

Introduction

Drug Development and Politics

On November 30, 2009, a press conference titled “Pharma-2020: Future of the Russian pharmaceutical industry” begins with this introduction by the moderator:

Today we are discussing an important topic related to the situation with the Russian pharmaceutical market. This is a crucial topic that is relevant for many, relevant in a personal way. Everybody knows that there is a problem of supplying Russian people with inexpensive, quality drugs produced locally. This problem has not been solved yet, and the government is continuously working on it. Also the industry experiences problems such as lack of modern equipment and nontransparency of state procurement. A strategy that does not only solve these immediate problems, but also defines the future of this market, has been developed by the Ministry of Industry and Trade.

Before the floor is given to Sergey Tsib, a representative of the Ministry of Industry and Trade, the attention of the audience is directed toward a large screen where a video recording of then-president Dmitry Medvedev’s speech is played. The recording was produced earlier the same month during the traditional presidential address to the Federal Assembly. On the screen, the press conference attendees see Georgievsky Hall in the Grand Kremlin Palace with hundreds of people listening to the president, who is standing on a large podium with Russian flags in the background. Medvedev says:

In the nearest future we will substantially increase the production of our own drugs. . . . Already in five years the share of local production on the pharmaceutical market has to become not less than a quarter, while by 2020, more than half of all medicines. This is the aim.

Federal Assembly members applaud. The video is then turned off, and Sergey Tsib turns on his microphone. He explains that after about a year and a half of work, the Ministry of Industry and Trade is ready to present the first programmatic document in the entire course of the country's pharmaceutical industry, titled the Strategy for the Development of the Pharmaceutical Industry of the Russian Federation (Pharma-2020). "We have every chance to meet the targets . . . specified by the president," Tsib adds. He finishes by delineating two main tasks: to improve the competitiveness of the Russian pharmaceutical industry and to ensure pharmaceutical security of the country as a whole.

This episode goes directly to the heart of the issues this book explores. At the very beginning of the press conference, the moderator announces that the topic at hand is local research, development, and production of drugs. Yet the ensuing statements and exchange are not limited to the matters of (bio)pharmaceutical science and technology. In fact, the discussion swiftly moves to anything but science and technology as such: societal problems of access to quality drugs, economic questions of dominance in the country's internal market, and issues of national security. What stands out is how drug research and innovation have made their way to the highest political levels and become involved with questions of public good provision, national interests, and the country's international standing.

I encountered these engagements between science, technology, and politics when I watched the recordings of this press conference and other events, browsed through media publications, talked to those involved in the pharmaceuticals field in Russia, and went everywhere my research project took me. Of course, by now it is commonly acknowledged that drug development and production are not a matter of technoscientific developments alone. Media have covered how pharmaceutical industry promotion practices work to establish conditions that make specific diagnoses and prescriptions as frequent as possible. Scholars have produced critiques of burgeoning consumption of medicines and continual growth of disease categories, health risks, and costs. Widespread debates about evidence have highlighted how the pharmaceutical industry carefully

curates available knowledge through publication planning when companies and their agents shape multiple steps in the research, data analysis, writing, and publication of articles in ways that remain hidden from the public eye. These instances make it abundantly clear that drug innovations are shaped and driven not only by scientific breakthroughs but also by agendas, ambitions, and profits.

While previous research has demonstrated how diseases and patients emerge together with revenues and capital, in this book I analyze relationships between pharmaceuticals and society from a different angle. My concern here is not so much with the politics of the markets already extensively discussed by other scholars; rather, it is with politics of the state—closely related, but until now much less explored by critical social sciences. I am interested in how visions of the nation emerge together with state-led pharmaceutical industry development efforts. Following this interest, in this book I trace how pharmaceutical innovation in Soviet and post-Soviet Russia has become entangled with processes of rebuilding the nation and reimagining its identity and future, merging into what I call “pharmapolitics.”

The case of (post-)Soviet pharmapolitics provides a fruitful contrast to common critiques of capitalist pharmaceutical industry and allows an opportunity to reexamine our ideas about governance of pharmaceutical development and production. Many accounts of Soviet science and industry remain centered on the question of political interference that introduces bias into knowledge produced and curbs innovation. This question reemerges in relation to the Russian state-dominated pharmaceutical arena as well. Yet, in essence, both critiques of profit-pursuing capitalist pharmaceutical industry and critiques of the power-accumulating nondemocratic state share the same ideal of technoscience untainted by market influences or political interference. Critical social science scholarship, in particular science and technology studies (STS), has long sought to disabuse us of this ideal, which implies a possibility of straightforwardly distinguishing technoscience and politics and keeping them separate. In this book, a view of pharmaceutical development as always shot through with political concerns and engaged in societal transformations is taken as a starting point to examine specific forms of pharmaceutical technoscience-society interactions and their consequences in a situation where it is not politics of the market but politics of the state that comes to the fore. A question that needs answering then is not how to safeguard pharmaceutical research and development (R&D) from politics, but rather how to respond to their

interconnections in a transparent and equitable way. In the final chapter I return to this question with regard to both capitalist multinational pharmaceutical industry and nondemocratic state efforts to stimulate drug innovation, which themselves will turn out to be more alike than they may seem.

This book focuses on pharmaceuticals among the entire spectrum of science and technology. Pharmaceuticals may appear to be less spectacular and impactful compared to a rocket being launched into space or nuclear reactors powering up cities and simultaneously carrying a risk of the most enormous manmade disasters. Nonetheless, today pharmaceuticals—their development, production, and use—occupy a special place in the world. First, pharmaceuticals have an immediate connection to public health and well-being as a way to respond to major, long-standing health problems, for example, various forms of cancer faced by increasing numbers of people; to tackle new health threats, such as drug-resistant tuberculosis and AIDS, that endanger large populations; and to ward off aging, infirmity, mental decline, and other conditions from which humanity has dreamed of breaking free for centuries. Second, new pharmaceuticals are also associated with vast economic profits. More generally, they appear to hold great promise of better futures, tapping into imaginaries of prosperous and cohesive societies, where wealth is generated through finding applications for new biomedical knowledge and people whose health needs are met have better and more productive lives (Abraham 2010; Williams, Martin, and Gabe 2011). The recent formulation and implementation of the Russian government's Pharma-2020 Strategy announced in the opening vignette of this introduction is one of the attempts to harvest the potential of pharmaceutical innovation in Russia, while simultaneously enacting a particular mode of relations between pharmaceutical technoscience, state, and society.

Considering the far-reaching roles of pharmaceuticals in societies, it is important to reflect on who has the power to articulate and materialize these imaginaries pertaining to pharmaceuticals, how inclusion in and exclusion from these processes are arranged, and how particular decisions are represented, framed, and justified. It is equally important to understand how exactly pharmaceutical science and technology become entangled with politics, why these entanglements take specific shapes, and how they work to direct sociotechnical change along particular paths. Therefore, from the beginning of this project, my goal was both to open up new opportunities for critical appraisal and social action in regard to connections between

pharmaceutical innovation and people's well-being in Russia, and to contribute to understanding the dynamics of relations between technoscience and politics, equally relevant for many contemporary societies.

I begin approaching this task by outlining the accounts of the drug development field in the next section to provide the necessary background for the exploration to follow.

Accounts of Drug Development

The account of the drug development field can be conveyed in different ways. Two broad accounts are offered by the scholarship in the history of science, technology, and medicine and in the sociology of medicine. These accounts are complementary in that one traces the evolution of our understanding of human body and the emergence of new technologies that enable creating new therapeutic agents, while the other turns to the social life of pharmaceuticals and its role in drug development trends.

Advances in Pharmaceutical Science and Technology

The account offered by the historical scholarship emphasizes that the pharmaceutical industry is driven by advances in science and technology as are few others. The contemporary pharmaceutical industry can be traced to the beginning of the nineteenth century, and its 200-year history shows a strong record of innovation and continuous close relations with academic research in chemistry, pharmacology, life sciences, and medicine. Before describing the phases historians offer to structure the shifts in drug development and innovation over the past two centuries, I pause to note that accounts of drug development history tend to center on developments in Western Europe and the United States. This is because about 80 percent of pharmaceutical products commercialized from 1800 to 1990 came from the United States, Germany, Switzerland, the United Kingdom, and France (Achilladelis and Antonakis 2001), signaling a strong concentration of drug development activities in these countries, with more recent input from other European countries and Japan. Drug development activities, however, took place in other locations as well. In particular, as chapter 1 of this book will show, in the Union of Soviet Socialist Republics, or USSR, a considerable pharmaceutical sector emerged that, importantly,

was structured and governed differently from this same sector in Western Europe and the United States. One can argue that the scant attention given to locations outside Western Europe and the US in the literature on the history of pharmaceutical science and technology is attributable to the small contribution these outsiders made to the list of widely commercialized and used drugs. I would add that such focus in the historical literature also reflects a particular view of innovation as centered around profit, entrepreneurial firms, and market, where commercialization is the primary measure of innovativeness and success. This discourse is traceable in part to the enduring legacy of the economist Joseph Schumpeter (1883–1950), whose work inspired circumscription of the meaning of innovation to a particular mode of capitalist production and circulation of goods and values. In the decades to follow, most discussions and theorizing about innovation have continued to be dominated by market-centered thinking and the imperative of making profit. Consequently, other possible modes of innovating in areas, including pharmaceuticals, tend to be excluded from consideration (Marcelle 2015).

Attention to the imperatives of commercialization and of profit making was prominent in my conversations with those currently involved in pharmaceutical innovating in Russia and in the local science and technology policies now in effect. Yet the book resists taking for granted the assumptions underpinning this view of innovation, instead highlighting the ambivalence and tensions associated with the prominence of a commercial metric in Russian pharmaceutical science and technology. Therefore, I avoid defining what innovation is from the onset to critically engage with the plurality of understandings of drug innovation in various chapters of this book, most prominently in chapters 4 and 5, where current efforts to boost pharmaceutical innovation in Russia are explored, and in chapter 1, where the Soviet socialized pharmaceutical industry is analyzed. From the point of view adopted in this book—that is, recognizing innovation beyond the realm of economics and outside the emphasis on profit making—the story of drug development generally told by historians of science, technology, and medicine can be enriched by narratives from locations outside the United States and Western Europe that illuminate innovations in, for example, systems of pharmaceutical knowledge production.

Structuring the past and present of drug development around technoscientific advances produces accounts of consecutive changes in drug development paradigms or drug generations (Achilladelis 1999; Achilladelis and Antonakis 2001; Landau, Achilladelis, and Scriabine 1999). These accounts locate the beginning of modern drug R&D in 1820–1880, when

the first generation of drugs evolved. In this period, academic researchers and physicians who turned to chemistry worked mainly on natural plant products and their “active principles,” including isolation of morphine from opium and quinine from cinchona bark, which in turn gave rise to a new discipline, pharmacology. Discovery of the medical properties of simple organic chemicals that were synthesized or isolated from coal tar or plants (e.g., anesthetic properties of ether) was also a landmark of this period. Finally, historians note a rise of industrial organic chemistry leading to the development of the dyestuffs industry in the second half of the nineteenth century, most prominently in Germany. It was mainly the dyestuffs industry that gradually gave rise to the influential pharmaceutical companies that we know today as “Big Pharma.”

To return to the past and present of drug development as offered by historical accounts focusing on advances in science and technology, the second generation of drugs came to life in roughly 1880–1930. This period witnessed intensified collaboration between academic scientists, chemical companies, and public health institutes to construct the foundation of a research-intensive pharmaceutical industry. The first synthetic drugs and vaccines were marketed. While most medical discoveries originated in academic hospitals and universities, their development and commercialization moved to public health and medical research institutions established by the European and American governments, for example, the Pasteur Institute and the Rockefeller Institute and (predominantly German) dyestuffs companies, the most prominent being Bayer and Hoechst. These companies were also building their own drug R&D capabilities. By 1910, equipped with industrial manufacturing and pill-making machines, apothecaries, including Abbott, Lilly, Burroughs–Wellcome, and Parke–Davis in Great Britain and the United States, also began investing in in-house R&D. Most current Big Pharma companies came into existence during this second generation of drugs. Concurrently, as I describe in chapter 1, in the Soviet Union a different, public pharmaceutical industry was developing. On the basis of small entrepreneurial companies that existed in the Russian Empire, the new Soviet state was creating an integrated industrial complex focused on science and technology to produce drugs of the first, second, and, soon, third generation.

In the course of the third generation of drugs, which can be located in 1930–1960, most pharmaceutical companies became strongly committed to in-house R&D; drug marketing methods changed to intensively target health professionals, hospitals, and drugstores; and corporate structures began to be organized in a way that would solidify during the rest of the

twentieth century. During World War II, governments supported development and production of pharmaceuticals to meet the needs of their armed forces. Many new hormones, vitamins, antibiotics, and anti-inflammatory drugs were developed. The number of pharmaceutical companies to introduce their versions of new types of drugs increased significantly, sharpening the competition among them and speeding the diffusion of new drug development technologies, while enlarging markets stimulated further growth of pharmaceutical companies and attracted companies from other sectors into the profitable business of pharmaceuticals. In the USSR, drug development continued along its socialized path with no private businesses and therefore no drug commercialization, but with a state-organized and state-controlled industry.

During the fourth generation of drugs in 1960–1980, the pharmaceutical industry's scientific basis shifted from chemistry and pharmacology to life sciences. Growing understanding of cellular-level processes enabled developing hundreds of new drugs, mainly for noncommunicable diseases such as cardiovascular disease, cancer, and central nervous system diseases; antidepressants, tranquilizers, and anxiolytics arrived. While the US industry retained its dominance in the field that it had gained during the postwar years, the Western European and Japanese economies recovered, and companies from these regions entered the pharmaceutical markets. With an abundance of new drugs, many of which did not offer a clear advantage over already existing ones, and the international thalidomide scandal in 1961, governments became increasingly concerned with ensuring the safety and efficacy of drugs and proper regulation of the pharmaceutical industry. Of central importance were the 1962 Kefauver-Harris Amendments to the United States' Federal Food, Drug, and Cosmetic Act, which specified critical components of contemporary pharmaceutical regulation: premarket review and well-controlled studies to prove safety and efficacy (Hogarth 2015). Following the Amendments, the US Food and Drug Administration (FDA), the federal agency tasked with regulating pharmaceuticals, was influential in spelling out and enforcing the three-phase system of clinical trials and stipulating randomized controlled trials (RCTs) as the "gold standard" of evidence (Carpenter 2010). Similar legislation and regulatory practices were adopted in most European states during the next decade. In part because of these developments, the costs of discovery, development, approval, and marketing of drugs continued to rise, promoting the dominance of larger companies. By contrast, as chapter 1 of this book demonstrates, the USSR adopted a different system to regulate drug development. This system, while being plagued by its own

drawbacks, was meant to prevent the duplication of efforts and waste of resources that were perceived in capitalist drug development.

The fifth generation of drugs began in 1990, according to Achilladelis (1999); Achilladelis and Antonakis (2001); and Landau, Achilladelis, and Scriabine (1999); and it has not yet run its full course. Further developments in the life sciences allowed designing precisely targeted and highly specific drugs, particularly for cancer and viral and age-debilitating diseases, with major advances brought by the rise of biotechnology. The pharmaceutical industry underwent a massive process of mergers and acquisitions in the 1990s and at the beginning of the 2000s, which accomplished the formation of unprecedentedly concentrated global companies. Simultaneously, the promise held by new, revolutionary biotechnologies attracted investments enabling the creation of many smaller biotechnology companies. Currently biotechnology firms tend to engage in upstream research, that is, identification of drug candidates—drug discovery. Because it is mostly pharmaceutical companies that possess resources sufficient to bring drugs through the extremely costly development and registration process in the current environment, pharmaceutical companies focus on the downstream stages, further developing methodologies and substances discovered by biotechnology companies (or public laboratories) for a commercial drug (Sternitzke 2010). Pharmaceutical companies increasingly tend to in-license molecules from biotechnology firms or buy biotechnology companies with promising molecules in the pipeline to strategically assimilate new technology as a source of potential value (Henderson, Orsenigo, and Pisano 1999; Kneller 2003; Sunder Rajan 2006).

In this same period, at the beginning of the 1990s, Russia became an independent state. Then the socialist drug development system was quickly dismantled, making way for a deregulated field where large multinational pharmaceutical companies powerfully stepped in. Local pharmaceutical industry came to a halt, followed by efforts to find a workable way of organizing and governing drug development that came to incorporate elements of the Western market-oriented system together with Soviet-rooted approaches and an ambition to master and employ technologies of the fifth drug generation.

Pharmaceuticalization and the Social Life of Drugs

The sociology of medicine takes another approach to providing an account of the drug development field, focusing on the social life of drugs. This

strand of scholarship highlights how pharmaceuticals increasingly have come to be seen as preeminent solutions to health problems and analyzes associated changes in patterns of their development, production, and use. It offers the concept of pharmaceuticalization to account for the growing importance of pharmaceuticals and their multiplying and diversifying roles in society.

The ongoing reflection on the contours and meaning of pharmaceuticalization was instigated by works of Abraham (Abraham 2010, 2011) and Williams, Martin, and Gabe (2011). While Abraham suggests that pharmaceuticalization is a “process by which social, behavioural, or bodily conditions are treated or deemed to be in need of treatment, with medical drugs by doctors or patients” (2010, 604), Williams, Martin, and Gabe (2011) argue that analysis of pharmaceuticalization should not be restricted to the use of pharmaceuticals by doctors or patients for treatment purposes, but rather that pharmaceuticalization “denotes the translation or transformation of human conditions, capabilities and capacities into opportunities for pharmaceutical intervention” (Williams, Martin, and Gabe 2011, 711). Furthermore, Williams, Martin, and Gabe (2011) suggest that it is useful to frame pharmaceuticalization as a sociotechnical process that is part of a so-called pharmaceutical regime—heterogeneous networks of institutions, actors, and artifacts associated with the creation, circulation, and use of pharmaceuticals. Further chapters of this book make visible the evolution and contours of the present pharmaceutical regime in Russia, contributing to the sociological scholarship concerned with pharmaceuticals, which to date has mostly been concerned with discussing changes within Western societies, as noted recently by Sariola and colleagues (2015).

Analysts have discerned several important trends in the recent transformations of the pharmaceutical regime globally, including massive growth of drug markets, changing forms of governance, and the increasing prominence of pharmaceuticals in imaginaries of societal futures. The astonishing growth rate of the pharmaceutical industry, as reflected, for example, in worldwide sales having risen 11.1 percent annually from 1970 to 2002 (PhRMA 2003 as cited by (Gassmann, Reepmeyer, and Von Zedtwitz 2008), signals profound expansion of the global pharmaceutical regime. Correspondingly, a large increase in the use of drugs has been documented. Busfield (2015), for instance, shows that in England the average number of prescriptions dispensed per person increased from 8.0 in 1989 to 18.7 in 2012, and he argues that because this rise occurred well

after the introduction of the major new drugs of the previous century, such as antibiotics and antihistamines, its drivers cannot be reduced to the developments in pharmaceutical technology.

The distribution of pharmaceutical sales and consumption, however, has been uneven across the globe. WHO states that while between 2000 and 2008 consumption of pharmaceuticals has grown in countries of all income categories, and the percentage growth is higher in low-income countries than in high-income countries, the growth in absolute terms is far greater in the latter, with high-income countries as a whole consuming “very much more [pharmaceuticals] than lower-income ones” (Hoebert, Laing, and Stephens 2011). Against this background, vocal concerns about overuse of pharmaceuticals are accompanied by no less justified concerns about underuse due to inaccessibility, as exemplified by the worrisome data showing that about one-third of the world’s population lacks access to essential medicines (World Health Organization 2004, 61–74). Therefore, while pharmaceutical markets are clearly expanding both commercially and geographically, this expansion is neither homogenous nor even.

Concurrently with the growth and expansion of pharmaceutical markets, related governance forms have been shifting as well, affecting drug development practices. A push toward deregulation since the end of the 1980s has been noted by researchers interested in the work of such regulatory bodies as the FDA in the United States, the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom, and the European Medicines Agency (EMA) in the European Union. These regulatory agencies have been increasingly reliant on industry funding (“100% funding for the MHRA since 1989, with similar trends in the EU [70% funding] and the USA [50% funding] since the mid-1990s,” according to Williams, Martin, and Gabe [2011]). This arrangement has committed regulators to significantly decrease review times for new drugs and encouraged them to introduce fast-tracking approval procedures for drugs targeting life-threatening conditions or addressing unmet health needs requiring less data to demonstrate safety or efficacy (Abraham and Davis 2007; Abraham and Lewis 2000).¹ Subjected to criticisms by industry for stifling innovation and impeding prompt arrival of new drugs to the market, and hence to patients who need them, regulatory agencies have come to embrace more flexible and open relationships with industry (Abraham 2010; Hogarth 2015). Moreover, major drug regulatory agencies increasingly position themselves as enablers of innovation. Against the background of the “productivity crisis” in the pharmaceutical industry, that is, ever-increas-

ing spending on R&D coupled with decreasing numbers of approved new drugs (Gassman, Reepmeyer, and Von Zedtwitz 2008) and, as some authors point out, shrinking numbers of new drugs actually offering significant therapeutic advances (Martin et al. 2006), regulatory agencies have begun to play a greater role in supporting pharmaceutical innovation in addition to a more traditional role as guardians of public health. For example, in 2004 the FDA introduced the Critical Path Initiative, which is defined as a “strategy to drive innovation in the scientific processes through which medical products are developed, evaluated, and manufactured to improve and accelerate translation of recent scientific advances into innovative medical treatments.”² Finally, along with making efforts to rethink ways of governing pharmaceuticals, the established system of regulation has been globalizing, as exemplified by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and its influential Tripartite Harmonised Guidelines. ICH originally brought together regulators from Europe, Japan, and the United States, but the geographical focus of the initiative is changing. The history section of the ICH website states: “Entering into its third decade of activity, ICH’s attention is directed towards extending the benefits of harmonisation beyond the ICH regions.”³ Currently, representatives of non-ICH regions are increasingly involved in ICH work, and the guidelines are being incorporated in the regulatory practices outside Europe, Japan, and the United States.⁴ Efforts to expand regulations for drug development and approval facilitate access by international pharmaceutical companies to new markets and enable outsourcing some parts of drug development and production to lower-income locations. The reverse is also possible: harmonization of the regulatory system could allow drugs developed outside the high-income Western locations that historically have been the center of most commercial innovation in pharmaceuticals to enter Western markets, but this reverse movement has been much less noticeable.

The third trend in transformations of the pharmaceutical regime noted in the pharmaceuticalization scholarship is related to a heightened attention to the futures associated with pharmaceutical innovations. It is well known that expectations and visions play a crucial role in scientific and technological change through driving activities, attracting interest and resources, and providing legitimation (Borup et al. 2006). Pharmaceuticals in particular appeal to deep-seated imaginings of many people—we generally want to live healthier lives devoid of suffering and premature death. Imaginaries of (better) futures are at play on many levels of the pharmaceutical regime, from individual patients to transnational structures

and discourses. Many patients participating in development of particular drugs as research subjects, especially those with currently untreatable conditions or with conditions nonresponsive to standard treatments, hope that novel medicines accessed through trials will improve their condition and prospects (Brown et al. 2015). Patient organizations engage in political activism, fundraising, and awareness raising and work to shape the field of biomedical research in attempts “to bring to fruition the many future possibilities inherent in the science of the present” (Novas 2006, 289; see also Epstein 1996; Rabeharisoa and Callon 2004). The development of new technoscientific fields such as pharmacogenetics is shaped by visions emerging of its impact on medical practice, on industrial landscapes, on research agendas, and on ethical discourses, with different visions competing and developing in synergy with each other (Brown and Michael 2003; Hedgecoe and Martin 2003).

Taken together, the two broad accounts of the drug development domain offered by the fields of history of science, technology, and medicine and the sociology of medicine suggest that changes in the area of drug development are attributable to both advances in pharmaceutical science and technology and related societal dynamics, such as growing numbers of conditions identified as suitable for pharmaceutical treatment. Consequently, in this book, changes in drug development are not viewed as a matter of technoscience or social processes alone. Rather, I consider drug development as being shaped both by advances in technoscience and changing roles of drugs in society.

The notion of coproduction of technoscience and society proposes viewing scientific knowledge and technologies as both embedding and being embedded in the social, including identities, norms, discourses, institutions, and practices (Jasanoff 2004) and conveys the gist of my approach in this book. Taking coproduction as a starting point enables me to take account of both technoscientific advances and social processes in this study of pharmaceuticals and their engagements with politics, which here I take to mean material and discursive practices of the production, exercise, and contestation of power.

Strategic Technopolitical Practices

Beyond the broad idea of coproduction, several specific concepts proved to be particularly inspiring for analyzing relations between politics and pharmaceutical science and technology in Russia. One is a notion of

technopolitics that is attentive to practices of using technologies in political processes and to the workings of power in these peculiar hybrids.

The concept of technopolitics has been elaborated by Hecht (2009, 2001), who defined it as “the strategic practice of designing or using technology to constitute, embody, or enact political goals” (2001, 256). Using the example of French nuclear reactors, Hecht showed that many of the criteria that shaped technical design choices in that case were deliberately political. She moves beyond calling the resulting reactors “socially constructed technologies” in stressing that these hybrids were intended and used as tools in political negotiation. At the same time, it is also not enough to call these technologies “politics” because of their materiality and the importance of the effectiveness of these technologies for achieving material purposes for their political effectiveness. Rather, the practice of using technologies “in political processes and/or towards political aims constitutes technopolitics” (Hecht 2001, 257).

The analytical approach of technopolitics means not only taking into account how technologies, broadly defined as “artefacts as well as nonphysical, systematic means of making or doing things” (Hecht 2001, 256), become sites and objects of politics, but also tracing how political ambitions and agendas interact with technological developments and are shaped in the process of such interactions. In this sense, a technopolitical approach is in accord with the notion of coproduction of technoscience and society.

At the same time, a technopolitics approach has a particular focus on the workings of power and shades of local politics and ideologies. This focus is important to explain how authority is being established and performed, how specific meanings become prevalent, and how certain assemblages persist over alternative ones—that is, to explain the shaping of sociotechnical trajectories. Furthermore, as Gagliardone (2014) suggests in his study of technopolitics, nation building, and information and communications technology (ICT) in Ethiopia, the concept of technopolitics, being attentive to differences in power, places a greater emphasis on the role of governments in shaping technology. He explains that in many settings, the state is not just one actor among many. Rather, while it may not always be able to perform its stated functions in terms of the delivery of public services and goods, it still does tend to occupy a position of prominence among other actors involved in policy making and implementation.

Although Gagliardone’s reflection refers to the ICT sector in Ethiopia, attention to power and governmental practices is important to understand

coproduction of pharmaceutical innovation and politics in Russia as well. While the authoritarian Soviet state was left behind, the new Russian state inherited its elements and practices. Experimenting with new relationships between the government and the public, and still possessing significant resources to enforce its visions, the government has tried exercising varying degrees of control over various spheres of life; therefore, its activities are worth looking at in greater detail.

Here I would like to note that in analyzing entwinements of science, technology, and politics, this book looks beyond formal political organization and power centers, not taking such entities as “state” for granted or considering that their structures fully explain particularities of sociotechnical outcomes. Previous research shows that many differences in how science and technology are dealt with, how related problems are framed, and which solutions are presented as acceptable are organized along the national borders. For example, the field of biotechnology regulation in Europe and the United States demonstrates that different national discourses have arisen around risk and safety, innovation and bioethics, naturalness and artificiality, and gave rise to different approaches to dealing with biotechnological advances (Jasanoff 2005). Here comes the next concept that became important to my investigation of pharmapolitics in Russia—that of political culture. The idea of political culture reflects the importance of interpretations and attribution of meaning and offers a reflexive and dynamic way of thinking about relations between states and sociotechnical trajectories, going beyond formal structures. Jasanoff (2005) defines political culture as a “systematic means by which a political community makes binding collective choices” with political culture encompassing written and unwritten codes and practices of political decision making and institutionalized approaches to reasoning as well as less explicit cultural commitments to forms of legitimation. The concept of political culture highlights the importance of capturing stabilities in meaning making to analyze particularities of national discourses about risks, benefits, and goals of innovation, and to understand how policy problems are constructed. Therefore, while taking the analytical approach of technopolitics and paying attention to power and state, I engage in an exploration of meaning making in the pharmapolitical nexus I am studying.

Finally, the notion of sociotechnical imaginaries provides another stepping-stone to understanding the interconnections of science, technology, and politics. This notion, developed by Jasanoff and Kim (2009, 2015), builds on previous work of social and political theorists on collective

imaginings. For example, Anderson (2006) highlighted the centrality of imagination in nation building. He suggested viewing the nation as an imagined community tied together through shared cultural, political, and also technoscientific practices and highlighted the necessity of paying attention to actions required to produce and maintain common imaginaries.

The concept of sociotechnical imaginaries refers to “collectively held, institutionally stabilized, and publicly performed visions of desirable futures, animated by shared understandings of forms of social life and social order attainable through, and supportive of, advances in science and technology” (Jasanoff and Kim 2015, 4). This theoretical concept attends symmetrically to both technoscientific and social processes. For example, Hecht, in her investigation of technopolitics in France, reflects on how national identity is being imagined and negotiated in the processes of coproduction of science, technology, culture, and politics. She argues that national identities do not grow by themselves; rather they require cultivation through articulation, rehearsal, and grounding in materiality of technological systems. Alternatively, as Felt (2015) shows in her study of reception of several technologies, including agricultural biotechnologies in Austria, national identities can become tied to rejection of certain technologies. In this case, a specific kind of “Austrianness” became tied to an imaginary of keeping a group of technologies out of the country and thereby becoming distinctive as a nation. Importantly, sociotechnical imaginaries not only describe what is attainable through science and technology in the future, but they also prescribe what ought to be attained, encoding societal normative visions. Relying on this notion of sociotechnical imaginaries, in this book I analyze how political culture is working to frame the rules, goals, and trajectories of drug innovation that are simultaneously describing and prescribing national futures in Russia.

Investigating Pharmapolitics

Beginning this project, I faced the question of where exactly I should do my research. Where would I be able to see how pharmaceutical science and technology relate to politics? One thing was clear: logics through which pharmapolitics are constituted and operate would not be visible in any one particular site. Therefore, my research was not to be restricted to a single location to enable me to study the circulation and evolution of meanings, identities, and objects in time and space. This led me to

adopt a multisite approach, where site is understood broadly and can include, among others, communities, technologies, and even discourses. Anthropologist Peter Metcalf wrote that “the sites of fieldwork cannot be the result of some prior theoretical agenda. Instead, they have to be discovered” (Metcalf 2001). And, indeed, it was only in the process of doing this research that it became fully clear to me where exactly to look for pharmapolitics.

My entry point was clinical trial sites—places where new drugs are tested on humans to check their effectiveness and safety. Studying these sites through interviews with investigators, trial participants, and representatives of business (twenty-seven in total) and observations of the work performed there together with continuous informal talks with those doing this work directed my further search. There I learned about how sweeping political changes that followed the dissolution of the USSR allowed globalized clinical trial enterprise to arrive in Russia and how this enterprise found and secured its uneasy place amid decaying welfare provision and new market institutions. But apart from this, my informants kept telling me that most advanced-stage and large-scale trials are sponsored by foreign pharmaceutical companies and volunteered to offer their opinions on the dismal state of the local pharmaceutical industry and current governmental attempts to revive it.

Following this lead, I started to go through materials and documents pertaining to these attempts to boost local drug development. I read programs and strategies, regulations, minutes and records of regulatory meetings, statements of regulators made in the press and during public events, and comments on these developments made in popular and professional media. But to understand how these relate to day-to-day practices of actors involved in pharmaceutical science and technology and how those actors themselves perceive and respond to the government actions, I needed to go beyond documents. So I went on to have thirty interviews with individuals involved in local drug innovation: those from academia, with a few of these academics also having positions in relevant regulatory structures; those from business, with one of those businessmen being involved as a consultant in a relevant regulatory structure; and those from development institutes and R&D infrastructure organizations such as industrial parks. Furthermore, I participated in events that allowed me to observe firsthand discussions among professionals and between professionals and regulators pertaining to infrastructure for innovative drug development and regulation and practices of drug development. During

this stage, I learned about how attempts to revitalize local pharmaceutical science and technology link to the wider political aspirations and why actors involved in pharmaceutical innovating find it difficult to deliver the expected material results. When discussing the current state of drug development in the country and its political significance, my informants often referred back to the strengths of Soviet pharmaceutical sector and to the period immediately following the end of the Soviet Union, which in their narratives marked the destruction of local pharmaceutical science and technology.

It became clear that to understand current pharmapolitics in Russia and how actors involved make sense of it, I also needed to dig deeper into the relations between politics and pharmaceutical science and technology in Soviet and early post-Soviet times. In doing so, I relied on stories of my older informants, who witnessed these transformations firsthand, and documents and publications of Soviet and foreign authors. Then I was able to reconstruct how the pharmapolitical nexus in which I was interested was changing shape with time and producing different imaginaries of the nation and its future. I finalized the main period of data collection for this project by organizing two focus groups with drug developers, where I posed questions regarding governance and trajectories of pharmaceutical innovations in Russia. These questions arose from my research, and having them discussed by relevant actors allowed me to ascertain and refine my interpretations.

It must be noted, though, that it was not possible for me to treat all sites uniformly in terms of the kinds and amount of data collected; nor was it necessary, because the aim was to bring into the same frame of analysis different sites where pharmaceutical technologies and politics in Russia meet and ascertain relationships between them. These sites are distributed in time from the period of the USSR to the beginning of the new Russia's existence at the turn of 1991 to 2015. They include drug discovery and development, clinical trial conduct, and spaces where related policies are developed, articulated, and appraised, as well as some wider interconnections between them.

What emerged from my study of politics and pharmaceutical technoscience in Russia is a picture of four interconnected processes that together shape both pharmaceutical and political trajectories. While the notion of coproduction of technoscience and society was a starting point, it remained important to specify how exactly this coproduction occurs and to what effect. My analysis suggests that pharmaceutical technoscience and politics

underwrite each other's existence through vision production, problem definition, collaboration, and value generation. Vision production refers to the process whereby the organization and practice of pharmaceutical development interact with political imagination to enable the emergence of specific visions of societal futures, which in turn feed back into the governance of drug innovation and wider regulatory agendas. Problem definition here is taken to mean a mutual dynamic where drug innovations define possibilities for solving societal problems, while simultaneously the ways in which societal problems to be solved through pharmaceutical R&D are defined shape directions of drug innovations. Collaboration denotes how relations between actors in the pharmaceutical arena are influenced by political culture and, conversely, how the ways in which actors on the ground choose to engage with each other affect implementation of the national political agendas. Value generation highlights that the type of value that is generated through pharmaceutical technoscience depends on which visions of the future animate drug development efforts, how the problems to be solved with the use of pharmaceutical science and technology are defined, and how the actors in the drug innovation domain engage with each other. At the same time, the value generation process here also highlights how potential and actually generated value contribute to formulating political priorities and strategies. How these four processes unfold defines the specific shapes that pharmapolitics take.

The chapters in this book, arranged in a chronological order, systematically attend to vision production (chapter 2), value generation (chapter 3), problem definition (chapter 4), and collaboration (chapter 5), the processes that take part in the configuration of the pharmapolitical nexus. I begin by exploring the emergence and consolidation of the Soviet national pharmapolitical regime in chapter 1. Here I trace how a constellation of institutions, technoscientific practices and artifacts, political programs, and ideologies came to act together to direct development of the pharmaceutical sector and pursue politics. Immediately after the beginning of the Soviet state, its pharmaceutical industry was reorganized into a centrally managed and planned sector with no involvement of private capital. Gradually the system settled into a situation where new drugs developed at the state research institutes would move into state production factories and then into state health-care organizations and pharmacies under the guidance and control of expert scientists, government decision makers, and bureaucrats. The effectiveness, safety, and quality of medicines were established without making use of the three-phase clinical trial system

introduced in the United States in the 1960s and currently dominant in drug development globally. The chapter argues that Soviet drug research, development, and production were shaped by an imaginary of an ultimately socially just society and organized in explicit opposition to the capitalist system of countries such as the United States whose drawbacks included bias introduced by profit motives, resource duplication, and exploitation of clinical research participants. Simultaneously, Soviet pharmaceuticals enabled a forceful articulation of communist ideas about society and contributed to shaping Soviet political agendas. My analysis of Soviet pharmaceutical science and technology as a case of pharmapolitics additionally suggests that it was not particularly good or bad in developing innovative drugs. Rather, it operated with its own definition of innovation that involved the ability to quickly develop and produce required drugs, irrespective of how such ability was achieved.

After the end of Communist rule at the beginning of the 1990s, Russia quickly adopted many of the previously rejected elements of pharmaceutical research, development, and production, such as strong involvement of private interests and withdrawal of the state from managing and organizing the sector. In chapter 2, I investigate what enabled such radical transformation and explicate how the process of *producing visions* operates to shape pharmapolitical practices. At the time of the USSR's collapse, conflicting visions of the Russian nation and its future were being articulated. One vision originally became particularly powerful: a set of neoliberal ideas championing the market, which has to be safeguarded from state intervention, and placing entrepreneurship at the center of economic and social development. The power of this neoliberal view, initially articulated by a small group of young politicians, came from the full support of the new government, which swiftly put to force such radical reforms as privatization and decentralization, embodying and disseminating neoliberal ideas. I show that specifically in the field of pharmaceuticals, the neoliberal agenda has exercised significant influence in other settings, such as Western Europe and North America, but nowhere was it put into action so quickly and to such an extent as in post-Soviet Russia. The chapter analyzes how the Russian pharmaceutical sector was molded by neoliberal ideas and shows that, despite their impact, these ideas failed to take root among those involved with pharmaceutical science and technology. Rapid deterioration of the already troubled Russian pharmaceutical sector in the 1990s greatly contributed to a wide resistance to the neoliberal vision of the Russian future both among those involved