Pharmocracy

Value, Politics, and Knowledge in Global Biomedicine

Kaushik Sunder Rajan

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Experimental Futures

Technological lives, scientific arts, anthropological voices

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For Q.

HOW NOW?

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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

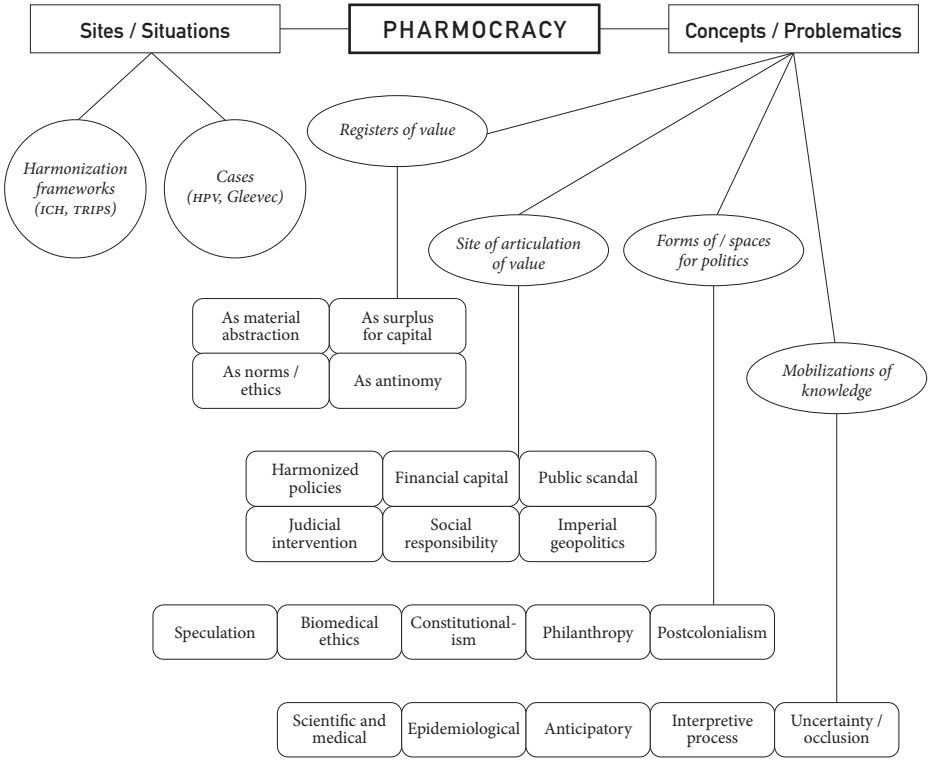

FIGURE I.1

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.

NOTES

INTRODUCTION

1. Conversation with the author, Qazi Camp, Bhopal, November 23, 2011 (translated from Hindi).

2. Satinath Sarangi, conversation with the author, October 31, 2012. See also Hanna (2006).

3. Yusuf Hamied, interview with the author, August 28, 2008.

4. Interview with the author, November 2, 2012.

5. Current industry estimates put the cost of developing a new drug molecule in excess of $2 billion, with a failure rate of nearly 80 percent. While such figures have been disputed in some corners, they are widely accepted and form a basis for the justification of patent monopolies and high drug prices in the United States. I discuss this in greater detail in chapter 1, and unpack the ideology of innovation that underlies assumptions such as these through the course of this book.

6. Gramsci developed the notion of hegemony through a series of observations, many of which were recorded when he was imprisoned by the Italian Fascist government in the late 1920s and 1930s, and subsequently compiled into his famous *Prison Notebooks* (Hoare and Nowell-Smith 1971). Therefore this is not a term that he describes with a single definition, but is rather a problematic that he developed through fragmentary writings on a range of contemporary political issues over a number of years.

7. Even though I am uncomfortable with the term *harmonization*, I use it here as an actor's category that describes the processes I am interesting in unpacking.

8. I am referring here to pharmaceutical clinical trials, that is, the conduct of clinical trials to approve new drugs for market. There are many other forms of clinical research that may not be about drug approval: for example, epidemiological, outcomes-based public health research. While it is important to distinguish between the two, it is not always easy to make clean-cut distinctions (see chapter 2).

9. Important ethnographic work describing the rise of the CRO industry in the United States and globally includes Adriana Petryna's (2009) *When Experiments Travel* and Jill Fisher's (2008) *Medical Research for Hire*. Petryna is especially concerned with the globalization of clinical trials, a process that started in earnest in the mid-1990s, and the consequent "ethical variability" that has emerged in the conduct

of trials in different parts of the world. Fisher is more concerned with the privatization of trials as a function of broader neoliberal transformations in health care in the United States.

10. See Wen-Hua Kuo (2005, 2012) for an ethnographic account of ICH deliberations in the first decade of the 2000s in the context of establishing drug regulatory frameworks in Japan, Taiwan, and Singapore.

11. For an elaboration of the lobbying power of the multinational pharmaceutical industry in the Uruguay Round of TRIPS negotiations, see Sell (2003).

12. See Lawrence Cohen's (1999) elaboration of what he calls ethical and scandalous publicity as forms of publicity that operate alongside each other in the context of the debate around the organ trade, and João Biehl and Adriana Petryna's (2011) elaboration of the judicialization of pharmaceutical politics in Brazil. I elaborate upon these notions in chapters 2 and 3 respectively.

13. There is now a body of ethnographic work on science and technology that takes the hypercomplexity of the worlds it studies as a starting point and attempts to wade through and unpack that complexity rather than analytically reduce it. For some exemplary works in this regard (by no means a comprehensive list), see Lochlann Jain's (2013) *Malignant* (on cancer), Joseph Masco's (2014) *The Theater of Operations* (on the American security state), Michelle Murphy's (2017) *The Economization of Life* (a transnational history of U.S.-funded demography); Jake Kosek's forthcoming *Homo-Apians* (a critical history of the modern honey-bee), and Kim Fortun's book in progress, *Late Industrialism: Making Environmental Sense* (on environmental knowledge making over the past two decades). The strategies and entry point into studying complex worlds in these works are all different, but they all operate in various ways across sites, scales, and domains in their analysis. Kim Fortun's (2001) *Advocacy after Bhopal*, to me, remains an early template and model of such ambitious work.

14. The drug in question has been marketed by Novartis as Gleevec in the United States, and as Glivec in the rest of the world. For the sake of consistency, I use Gleevec throughout the book, even though as the drug become a site of legal and political contestation in India, it was referred to as Glivec.

15. See Wailoo et al. (2010) for a collection of essays addressing the biomedical and political significance of the HPV vaccine.

16. See Mukherjee (2010) and Keating and Cambrosio (2012) for accounts of Gleevec's importance in the history of cancer research and therapy.

17. There is a rich body of work that theorizes reproductive politics in the context of biotechnology and biomedicine (see for instance Clarke 1998; Cooper and Waldby 2014; Franklin 2013; Ginsburg and Rapp 1995; Murphy 2012, 2017; Thompson 2006, 2013; Rapp 2000).

18. While the trajectory of access to medicines politics in India is marked by judicialization and that of clinical trials politics by public scandal, this distinction is not absolute. In 2007, there was significant civil society mobilization in India and elsewhere against Novartis taking the Indian Patent Office to the Madras High Court, which manifested as a Drop the Case campaign orchestrated by MSF and explicitly framed Novartis's actions as scandalously denying essential medications to poor

people who needed them by insisting upon monopoly rights for Gleevec. And conversely, clinical trials politics have subsequently come to be judicialized, subsequent to the filing of public interest litigation in the Indian Supreme Court in 2013 that demanded further investigation into the HPV vaccine studies.

19. Biehl and Petryna develop their notion in relation to empirical material from Brazil. The processes that I trace in India show similar trajectories but also empirical and contextual specificities. A broader comparison of pharmaceutical politics in different parts of the Global South would be an essential exercise, and is being undertaken by Jean-Paul Gaudilliere, Laurent Pordie, and Maurice Cassier and colleagues (see for instance Cassier 2012). Biehl and Petryna's concept itself draws upon Jean and John Comaroff's account of the judicialization of politics in South Africa, another critical node in Global Southern politics around health (Comaroff and Comaroff 2006). While they consider politics in a broad sense, the Comaroffs specifically point to the domain of pharmaceutical and especially antiretroviral politics in their account of judicialization.

20. In her account of the Ameena case, Rajeswari Sunder Rajan uses the case as a problem space of "having to think *beyond* exemplarity yet well *before* an untheorizable particularity" (R. Sunder Rajan 2003, 41–71, esp. 42). Sunder Rajan describes the rescue of a girl, Ameena, who had been married to an elderly Saudi national by her parents in Hyderabad. When situated alongside another seminal case from a few years earlier that Sunder Rajan (with Zakia Pathak) has also written about, the Shahbano case (Pathak and R. Sunder Rajan 1989), the value of the case as elucidating the terrain of the political becomes particularly resonant. Taken together, the Shahbano and Ameena cases, while significant critical events in and of themselves, also frame a broader political conjuncture of importance. I will elaborate upon the importance of the notion of conjuncture for my analysis subsequently.

21. He says as much in *The Grundrisse*: "To develop the concept of capital it is necessary to begin not with labour but with value, and precisely, with exchange value in an already developed movement of circulation" (Marx [1857] 1993, 259). This does not mean that labor is unimportant; just that one can only understand how it comes to be at stake, alienated, and exploited if one begins one's analysis from the question of value.

22. My readings of value theory in Marx have been influenced greatly Louis Althusser and Etienne Balibar's ([1970] 2009) *Reading Capital*, Balibar's (1995) *Philosophy of Marx*, Antonio Negri's ([1973] 1992) *Marx beyond Marx*, Gayatri Spivak's (1985) "Scattered Speculations on the Question of Value," and Moishe Postone's (1993) *Time, Labor and Social Domination*. Each of these authors has different specific inflections and investments in their reading of Marx; but all of them develop the critical potential of his labor theory of value through a close attention to his analytic method.

23. Marx writes this at precisely the moment when he introduces the concept of surplus value in volume 1 of *Capital*.

24. Other work that discusses the political economy of health in the context of capitalist modes and relations of production includes Vicente Navarro's (1976) *Medicine under Capitalism*, Lesley Doyal's (1979) *The Political Economy of Health*, and Milton

Silverman and Philip Lee's (1974) *Pills, Profits and Politics*. See also Michael Taussig's (1980) "Reification and the Consciousness of the Patient" for a more conceptual development of these issues that anticipates elements of the argument Dumit makes three decades later.

25. In this regard, see also Dumit's "BioMarx" experiment, a search-and-replace in volume 1 of *Capital*, at http://dumit.net/biomarx-experiment/ (last accessed September 2, 2015).

26. While my own conceptualization of value is deeply influenced by Dumit's reading of Marx, it should be emphasized that his is just one mode of conceptualizing value in relation to health and pharmaceuticals. There are a number of other modes of analysis that are complementary to Dumit's, all interested in modes and relations of production but using different entry points and foregrounding different conceptual questions. A (by no means comprehensive) list of some of these other approaches includes Laurent Pordie and Jean-Paul Gaudilliere's (2014) focus on use values in pharmaceutical development through a study of reformulation practices in Ayurveda; Kristin Peterson's (2014a, 2014b) focus on the constitution of different kinds of markets in Nigeria, from monopoly markets in patent medications controlled by Euro-American pharmaceutical companies to free markets in generic drugs controlled by Indian companies to informal markets in fake and counterfeit drugs, all often operating in the same physical spaces of exchange; Maurice Cassier's (forthcoming) ongoing study of the reconstitution of modes of production and industrial organization of pharmaceutical manufacture; Cori Hayden's (2007, 2010) analysis of "the politics of the copy," focusing on the values and politics entailed in the constitution of novelty, similarity, and genericity in pharmaceuticals in different national and global contexts; Vinh-Kim Nguyen's (2010) analysis of the ways in which diseased bodies come to be valued in biomedical situations that demand emergency care, such as the HIV-AIDS epidemic in Africa in the 1990s; work that thinks about pharmaceutical value in terms of embodiment and bodily relations (in very different ways, Julie Livingston's [2012] and Lochlann Jain's [2013] analysis of cancer as bodily and political economic relation, or Emilia Sanabria's work on sex hormones in Brazil [Sanabria 2016; Edmonds and Sanabria 2014]); work that elaborates value in relation to institutions of national and global health ([Mahajan 2008, forthcoming; Brotherton 2012; McGoey 2015]; Veena Das's focus on everyday practices of pharmaceutical consumption and the experience of health and illness [Das and Das 2006; Das 2015]; Judith Farquhar and Lili Lai's [2014] focus on relating value to questions of epistemology in their work on ethnic Chinese medicine); and the various kinds of what Donna Haraway (2007) calls "encounter value" that mediate transspecies and multispecies interactions in the life sciences (also see Gail Davies's [2012a, 2012b, 2013a, 2013b] work on geographies of mouse research; Natalie Porter [2013, 2015] on securitized economies of research into and exchanges of virus in the context of the management of bird flu; and Jake Kosek [forthcoming] on the history of the industrialized honeybee, for examples of multispecies work that explicitly reconceptualizes value).

27. But also very much in relation to new reproductive technologies, which is why Melinda Cooper and Catherine Waldby (2014) think about experimental subjectivity

and new forms of reproductive labor together in their conceptualization of clinical labor. See Mezzadra and Neilson (2013) for the notion of multiplication of labor, which I discuss at greater length in chapter 2.

28. For an extraordinary manual that provides an example of one way in which this can be done, see Edward Grefe and Martin Linsky (1995), *New Corporate Activism*.

29. The former move is to be found in the trajectory of Bruno Latour's work, starting with *We Have Never Been Modern* (Latour 1993) and perhaps most explicitly in *Politics of Nature* (Latour 2004). The latter is at the heart of Marshall Sahlins's conceptualizations of value (for a recent exposition of which, see his essay "On the Culture of Material Value and the Cosmography of Riches" [Sahlins 2013]; see also his well-known reflections, "Cosmologies of Capitalism" [Sahlins 1988]). For elaborations of both investments, see the summer 2014 issue of *Hau: Journal of Ethnographic Theory*.

30. Of course, this leads to vexed questions for progressive politics around health in India, given on the one hand the deeply failed history of the postcolonial Indian state in providing adequate health care for large segments of its population, and on the other hand the fact that the state does remain an institution that can potentially be made structurally accountable to its citizenry in a way that institutions purely serving the interests of capital cannot. The structure of this dilemma, which inhabits every activist political engagement with the state in India around the question of health, is identical to that traced by Rajeswari Sunder Rajan (2003) in relation to feminist politics in India over the past three decades in *The Scandal of the State*. The parallels of politics around health to feminist politics in India are considerable, certainly in terms of the question of how such politics should engage and orient itself toward the state. But there are more than just parallels at stake. Some of the most important civil society initiatives against unethical clinical trials in India have been driven by feminist groups concerned with questions of women and health. While they might articulate with other groups that organize around these issues in less explicitly gendered terms (those concerned with biomedical ethics, or people's health and science movements), there are long histories of feminist engagements with the state around issues of women's health and reproductive rights that provide essential context to these struggles. Of relevance here are feminist engagements with the state's coercive family planning programs of the 1970s, extending all the way forward to contemporary engagements with new reproductive technologies, for instance, around the global political economies of surrogacy that, like clinical trials, have come to be outsourced to India with greater frequency in recent years (Sama 2010). It is not just in the domain of activist engagement that feminist histories matter: understanding Indian legal and judicial cultures in India in relation to the politics of health also requires an appreciation of the context of postcolonial engagements between women and the state. For instance, Lawyers Collective, the group that has been at the forefront of legal battles against Novartis around the Gleevec case, has a wing devoted to women's issues, and the collective's founding secretary, Indira Jaising, has a long record of involvement in feminist legal politics. The judge who delivered the Madras High Court verdict against Novartis in the Gleevec case, Prabha Sridevan, also has a record of seminal rulings on issues of women's rights.

31. Raymond Williams's (1978) formulation of residual, dominant, and emergent cultural formations is resonant here.

32. A dominant contemporary mode of theorizing the politics of health and illness is in terms of Michel Foucault's ([1976] 1990, 2008) notion of biopolitics, which has been developed by a range of theorists concerned with questions of life itself. Biopolitics speaks to the question of governmental rationalities engaged in the care of the population, to the singular power of the modern nation-state to "make live and let die" (Foucault [1976] 1990, 137–140). This book is obviously concerned with dimensions of the biopolitical, and the specter of Foucault constantly haunts the conceptualization of politics that it undertakes. However, I am ambivalent about the term in that too often it functions, too quickly, as the point at which explanations run out. There are at least three ways in which a biopolitical framework, while necessary, proves insufficient to the analysis this book undertakes. First, Foucault himself develops this term in the context of advanced liberal modernity, and some of the most faithful developments of the concept in relation to contemporary life sciences (such as Rose 2006) fail to attend to the question of whether and how it might be applicable to non-Euro-American contexts. The very different trajectories of modern governmental rationality in the context of colonial law and governance in particular are often completely elided. This is not to say that biopolitics is inapplicable to contexts outside Euro-American advanced liberalism (see, for instance, Biehl 2005, 2009; Mezzadra, Reed, and Samaddar 2013); just that one has to be careful not to extrapolate Foucault to other contexts in ways that evacuate historical and situational specificity. Second, there are limits of a biopolitical analysis to understanding logics of capital. In *The Birth of Biopolitics*, Foucault articulates biopolitical governance to forms of neoliberal economic rationality, but economic rationality is not the same as logics of capital. One of Marx's moves in volume 1 of *Capital* was precisely to explicate the relationship between the two as he undertook a critique of bourgeois political economy alongside his development of the labor theory of value. Hence, biopolitics is centrally relevant to an understanding of what myself and others have called biocapital (K. Sunder Rajan 2006; Helmreich 2008). But an analysis of biocapital cannot be reduced to one of biopolitics. Third, perhaps of most relevance to the ways in which I consider politics in this book, Foucault's theorization of governance thinks of the modern state entirely in terms of sovereign power. In contrast, my own interest in institutions of governance (including and other than the state) is in terms of their representative power.

33. Of course theorizations of the democratic go well beyond the Jurgen Habermas–Partha Chatterjee duality that I state here; but they are important touchstones for me because there is an empirical resonance of their conceptualizations of democracy in the material that I study. Global harmonization has echoes of a Habermasian ethic, which makes me additionally uncomfortable with his model of deliberative democracy: not only is it poorly suited to understanding the realities of democracy in what Chatterjee (2004) would call "most of the world," it also potentially blinds us to those situations of consensual harmonization that are in fact about the consolidation of hegemony. For an important critique of theories of deliberative democracy, see Bonnie Honig's (2009) *Emergency Politics*. Meanwhile, I do not think that one can discuss

theories of South Asian democracy today without taking into account Chatterjee's conception of it in terms of the popular.

34. To be sure, Chatterjee (2008, 2011) does complicate and specify this as he distinguishes corporate from noncorporate capitalism in discussing democracy in relation to economic transformation. In the process, he acknowledges an important democratic space within civil society and representative political arenas; it is just that those spaces are not the ones from which he develops his democratic theory. In relation to biomedicine, a similar limit is encountered in Veena Das's conceptualization of the experience of health and illness in India in terms of what she calls "the everyday" (Das 2006, 2011, 2015; Das and Das 2006).

35. Of course, many theorists of the political in India pay attention to the representative sphere in empirically rigorous ways. Sudipta Kaviraj (see especially 1997, 2010) over the arc of his work has perhaps been the most influential to my overall thinking on this. This influence extends all the way back to high school, when I studied a civics textbook that he had authored, which shaped many of my formative interests in and ideas of politics in India (Kaviraj 1989).

36. These are relationships that I have collectively investigated with a number of colleagues through a series of conferences organized at the University of Chicago and elsewhere under the rubric "Knowledge/Value" (see http://knowledge-value.org/, accessed October 10, 2015).

37. See Jasanoff (1997, 2015) for her notion of "serviceable truths" as scientific knowledge that operates in legal and policy domains. For an account of the very different ways in which knowing is structured in laboratory science as opposed to clinical medicine, see Ludwik Fleck's ([1927] 1986) essay "Some Specific Features of the Medical Way of Thinking." For an important theorization of knowledge in terms of its mobility, see Sabina Leonelli's (2016) analysis of big data in contemporary life sciences in terms of what she calls "data journeys." Also see Howlett and Morgan (2010) and K. Sunder Rajan and Leonelli (2013) for further theorizations of knowledge in terms of its mobility.

38. See note 32 for an elaboration of my thinking with and against Foucault's notion of biopolitics.

39. Foucault ([1970] 1994) himself has a more differentiated classification of knowledge in *The Order of Things*, wherein he describes knowledge in terms of attribution, articulation, designation, and derivation. But it is in his formulation of Power/Knowledge and his articulation of the relationship between truth and power that Foucault develops his most explicit conceptualization of knowledge to politics.

40. One important genealogy for theorizing knowledge as translation within science and technology studies (STS) is actor-network theory, developed by Michel Callon (1986) and Bruno Latour (1987, 1988). However, the conceptualization of politics in Callon's and Latour's rendering is altogether too flat, reduced to a recruitment of interests by rational actors. Emily Martin (1998) provides an important anthropological and feminist counter to their model of knowledge production, taking into account the fundamentally differentiated power structures and cultural contexts within which knowledge is produced. More recently, Kim Fortun (2014) and Michael Fischer (2014)

have critiqued the "ontological turn" that Latour's actor-network model has taken. I organized a conference around the question of the translations of knowledge, value, and politics with colleagues at the University of Chicago in 2012, called "Trans-science." A relevant bibliography that relates to such questions, going beyond actor-network theory to think through conceptualizations of translation in STS, linguistic anthropology, and postcolonial studies, can be found on the conference webpage (Department of Anthropology 2012).

41. The term "knowledge-for-itself" follows Marx's ([1852] 1977) distinction in *The Eighteenth Brumaire of Louis Bonaparte* between a class-in-itself and for-itself. By "class-in-itself," Marx refers to the structural subject-position of a given social group within particular modes of production; by "class-for-itself," he refers to the ways in which that subject-position is acted out through materializations of relations of production, which need not correspond in any simple way to structural positions at all but is rather thoroughly political. Similarly, I am interested less in arriving at a definition of knowledge adequate to contemporary biomedicine than I am in seeing how knowledge gets acted out.

42. I develop the idea of situation in conclusion to this introductory chapter. Again, because of the fragmentary nature of his writings, it is difficult to pinpoint an exact citation within Gramsci for a concern that in fact pervades his writing. However, there are writings where Gramsci specifically develops his ideas of knowledge in relation to the problem of what constitutes the intellectual (see especially "Intellectuals," Gramsci 2000, 300–311). These writings are central to understanding how he thinks about the function of knowledge, intellectuals, and expertise in the constitution of hegemony.

43. This follows Gregory Bateson's ([1936] 1958) demonstration of the analytic potential of ethnographic situation in his account of the Naven. Situated attentiveness is reflected in the structure of this book and in the organization of its chapters, as already described. If Bateson uses situation as a device of comparison and juxtaposition to generate a thick account, then there is additionally the possibility of using it as the ground from which politics can be theorized. Situated analysis of this sort is central to Karl Marx's ([1852] 1977, [1871] 2009) historical writings, such as *The Eighteenth Brumaire of Louis Bonaparte* and *The Civil War in France*, and to Gramsci's ([1926] 2000) accounts of contemporary Italian politics in the 1920s, such as on "the Southern Question." Ethnographies that theorize politics out of situated analysis include Michael Fischer and Mehdi Abedi's conceptualizations of relationships between Islam and politics in Iran (Fischer 1980; Fischer and Abedi 1990). Donna Haraway's (1991) call for situated knowledge in relation to practices of feminist objectivity has been foundational to subsequent thinking in STS.

44. This figure is based on conversations with members of MSF's Access to Medicines and Treatment Campaign in New Delhi and Geneva over the past few years. For MSF, the survival of India's generic industry is vital.

45. The question of how to generate an adequate "anthropology of the contemporary" is a lively source of debate. See Paul Rabinow's (2003) *Anthropos Today* for a provocative methodological guide and Michael Fischer's (2003, 2009) *Emergent Forms of Life and the Anthropological Voice* for an alternative methodological and

conceptual modality. Rabinow's method is grounded in the notion of assemblage, referring to the contingent articulation of heterogenous elements. The anthropologist's task then becomes one of mapping this radical contingency. The notion of assemblage has received much traction in contemporary anthropological social theory, especially as developed in Bruno Latour's (2005) influential program for actor-network theory, *Reassembling the Social*. Fischer's method in contrast is more historically grounded, drawing upon Raymond Williams's (1978) formulation concerning residual, dominant, and emergent horizons and articulating it to Ludwig Wittgenstein's (1972) notion of a "form of life," invoking socialities of action. For Fischer, understanding these socialities involves being attentive to the ghosts of formations past that endure and to the traces of emergent possibilities yet to come, even as it involves tracing the dominant modes of production and forms of social relation prevalent in a particular place and time. This does not mean that any given event is not contingent; it just means that the conceptual project of understanding the contemporary must go beyond the mere mapping and declaration of contingency to include a deeper historical sensibility. It is this latter sense of the conjuncture that I adopt in my own reading of contemporary global pharmaceutical politics as situated in India.

46. In this section, I am drawing upon Gramsci's (2000, 200–209) notes on "Analysis of Situations: Relations of Force."

47. All of these could be seen as attributes of neoliberalism. As representative (but no means comprehensive) examples of analyses of neoliberalism, see Melinda Cooper's (2008) account of the capitalization and neoliberalization of the life sciences; David Harvey's (2003, 2007) diagnoses of neoliberalism and its relationship to accumulation by dispossession; Neil Brenner, Jamie Peck, and Nik Theodor's (2010) analyses of the spatialities of neoliberalism; work by scholars following and developing Michel Foucault's notion of governmentality and applying it to questions of contemporary neoliberal governance (Rose 2006); the work of anthropologists involved in the elucidation of the "global assemblages" of neoliberalism (Ong and Collier 2005); and Michel Foucault's (2008) theorization of *homo economicus* as the subject of neoliberalism, elaborated upon by Wendy Brown (2015). While in broad agreement with this range of scholarship, my own interest is less in the diagnosis of neoliberalism than in the question of the specificities and intricacies of this capitalist moment in India and of how global capital is constructed, perceived, and experienced from the situation of these specificities.

48. While beyond the scope of this book, the question of how poverty gets measured is absolutely central in this regard, and has indeed been an important facet of policy debates in Indian economics (Subramanian 2001), alongside more neoliberal concerns and articulations such as the obsession with economic growth.

49. The Right to Information Act and the National Rural Employment Guarantee Act were passed in India in 2005. The Right to Education Act was enacted in 2009. The National Food Security Act, popularly known as the Right to Food bill, was proposed in 2011. While an account of the NRHM is beyond the scope of this book, the HPV vaccine studies described in chapter 2 are an example of a public-private partnership that operates under its aegis.

50. Kim Fortun describes discursive gaps as emerging "when there are conditions to deal with for which there is no available idiom, no way of thinking that can grasp what is at hand" (2012, 452). In the case that I am describing, the discursive gaps were not so much because "there was no way of thinking" of an ethics that included therapeutic access, but because of the particular institutional investments that were structuring this moment, investments focused on maximizing the amount of clinical experimentation coming to India but not coupling that to therapeutic access or building broader health care infrastructures.

51. See the report put out by the Sama resource group on women and health that highlights some of these scandals (Sarojini, Anjali, and Ashalata 2011).

CHAPTER ONE. Speculative Values

1. In this regard, it is worth thinking about three registers of time that Jacques Derrida (1994) has alluded to: *histoire*, *le temps*, and *le monde*, referring respectively to specific histories, the time in which we live, and the time of "the world." See also Paul Rabinow's (2003) similar development of notions of epoch, present, and event. While Rabinow's aim is to develop the utility of these notions for an anthropology of the contemporary (ultimately privileging attentiveness to the radical contingency of the assemblage), Derrida's interest is in precisely avoiding such definitive resolution. Rather, following the method of deconstruction, he wishes to show how time is "out of joint." He was thinking of this precisely in a moment of crisis, in this case of Marxism after the dissolution of the Soviet Union. This was a moment when the old had died and the new had not yet been born, when Francis Fukuyama ([1991] 2006) was proclaiming "the end of history," and when the world historical importance of particular events was recognized even as the question of their long-term structural causes and implications was rife.

2. See the analysis of the 2008 financial crisis by Moishe Postone (2012). For an exploration of the humanitarian crisis in relation to contemporary pharmaceutical economies, see especially Peter Redfield's (2013) ethnography of MSF in relation to situations of "life in crisis." Redfield is interested in the work of an organization that has emerged at a historical moment when humanitarianism has become a dominant register through which the global gets thought and acted upon—a moment (starting in the 1970s) that also happens to be one that has witnessed the disintegration of the Keynesian welfare state and its replacement by neoliberal avatars in most of the developed world. See Kosselleck and Richter (2006) for an important overview of the philosophy of crisis, and Roitman (2013) for an important ethnographic conceptualization.

3. Of course, categories such as "developing" and "developed" countries are provisional, given the wide disparities in access to health care within most national contexts. Still, the distinction is not entirely invalid if one considers global power relations and geopolitical configurations that witness, more often than not, First World hegemony over Third World interests (even if many people within the former are denied the benefits of such hegemony). See chapter 5 for an elaboration of such geopolitics.