PART III

Regulatory Redemption

Having regulation in place can allow and justify clinical interventions that otherwise would be viewed as unauthorised and experimental. Being able to refer to the 'right' regulations therefore has immense redemptive force in clinical research applications. I speak of regulatory redemption when there is a need to emphasise the symbolic and ideological aspects of regulation: applying the 'right' regulation communicates a symbolic – not necessarily a realistic – commitment to responsibilities for patients and scientific development. In Part III, I use the notion of regulatory redemption to discuss the redemptive force of Japan's regulatory reforms of regenerative medicine in 2014 (Chapter 6) and to investigate the redemptive performance of down-regulation advocated in international patient activism (Chapter 7).

The Redemptive and Performative Aspects of Regulation

Clinical research regulations have redemptive and performative aspects: redemptive, because they create the circumstances that enable clinical research and the development of innovative scientific products for the protection of the well-being and rights of patients; and performative, because the enactment of regulations vary. For instance, it can be slack, careless, absent or strictly audited. The politics behind regulatory boundary-making can easily result in a mismatch between the regulation and the domain it purports to address. In that case, the redemptive force of the regulation conceals a messy reality that may harm patients. For example, the creation of 'constrictive' regulation may help to enhance a country's scientific reputation for political purposes and attract international collaborators, but it's half-hearted implementation will neither protect the quality of science applications nor protect the safety of patients.

Part III shows how the enactment of the redemptive force of regulation needs to be understood in both the context of its collective global creation and that of its local meaning and functionality. In a world dominated by

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regulatory capitalism, regulators in their respective countries and regions tend to broker their regulation in relation to that of other countries and regions in such a way that they will gain a comparative edge. We saw in Part II how countries with relatively weak regulatory immunity struggle to maintain or improve their regulatory reputation, while countries assured of their regulatory immunity can afford to tolerate internal regulatory violations. In all cases, regulation is brokered to (positively or negatively) connect international regulatory values with those that sustain local practices. As a mode of coordinating regulatory values, I argue that the politics of regulatory redemption coordinates global regulatory regimes with regulatory capabilities on a national level, where its redemptive symbolism is mobilised in support of 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.

The politics of regulatory redemption is rooted in hegemonic powers and involve the status of reigning symbolic frameworks, such as those of 'curing patients', 'technological fix' and embedding regulation as 'common-sense' in a moral order, which is confirmed and nuanced in a person's experience as real. But these hegemonic powers are changing and 'power' here goes beyond direct coercion and notions of false consciousness and ideology; it cannot be reduced to stakeholder theories, as it does not neatly correspond to the interest of one or another stakeholder or class. Its redemptive symbolism facilitates allegiance with the regulation by all involved, including the ideas of regulators, scientists, entrepreneurs, patients and other groups, such as notions of fairness, safety, freedom, care, obligation and truth, which develop and are reformulated in light of the ideals formulated in the discursive politics of regulatory redemption.

The Co-production of Regulation and the Politics of Redemption

Regulation is co-created globally, as its structures are produced dialectically through local and international pressures. This dialectic is negative and positive: negative, as competition and collaboration with the wider world puts constraints on the material conditions and conceptual apparatuses used in local regulatory design; and, positive, as it provides a resource for the generation of ideas and measures for national/regional regulatory strategy.

Regulatory documents embody and affect ideas about safety, risk, health and regulation in society, both at home and abroad. As the endpoints of a political process of deliberation, ratified regulatory documents have 'the capacity to generate or enact effects in the social material world' (Faulkner 2012: 754). But the performative and redemptive force of regulation cannot be understood outside the worldviews they embody, their presumptions

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about risk and ethics, their regulatory status as law, clause or draft and the discursive language in which they are couched. The performance of regulation ensues from its institutional status and organisation: regulation performs through the social legitimacy endowed in it, its scope, its details, the expectations it enshrines and the ways in which its procedures, committees and audits compel enactment of its implementation by researchers, managers, patients and the regulators themselves (Faulkner 2012).

The dialectic of regulatory reproduction means that the redemptive force of regulation has to be re-imagined, reconsidered and redefined through regulators and their networks. Within a national jurisdiction, regulation is brokered through informal and formal consultations and negotiation with stakeholders at various organisational levels, involving industry, scientists, patient organisation and the public (Abbott et al. 2017), which in turn communicate with international regulatory agencies, professional organisations and governments. These international interactions can be bilateral and multilateral, through international and regional conferences and organisations of epistemic communities (Haas 1992: 3; Salter and Qiu 2009: 47–48), but the extent of international consultation and collaboration varies. Countries with high regulatory immunity can afford to take the lead on authoritative international platforms, such as the ISSCR and ARMS, while scientists and officials in other countries regularly mention their low input (see also Zhang and Datta-Burton 2021). The observation of one leading Japanese scientist and official is telling: 'Before the change of the [more permissive] law, the FDA always went to Europe to discuss the regulation, but now they come to Japan first' (Interview Umeda, 27/2/2016*).

The credibility of regulatory performance empowers redemptive force and its norms and values are contingent on local practices. If they do not match, regulatory redemption becomes a matter of political strategy. What is crucial here is that, rather than based on local considerations of health needs, bioethics, clinical safety and scientific efficacy, local regulatory regimes are conditioned by standards and competition inherent to the global relations of regulatory production. This means that the integrity of any redemptive force exerted through research regulation is always already compromised by the international political strategies it is subjected to and creator of.

Regulatory Redemption and Its Transcendental Force

Regulatory authority enforces guidelines not only through bureaucratic powers, political strategy and through their appeal to local commonsense values. Rather, it is the way in which these are configured that creates an additional space for a symbolic order: because regulatory

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authority is symbolically located 'above' the members of its jurisdiction, and is rooted in the values of the community, it can gain transcendental force. Like ritual, regulation has the ability to reconfigure a vision of order or power in the world through fortified symbolic hierarchies. And as a strategic orientation for acting, regulation embodies the *unexpressed assumptions* that constitute the most influential actors' understandings of the purposes, trajectories and places of its enactment. The institutional isation of these regulatory assumptions, in fact, direct the socio-political boundaries of scientific discourses both in advance of and during the development and application of stem cell interventions.

The regulation of stem cell interventions both reverberates with and transcends the values asserted in local struggles, which cluster around socio-political positions ranging from 'patient rights to safe therapy' to the 'freedom to choose medicine' and from 'the freedom to conduct research' and 'the need for regenerative medicine industry to battle ageing society' to preferences for financing public health using other forms of socio-medical care. If we understand regulation as a process of clinical research vindication with complex ethical and safety guidelines and rules, involving committees of regulators and moral hierarchies that authorise 'regular' scientific research or not, we can start to appreciate the redemptive force of regulatory enactment. Although this force may meet with resistance among stakeholders and users, its authorised transcendental values are embedded in the polities of the reigning regulatory regime. To use a widely known example, when former US President Bush announced a moratorium on federal funding for embryonic stem cell research, the regulation proscribed and prescribed scientific behaviour but also embodied the outcomes of ethical struggles, conflicting economic interests, political ideals that gave meaning to the transcendental values embodied in the symbolic order.

As regulation cannot accommodate the needs of all stakeholders, it has to speak to multiple agendas without subscribing to them. Consequently, the enactment of regulation has to deal with the gaps between what practices are envisaged in the regulation and the needs and practices of its users. Such discrepancies are crucial junctures at which regulators extoll the redeeming functions of the regulation, directing its authority towards regulatory subjects. In other words, the reality of some users is always manipulated, but when such manipulation becomes a regular political mechanism, we need to speak of the politics of misrecognition.

Misrecognition

Regulation is usually thought of as fixed, formal, uniform in application and meticulously defined. But in regulatory capitalism, regulation is

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compromised by definition: it is situated, strategic and embedded in misrecognition. Inspired by Catherine Bell's definition of ritual strategies, I claim that the strategic practice of implementing regulation is rooted in the intentional misrecognition of the practice it is enacting. In other words, the spirit or intention that justifies the creation of regulation or regulatory change is blind to the aims and practices of the environments it regulates, so that it literally 'misrecognises' what is happening on the ground. For instance, strategic down-regulation, also when called for by patients and industry, is blind to the practical consequences for patients.

The politics of regulatory redemption presumes translational work done that turns political strategy into regulatory guidelines and the redemptive beliefs that underlie it by shifting attention away from issues of medical practice, such as safety, profiteering, long-term care and actual patient needs to abstract ideals, such as those of 'saving lives' and 'developing innovative science'. In other words, the symbolic value of 'saving lives' dramatises the idealised endpoint of clinical research and therapy provision and is 'justified' through regulatory redemption. But the politics of regulatory redemption is not about the 'saving of people's lives' per se. Rather, its redemptive value is constituted in *the belief* that particular regulation will redeem what otherwise would be a deplorable or inferior medical practice. The authorisation of this belief and its juridical enactment in countless practices make for the ritualisation of regulation, regardless of how and if it is enforced to the letter. The reiterations and elaborations of the regulatory script and its underlying and embodied ideals by different stakeholders roots a diversity of ritualised regulatory enactments in both discursive and clinical practices.

Regulatory redemption, then, comprises both the ritualisation of regulation, involving the reiteration of formalities and its envisaged hallowed aims, and the strategic disregard of what actually happens on the ground. The regulation of regenerative medicine, whether up or down, may be incentivised by the aim to reduce public health bills, to stimulate the economy or to support other political targets. Here, regulatory facilitation is brokered by disregarding the existence of practices that do not fit the bill. In this sense, regulation is embedded in the misrecognition of what regulation is for and is biased about what it entails in practice. The ritualisation of regulation in regenerative medicine looks as if it is about fixed guidelines, rooted in the determination to protect patient needs and robust scientific protocol, but, and as we shall see, it is strategic, experimental and forces scientific development in new, and sometimes clashing, directions.

In short, Part III explores the redemptive aspects of the politics of regulation. Political ideologues, on the one hand, hallow regulation as

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promising and protective, while, on the other, it camouflages the political and economic interests behind discourses of ethical, medical and scientific progress. The politics of regulatory redemption then is violent in that it is blind to the actual scientific practices that it steers and the medical needs it purports to address.

Exploring the performance of the regulation 2013 reforms in Japan (Chapter 6) shows us how the political aims and ideas embodied in regulation support certain industries and sanctifies particular clinical targets, to gain a global competitive edge, as well as pursuing scientific, economic and public health goals. Regulatory reforms in Japan transformed the regulation of regenerative medicine from a cautious protector of patients and the scientific reputation to a scientific saviour of public health in Japan as an ageing society. An examination of the All Japan System, which symbolises these ideals, illustrates how the new regulation figures as both a socio-cultural text and as a performative subject. As a socio-cultural text, embodying various aims, it does not just tell us about the clinical trials and scientific research it regulates but also about the ethos that makes guidelines morally compelling and redemptive; as a performative subject, it actively shapes peoples' conceptions of its aims at the neglect of other scientific and clinical needs.

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. Taking a cue from slogans of 'freedom to choose medicine' and the 'right to try' in the US, some influential international patient organisations tend to present 'down regulation' as a political way forward. Politically focusing on the redemptive aspects of down-regulation, they criticise those that see regulation as a safety valve and guarantor of reliable scientific research and clinical interventions as bureaucratic ritualism and defending the status quo (Braithwaite 2008). In an international context, however, this view is problematic. Conversations with and among patient organisations (health movements) show how regulation as a tool deployed by political 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 risk reconfiguring healthcare developments by a misrecognition of actual patient needs and local practices.

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