Hence, the very same pharmaceutical company logics that make it attractive to outsource clinical trials to developing country locations like India also make it attractive to imagine India as a potential pharmaceutical market. I discuss the manner in which this plays out in terms of impacts on access to medicines.

Access to Medicines

The envisaging of countries like India as a potential therapeutic market by the Western pharmaceutical industry is constrained by one important factor and conditioned by another. The condition is a stringent intellectual property regime, which is what these companies now have post-WTO. This allows companies a monopoly and allows them to set prices as they would in the United States or Europe, which is essential for them in order to protect their high prices in those primary markets. But it is precisely this that limits how much countries like India can be imagined as markets at all, since this necessarily leads to the pricing of many patented therapeutics beyond what many Indian patients can afford. This potentially puts Indian populations into crisis in another register, the denial of access to many essential medicines for large sections that might have been able to afford this medication under a previous process patent regime, not because of market exclusion, but because of the inclusion of India in a global market regime that operates through logics that require the establishment of monopolistic business models at the expense of the free market competition in generic drugs that prevailed earlier.

India's insertion into a surplus health economy also means that it puts the Indian generic industry potentially in crisis, even as it leverages this terrain in strategic ways. Indeed, Indian generics companies use these logics of capital as gestures of public service that are animated both by strategic calculation and often by postcolonial nationalist impulses, even as they thus legitimize their own claim to profits (see chapter 5). Nonetheless, these maneuvers occur on uneven playing fields against powerful competitors. One is already seeing a trend whereby larger Indian companies have emerged as attractive acquisition targets for multinational pharmaceutical companies, not least because of their generic capabilities that are potentially attractive to leverage for revenues by acquiring companies in post–patent cliff scenarios in the West. Hence, there is a movement whereby Indian companies are shifting from being the manufacturers of bulk drugs as commodities for

sale in Indian markets to becoming outsourced manufacturing facilities for multinational pharmaceutical companies—that is, if they are not going out of business entirely. Examples of major acquisitions in the past few years include the part sale of Ranbaxy, India's largest pharmaceutical company, to the Japanese company Daiichi Sankyo; of Nicholas Piramal India Limited, India's fourth largest pharmaceutical company, to the American company Abbott Laboratories; and of Shantha Biotechnics, one of India's largest biotechnology companies, to the French company Sanofi-Aventis. These moves suggest the difficulties of surviving as a large Indian generics company in the post-WTO climate, where reverse engineering new drugs becomes legally difficult or impossible and where moving to an R&D-driven business model that involves competing with global pharmaceutical powers is strategically difficult. But they are also consonant with the move of the Euro-American R&D-driven industry to focus increasingly on M&A rather than R&D to build their own capabilities and ensure their own survival.[13]

The progressive acquisition of the Indian industry is consequential not just for Indian patients, but for patients throughout the developing world, especially when it comes to access to essential medications such as antiretrovirals. This is particularly the case given that drug prices under monopoly regimes are likely to be significantly higher than those under a regime of free market competition, especially if the monopolistic price point is identical to the price point set in the United States. This opens up the broader question of the constraints of drug pricing, which involves understanding the institutional relationships of R&D-driven pharmaceutical companies to the consumer marketplace. I explain the structure of this relationship next.

Consumer Markets and Global Drug Pricing

I have argued that the monopoly provided by the patent to the multinational, R&D-driven Euro-American pharmaceutical industry is fundamental to protecting its market interests. Understanding this involves explaining how this consumer market is constituted globally. The economic rationalization for the patent follows the argument for monopoly capitalism propounded by Joseph Schumpeter (1942), which is that monopoly provides incentives to innovate. The post-1980s history of the R&D-driven pharmaceutical industry—one that sees it driven less and less by R&D—should force us to at least complicate this assumption. What does an "incentive to innovate" mean in the context of an industry that is increasingly speculative rather than innovative? How does the monopoly provide security to speculate rather than or in addition to

incentive to innovate? In order to answer this question, I explain some of the complexities faced by pharmaceutical companies as they price drugs globally. But before I do so, it is worth layering this Schumpeterian rationality that justifies monopolistic action on the part of the pharmaceutical industry upon another important rationality from the early twentieth century that is important to understanding the operation of speculative financial markets. This concerns the distinction made by Frank Knight (1921) between risk, as something that is in principle calculable and probabilistic, and uncertainty, which is fundamentally not.

There are three kinds of risk or uncertainty that contemporary R&D-driven pharmaceutical companies potentially face. The first, which intuitively seems the riskiest, is financial speculation. The pressures of the financial marketplace place enormous constraints on the innovative activities of these companies. And yet, from the perspective of pharmaceutical corporate logic, financial speculation is in many ways the safest of the three kinds of risk or uncertainty precisely because it is risky as opposed to uncertain. However speculative financialization might actually be, there remains the constant fiction of calculability.[14] The second is the risk of the clinical trials process. This shades into uncertainty rather than risk, since it is ultimately impossible to predict how a therapeutic molecule will interact with human physiologies, whether those interactions will lead to favorable safety and efficacy profiles, and if those profiles, even if favorable, are attractive enough relative to other drugs for the indication in question to actually garner a market. Reducing the cost of clinical trials by outsourcing them to cheaper locales cannot reduce its biomedical uncertainty, but could in principle reduce financial risk simply by decreasing the amount of capital investment required. But this is also uncertainty that pharmaceutical companies try and convert to risk through innovations in the clinical trials process itself—for instance, by designing procedures that can kill molecules unlikely to come through clinical trials as early in the process as possible (such as through the development of surrogate markers that can provisionally indicate probabilities of safety or efficacy in simulated experimental systems), or by developing adaptive clinical trials that constantly feed results of a particular stage of the process back in ways that allow for a more precise calibration and design of subsequent stages.

It is the third kind of uncertainty that is the least calculable—and that is market uncertainty, especially in different parts of the world. This in part is caused by the prospect of generic competition; but it is also constituted by the fact that drug consumption is mediated by two parties other than the

patient—the prescriber and the payer. In some systems, such as the American managed care system, the payer is a private entity such as an insurance company (except in programs such as Medicare and Medicaid, or institutions such as the Veterans Administration, in which the government acts as the payer). In other systems—including most major non-U.S. pharmaceutical markets such as western Europe, Canada, Japan, and Australia—the government is the payer. In a very few countries, India being one, drugs are directly sold (through prescribers) to patients, as commodities in a consumer market. India does not have any system of nationalized dispensation of drugs for the majority of its population (though it does for central government employees through the Central Government Health Scheme), and private insurance, while an emerging market segment, does not structure drug payment the way it does in American managed care environments. Therefore, pharmaceutical companies have to negotiate a different kind of consumer market terrain in different countries, constituted by the willingness of particular kinds of payers to pay for certain drugs. In addition, governments have the ability to control markets not just by deciding (in nationalized health systems) which drugs they will buy, but also by imposing price controls on drugs. In principle therefore, the desire for monopoly is offset (and indeed fueled) by the possibility of monopsony, a market form in which one buyer faces many sellers. Negotiating this uncertain terrain—which is variegated across space and always capable of changing over time because of political pressure or policy modification—is a source of enormous and constant structural and strategic anxiety for the pharmaceutical industry.

Even in primarily free drug consumer markets such as India, the structure of monopsony elsewhere conditions pharmaceutical company pricing decisions.[15] One could imagine a situation in which the vast emerging market that India potentially represents could be tapped by the R&D-driven pharmaceutical industry simply by pricing drugs competitively. While there are certainly examples of such differential pricing strategies in emerging markets or the developing world more generally, it is the exception rather than the norm, which tends toward pricing drugs globally similarly to how they are priced in the United States. This often means setting prices beyond what many developing and emerging markets can bear.[16] One sees this in the case of Gleevec (elaborated in chapter 3), as Novartis's Indian price for the drug was the same as in the United States (at the time of approval, this was approximately $2,700 per patient per month), thereby making it effectively unaffordable even for relatively affluent Indian consumers. At the same time, the company attempted to enforce a monopoly on the drug and prevent generic

manufacturers, who were making the drug available for $100–300 per patient per month, from selling it. In other words, it was preventing free market competition in a life-saving drug in a context in which it was not going to make much money on that drug anyway. This intuitively seems perverse, and Novartis indeed garnered enormous bad publicity as a consequence; this was the strategy that epitomized the caricature of the evil pharmaceutical corporation.

Without wishing to defend Novartis's actions, I argue that this reflects the stakes of global drug pricing for the R&D-driven pharmaceutical industry, which are to protect market interests in Euro-American (and Japanese) markets. The two factors that pressure pharmaceutical companies in this regard are monopsonistic government payer systems (especially in Europe) and the threat of arbitrage. Monopsony allows governments to make their own calculations of how much they are willing to pay for a drug, how much they are willing to allow it to be priced on their national market (direct price controls), and what instruments they will use to make these determinations. In some countries—the United Kingdom, most notably—health economics has developed as an elaborate discipline precisely in order to make such cost-benefit calculations, between expense to the government and the quality of life years that would accrue through the use of a particular drug.[17] Other governments (including in the U.K. and most European countries) use systems of international price referencing, by which they will study the prices of the drugs in other markets and determine their own willingness to pay based on those prices. Such interactions with governments—whether through economic instruments of price determination or through more direct political pressures—constrain the willingness of companies to sell drugs far more cheaply in some countries than others. Had Novartis sold Gleevec at $300 per patient per month in India, it might have faced consequences for how much European governments would have been willing to pay for the drug. It would certainly have faced political ramifications in the United States for selling it at a tenfold price differential, given the justifications for high drug prices because of the enormous investment companies put into developing a new molecule.[18]

Largely different prices in different countries also imply the possibility of arbitrage. The homogenization of intellectual property regimes is one form of globalization, an attempt to create a uniformly monopolistic global market. But there is the threat of another kind of globalization, the creation of a diasporic pharmaceutical that crosses borders, especially if drugs in one country are much cheaper than in another. One sees a version of this phe-

nomenon in relation to advanced medical and hospital care through medical tourism, where patients cross borders (usually from affluent nations where care is expensive to developing nations such as India and Thailand that have strong medical infrastructures). Pharmaceutical companies are wary of a similar (though inverse) flow of medication, from cheaper to more expensive markets. Uniform pricing of their drugs is a way to prevent that.

This creates additional incentives for global monopoly, as generic drugs also present a threat of arbitrage. There would not just have been a danger of political ramifications or price referencing had Novartis priced Gleevec competitively in India; there would also have been the danger of patients in Western markets importing the drug from India. And even though Novartis priced Gleevec at U.S. price points, the manufacture of generic versions of the drug in India even as Gleevec was a patented medication in other countries presented the threat of arbitrage and an effective decrease in market monopoly even in markets where Novartis legally had one. Indeed, one saw such arbitrage occurring between India and South Korea: consequent to Novartis's refusal to price the drug competitively in Korean markets, leukemia patient groups arranged to buy the drug from the Hyderabad-based generic company Natco Pharmaceuticals for a fraction of the cost. In addition to such exceptional arrangements that emerged in relation to particular political moments, parallel trading companies have developed in Europe, the Middle East, and parts of Asia as wholesalers that purchase pharmaceuticals in low-priced countries and sell them at cheaper rates in higher-priced countries. The threat of arbitrage, therefore, is not hypothetical.[19]

Speculative Trajectories of Pharmaceutical Development

I have thus far argued that the Euro-American, R&D-driven pharmaceutical industry is shaped and constrained by two kinds of markets, the speculative market and the global consumer market. How might we think about the relationship between these specific sectoral constraints and relationships, logics of capital, and emergent forms of and spaces for politics? Here it is worth remembering two things. First, the particular dynamics of American speculative capital are both specific and differentiated. In other words, the logics of financialization that capture the industry are particularly American materializations of the logics of capital. Many larger Indian pharmaceutical companies, for instance, are also publicly traded, but Indian financial markets do not structure the ways they are valued to the degree and intensity that American financial markets do for the big multinational companies. Hence

even as it is important to understand the logics of capital that undergird the structure of crisis that I have outlined, one should stay attentive to the trajectories and dynamics of twentieth-century American corporate capitalism that shape the materializations of this structure.[20] Also, financial capitalism is not singular; it has its own histories and trajectories. The capture of the pharmaceutical industry by speculative financial capitalism speaks on the one hand to certain structural dynamics and constraints in modes and relations of production as they come to be underwritten by logics of capital, as analyzed in the preceding pages. But on the other hand, what this capture means is also shaped by and reflective of evolutions of and transformations within financial capital itself.[21]

How do we think about emergent forms of and spaces for politics in the context of a global biomedicine that is influenced by the capture of the Euro-American pharmaceutical industry by financial capital? Crisis is the structural manifestation of this capture; but crisis by itself does not lead to a destabilization of capital's own impetus toward accumulation and appreciation. On the contrary, as seen in the response across the representative political spectrum in the United States to the 2008 financial crisis, one often sees actions in response to crisis that bail out the entities and structures responsible for the crisis in the first place. This could be because of ideological and pragmatic commitments to institutions of capital accumulation and appreciation, or because of the reality or perception that the consequences of not bailing out those institutions would lead to crisis of even more cataclysmic proportions. It is a function of living in a world where it is not easy to imagine institutional structures that are outside of capital, which in Slavoj Žižek's formulation forms "the concrete universal of our historical epoch" (2004, 294).

What one does see in the case of the pharmaceutical industry is the destabilization of particular processes and actors—the blockbuster model of drug development is widely believed to be unviable; many companies in the United States have gone out of business or have been acquired over the past decade; and those companies that remain are in the process of going through massive reorganization. Both acquisition and reorganization require large-scale retrenchment. There are consequences here both for workers and for patients; for those patients who need drugs, as well as those who are imagined as always already needing drugs; for those who die due to a lack of therapeutic access, and for those who might die due to therapeutic excess. But the power of the speculative terrains upon which the pharmaceutical industry operates and to which it has increasingly come to be beholden con-

tinues undiminished. As an example, I discuss an epistemic rationalization for solving the crises I have just described through further intensification of speculative financialization. This speaks to one emergent form of a politics of financialization, which responds to its contradictions and crises by imagining and propounding a horizon of more derivative financialization.

In 2012, Jose-Maria Fernandez, Roger Stein, and Andrew Lo put forward a proposal in *Nature Biotechnology*. Written at the height of the patent cliff, they argued for funding biomedical innovation through financial engineering techniques such as portfolio theory and securitization through the creation of a speculative megafund that would invest solely in biomedical discovery and development.[22] The article provided a rationalization, using economic modeling, for solving a crisis of speculative capitalism in terms of even more speculative financialization.

Fernandez and colleagues recognize the pharmaceutical crisis that I have argued for, most especially the fact that being responsive to shareholders forces the industry to focus on near-term growth, leading to a business model that increasingly moves away from R&D toward M&A. The authors further recognize that a focus on M&A exacerbates the innovation crisis afflicting the industry; they understand that what the industry needs is the freedom to refocus on R&D, which the stock market does not provide. Their solution, however, is not a curtailment of speculation, but its intensification, involving the creation of investment structures that are more willing than public markets to bet broadly and over longer time periods on biomedical innovation. This is a proposal that is based on two ground realities: first, that biomedical innovation is highly capital intensive and requires initial investments that might not see immediate dividends and that are subject to a high risk of failure; and second, that the financial market is itself not a singular entity, but comprises many different kinds of real and possible vehicles for speculative capital investment. Fernandez and colleagues do not diagnose speculation itself as the cause of pharmaceutical crisis; only the particular kinds of speculative vehicles (based either in public equity markets, or, in the case of start-up or private biotechnology firms, often in venture capital) as being insufficient for the kinds of sustainable capital investment that pharmaceutical development requires.

Hence, the problem as diagnosed by Fernandez and colleagues is not that the pharmaceutical industry is beholden to financial markets and the expectations of speculative capital, but that they are to shareholders in public-equity markets, whose speculative horizons are necessarily short term and on the whole more risk averse than what the industry requires. Their solution

involves the creation of a special investment vehicle that is capable of bearing greater technoscientific and economic risk, associated respectively with the high probability of failure of any particular drug development venture, and with the high probability of consequent failed capital investment. Precisely because drug development is such a speculative scientific activity—a bet on the promise of a molecule successfully being developed as a safe and efficacious therapeutic that is able to garner enough of a consumer market to recoup the investment of time and capital spent in developing it—the authors argue for a more financially speculative instrument to accommodate it.

The investment vehicle that the authors propose involves creating large diversified portfolios of $5–30 billion called megafunds, consisting of biomedical innovations in different stages of development, and financed by a combination of equity and securitized debt. These are different from traditional investment vehicles for pharmaceuticals, therefore, in the nature of both the portfolio and the financing structure.

In terms of the portfolio, what the authors propose is an investment not in the company, but in particular drug development and biomedical innovation projects. The investors then would not acquire equity in a company, but rather royalties on particular products that might be developed. This allows for capital investment in a wide range of products spanning a large number of companies and is not constrained by the limited pipelines of any individual company. Such a broad range of product investment allows for risk pooling in a manner analogous to, albeit the inverse of, strategies adopted by the insurance industry. The insurance industry hedges its bets on having to make a large payoff on any single event, by offsetting it against many premiums that are collected which might never have to be paid out.[23] Similarly but inversely, the megafund would hedge its bets against a large number of failed drug candidates by hoping that a blockbuster success would offset those failures. This is a portfolio theory that makes use of the structure of the blockbuster model—one that sees a large number of failures, but potential billion-dollar molecules from its rare successes. Investing in a company's equity implies being constrained by the pipelines and growth prospects of each individual company, leading to the kinds of pressures described earlier by financial analysts for a company such as Eli Lilly that might face a patent cliff combined with an anemic pipeline, and the resulting structural push toward M&A. Investing in a broad range of biomedical innovation projects across multiple companies at different stages of development, on the other hand, reduces these near-term, company-specific pressures and would therefore, the authors suggest, allow companies to refocus on long-term R&D projects.

In terms of financing, the authors propose securitization, which they define as "a financing method in which a pool of investment capital is raised by issuing equity as well as several classes of bonds that differ from each other in their risk-reward profile to a diverse population of investors, and in which the funds are used to invest in various assets that serve as collaterals for the bonds" (Fernandez, Stein, and Lo 2012, 965). In other words, rather than just issuing equity—part ownership of a company to a shareholder through stocks in the company—securitization is the creation of a tradable financial instrument (which may include equity in the company, but also other kinds of investments such as bonds). Rather than buying and selling direct ownership in the company, an investor would be trading the instrument itself—in this case, an instrument that is not attached to any single company, but to multiple product pipelines in different stages of development.[24] The classic (and now infamous) example of securitized debt is mortgage-backed securities, which combined mortgages into a large pool that was then divided into smaller pieces that could be sold to investors as a type of bond. As with the megafund proposal, the foundation of mortgage-backed securities was risk pooling—an assumption that if enough mortgages were pooled, then the risk of collective default would be mitigated. Similarly, the assumption of Fernandez and colleagues is that if enough biomedical innovation projects are pooled into the megafund, the risk of collective failure would be mitigated. Hence, the portfolio structure and the financing instruments mutually constitute one another.[25]

Fernandez and colleagues' proposal extends the domain of speculation beyond anything that currently exists. Biopharmaceutical mutual funds, for example, also pool risks by including multiple different companies in the fund, but invest only in publicly traded companies. The megafund proposal calls for investment not just in public companies but also in startups (typically the domain of venture capital), private companies, royalty streams, and intellectual property. However, elements of their proposal do already exist. For instance, there are speculative entities called drug-royalty investment companies that invest in pipelines in exchange for a share in royalties accruing from products that might emerge. But they only invest in product candidates in late-stage clinical trials or acquire royalty interests in products already approved for market. The authors, however, seek to extend financial speculation into the domain of early stage drug discovery, the more upstream components of the process of biopharmaceutical development that have tended to be conducted largely out of universities or smaller entrepreneurial companies (often seeded out of universities). Therefore while the contradictions

and crises that emerge from the appropriation of health by capital have led to calls for greater public investment in downstream research, especially in clinical trials (Lewis, Reichman, and So 2007), Fernandez and colleagues, in contrast, call for even greater speculative capitalization of R&D, ever more upstream. The terrain of the political within which pharmaceutical crisis unfolds is constituted by both possible directions in which it could resolve.

There are two problems with the assumptions that underlie the megafund proposal. First, the authors assume that the only thing that prevents pharmaceutical corporations from focusing on R&D is the short-term capital pressures that force them toward M&A. In other words, they assume that given appropriate long-term capital investment and financial security, corporations will innovate and leave it to investors to speculate. This does not account for the radical extent to which the (especially American) corporation has itself become financialized. Pharmaceutical companies do not just respond to investment pressures that are imposed by a financial market that is external to them; they are active speculators in that market themselves. Speculation is no longer just an action undertaken by the (American) corporation; it is increasingly its very raison d'être.

Business historian William Lazonick (2010) identifies the financialization of the American corporation as the major attribute of the post-1970s high-tech corporate economy. Lazonick contrasts many attributes of this "new economy" corporation to that of the older, "managerial" corporation of the early to mid-twentieth century. Most pertinent here is his argument that a speculative and liquid stock market as a defining feature of this financialized economy is an inducement not just to capital (upon which Fernandez an colleagues base their proposal) but also to labor: especially to corporate executives, whose own incentives and compensation have become increasingly tied to speculative instruments such as stock options. In other words, those who run American corporations have over the past two decades been increasingly incentivized to themselves speculate on the financial markets. Lazonick shows that while stock prices were driven in the high-tech economy by innovation in the 1980s, it was speculation that was the major driver in the 1990s. He points to how companies have since 2000 engaged in stock price manipulations through massive stock repurchases.[26] Pharmaceutical companies have been among the largest repurchasers of stock: between 2000 and 2008, Pfizer repurchased $50.6 billion of its own stock, Johnson and Johnson $33.3 billion, Amgen $22.6 billion, and Merck $18.7 billion (Lazonick 2010, 699). Repurchases are an indicator of a move to purer and purer speculation that is not coupled to innovation.[27] Fernandez, Stein, and Lo's

assumption that a pharmaceutical corporation is fundamentally an innovative rather than a speculative entity is not borne out by recent history. Add to this Dumit's analysis of how the R&D-driven pharmaceutical industry is now driven also by the fiction of speculative treatments to increase market share, and what one sees is a structure of speculation all the way down.

The second assumption that Fernandez, Stein, and Lo make is a "growing demand for therapeutics from a grateful and price-insensitive clientele" (2012, 964). Undoubtedly, prescription rates for pharmaceuticals in the United States have continued to grow with no signs of abatement. But the idea that this is occurring among a "price-insensitive clientele" is simply wrong. Drug pricing has become an increasingly political issue in the United States and remains a vexed issue globally, as I have described.[28] However, this is elided in the arguments for ever more intense and derivative forms of financialization. Regardless of whether, how, and where such forms are realized, such arguments are a reminder of the sensibilities that have appropriated Euro-American multinational pharmaceutical capital. The global consequence of these appropriations is worth empirically attending to. Indeed, the emergent and constitutive forms of pharmaceutical politics in India are precisely not financialized, and operate through other registers and modalities, as explored in subsequent chapters. But the power of financial capital to structure political economic terrains of global biomedicine remains. It is important to attend to the simultaneous particularity (and hence nonuniversality) of financialized pharmaceutical capitalism and to its hegemony.

In this chapter, I have schematically mapped a political economic structure of crisis, which is also a structure of therapeutic development and value generation. This structure, however, is not singular. It is striated, differentiated, and layered. One can see this in the various kinds of economies that are at stake in this analysis. First, there is an economy of manufacturing and sale, which is an industrial economy and has to do with the making and selling of therapeutic molecules. With the reorganization and downsizing of large R&D-driven pharmaceutical industries and the acquisition of smaller companies and generics companies, this economy is marked by labor insecurity and large-scale retrenchment. But this reflects a more general condition of the crisis of contemporary capitalism, marked by high unemployment and more and more precarious conditions of labor.

Second, there is an economy of research and development, which is a knowledge economy. This operates in the register of innovation, and has to do with intellectual labor. This is a structure of value generation within the pharmaceutical industry that is itself in crisis. This does not mean that R&D

no longer happens; but its nature, contexts, and locations shift. One of the major directions of this shift is toward smaller biotechnology companies and in association with universities that are themselves becoming more entrepreneurial and corporate. There is also a shift toward more rational or translational forms of drug development—the development of drugs that are designed to set right abnormally functioning processes at a cellular or molecular level, developed out of an understanding of basic biological processes.[29]

Third, there is an economy of clinical trials. Institutionally, this has emerged as a more and more autonomous structure, with the development of for-profit CROs as outsourcing service shops to conduct trials for pharmaceutical companies, including especially globally. This creates new forms of labor, especially the labor of experimental subjectivity, a function of the bioavailability of (often previously marginalized and/or dispossessed) subject populations for biomedical research, but also the labor of conducting and monitoring clinical trials, something I do not explore in this book, but which is also usually relatively low-wage, high-intensity work that is often gendered. (Most clinical research monitors tend to be women, since most of this labor pool is drawn from the nursing profession.) This is an economy that maps onto other kinds of globalizing labor that depends upon the bioavailability of (marginal or dispossessed) bodies, such as that of surrogacy and other forms of reproductive labor (Waldby and Cooper 2008; Cooper and Waldby 2014).

And fourth, there is the economy of health itself, which maps onto the various labor economies that are at stake. This concerns the appropriation of health by capital, the way in which health itself becomes the locus of value generation (rather than, as in Marx's analysis of industrial capital, simply the means to reproducing the conditions of production by maintaining a healthy labor force). This is not just about health becoming valuable; it also speaks to all the deeply charged ethical dimensions in play when questions of life and death come to be at stake. It is in part about what Mary-Jo DelVecchio Good and colleagues (1990) have called a political economy of hope but also involves other kinds of affective entanglements, of obligation, commitment, indebtedness, and love.[30] This is an economy in relation to which the development of a critical voice is always fraught and contradictory—how to simultaneously argue for therapeutic access to essential medicines for those who need it while critiquing economies of therapeutic excess and saturation? This is where the turn to the state, and the empirical specificities of political engagement with the state, become important. This is the focus of the chapters 2 and 3, concerning the HPV vaccine and Gleevec cases respectively.

I do not outline the structure of crisis in pharmaceutical economies consequent to their operation under logics of capital simply in order to make a diagnosis. Rather, I develop the idea of contending different relations of production in order to open up questions (tackled in the next two chapters) of the antinomies of the state as it confronts its obligations to fulfill and balance the opposed imperatives of providing for the health of its population (biopolitics) and using biomedicine as an engine of economic and capital expansion (biocapital). For this, understanding the speculative financialized logics under which the multinational R&D-driven industry operates is important.

The question of market value is a central structural feature of this analysis, speaking as it does to the logics of capital under which pharmaceutical economies operate. This does not mean that all value is reduced to monetary value; quite the contrary. This book as a whole attempts to parse out the multiplicity of value forms at stake in contemporary global pharmaceutical economies (see introduction). But I also want to be attentive to the relations of power between these forms. Logics of capital are never purely internal to capital; they have the ability, indeed the need, to appropriate other kinds of value logics that are seemingly external to capital. This is precisely what happens when health becomes surplus health. This appropriation does not occur seamlessly or similarly across place or time, and these are the differentiations that constitute the terrain of the political. This is where the institutional mediation of the materializations of logics of capital through governance regimes becomes important. The corporation itself is not a singular entity, and different types of corporation are subject to different trajectories of capitalization as they are located in different relations of production. My focus in this chapter has been on the speculative financialization that comes to possess the R&D-driven pharmaceutical corporation; because of the power of such corporations, such financialization has broader structuring effects on global pharmaceutical economies as a whole. But there are other trajectories, such as those followed by Indian generics companies, which speak to different relations of production (see chapter 5).

In other words, even if the logics of corporate capital are based on the generation of surplus, there are still multiple different capitalisms that see the materializations of these logics in different ways, times, and places. At a basic level, two kinds of relations of production I am interested in tracing include that which the Euro-American, R&D-driven pharmaceutical industry operates within and that which the Indian generic industry operates within. There are many intricacies to each of these sectors that I have not explored, but the

operational distinction I am making between them concerns different strategies for drug development (based, respectively, on the R&D of novel therapeutic entities and their movement to market after an elaborate process of clinical trials for regulatory approval, and on reverse engineering generic versions of molecules that are already on the market) as well as different market terrains (the former, increasingly, highly speculative and financialized, and dependent upon monopoly protections afforded by the patent; the latter based more in a terrain that sees drugs sold as commodities, competing with each other on price through the free market).

At the start of The Grundrisse, *Marx analyzed the banking crisis of 1855 by engaging in a polemic against socialists who attributed the crisis to the malfeasance of the banks. Marx responded by showing that in fact, the so-called malfeasance of the banks was simply a case of banks acting like, well, banks.*[31] *In other words, what is critical for Marx is an understanding of the crisis in structural terms. But what does* structure *mean in this case? I suggest that it concerns first an elucidation of the logics of capital, and second an account of the ways in which institutional actors historically came to be captured within those logics, so that it became both sensible and apparently natural for these actors to act in the interests of capital. This does not mean that there is no variance in the particular strategic actions of particular actors. Novartis's refusal to differentially price Gleevec is a different response than GlaxoSmithKline's more aggressive embrace of differential pricing strategies in recent years (Froud and Sukhdev 2006); similarly, the megafund proposal put forth by Fernandez, Stein, and Lo speaks to different modalities, strategies, and intensities of speculative activity and reminds us that financialization is not a singular process but has its own histories and divergences. But it is nonetheless possible to discern certain sectoral trajectories that see the appropriation of health by increasingly financialized capital. This leads to crisis: not just because the interests of capital invariably involve alienation, expropriation, and exploitation, but because, left to itself, capital cannot set itself limits, and hence ends up putting its own institutions in crisis. This is what happened with the banks in 1855; it is what happened with the banks in 2008.*

The pharmaceutical industry is an industry that is itself in crisis, and I emphasize the historical tendencies toward privatization, leading to an appropriation of health itself by capital; toward speculation, leading to a move away from research and development toward mergers and acquisitions; and toward globalization, a terrain that is secured through globally harmonized intellectual property and clinical trials regulatory regimes. In the process, the attempts to respond to pharmaceutical crisis lead, on the one hand, to larger,

even more speculative industries, thereby reinforcing the very conditions that led to the crisis in the first place. And on the other hand, the globalization of the crisis impacts people and industries in other parts of the world. What crisis might mean is different for different actors. This difference also precludes the possibility of easy solidarity and makes it difficult to understand the ways in which, for instance, there is a structural relationship between an affluent patient in a therapeutically saturated market who has died because of side effects of Vioxx, which has everything to do with things like off-label use and therapeutic saturation, and a patient who has been excluded from drug markets altogether, perhaps in the so-called Global South, who has died because she could not afford an essential anticancer or antiretroviral medication that could have allowed her to live, and for which manufacturing capacity at an affordable cost exists. Any adequate critical and political response to this crisis has to understand the ways in which health itself has come to be redefined through its appropriation by a globalizing, speculative capital, and has to insist upon an imagination and institutionalization of a form of health that resists such appropriation. Unless we understand the genesis of crisis as residing in the value form itself as it gets appropriated by logics of capital (so that these logics come to define what value means, in all of its material, abstract, symbolic, and agential manifestations), it is impossible to think of transcending the crisis through simply institutional responses.