PART I

Regulatory Capitalism

The theoretical importance of the notion of regulatory capitalism to today's global trade-flows cannot be overestimated (Jordana and Levi-Faur 2004; Braithwaite 2008). Many scholars regard 'neoliberalism' as the culprit of most of what is socially, economically, politically and culturally wrong with the world. But it is regulatory capitalism that sets the rules and norms of economic exchanges, which is especially crucial to the development of innovative biomedicine. The dynamics of regulatory capitalism crosses the boundaries of all jurisdictions, no matter what political systems rulers defend.

Regulatory capitalism forms the backdrop to my discussion of regulatory brokerage and regulatory violence in the field of regenerative medicine. Regulatory capitalism does not just account for an epidemic of national, professional and global regulations in terms of market mechanisms. Rather, its global reach makes possible the brokering of regulation among market economies, whether socialist, democratic, autocratic or other for economic gain. As a result, regulatory measures are introduced that are biased by illegitimate interests, the consequences of which are played out on the bodies of patients.

From Neoliberalism to Regulatory Capitalism

Under regulatory capitalism, the economic compatibility of trade is shaped and defined, not by financial security and innovation but by regulation and standards. In today's global scenario, Hobbesian visions of a world ruled by free-market competition are outdated. Rather, the globalised economy is a consumer-targeted market regulated by countless guidelines and standards for safety, security, quality, sustainability, fairness, health, the environment, climate and, of course, research. In our globalised world, compatibility is not just based on the price and quality of a product but also on how you can shape, ignore, use and manipulate the rules that underlie its trade. The difference with what is usually

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understood as neoliberalism is that it is not the invisible hand of the market that determines what and who may be 'fit' for purpose, but the geopolitical activities of the nation-state. This is why any country that wants to compete internationally needs a set of regulations, whether guidelines or laws, to enable competition on an international level. But how does this tally with the idea that we live in a world of neoliberalism?

Sociologist Lawrence Busch describes in *Standards* (2011) how Old School liberals such as Adam Smith emphasised the importance of individual liberty and the need to separate the state from the market and to delimit its powers. Neoliberal theory, developed since the 1930s by Henry Simons, Walter Lippmann and others, criticised national-plan economies. Both Simons and Lippman sought to minimise state powers, but they gave it regulatory functions instead. The former believed in a state that would maintain adequate rules for money, eliminate monopolies and minimise subsidies and protective tariffs, while the latter argued that the market was built on law, such as property law and contract, and their enforcement (Busch 2011: 180–182). These ideas were followed up by a group of leading advocates of liberalism, including Lippman, Michael Polanyi, Alfred Schutz and Friedrich A. Hayek, who were resolved to create a 'Road Code' for the market. In this view, economic monopoly and oligopoly were not a result of the concentration of capital, as argued by Marxists, but by state protectionism. The power of the state, then, was to be limited to the maintenance of a competitive price system, and state funds curtailed to support national defence, education, social services and scientific research.

After the Second World War, this neoliberal project resumed its quest against central planning, including Keynesian policies. It became especially associated with the neoliberalism of Hayek and Milton Friedman, who argued that free markets should be promoted, as they can distribute goods and services without recourse to a central authority; the social order must be reorganised such that it meets the conditions established by the formal mathematical models underlying the free market; and, the power of the government is mainly limited to regulating economic, social and political affairs through the market mechanism (Busch 2011: 182–187). An increase in regulation is not usually associated with neoliberal policies, as the power of the state to regulate is supposed to be limited in this view. Nevertheless, in the post-war period, when countries started to stimulate production internationally, regulation was developed to support global expansion.

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Global capitalism required an increase in regulation to guarantee the standards and regulations used by the international dominant, 'advanced' industrial nations (Braithwaite 2008), and it was the intensification of globalisation in the 1970s that warranted global regulation of international free trade. The expansion of the regulatory functions of the state and international corporate and professional networks led to a mushrooming of regulatory agencies since the 1990s on both global and national levels (Vogel 1996; Levi-Faur, Jordana and Gilardi 2005). More so than the notion of neoliberalism, which is confusingly applied to characterise various political regimes and geographical areas (Kipnis 2007), an exploration of regulatory capitalism, originally developed by political scientists David Levi-Faur and Jacint Jordana, can shed light on changes in the standards and norms of social, economic and political legitimacy and effectiveness (Jordana and Levi-Four 2004). For theories of regulatory capitalism claim that the increase in regulation in the United States, Western Europe and Japan since the 1980s was not a mere matter of home-politics but a trend more broadly inherent to the expansion of global capitalism (Levi-Faur 2005b; Braithwaite 2008).

The acceleration of the global expansion of production in the post-war era meant a change in the ways in which standards and norms were set. Sociologist Manuel Castells showed how Fordist hierarchical production management transformed into transnational networks that straddled the market with varying dynamics prevalent in different geopolitical regions of the world through international mergers, collaborations and agreements (Castells 2000). Crucially, within these horizontal links, collaborative private and public networks started to define the standards of excellence. Lobbying among competitors led to a blurred line between regulators and the 'players' of the game. This is important, as the global playing field was not one of free trade and equal opportunity but one of a reconfigured playing field of unequal players. Many players that cannot live up to the benchmarks set stay on board through intricate systems of collaboration and regulatory manipulation. Those who cannot afford to keep up this game feel forced to operate at the 'margins' and develop their own rules. A large majority, however, develop practices that fall somewhere between 'global' and 'marginal' standards, a grey area with an enormous scope for regulatory brokering of the rules as will be explained and illustrated in this book. But first, we discuss what it means to be in a world characterised by regulatory capitalism.

Criminologist John Braithwaite in *Regulatory Capitalism* (2008) argued that the realisation of the neoliberal ideal of privatisation,

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deregulation and a diminished public sphere is a myth: deregulatory policies in both the US and Europe were limited in the 1960s and 1970s, and many of the policies cut were reintroduced through the G10 after the banking crisis in the mid-1980s (Braithwaite 2008). Similarly, after the Asian financial crisis of 1987, some Asian countries survived by protecting their regulation. Ignoring the International Monetary Fund's (IMF) advice to liberalise and deregulate their financial markets helped them recover faster than those that had followed it (Stiglitz 2002). Political protectionism and the promotion of particular industries were conceived as 'unfair' and counter to global economic integration and market liberalisation. To many, it appeared that the promotion of international economic governance through the World Trade Organisation's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), the Agreement on Trade Related Investment Measures (TRIMS) and the General Agreement on Trade in Services (GATS) served to fend off competition from developing economies (Wade 2003; Salter 2007). Even arch-liberal Milton Friedman admitted that the 1990s had been more about law than about privatisation (Fukuyama 2004: 28). The political question was not so much whether to regulate but how to regulate and to what extent. In regulatory capitalism, then, in contrast with 'the neoliberal schema of markets as the antithesis of regulation' (Braithwaite 2008: 8), regulation does not level international markets but it skews them.

Regulation and the Reputation of Biomedical Products

But how do global markets become skewed? Regulations are a matter of compromise, for they are meant to coordinate the actions of producers to work in a compatible way. Regulators combine knowledge from different fields of expertise (Braithwaite 2008). For instance, regulatory standards and procedures for regenerative medicine draw on expertise from a number of fields, including chemistry, bioinformatics, biomedicine, public health and economics. Regulation impacts production in various ways: producers have to adjust their ways of doing things by using new ingredients, different formulae, different suppliers. In the life sciences, Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) are examples of standards for clinical research and manufacturing that are expensive to attain and maintain. Those that follow the regulations meticulously will feel disadvantaged compared to those who profit by not doing so. Producers who are close to regulators may have an

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advantage, as they can try to influence the regulation through lobbying. Reputation also matters: those whose 'ways of doing things' are perceived to be 'inferior' may not be able to compete, whether these perceptions are correct or not. The regulations will affect the playing field in general, as those with the technological expertise, scientific, managerial and financial capacity to integrate regulatory requirements in the production process will have an advantage compared to competitors that do not. Also, users of regenerative therapy products can refer to regulation when purchasing products or services and when lodging complaints.

Under regulatory capitalism, then, regulation regulates competition (Kingsbury et al. 2019): it sets the rules for compatibility. Science innovation is especially vulnerable to regulatory capitalism, as its regulation also involves the innovation of society and its values, which may differ from society to society. Such competition, as I will show, goes beyond one or the other interest group dominating or capturing regulation, involving complex dynamics of interactions between norms and values, material conditions and international relations, no longer headed by a global authority, be it in the shape of a country, region, institution or power. For conflict occurs where no common international rules have been agreed upon but also where regulation is introduced to harmonise global practices (Abraham 2002; Görg and Brand 2006). This is not surprising, as regulation can divide those that have the means to follow them from those who do not. Apart from being a matter of financial affordability, scientific knowledge and technological expertise, regulatory reputation is of great importance in scientific competition (Carpenter 2010). I use the notion of regulatory reputation to refer to how a jurisdiction's regulation and its implementation are subjectively rated in other jurisdictions. Regulatory reputation is important in the context of international competition, where scientific products and services in one country or area are avoided when aspersions of 'unreliability' have been cast. Such 'boundary-work', as we shall see, can have devastating consequences for scientists in entire parts of the world, as was the case when Asia was referred to as the 'Wild East', implying that 'international' rules were systematically flaunted (Bionet 2007; Zhai et al. 2020).

It is in this context that Chapters 2 and 3 will introduce the notion of regulatory boundary-work. The makers of scientific products, scientists, make political distinctions between their own work and that of others through what sociologist Thomas Gieryn calls scientific boundary-work. Gieryn argues that scientists draw up boundaries 'between the realm of science and non-science' in order to claim and defend their own territory:

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Such boundary-work is useful in the light of scientists' pursuit of professional goals, such as the 'acquisition of intellectual authority and career opportunities, denial of these resources to 'pseudoscientists' and protection of the autonomy of scientific research from political interference' (Gieryn 1983: 781). According to Gieryn, scientists deploy an ideological style to create a public image for science by contrasting it favourably to what they portray as non-scientific intellectual or technical activities (Gieryn 1983). Apart from scientific boundary-work, we can also speak of regulatory boundary-work, which I define as the politics of regulatory reputation.

Chapters 2 and 3 show how regulatory capitalism shapes a multitude of regulatory hegemonies as a result of power reconfigurations in the world of science innovation. These trends, I will argue in Chapter 2, create the structural spaces for activities of regulatory boundary-work and regulatory brokerage practiced by individual enterprises and regulators alike. Neither global hegemony approaches nor approaches that emphasise the scientific rationale of regulations are sufficient to explain the global dynamics of regulatory development in the field of regenerative medicine. Chapter 3 illustrates how the nation-state plays a central role as main shaping agent of regulatory boundaries at provincial, national and global levels of organisation. The nation-state also plays an important role in developing a regulatory framework appropriate to the country's scientific capacity and economic aspirations. Adapting 'foreign' regulations requires compromising between 'the ideal' models used by the laboratories of the global elites and standards aimed at home. And as the aims and aspirations of regulatory regimes within a country differ, the state plays an important role in channelising, managing and policing them.

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