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Regulatory Violence and Beyond

Regenerative Medicine and Competitive Desire

Why Would Any Regulatory Agency Produce Regulations That Normalise Violent Outcomes?

Harm may be caused by unintended violence, and such violence may be both foreseeable and preventable (Bufacchi 2007). The research in this book provides evidence from the field of regenerative medicine that unintended but foreseeable violence takes place driven by global and local pressures on the way clinical applications are regulated. This is not just the case in low- and middle-income countries (LMICs). Evidence-based analysis of international case studies on science collaboration in the field of regenerative medicine shows how competition and political, economic and social pressures on national regulators condition the development of countries' regulations that are, at least partially, unsuitable for their populations and for the development of high-quality science. As the quality of clinical therapies and scientific research hinges on appropriate regulation, this is problematic, as evidenced by numerous works (e.g., Srinivasan 2006; Sheldon 2007; Kiatpongsan and Sipp 2008; McCullough 2008; Lindvall and Hyun 2009; Gunter et al. 2010; McMahon and Thorsteinsdóttir 2010; Song 2011; Brown 2012; Sipp 2012; McMahon 2014; Bianco and Sipp 2014; Holbein et al. 2015; Sipp et al. 2017; Peterson et al. 2017; Caulfield and Murdoch 2019; Smith 2021; Cyranoski et al. 2023). Although regulatory measures may stimulate investment and the mushrooming of international science collaborations, regulation that foreseeably fails to guarantee the promised optimal protection of the quality of clinical therapies and scientific research appropriate to its jurisdiction is violent, even if unintended. So, if research regulation is developed for reasons other than patient safety and scientific development, then it will cause foreseeable harm. This is why I speak of regulatory violence. If similar illegitimate pressures condition the development of regulation in other regulatory fields, for

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instance, ecology, then we can also speak of foreseeable and possibly preventable violence, that is, regulatory violence.

But regulatory violence is not unavoidable; some countries do try to regulate with an exclusive focus on patient needs and high-quality science. In some countries, politicians, scientists and regulators decide not to give in to political, economic and other pressures to adjust their regulation of innovative medicine for the 'wrong' reasons. The high costs of the 'game' of competing in the field of regenerative medicine also make governments realise that resources in their jurisdiction are needed to cater to other health priorities. Thus, rather than adjusting regulation to facilitate international competition in innovative health technologies, for instance, to stimulate their economy and to discover quick-fix biomedical solutions, they might prioritise the provision of basic, sustainable or alternative care to address health needs in their communities.

The global evidence in this book challenges the belief that regulation is what is needed to deal with problematic practices in regenerative medicine, to align biomedical practitioners with good science and to guard patients' safety. Even when well-intended, the regulation of regenerative medicine is caught up in the fierce international competition and the loud claims of benefits in terms of both public health and national wealth. Its real-world implications are foreseeable violence towards patients and public losses. This book explains why this is so and points to ways in which science could help us address healthcare issues in greater solidarity. Because 'violence' is an emotive term, I start by clarifying what I mean by regulatory violence.

Regulatory Violence

After the Second World War, international economic competition between countries and regions became increasingly based on the power to set the rules for production, also in the field of biomedicine. This form of competition I refer to as regulatory capitalism. As the protection of patients and the quality of therapies depend on these rules, it is foreseeable that regulatory competition could result in harm to patients. The rise of regenerative medicine – an emergent field of biomedical innovation that aims to restore, maintain or enhance cell, tissue and organ function – is a case in point.

Regulatory violence is about (mis)using regulations that are meant to protect research subjects (often patients) in clinical research trials and other forms of therapy provision in a jurisdiction for the pursuit of other,

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illegitimate interests, thereby inflicting not necessarily intended but foreseeable harm to the people they are meant to protect. In the context of innovative clinical research or treatment, similarly, regulatory violence occurs when regulation, meant to protect the quality of treatment and clinical research, is used to satisfy other, often lucrative aims. I speak of violence, here, as one could foresee that harm is likely to be inflicted on patients or clinical trial subjects, who might be receiving unsafe interventions or, indirectly, when patients/subjects are harmed as a result of suboptimal treatment.

This relation between regulation and violence may come across as puzzling: people usually think of violence as harmful acts directed against individuals in a direct way; we tend to make a direct link between *the cause of violence*, say, a person intentionally hitting a neighbour, and *its result*, an injured neighbour. Also, we usually associate regulation with political order and legitimacy. German sociologist and jurist Max Weber described how the state's monopoly on the use of physical force, including incarceration, expropriation and death threats, serves the protection of people against violence in its jurisdiction (Waters and Waters 2015). This is how the law is legitimated. So, the directness of concrete violent acts and the abstraction of regulation in 'regulatory violence' do not sit together comfortably.

Nevertheless, for over a decade, I have witnessed many instances in which regulatory compromise was predictably related to violence. My research on collaborations among scientists and industry in LMICs and high-income countries (HICs) shows how regulation becomes a source of negotiation and manipulation. Here, science collaborations are not just based on the sharing of a pool of scientific, material and human resources among collaborative partners. Although usually expressing positivity focused on a win-win basis, collaborations also show signs of mutual mistrust, competition and carefully managed exchanges. The collaborations I observed all revolved around *differences in regulations* between countries. Further examination made me realise that clinical research regulation is not always used to protect patients and the quality of scientific research but can also be manipulated, dodged, reformed and designed to gain an economic competitive edge internationally. What I witnessed was the brokering of regulation: regulation, purportedly designed to protect research subjects and patients, was tinkered with and had foreseeable consequences for the quality of patient treatment. Although often not intended, regulatory brokerage is a violent act. Regulatory violence, I maintain in this book, is a symptom of a form

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of international competition in an international capitalist order. The cumulative evidence for this can be found in the following chapters.

Before turning to the regulation of regenerative medicine, I first discuss how the notion of regulatory violence sits with the current literature on regulation and violence. It explains why regulatory violence needs to be recognised as part of a world order characterised by both illegitimate violence and poor priority-setting in the area of health.

Regulation

Among the many (contested) definitions of regulation, none seems to conceptually capture the dynamics of global regulation adequately. Usually, definitions of regulation are state-centred and legalistic. Thus, *regulation*, according to the OECD (2002), refers to 'rules or directives made and overseen by an authority, such as the state or international organisations. States use regulation, rules or directives, to direct economic behaviour'. Less common, de-centred definitions of regulation include all the activities that are designed to influence behaviour. These definitions cast the net too widely for them to be analytically precise. Many scholars take an intermediate position, emphasising the centrality of government and the intent behind regulation to change behaviour. Thus, Julia Black defines regulation as 'a structured process undertaken by or under the auspices of government designed to modify the behaviour of persons or entities according to defined standards' (Black 2002). In a national context, then, a polycentric notion of regulation includes both non-government organisations and subnational regulatory institutions; and in an international context, it involves regulations produced by intergovernmental, supranational and international professional organisations (Black 2005, 2021). The international power dynamics between regulatory bodies and the ways in which they influence regulation, however, have not been adequately conceptualised. This is a crucial omission, as it is only this element that can explain regulatory decision-making in a world ruled by regulatory capitalism, a term I explain below. The omission becomes obvious in the context of an unprecedented increase of regulation since the Second World War.

Critical notions of neoliberalism usually presume that the post-war economy is about de-regulation. But an increasing reliance on market mechanisms to deliver government services, such as social healthcare, an expansion of human and bioethical rights and the push for scientific and technological innovations have actually required an increase in

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regulation. Accordingly, regulators have been tasked with the creation of a regulatory environment in which innovation, new technologies and markets could flourish while protecting citizens from its excesses (Windholz 2018: 4). As will be elaborated in Part I, an increase in regulations gave industries the confidence to invest in risky ventures, including biomedical experimentation and innovative research, and instilled trust in citizens to participate in these undertakings. And in the 1990s, demands for 'better regulation' were matched with 'responsive-market based regulatory tools' and 'flexible performance' (Baldwin and Black 2007: 45) built on regulatory standards to incentivise, persuade and assist compliance (Windholz 2018: 23).

The late 1990s and early 2000s saw an increase in theories that describe regulation as a dominant form of governance. Political scientist Giandomenico Majone's theory on the regulatory state (1994) had described a separation between policy-making functions and regulatory functions in Europe, whereby the state outsources regulation. Majone argued that regulatory regimes compete internationally (Majone 1997). But the regulatory state approach, as shown by political scientist David Levi-Faur (2005c), does not show what drives the creation of regulation and it does not explain its external links, such as interstate governance, and internal links, such as collaboration with non-governmental sectors

The theory of *regulatory capitalism*, developed by David Levi-Faur and Jacint Jordana (Jordana and Levi-Faur 2004; Levi-Faur 2005a, 2005b) did try to address these questions. Their work moved beyond formal state-centred rule-making and national boundaries, and it describes hybrid forms of regulation that result from the delegation of regulatory responsibilities to regulatory agencies, civil society, businesses and professionals. This theory also allowed for the global expansion of national regulation and the increased influence of international regulatory networks. Criminologist John Braithwaite, in this context, persuasively showed how more capitalism meant more regulation (Braithwaite 2008). Nevertheless, as it was criticised for implying a belief in markets and being a capitalist-centric view of the world, regulatory scholar Eric Windholz set aside the notion of regulatory capitalism in favour of 'regulatory governance'. This term reflects that regulation is the expanding part of governance (Windholz 2018: 26), while also recognising non-governmental actors at national, supranational and global levels. But the term 'regulatory governance', itself shaped by the presumption of democratic, liberal and capitalist views of societies, is often used as a benchmark for testing the applicability of various regulatory theories. As such, it biases the analysis of regulation

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in a politically diverse international context in which risk is calculated and packaged. Such contexts impact both the creation and implementation of regulation (Baldwin and Black 2016: 569; Black 2021), and, as we shall see, have far-reaching implications for the dynamics of international regulatory developments.

I prefer to use the term regulatory capitalism, because all countries that are interested in developing regenerative medicine (as shown in this book) are subjected to international capitalism, regardless of whether they believe in it or not. Nevertheless, countries have their own styles of regulatory capitalism; that is, the ways in which regulation relates to government and national and international non-governmental actors vary (Minoque and Carino 2006). In this international context, the notion of regulatory governance is problematic, if used as an extension of the political preference of particular governments and their state activities. Such a notion would be blind to the fact that nation-states, rather than just adhering to the rules of a political system, adopt particular regulations under the pressure of destructive forms of competition in the context of an international capitalist order. In this book, therefore, I use the notion of regulatory governance only when this concerns the particular internal regulatory activities of nation-states.

A growing number of theories conceptualise the politics of regulation, many of which are developed in the Anglo-American academic world. I here borrow Windholz's distinction between public interest and private interest (Windholz 2018). *Public interest theories* conceptualise regulation based on value-orientations, such as justice, equity, fairness and risk control, including the maintenance of social cohesion, environmental protection and social security, and identify detrimental market influence, such as market failure, anti-trust and monopolies. *Private interest theories*, such as public choice theory and interest-group theories, emphasise the failure of regulation. For instance, Majone's 'regulatory capture' theory (1994, 1997) shows how regulation is captured by particular interest groups, such as trade unions, politicians or industry. In Europe and the US, where these theories are prevalent, public and private interest theories compete. Thus, legal scholar and lawyer Steven Croley argues against private interest theories by showing how regulation for public purposes, such as social welfare and healthcare, can be successful if certain conditions are met (Croley 2007).

Though important in the context of some political systems, including in the field of regenerative medicine, the divide among public and private interest theories, as we shall see, detracts our attention from their political and international scope (see Chapter 8). And although the notion of

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'regulatory capture' can be critically applied to regulatory governance internationally, it does not explain the drivers of regulatory capture and its contextual significance (Minogue and Carino 2006). Julia Black provides a more rounded analytical model, which covers core elements of regulatory theory, including the underlying normative framework of regulation, its cognitive framework, the regulatory tools and techniques used by the system, the behaviour of individuals, the dynamics of organisations of regulators and regulates and notions of trust in and legitimacy of the regulatory system (Black 2021). But although the model is referred to as dynamic (Black 2021), the theory itself is not equipped to map and theorise the politics behind international power dynamics of interacting regulatory systems.

Another shortcoming shared by most regulatory theories is the presumed binary between regulators and regulatees. Although the role of regulator is extended to 'intemediaries' and 'advisors' (Abbott, Levi-Faur and Snidal 2017; Black 2022) the point of departure even of these nuanced approaches is that regulators and bureaucrats create regulation for regulatees to follow as the norm. It is true that mediators and advisors influence the formal creation of regulation, but, as we shall see in this book, so do all sorts of pressures, opponents, competitors, manipulators, dodgers and so on.

Based on the above, I propose to use a concept of regulation that pertains to the international dynamics of its development and change, affected by the international variability in the availability of financial, cultural and knowledge resources and reigning political ideologies. This concept of regulation questions the binary between regulators and regulatees and is open to the view that governments do not only create regulation but also manipulate it: regulatees are not just subject to regulation; they also co-create it. Regulatees have the capacity to 'perform' regulation through the ways in which they present it and act upon it, thereby contributing to the regulatory process. And, finally, this concept of regulation both magnifies the micro-context in which regulation is created and widens its scope to incorporate the global pressures that shape the micro-context. The concept aims to capture relevant pressures on regulators and regulatees at multiple levels of governance. I discuss the methodological implications of this in the Methodology section.

Violence

As indicated above, this study on regulation is concerned about the (human) violence its misuse entails. Throughout the research for this book, I have thought about regulatory violence in terms of the direct and

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indirect violence inflicted upon patients and research subjects. The current formulation, however, is largely inspired by philosopher Vittorio Bufacchi's notion of foreseeable violence (Bufacchi 2005, 2007), leaves open whether the violence was intended. However, unlike broadly defined notions of violence, this definition is able to say what makes an act of violence an act of violence and why it is to be rejected.

An act of violence (from Latin, *violentia*, meaning 'vehemence', a passionate and uncontrolled force) is often associated with an act of physical force that inflicts harm and causes destruction to persons (Bufacchi 2005: 194). In the context of health, restricting 'acts of violence' to intentional, direct physical force against others leaves out important dimensions of acts of violence. Psychological violence on patients is often invisible but very real, including when inflicted indirectly (Galtung 1969). Acts of violence, then, should not exclude broader, indirect forms of both physical and psychological violence that are foreseeable consequences of the illegitimate creation, use, avoidance and manipulation of regulation.

To determine whether a certain act qualifies as violence and to decide whether the act is malevolent or not, we often refer to the intentionality behind it. But sometimes other necessary conditions are preferred, such as the foreseeability of inevitable consequences of an action. For instance, if necessary to the purpose of healing but un-intended, a doctor does not commit a violent act when causing a patient pain. A doctor prescribing 'snake-oil' to patients with the aim of making profit, however, commits an act of violence. In the first case, the suffering is legitimated as a by-product of treatment; in the latter case, it is intended for illegitimate reasons.

It is also possible to commit violent acts without using any physical force directly and without intending harm to others: when regulation meant to protect patients is manipulated for reasons other than patient protection. In this case, regulatory violence takes place through regulatory violation (from the Latin *violare*, meaning 'infringement' [Bufacchi 2005: 194]). I also speak of regulatory violence when the *creation* (rather than the manipulation) of regulation takes place for purposes other than for the protection of patient rights and the quality of science: it indirectly inflicts foreseeable harm, even if unintended.

To further define regulatory violence (and following Bufacchi 2005), I delineate the concept from notions of structural/socio-economic (Galtung 1969; Farmer 2010) and political violence. Certain types of regulation make clinical research expensive, thereby indirectly and foreseeably excluding certain patients for socio-economic reasons. Here, the

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resultant inaccessibility of important treatment to large groups of patients could cause harm. This, many scholars would consider structural violence (Galtung 1969; Falmer 2010). The implication is that a less expensive form of therapy should be developed or the available therapy subsidised. But, in this example we do not know if regulation is primarily created to protect patients from harm and inferior treatment or whether it serves the monopoly position of some pharmaceutical cartel. In this case, I would speak of regulatory violence only if governing bodies change or create regulation for reasons other than to protect patients from harm and scientific research quality, such as reputation and profit. If this means that regulation makes therapy 'expensive' to a part of the population, these inequalities need to be addressed by considering health priorities in the jurisdiction in the light of social justice and affordable healthcare. In brief, structural violence is about health policies on social justice and affordable healthcare, while regulatory violence is about not prioritising the protection of patients and science quality.

It is also important to delineate regulatory violence from political violence. The notion of political violence, though resembling that of structural violence (Sousa 2013), pertains to human relationships that involve power, rule and authority used by and against systems of government (Kalyvas 2019). Political action can involve intended, unintended and foreseeable violence, but the notion of political violence lacks the necessary precision for analysing how regulation is created and maintained. According to Hannah Arendt, in a bureaucracy no one can be held responsible for violence. Therefore, it can be called 'rule by nobody' (Arendt 1970: 38–39; 48). Other views, though speaking of technologies for governing at a distance' (Rose and Miller 1995), define the work of bureaucrats in terms of responsibility and initiative delegated to them. These examples illustrate the political variability of systems of governance, which needs to be understood if we aim to identify the harm inflicted by regulatory violence with a more finely-toothed analytical comb. But for this exploration, we first need to know what regulation is meant to do, and in this book, what it is meant to do in the context of regenerative medicine.

Regenerative Medicine: The Regulation of Safety and Quality of New Regenerative Therapies and Its Challenges

This short introduction to regenerative medicine explains some core concepts and shows how regulation aims to ensure the safety and quality

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of new stem cell therapies and is challenged at the same time. The case studies used in this book mainly focus on mesenchymal stem cells (MSCs) and pluripotent stem cells (PSCs) – concepts that are explained below, leaving aside current developments in gene therapies and the new cell-engineering approaches, which are the subjects of a new generation of stem cell technologies (Kimbrel and Lanza 2020). And, although I here mention some contemporary promises and challenges of the technologies introduced, the chapters themselves will refer to and explain the issues that were relevant to the case studies at the time of research. After all, what is at stake here is the ways in which regulatory decision-making takes place given the kind of technologies societies engage with at a particular point of time. If you are familiar with stem cell terminology or prefer to use the index to look up certain terms, you can use the index to look them up and skip the next sub-section.

Different Stem Cells, Different Issues

Regenerative medicine is the branch of medicine that develops methods to regrow, repair or replace damaged or diseased cells, organs or tissues. It includes the generation and use of therapeutic stem cells, tissue engineering and the production of artificial organs (Nature 2021), A stem cell is a cell with the unique ability to develop into the over two hundred specialised cell types in the body, such as bone marrow stem cells, hematopoietic stem cells (HSCs, or blood stem cells) and mesenchymal stem cells (MSCs). Usually stem cells are divided into 'adult' or 'somatic' stem cells (HSCs, MSCs, Neural Stem Cells, Epithelial Stem Cells, Skin Stem Cells) and 'pluripotent' stem cells (PSCs) (embryonic stem cells [ESCs] and induced pluripotent stem cells [iPSCs]). 'Somatic stem cells' – stem cells not used for reproduction, are generated throughout one's life by many bodily tissues, including the umbilical cord, placenta, bone marrow, muscle, brain, fat tissue, skin and the gut, where they replace those that have died (apoptosis). PSCs have the potential to become almost any cell type and are only found during the first stages of development of an organism. Although blood diseases, such as leukemia, have been treated successfully with bone marrow stem cell therapies for decades, in other areas, the promises of research leaders of regenerative therapies for serious intractable conditions have not been realised as hoped for.

Stem cell therapies, broadly, can be viewed as medical procedures in which stem cells represent the medical product, but they differ widely

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depending on what kind of stem cell therapy is opted for (Cossu et al. 2018). For instance, HSC-therapies used routinely for blood diseases can be 'autologous' (transplantation of cells from the same individual) or 'allogeneic' (transplantation of cells from anther individual), while 'endogenous' therapies direct particular bioactive molecules to the diseased location. HSCs, which have been researched for therapeutic applications to treat a variety of immune-mediated diseases for over thirty years, appear to work quite differently from MSCs (Pittenger et al. 2019). Although initially heralded as a regenerative therapy for skeletal tissue repair, the therapeutic effects afforded by MSC transplantation are short-lived and related to dynamic, paracrine (signaling) interactions between MSCs and host cells (Parekkadan and Milwid 2010; Jovic et al. 2022). Variability in effect seems to derive from the MSC source (donors), cultivation media (e.g., bovine, human or synthetic) and the metabolic environment of the transplantation (Boland et al. 2019). Furthermore, uncertainty still exists about the MSC-potential through this intracellular and intercellular signaling, about delivery methods (Pittenger et al. 2019; Jovic et al. 2022) and the types of diseases that can be targeted (Jovic et al. 2022).

Therapies using human embryonic stem cell (hESCs) are 'pluripotent' and initially raised high hopes for applications of 'somatic call nuclear transfer' (SCNT) or 'therapeutic cloning' for the purpose of cell therapy. In theory, SCNT could replace a large range of faulty cells, as the procedure uses stem cells genetically identical to the somatic cell they are derived from. The first embryonic stem cell lines were derived by developmental biologist James Thomson (Thomson et al. 1998). But the differentiation process into specialised cell types for clinical application has been challenging, as it is not entirely efficacious and risks tumour formation. Right from the start, SCNT has been plagued by ethical controversies about the sourcing of human embryos and human oocytes (Nakatsuji 2007; Thompson 2013; Isasi et al. 2022). But while patient-specific lines are needed for some conditions, others can be addressed using allogenic lines that are HLA (human leukocyte antigen)–matched to the patient. This would limit the need for sourcing oocytes and make it unnecessary to create embryos for each patient.

In 2007, stem cell scientists Kazutoshi Takahashi and Shinya Yamanaka 'discovered' induced pluripotent stem cells (iPSCs), which are derived from reprogrammed adult somatic cells, such as skin cells (Takahashi et al. 2007). Using iPSCs, it was hoped, would lead to cell-replacement therapies that could address numerous intractable conditions. iPSCs do not share the same ethical controversies as those associated with

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hESCs, and they do not have the same level of immune rejection, as the cells are sourced autologously. But when the patient's cells are affected by genetic conditions, it is necessary to use iPSCs heterologously (from other people). This would still create immune reactions, though they could be limited through HLA-matching. Two issues are often mentioned in connection with iPSCs reprogramming. The first concerns tumorigenicity caused by the reprogramming factors used to obtain iPSCs (Yamanaka 2020), and the second pertains to the 'somatic epigenetic memory' of the somatic cell used to derive them, which may bias or limit the differentiation into cells of a particular lineage (Equizabal et al. 2019). These issues figure in debate on whether hESCs or iPSCs methods of reprogramming are better (Matoba and Zhang 2018).

Nevertheless, pluripotent stem cells (PSCs) share a number of challenges related to the need to optimise differentiation protocols (Doss and Sanchinidis 2019), and the development of clinically graded culture conditions, which can affect the genetic and epigenetic stability of PSCs (Equizabal et al. 2019). Other PSC challenges are currently under research: First, tumorigenicity: tumours can be caused by both germline and somatic cells that carry genetic mutations and by the *in vitro* expansion of PSCs that cause genetic alterations (Yamanaka 2020); second, 'heterogeneity': cell lines are heterogeneous with respect to gene expression, epigenetic status and differentiation ability (Yamanaka 2020); and, third, the allogeneic use of both hESCs and iPSCs raises immunological issues (Liu et al. 2017; Ye et al. 2017). Upscaling to allow 'off-the-shelf distribution' is thought to be crucial for the future of regenerative medicine in terms of economies of scale and timely clinical application. This would require HLA-matching for different blood types and the creation of haplotype banks. Although HLA-matching to some extent can prevent immune-reaction, it would still require the patient to take immune suppressant drugs. An alternative would be the use of 'immune-cloaking', a technique that makes use of multiple rounds of gene-editing. One of these, in principle, could serve as a universal cell source (Yamanaka 2020; Madrid et al. 2021).

Because and despite of these various challenges, clinical PSC studies and clinical trials are under development, but they are limited in number. A global database study involving 'ClinicalTrials.gov' and ICTRP by Deinsberger et al. (2020) identified 131 clinical trials involving PSCs, of which only 22.9 per cent were interventional, that is, where cells are actually transplanted, and most of these involved hESCs (73.3 per cent). It is striking that the majority of the interventional studies (63.3 per cent)

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focused on ophthalmic diseases; most others targeted cardiovascular and neurological conditions. Although there is likely to be a reporting bias, among the registered clinical trials involving PSCs, most were performed in China (36.7 per cent), Japan (13.3 per cent) and South Korea (10 per cent), which is most likely related to research policies and differences in national ethical regulation (Deinsberger et al. 2020). These differences, as shown in this book, are a major issue of contention, as well as a major source of competition in the context of regulatory capitalism.

Investment, Promise and Regulation

Governments around the world have greatly invested in the field of regenerative medicine, and there is a huge potential market for therapeutic applications on a global scale. The report Regenerative Medicine Markets Analysis and Forecast tells us that the global regenerative medicine market was worth $35 billion in 2019 and will grow to over $124 billion by 2025 (Department of Business Innovation & Skills 2011; Research and Markets 2020). Regenerative medicine is hoped to address conditions related to ageing populations, to find easy and cheap solutions to alleviate health budgets, to stimulate economic growth by gaining an edge in the competition for clinical applications and trade in resources for the research for which there is a huge market. Applications are developed for therapeutic purposes: the intention is to regenerate damaged tissues and organs *in vivo* through reparative techniques that stimulate previously irreparable organs into healing themselves. In addition, regenerative medicine promises to allow scientists to grow tissues and organs *in vitro* and implant them. The future value of regenerative medicine lies in its claimed capacity to produce therapies for a broad range of diseases and conditions including diabetes, heart disease, renal failure, osteoporosis and spinal cord injuries for which there is at present only partial treatment or none at all.

Although few of its promises have been realised (Gardner 2017; Cossu et al. 2018), there are many commercial opportunities in the field that are driven by products other than the therapies themselves. For example, as long as the promises of regenerative medicine are credible and can be used for other purposes, such as diagnosis or screening, the industry around regenerative medicine is likely to keep buzzing. Thus, cell lines from hESCs and iPSCs are used as disease models to explore the pathology of diseases; they are used as drug screening assays to demonstrate efficacy; and, they are used as the means for the toxicity testing of

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candidate drugs. In fact, a veritable industry around equipment, materials, software and knowledge assets thus far has been a successful business model across the world, generating enough cash flow to nurture the development of the field (Salter 2009). Therefore, even though the outcome of the drive for clinical applications in the field of regenerative medicine has been disappointing, its promises are such that governments and industry, including in LMICs, continue to pour investment into the field so as not to fall behind. And, as shown in Chapter 2, business in the field continues to boom.

The more investment, it seems, the higher the stakes become and the higher the hopes, which, at the same time risks financial loss and disappointment for both researchers and patients. Translating scientific theory into clinical practice proves difficult, even when healthcare and scientific resources are diverted from elsewhere and pumped into the field. In such circumstances, the role of regulation is emphasised: first, to protect patients, as some may be tempted to pay highly for unauthorised or immature 'therapeutic' products provided by clinics; and, second, to enable responsible innovation with the appropriate authorisations. As experimentation on humans (and animals) is complex and often dangerous, in their efforts to find effective treatments, doctors and researchers often put vulnerable patients at risk. It was only in the 1960s, after the highly publicised cases where the concerns of human subjects were discounted in favour of a researcher's professional interests, that legislation or regulation with a focus on the protection of human subjects was adopted in countries with advanced centres of biomedical research (Krimsky 2006). Furthermore, clinical trials – research that tests the safety and effectiveness of new treatment in people, usually in four phases, were developed to ensure both the optimal testing conditions to produce valid, scientific results and also to safeguard the rights and well-being of participants.

Biomedical Innovation: The Tension between the Aims of Research and Therapy

The point has often been made that in biomedical research a distinction must be made between research and therapy (Glass 2006). The aim of clinical research trials is not primarily the well-being of the research participants (although knowledge about, for instance, safety can certainly contribute to patient well-being) but to obtain answers to research questions and, often, the opportunity to publish them in scientific journals. In the case of therapy, however, physician-researchers need to

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balance their commitment to research and to therapy. Although the separation between the two is usually reflected in regulation, the distinction often disappears in practice, especially in situations where the 'drive to the clinic' has gained momentum under political, financial or other pressures, such as those of patient groups.

The regulatory culture that stressed protection from risk in the 1970s, especially among advocacy groups among patients with breast cancer and people with AIDS in the US, began to shift in the late 1980s to stress access to, and the fair distribution of, the prospective benefits of research (Epstein 1995; Lemmens and Waring 2006). The notion of justice as patient protection began to include justice in the sense of available access to medicine. In fact, since 2014, more than half of US states have passed 'right to try' laws. These laws allow terminally ill patients to receive experimental therapies that have passed phase 1 clinical trials without the need to apply for FDA approval (Cossu et al. 2018: 904). The various pressures to slow down and to accelerate the development of marketable medical products created tensions that will be central to the issues of regulatory brokerage and regulatory violence in this book.

This tension is also palpable within the social-science literature and among critics and relates to discussions about the ethics of 'unproven stem cell interventions' versus those who support alternatives to 'Western' 'evidence-based medicine' and 'clinical trials'. The former advocate internationally agreed forms of scientifically proven non-commercial provision using robust regulation (e.g., Murdoch et al. 2018; Cauldfield et al. 2019), while the latter often view evidence-based medicine as a 'Western' kind of normative regulation (Lambert 2006) and support either less prohibitive or alternative forms of regulation (e.g., Bharadwaj and Glasner 2008; Montgommery 2012; Bharadwaj 2013; Hauskeller et al. 2017; Hauskeller 2018). At the same time, and as will be discussed in this book, in experimental therapy provision the notion of 'Western' is often used symbolically to emphasise the connotations of enlightenment ideals and capitalism. Nevertheless, as I shall show, the reasons for supporting other than 'Western' regulation are also related to a range of practical issues involving discussions of inequality, healthcare availability, government policies, competition and knowledge traditions.

The Slippery Vocabulary of Experimental and Regulatory Challenges

But what comprises 'optimal' conditions that make 'scientific' research results valid and constitute the 'rights' and 'well-being' of patients is much disputed. The answers to these questions appear to be different

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in the context of clinical research and clinical treatment. As we shall see below, the meanings of many notions that try to define the status of 'unauthorised therapeutic products' and 'immature experimental therapy' are confusing: the meanings of 'unauthorised', 'immature', 'experimental' and 'therapy' can change according to the research culture in which they are used. For instance, some critics argue that speaking of an 'immature therapy' is an oxymoron, as therapies are supposed to have a positive effect and therefore cannot be 'immature'. And how can we regard a 'therapeutic product' as unauthorised? After all, if the scientific authorities have not authorised a product for clinical use, on what basis would we view it as 'therapeutic' or even count it as a marketable product? And as will become clear, there is fundamental disagreement in the world of science about what is a scientifically authorised stem cell product; there is no organisation that can declare with global authority what constitutes a 'therapeutic product' and explain what counts as scientific evidence.

In the fast-innovating experimental field of regenerative medicine, regulation determines to a large extent the experimental, clinical and industrial possibilities of the field. The scale of the four-phased traditional clinical research trial for pharmaceutical drugs has been viewed as unnecessarily restrictive in the field of regenerative medicine (Mason and Hoare 2007). The large numbers of patients required in those trials have been criticised as being unrealistic in the case of regenerative medicine (Rosemann 2014a). And whereas a clinical trial is often used to learn if a new treatment is more effective and/or has less harmful side-effects than the standard treatment, in the case of regenerative medicine there is usually no standard treatment available (Mason and Hoare 2007). Whilst drugs can be understood in terms of molecules as a chemical event, regenerative medicine, based on live cells, needs to be viewed as a biochemical process. Clinical applications in regenerative medicine, therefore, are thought to carry different risks and to require different modes of testing (Mason and Hoare 2007). Such factors led scientists and regulators to conclude that the usual mode for testing pharmaceutical drugs – large-scale clinical trials – is not suitable for regenerative medicine, and new regulatory provisions were called for (Rosemann 2014a; Kleiderman et al. 2018).

In practice, what scientists have to work with are their national authorities for clinical trials and regenerative medicine and their institutional review boards (IRBs). This is where it is important to reflect on the notion of 'experimentality'. 'Experimental' often refers negatively to

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risky and unproven applications, not 'properly' tested, such as in clinical trials. Nevertheless, the term is also used to refer to the experimental phase in the development of treatment. For instance, the UK Nuffield Council on Bioethics' 'Bioethics Briefing Note' (2018) (hereafter, 'the Note') explains that some 'experimental therapies' have never been used in humans, while *experimentally* advanced therapies are routinely used if other treatments have not worked or are not available. In the UK, 'experimental' treatments can be offered legally through 'compassionate treatment', 'hospital exemptions' and 'special licenses'. And as long as they are 'ethical', according to the Note, regulatory exceptions are made for the clinical application of experimental advanced therapies. For this reason, the Note concludes, it is a core challenge to balance the interests of patients in accessing experimental treatments with the need to support innovation, while ensuring there are sufficient safeguards to protect patients from potential harm(s). *If* given due ethical consideration to the difficulties in assessing efficacy and safety, ensuring fairness of access, the challenges around decision-making and informed consent, potential impacts on knowledge generation and ensuring healthcare professionals act responsibly, the Note permits experimental therapies.

But this is a Big If and it is central to the validity of the authority that regulates it. Not fulfilling its conditions makes regulatory authorities complicit to the harm caused by translational experimentation, including the Valley of Death (Seyhan 2019). The question here is how these 'ifs' translate into what is considered 'ethical' in the global arena of researchers aiming for a 'clinical first' while addressing the conditions of patients. It is understandable that the field of regenerative medicine comes across as lacking in transparency: First, there is a great multiplicity of clinical applications in the field, and there is much controversy about the measurement, definitions and outcomes of clinical research trials; second, regenerative medicine concerns live cells, which are regarded as risky compared to the molecules used in pharmaceutical drugs. And, third, cells (depending on their source and application) may engraft and continue to divide for a substantial period of time as opposed to drugs that are metabolised and eliminated from the body within hours or days; and, fourth, the enormous promise of the field has resulted in fierce competition, and in an increased involvement of industry, both of which are contributing to the secrecy around the research process. Competition is further augmented by the huge investments from countries that do not want to miss the boat to regenerative panacea, even if they can't really afford the expenditure. The complexity, risk, secrecy, hyping and

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experimental diversity of the field, as we shall see, make it difficult to regulate regenerative medicine in a global context.

Investigating the Dynamics of International Regulation under Regulatory Capitalism

This book describes the global dynamics of regulation in the field of regenerative medicine – its creation, alterations, reforms and amendments – with a focus on regenerative medicine. Attempts to adjust the regulation to gain competitive edge have mushroomed, and without a credible transcendental (global) regulatory authority, a steep increase in regulatory uncertainty and regulatory competition occurred. An ethnographic exploration of how regulation changes and performs in practice can help us understand what is at stake when regulation is 'tightened' or 'loosened'. The book will shed light on the global dynamics of regulatory change in regenerative medicine. My aim is not to create a complete global overview of regulatory dynamics. Instead, I analyse understandings of science collaboration through the perceptions and connections of the scientists, regulators and medical professionals I met in the field of regenerative medicine.

It is not possible to detail the great complexity of the networks that people have in this field. But by recognising how and why scientists make connections with colleagues in other jurisdictions in the context of the resources available to them, we can learn about what incentivises science collaborations, including the role played by regulatory conditions. In short, through in-depth, interlinked ethnographic case studies based on periods of multi-sited fieldwork spread over more than a decade, I delineate the space regulation occupies in international science collaborations. The case studies from across Asia, Europe and the US that I present in this book challenge various assumption that prevail about the regulation of regenerative medicine:

* that more regulation makes for safer or better therapies;
* that regenerative medicine is developed to improve global health; scientific research is propelled forward by evidence-based medicine (Lambert 2006);
* that regenerative medicine will address the health problems of a majority of patients suffering from serious conditions;
* that international science collaboration (in contrast with competition) is just based on the pooling of scarce resources to fulfil a scientific target; and,

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* that the development of suspect clinical interventions in the field of regenerative medicine can be halted or banned by developing regulation underpinned by scientific or rational considerations and decision-making.

An illustration of how the global dynamics of regulatory brokerage in regenerative medicine has counterproductive side-effects is not intended to condemn the development of regenerative medicine in itself. Rather, its aim is to show that the global economic context of regulatory capitalism and the currently prevalent forms of governance that facilitate the creation of regenerative medicine are not conducive to a responsible development of innovative healthcare applications. In Chapter 9, I will suggest an approach to science based on 'caring solidarity', prioritising health needs and the well-being of others rather than the political economy it is absorbed by under regulatory capitalism.

Anthropological Fieldwork

Anthropological fieldwork can identify concerns that are formulated in the practice of everyday life. A concern about how life-science research translates into healthcare in a global context motivated me to visit laboratories, hospitals, clinics, conferences, companies and academic centres across the world. Conversations with the people populating these spaces focused on the fast-innovating field of regenerative medicine with its enormous implications for research budgets, public health and clinical experimentation. Reading and conversing about stem cell science and its products, and exploring why and how it is organised and practiced differently in various part of the world, taught me that the creation and performance of regulation are characterised by cultures that are subject to political strategising and often differ starkly.

The anthropological research underlying this book started out as a project on international science collaborations and the international networks that enable research innovation in the field of regenerative medicine. For this, I had conversations with academic and lay experts (Epstein 1995) in Japan (in Japanese), China (in Mandarin and English), the Netherlands (in Dutch) and in the UK, Thailand and India (in English). Over four years of ethnographic field visits and archival research spread over a decade (2006–2016) and a period of archival research (2006–2021) has enabled me to put together case studies that show what the regulation for clinical research and clinical trials means to

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a wide range of people, including scientists, entrepreneurs, professional organisations, patients and patient representatives of national and international patient organisations industry, regulators and other experts. The research materials I present and draw on are anonymised and the names of interlocutors are pseudonyms, except for where the knowledge in question is available in the public domain. Throughout the book, I make references to conversations I have had with scientists, regulators, patients and so on, indicated by a pseudonym and date*, e.g. Hunter 3/5/2023*. A list of these can be found in Appendix 1: Interlocutors.

The fieldwork in various countries prompted me to ask questions about regulation from a wider geographic perspective, linking local and higher-level regulatory processes of change. Rather than deducing and inferring from concepts, systems and questionnaires about the effectiveness, responsiveness or capture of particular regulations, anthropological fieldwork enabled me to gain understandings based on the real-life observation and communication with creators, implementers and users of regulation, as well as patients, their families and others who are affected by it. In combination with research in the international media and libraries, the understanding of the strategic action of those involved in the creation, implementation, use and effects of regulation, it became possible for me to detect patterns in regulatory changes that can be explained on the basis of observations data in everyday life decision-making.

Throughout the research, I realised that only a relatively independent stance would allow me to understand the dilemmas, pressures and harms associated with regulation from widely differing points of view, such as those of patients, scientists, regulators and entrepreneurs, and to understand the creation and performance of regulation through the eyes of regulators, scientists and entrepreneurs. This also required openness to understanding regulation in different global contexts: through the moral and ideological currencies of scientists, politicians and entrepreneurs alike (Chapters 2), through the efforts to build regulatory capacity in LMICs (Chapter 3), through the tolerance for regulatory violations in both HICs and LMICs (Chapter 4), through regulation used as capital for negotiating international collaborations (Chapter 5), through down-regulation used as a political source to save patients (Chapter 6) and through regulation as experienced by patient groups (Chapter 7). But discussions on the global dynamics of regulatory violence need to go beyond regulatory models, so as to incorporate the everyday performance of regulation; beyond relativist anthropological notions of violence, to

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incorporate the regularities in the dynamics of regulatory capitalism; and, beyond very narrow and very wide definitions of violence, to incorporate what I have described above as foreseeable violence. And, finally, we need to go beyond regulation of the life sciences to have a closer look at what is at stake.

The question of the regulation of regenerative medicine is intimately related to the ways in which public health institutions understand healthcare needs. The anthropological exploration of regulation in this book not only builds a picture of various dimension of regulatory manipulation but also comments on the dilemmas in which governments, regulators, scientists, entrepreneurs and patients find themselves. A core issue is that regulation, though purportedly aimed at the protection of patients and the quality of science, is also used for political and financial gain. The hope and (therefore) expectation of regenerative medicine is not just that it will bring advancement in healthcare products but also that the enormous investments in this area will radically decrease healthcare budgets. This equivocal form of planning linking economic gain with public health raises serious issues about the sustainability of healthcare in both HICs and LMICs. Querying the 'regulatory violence' and high-tech solutions to the health of populations as part of the global dynamic or regulatory capitalism, Part IV explores the possibility of another orientation towards healthcare.

Methodology: Common Concerns, Conversations, and Changed Understandings

Methodologically, I understand my 'field' visits in terms of interpersonal encounters, self-understanding and socialisation. My interpersonal encounters largely involved face-to-face meetings with people or groups of people in laboratories, hospitals, universities and clinics. It was usually myself who initiated contact with individuals involved in regenerative medicine to inquire whether they shared my interest in the global conditions and the norms and values through which life-science research leads or does not lead to improved conditions in healthcare provision. Conversations, I hoped, would lead to insight into the presumptions we have about, for instance, the meaning of 'good science' and 'good regulation'. Thus, when stem cell scientists in Country X agreed to tell me about their work, Dr X explained that their reputation had been badly affected by small providers of cosmetic therapy and other conditions, such as autism and cardiovascular disease. The mention of this forced

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him to explain the meaning of 'unethical' science, and it prompted me to 'admit' that Europe also has a history of unauthorised stem cell clinics and that EU regulation contains various regulatory exemptions. The dynamic of these conversations provided opportunities for mutual- and self-understanding and the creation of awareness of the limitations of how we observe and perceive the world.

As a process, increased self-understanding helped me to reformulate my views and to question them. But *it takes time* for new awareness to sink in and to change ways of attending to the world. This, I believe, is closely connected with how we carry our socio-cultural background into new situations and places. Intersubjectivities that emerge in the social microcosm of new encounters adjust and translate into complex social relations and hierarchies. The complexity of the transformation is productive and political as much as it is 'informative'. For instance, in the conversation above, Dr D. explained that the cell-therapy clinics that operate in his country are 'unethical' because they do not have 'ethical permission' from an IRB, let alone from the Country's Medical Council. When I enquired about the need for public discussion about therapy provision in clinics, Dr S. replied: 'Yes, it would be good to make the public responsible!' (location X, 23 June 2014). Being a female Caucasian from Europe, specialising in some vague social-science discipline, Dr S. took my question as both a naïve and a condescending form of political critique. He then deftly managed to criticise European 'democratic' discourse on 'public discussion', which, in his view, unfairly places the onus of risk in conducting clinical research on the country's population.

While speaking with scientists about the research and ethics regulation in regenerative medicine, I learnt which aspects they experienced as problematic. This seemed to differ per country, per laboratory and per research application. Not infrequently, I noticed, collaboration with researchers in other countries could resolve problems and offer new pathways to conducting research. But for this, I realised, familiarity with the regulation in other countries would be crucial. The availability of detailed and comparative knowledge of international research conditions led me to realise the important role of regulation as an incentive for researchers to invest and engage in, sometimes, very complex and labour-intensive, international science collaboration.

It took a considerable period of reflection before I became aware of changes in the ways in which I viewed my hosts and the functions I had ascribed to scientific governance and regulation. These changes are

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reflected in my understanding of regulation described in discussions on bioethics, hegemony, regulatory capitalism, science collaboration and patient movements. The conversations I have had with countless of people, then, were crucial to my analyses of how the material world presents itself in terms of statistics, numbers, regulation, political discourse and prejudice.

Overarching Arguments: From 'Competitive Desire' to 'Caring Solidarity'

The increased subservience of health and scientific research to wealth under regulatory capitalism is evident from the political and economic considerations that are taken into account when regulating regenerative medicine: in different medical and industrial contexts and in different parts of the world. These considerations were crucial to the main lines of argument developed in this book. The main terms through which I conceptualise these are regulatory boundary-work, regulatory capacity building, regulatory immunity, regulatory redemption, regulatory capital, regulatory brokerage, regulatory violence, competitive desire, caring solidarity and, of course, regulatory violence. I summarily explain these terms in this section and in the Chapter Overview below.

A first main line of argument is that the regulation of regenerative medicine is created in comparison with other jurisdictions and that differences between jurisdictions are exploited at local, national and international levels to gain competitive advantage. The creation of regulation does not merely respond to the needs of patient safety and science quality, it also takes into account a range of financial pressures and demands from politics, industry and society. The activities and aims of negotiating regulation for illegitimate reasons, that is, other than those proclaimed to be in the interest of patient health and the quality of scientific research, I refer to as 'regulatory brokerage'. Selected examples from different parts of the world (Asia, Europe, North America) show us why an understanding of practices of regulatory brokerage require us to view regulation as a global, dynamic activity, whereby regulation is objectified, commodified and traded in transactions, not just between scientists and companies but also by the very governments and international organisations that devise the regulation.

By examining how regulation has 'agency', or 'life' in the practices of those that use it, including scientists, entrepreneurs, medical experts, patients, officials and politicians, I illustrate how the performance of

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regulation can shed light on the international dynamics of regulation in the field of regenerative medicine. A performative perspective on regulation takes regulation seriously, not just as a mechanism for dealing with the development of clinical research according to bioethical principles and scientific criteria for safety and efficacy. Rather, it views regulation as the result of political activities shaped by political lobbying, moral belief, wheeling and dealing, economic strategy and scientific strife. Thus, regulatory policy needs to be viewed as an activity entailing strategy, politics and competition for resources.

A second main line of argument pertains to the ways in which communities try to protect their populations against condemned practices of 'snake-oil' provision and exploitative experimentation and the way in which communities build confidence in the reliability of their regulation to fend off undesired practices. The reputation this engenders I refer to as 'regulatory immunity'. Regulatory immunity is important, especially where state governments have the capacity to abuse their powers. When in the second half of the twentieth century the state took control over the governance of large areas of biomedicine from professional biomedical communities, it did not just take charge of biomedical regulation and research; it also acquired power over the well-being of patients, that is, the power to inflict regulatory violence, as I have defined it above. Countries whose regulatory institutions are reputed for stimulating high-quality science, while providing maximal protection of patients, are likely to enjoy regulatory immunity internationally. In this sense, some countries have stronger regulatory immunity than others. When inspiring trust in a country's regulation, regulation can provide enough immunity for it to tolerate, and thereby internalise unauthorised, rogue or exceptional practices. Regulatory immunity, then, can both nourish and conceal formally condemned practices. For instance, 'foreign' rogue practices may be vilified, while the same may be tolerated at home to bolster 'kosher' clinical research practices at home. Considering the role of regulatory immunity, I maintain and illustrate that global changes of regulation in regenerative medicine need to be understood through the ways in which regulation is capitalised, brokered and ritualised.

The regulation of regenerative medicine is not just subject to developments that play out politico-economic interests; it is also subject to forms of ritualisation prevalent in governance, whereby regulatory guidelines, including those for medical and research ethics, create a general atmosphere of safety and security about clinical applications. While the ritual

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power of regulation inspires confidence in its safety, which enables the development of promising high-tech solutions to a range of biomedical problems, the translation of new fields of biomedicine into clinical practice gives regulation its redemptive qualities. The third main line of argument is inspired by Catherine Bell's notion of ritual redemption (2009) and concerns the performative politics behind regulatory redemption: the ritualisation of regulation conceals the intensive economic and political strategising involved in the construction of regulations behind the ethical discourses promising health and science as moral goods. If we understand regulation as a repetitive process of vindication with complex ethical and safety guidelines and rules, involving committees of experienced seniors and moral hierarchies that determine what is authoritative scientific research (Faulkner 2012a), then we can begin to see how the development of regulation is affected by 'redemptive' performances: in circumstances of medical need, the advocacy of medical solutions promise salvation, and this redemption is foreshadowed in political and economic strategy.

In practice, regulatory brokerage, regulatory immunity and tolerance and regulatory redemption are intertwined in the politics of scientific development. Thus, 'elite' laboratories that can afford to comply with the guidelines of a regulatory immune jurisdiction and engage in practices that advertise how they navigate guidelines that redeem or bless its scientific products and that scapegoat the deleterious influence of the inadequate regulation of irresponsible foreign competitors. Political performances of regulatory redemption are crucial in creating political boundaries (Gieryn 1983) between 'Us' as responsible actors foiled against competing opponents as 'rogues'. My fourth main argument, in the context of what I call 'regulatory boundary-work' (Chapter 2), claims that in the international setting of competition and regulatory capitalism, policies of regulatory immunity and redemption force competitors, including LMICs, at least outwardly, to emulate the politics of regulatory redemption. For instance, it leads LMICs with ambition in the field of regenerative medicine to build regulatory capacity and invest scarce resources into new infrastructures to fulfil international regulatory requirements. At the same time, the remaining regulatory gaps between jurisdictions are exploited as 'regulatory capital' in international collaborations that trade regulatory advantage against, say, material investment and scientific know-how (Chapter 5). As the examples in this book illustrate, the resultant violation of regulatory integrity potentially affects the quality of scientific research, clinical applications and healthcare policies.

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My fifth main line of argument is inspired by Rene Girard's theory of 'triangular mimetic desire' (Feenberg 1988; Adams 2000; Girard 2000), which maintains that object relations can be reduced to prior social relations of competition and imitation. According to this theory, the acquisition of new objects, rather than determined by natural scarcity, is based on a desire for having the same as those who have more than 'us' in terms of property, reputation and prestige. Girard refers to this as 'acquisitive desire'. The powerful role played by mimetic rivalry and acquisitive desire in global competition I refer to as 'competitive desire'. Competition I understand as a condition of strife to gain possessions, including money, power and reputation, to establish superiority over others. Competitive desire, based on the envy of the possessions (such as power, money, knowledge, health and reputation) of Others, is a mode of attention that is cultivated under global capitalism.

Competitive desire as a generative principle and subjective force underlying global capitalism contrasts with theories that explain it through the objectivity of economic notions of scarcity, investment and economic growth. As detailed in this book, it is not necessarily the scarcity of the therapeutic products themselves but the possibility of finding cures and its implications for economic growth, scientific standing and biomedical power that has attracted investment into the field. Under the economic 'invisible hand' of the market economy based on free choice, business is commonly presumed to 'work' because corporations and individuals are somehow programmed to follow their self-interest, disregarding the possibility of other kinds of human choices. Under capitalism, outside the economic contract, there is no ethical or social residue of care or mutuality (Demouchel 2017). Here, the self-interested utilisation and manipulation of the regulations that are supposed to make the market 'fair' translates directly or indirectly into violence against patients.

The sixth main line of argument pertains to the possibility to substitute caring solidarity for competitive desire: competition based on acquisitive desire does not have to be a main determinant of the behaviour of individuals, enterprises and states. Under regulatory capitalism, a range of frictions have emerged in the interstices of regulatory governance: between market competition and democratic regulation, national interest and international regulation; acquisitive desire and ethical guidelines; regulatory redemption and regulatory tolerance; and medical science and clinical treatment. These separations are *spotted* and *exploited* by regulatory brokers with an eye for lucrative deals and results in

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regulatory violence. Instead of developing medicine on the basis of competitive desire regulated by systems that bless experimental therapies at the risk of the vulnerable, I believe, these separations can provide food for thought about the kind of human identities cultivated under regulatory capitalism and the potential for change that can be initiated in the area of regulation and science policy-making. They also can help us to reflect about the possibilities for developing a 'decent society' (Nussbaum 1986), which prioritises the empathy and care we need for approaching the vulnerability of all human beings above competition based on power.

Urging for a radically different approach to regulation, ethics and science policy-making is not just an idealistic whim but a necessity: the lives of patients, the health of communities, the quality of science, the kind of health technologies developed and the sustainability of medical systems are at stake. Violence generated through regulatory brokerage affects the lives of people in both low- and high-income countries, and its injustice must and can be addressed, as well as the ways in which communities protect the well-being and health of their populations. To encourage an orientation that looks for solutions for 'medical' problems in society and its relations with 'the environment' (Ellul 1964), Chapter 9 suggests a notion of 'caring solidarity', based on 'creative desire' (Adams 2000). Creative desire, like rivalry, is a mimetic principle but directed at desiring the 'well-being' rather than the 'possessions' of others, as well as the possibility of embedding this in what local communities experience as wisdom in terms of prudence and justice (Deane-Drummond 2014).

Chapter Overview

The book comprises four theoretical Parts: (I) Regulatory Capitalism; (II) Regulatory Immunity; (III) Regulatory Redemption; and (IV) Regulatory Brokerage and Its Regulatory Violence (IV), each followed by two chapters.

Part I's introduction of *regulatory capitalism* explains how regulatory competition shapes today's life-science research and how different regulatory standards affect local therapy provision in an international context. It also defines and outlines how strategic practices of 'regulatory boundary-work' characterise the regulatory policies and conditions that turn research into 'acceptable' science.

Chapter 2 provides an overview of the international regulatory landscape in the field of regenerative medicine in the mid-2010s, and it

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illustrates how regulation is subject to global competition. Specifically, regulation is used for gaining competitive advantage with foreseeable harm to patients and scientific development, that is, regulatory violence. This chapter questions theories of *regulatory hegemony* through the notion of *regulatory boundary-work*, which I define in terms of the nation-state politics of regulatory reputation. The patterns of regulatory boundary-work that I identify illustrate that neither global hegemony approaches nor approaches that emphasise the scientific rationale of regulations can adequately explain the global dynamics of regulatory development. Dissatisfied with strategies of regulatory boundary-work in countries that dominate in defining 'good' science, organisations and networks have emerged that champion their own international guidelines and standards. I conclude that 'international regulation' can be a flag proudly carried by privileged bearers, while masking extreme internal regulatory variation.

Chapter 3 introduces the notion of *regulatory capacity building*. It illustrates how, in the changing global reconfigurations of power and scientific institutions in the global life-sciences, individual enterprises and regulators alike broker regulation beyond the limits of its purported aim. Building regulatory capacity is not a matter of the wholesale import of internationally accepted regulation but of the nation-state, in negotiation with local developments and interest groups, shaping regulatory boundaries at provincial, national and global levels of organisation. Using ethnographic case studies from China and India, I illustrate how adapting 'foreign' regulation requires compromising between 'the ideal' models used by the laboratories of the global elites and standards aimed for 'at home'. This inevitably leads to suboptimal regulation of therapeutic practices, as they do not optimise regulation on the basis of the needs of patients and scientists locally and therefore are bound to generate regulatory violence.

Part II introduces the concept of 'regulatory immunity' to indicate the reputational protection that science communities enjoy in particular jurisdictions. A country's regulatory immunity is based on forms of historically and politically ascribed reputation, even protecting jurisdictions whose clinical and research activities violate their own regulation. The state's protection of its regulatory reputation (whether it is implemented or not), the violation of regulation by state actors and the 'regulatory tolerance' for regulatory violations all indicate the occurrence of foreseeable regulatory violence. I use the notions of 'regulatory immunity' and 'immune tolerance' to clarify the global dimension of

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regulatory boundary-work as part of nation-state political strategies, in science collaborations, in science discourses and in actual scientific practices.

Chapter 4 explores reputational effects on science as a result of regulatory boundary-work, and it explains how the 'kosher' science of the national Self is foiled against that of 'rogue' competitors, through regulatory scapegoating. Describing nation-state frictions between Self and Non-Self in terms of regulatory immunity, I use a range of examples of clinical applications in regenerative medicine to illustrate 'regulatory tolerance'. The state's tolerance for regulatory violations is an example of a political strategy with foreseeable harm done to patients and science. The cases of Beike Biotechnology's unauthorised clinical stem cell interventions in China and instances of the numerous regulatory provisions made for biomedical innovation and regenerative medicine in the US, Australia and the EU exemplify how 'regulatory tolerance' sheds light on otherwise mysterious regulatory conduct. Analysing this 'grey area' of stem cell science, the chapter illustrates how the desire to compete to gain a competitive advantage over others is endemic in common practices of regulatory scapegoating and 'boundary-making' among scientists and in the media (and replicated in social-science publications).

Chapter 5 introduces the notion of '*regulatory capital*', a source for negotiation in international science collaboration and an expression of disregard for regulation as protection of research subjects and guarantor of high-quality science. Under regulatory capitalism, there is no credible regulatory authority on a global level. National regulations are violated on a regular basis through international science collaborations, even by the governments responsible for their protection. In contrast with notions of science collaboration that view collaboration as a bond between two or more partners to attain a shared goal by pooling resources, this study shows how international collaboration and competition are part of the same process. The chapter's examination of the collaborative project between scientists in Chulalongkorn University (CU) in Bangkok and scientists and managers from Kawasaki Heavy Industry (KHI), Japan, shows that its goals are shared in different, often incompatible ways. The centrality of regulatory capital explains why the study of science collaboration is not just a matter of examining exchanges of scientific know-how and technological expertise; it also requires the investigation of the ways in which different socio-economic, political and regulatory conditions enable available resources to be mobilised to satisfy a range of goals, many of which may not be shared.

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Part III on '*regulatory redemption*' explores what I call the redemptive aspects of the politics of regulation. Political discourses of regulation, on the one hand, hail regulation as promising and protective, while, on the other, they camouflage the political and economic interests behind discourses of ethical, medical and scientific progress. The politics of regulatory redemption, I argue, is incentivised by competitive desire, and it is potentially violent in that it is designed to ignore the actual scientific practices that it steers and the medical needs it purports to address. I illustrate how the politics of regulatory redemption coordinates global regulatory regimes with regulatory capabilities on a national level, where its redemptive symbolism is mobilised to support particular life science and public health strategies. As such, the regulation of regenerative medicine is co-produced both at international and national levels via the politics of redemption.

Chapter 6 shows how Japan's regulatory reforms of 2013 brought regulatory redemption. The regulation of regenerative medicine metamorphosed from a cautious means of protecting patients and scientific quality into a saviour of public health, an enabler of scientific achievements and clinical firsts and a booster of the national economy. Exploring the performance of the regulatory reforms through the so-called *All Japan System* (the policy that symbolises and champions these redemptive ideals), I illustrate how the political aims and ideas embodied in the new regulation support certain industries and sanctify particular clinical targets to gain a global competitive edge, as well as pursuing scientific, economic and public health goals. Prompted by competitive desire, these regulatory policies were designed to strengthen financial budgets, national economic growth and international competition. They were based on a misrecognition of the structural alterations of Japan's science community and the role of patients and their families who would have to co-finance it and play a role as experimental subjects. In short, where the redemptive politics of 'down'-regulation presumes the safety of clinical application and a definite path to efficacy we can find foreseeable regulatory violence.

Chapter 7 examines how *international* patient movements, inspired by organisations in the US and Western Europe, have come to see 'deregulation' as a way to accelerate the translation of science into marketable medical products. However, conversations with international patient organisation (health organisation) representatives for Muscular Dystrophy (MD) and Spinal Cord Injury (SCI) from Asia, Europe and the US show how regulation as a redemptive tool deployed by political

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movements can never be neutral in a world characterised by regulatory capitalism and inequality: its performance is contingent upon the material and organisational resources available to them and the population in general in a juridical mandate. The politics of *redemptive regulation* in international health movements risks reconfiguring healthcare developments by a misrecognition of actual patient needs and local practices. Apart from considering the effects of policies of down-regulation on patients with various 'embodied conditions' in diverging environments, this chapter raises questions about both the potential benefits and costs of regenerative medicine to patient groups in societies with different standards of wealth, welfare and political governance. Catering for economic competition and international regulation rather than for the needs of particular patient groups in context, redemptive regulatory policies lead to foreseeable regulatory violence.

Part IV on *Regulatory Brokerage and Its Regulatory Violence* recapitulates the main arguments and discusses the global connectedness and dynamic of regulatory developments in regenerative medicine. It also suggests ways of moving beyond the competitive desire behind global regulatory violence by considering a form of competitive desire based on 'caring solidarity'.

Chapter 8 asks how various forms of regulatory brokerage discussed in previous chapters are interrelated and how they have emerged across time in the field of regenerative medicine. A distinction between opportunistic (profiting from discrepancies between jurisdictions to forge collaborations) and active forms of regulatory brokerage (involving activities directed at the creation of regulations) shows how awareness of regulation as capital has spread. Extending from individual science-entrepreneurs to larger organisations, including universities, companies, state institutions and international organisations, regulatory brokerage has become part of the entrepreneurial culture of science management, and, as a result, a proliferation of its accompanying regulatory violence can be expected.

Chapter 9 explores the meaning of *beyond* regulatory capitalism. The chapter sets out by explaining why 'free' market competition under regulatory capitalism underlies widespread unrecognised regulatory violence and argues that the cultivation of competitive desire (a notion inspired by Girard 2000) succeeds at the risk of patient's health and 'good' science. In the context of discussions of the social contract between science and public in the UK, I explain how, instead of regulatory capitalism based on competitive desire, a vision of caring solidarity

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applying the generative principle of creative desire (Adams 2000) embedded in the values and conditions of local communities would be more conducive to policies aimed at medical health. I argue that guidelines rooted in the cultivation of caring solidarity as mimetic principle could largely prevent the violence of regulatory competition that has become endemic to regulatory capitalism. By avoiding high-risk healthcare strategies of one-size-fit-all solutions that are expected to generate high-profit margins, the proposed vision of caring solidarity is oriented on sustainable health. The rudiments of such a model, I suggest, would be based on the generative principle of 'creative desire' (Adams 2000), building on local notions of wisdom, prudence and justice (Dean-Drummond 2014).

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