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