9

Beyond Regulatory Violence

Caring Solidarity

> I have been with my organisation seventeen years now, and back then I remember it was the first international conference and all these scientists from all over the world were saying, 'The cure is only ten to fifteen years away.' They're still saying the cure is only ten to fifteen years away.
>
> (Patient organisation representative, UK, May 2015)

Introduction

Under regulatory capitalism, only by viewing the regulation from a global perspective can we begin to understand national efforts made to regulate regenerative medicine. I have shown that regulatory brokerage in the field of regenerative medicine exists by dint of *global competition* (prompted by the desire for wealth, power and leadership), *global inequalities* (reproduced through regulatory capitalism) and *global regulatory discrepancies* (emerging as a result of competitive strategies of regulatory emulation and differentiation). I also showed how regulatory brokerage entails regulatory violence. This is related to, but differs from, the broader notion of 'structural violence' (Galtung 1969; Farmer 2010). Structural violence is the violence (e.g., poverty, ill health), which obtains as an indirect result of unequal socio-political and economic structures. Regulatory violence, however, directly captures how individual decision-makers follow their political, financial or other interests in manipulating, altering or implementing regulation, rather than making sure that new or altered regulations do not lead to harm by serving other aims than those of patients and the quality of science.

This book is a plea for individuals with regulatory powers located in institutions, ranging from small entrepreneurial companies and clinics to large pharma, universities, hospitals, administrations, governments and international organisations, to exercise forethought when in a position to co-create, manipulate, avoid, broker or ignore regulation. For much

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regulatory violence, because foreseeable, is avoidable: regulatory violence is not necessarily about causing deliberate harm. The issue is that competitive desire deflects attention away from the potential harm caused to patients, making the violence not so much intended as foreseeable. When it is not clear whether changes in regulation serve the safety and health of patients or creates opportunities to more effectively test stem cell interventions, further research is needed to scope long-term consequences for the community. In previous chapters, we have seen a number of examples that show that it is possible to refuse to submit to regulatory competition. Thus, Thai scientists did not support regulation created to accommodate the wishes of Japanese collaborators (Chapter 5) and international patient organisations in Chapter 7 did not want deregulation at the cost of treatment safety (though some did desire an acceleration of clinical applications). More examples will follow.

The harmful consequences of regulatory brokerage for patients and science, and its cascading effects around the world, illustrate how regulatory capitalism concentrates and steers the direction of competition in limited, potentially extremely lucrative high-tech areas of possible clinical research. Once scarce resources are invested into this area on a large scale, its financial force and hopeful message determines how many countries spend their health budgets and deal with the health of their populations. Awareness and openly available knowledge of the violence generated through regulatory brokerage means that the accountability of state administrators and politicians that design international and national science and public-health regulations are required to exercise a greater sense of care and foresight. More examples will follow in discussions of how regulation and health should be thought of together in the context of the lives lived in local communities.

In this final chapter, I take as my point of departure the informative and nuanced Lancet Report by Cossu et al. (2018), which proposes that, in the social contract between science and the public, the public needs to play a more active role to develop regenerative medicine. Placing this idea in the context of regulatory capitalism and the social contract between the government and science, I cast doubt on its feasibility. By understanding regulatory violence as a result of competitive cultures, theorised in terms of mimetic, acquisitive or destructive desire (Girard 1986, 2016) at a community level, I root its pervasiveness in the way we treat each other in everyday life. I argue that the corresponding competition among and within countries entails following the example of others as models of behaviour and development. This, I maintain, involves a

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form of national governance that should and can be replaced by other mimetic cultures that exemplify the generation of the well-being, rather than the (often unanticipated but foreseeable) harm of others.

Before detailing how I will show this, I first recapitulate evidence from previous chapters that make credible my claim that regulation is regularly brokered for illegitimate reasons and is driven by competition:

i. The alignments of regulatory changes and adjustments with the illegitimate interests of the scientists, regulators and politicians involved in them:

   a. Throughout this book, the kinds of regulation adopted by countries were closely aligned with the political and economic benefits that are hoped for/expected by investing in the infrastructures underlying regenerative medicine and the benefits that this might bring to the public health budget and the health of the population. As shown in Chapters 2 and 3, these aims are partly pursued through different regulatory strategies in global regions with unequal resources available to them. The regulatory patterns detected can also serve as evidence for the ways in which political and economic factors shape and reshape regulatory jurisdictions.

ii. Examples that reveal global patterns of conditions under which regulatory institutions do not do what they claim to do:

   a. where, in the context of scientific collaboration, one collaborative partner has little scientific expertise or where the government policies design/implement regulation to attract investors and to facilitate industry from abroad (see especially Chapters 5 and 6). In most cases, there will also be other drivers, including a patient pool willing to pay and infrastructures designed to collaborate in clinical trials;
   b. where countries consistently fail to implement their regulation, despite evidence of violations (see Chapter 4);
   c. where state institutions support international projects that violate their own regulation at home or the spirit of their regulations (Chapters 4, 5, 8);
   d. where jurisdictions adjust their regulations following other countries without evidence that there is a need for it from the point of view of patient safety/need and scientific quality (e.g. Chapters 3 and 4), for example, when scientists and industry lobby with regulators and government, pointing out that other countries'

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regulation give regenerative medicine in those jurisdictions an advantage;

e. where those involved in research collaboration explain that their collaboration is based on regulatory difference (see Chapters 4 and 5) and we can confirm among collaborating partners that regulation is being used as a bargaining chip or regulatory capital;

f. where international regulators and industry try to persuade each other of the expediency of liberal regulation without showing consideration for the consequences for the health of patients or for the quality of science in practice (e.g., Chapter 8).

iii. Evidence of regulatory consciousness, strategy and performance based on the widespread awareness of how regulation needs to be manipulated.

Close-up evidence in Chapters 4, 5 and 6 shows that regulatory discrepancies and adjustments are not just inconsequential facts: regulatory discrepancies are performative in that scientists, patient groups and entrepreneurs are often aware of them and may choose to act upon their identification. Action based upon regulatory knowledge has far-reaching consequences for decisions that are made about where and with whom to do what kind of research and consequently affect the kind of clinical interventions, international collaborations, investments, patent portfolios and profit sheets that are considered.

In Chapter 8, I presented a broader picture of regulatory brokerage in terms of temporal sequence of learning and awareness of effects of regulatory difference and how they can be used (see Chapter 8). Chapters 5, 6 and 7, in particular, indicated that regulators act politically: they do not just take into account patient safety, patient needs and the quality of science; they consider what regulation means for the country in terms of scientific and economic competition in accordance with its estimated regulatory immunity vis-à-vis that of the global constellation of jurisdictions. It is therefore not the accumulation of data on regulatory change in itself but the intentions, activities and attitudes behind them that are pertinent to and transpire in discussions, comparisons, strategies, arguments and relations among scientists, regulators, politicians, entrepreneurs and patient groups. In the overhyped discourses that celebrate the redemptive value of regenerative medicine, however, they are disguised, glossed over or just not noted.

The observed conditions, patterns and regularities that led me to diagnose practices of regulatory brokerage and its resultant violence are

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not meant to indicate causal laws set in stone. Underlying decisions to broker regulations for illegitimate aims are a wide range of considerations that also entail concerns with the health of patients and the quality of science. What is clear, however, is that the global context of regulatory capitalism limits regulatory possibilities through competition. But this is so, as long as countries' basic strategies rely on regulatory competition. After all, countries can decide whether or not to follow others in the race towards clinical firsts, whether or not to invest in regenerative medicine as a means of economic growth and whether and how to address the health issues of their populations.

In this final chapter, I claim that, institutionally, it is the state's regulatory sovereignty that has enabled regulatory violence on a national and interstate level. This global arrangement forms the normative setting in which states cultivate the desire to compete, reinforcing the potential for regulatory violence. To find a way forward, some scholars have argued for strengthening the social contract between the population and science, encouraging the public to play a more active role in clinical research. I will argue, however, that under regulatory capitalism, such social contracts will have either little or counterproductive effects. Rather than mobilising the population to get actively involved in clinical research on the basis of competitive desire, I suggest that a vision of caring solidarity could be more conducive to sustainable health in the long run. Substituting a model of caring solidarity for regulatory competition can decrease regulatory violence and achieve improved health, avoiding high-risk strategies that are oriented to one-size-fits-all solutions expected to generate high-profit margins. The rudiments of such a model, I suggest, would use the generative principle of creative desire, building on local notions of wisdom that incorporate the virtue ethics of prudence and justice.

The State and the Globalisation of Regulatory Violence

In most modern nation-states at least some regulatory authority has been relocated from local medical communities and professionals to the state. Thus, medical professionals have yielded regulatory and decision-making powers to state regulatory authorities. This power transfer presupposed that the state's supreme position enabled it to independently and rationally design guidelines and laws to regulate clinical research. But this very move made regulatory authority political. The state now decides not just what is legitimate, thereby gaining moral traction (cf. Demouchel 2015),

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but also who receives which resources and who has access to them (Mastroianni and Kahn 2006).

Over time, therefore, the logic of power transfer has shifted: it is the power of the regulator and its politics, rather than the interests of professionals, that have come to define what is rational regulation. This has also been the case in the field of regenerative medicine. Thus, political power struggles behind regulatory legitimacy have largely aimed to define the acceptability of risk to which patients can be exposed and the conditions under which the quality of clinical research is maintained. But if regulation is not based on the principles it declaims, regulatory authority transforms into the power of policy-makers to violate their own rules, entailing regulatory violence.

As we saw, regulatory *violence* involves both structural factors and individual intentions. Some structural factors, such as the national and regional difference between the wealthy and the poor and those with and without adequate healthcare access, are ethically important and should be the basis for creating fair regulation. Those structural factors, however, are not themselves the cause of regulatory violence as defined here, although they are related. Regulatory decision-making is about particular actions conducted by individuals that take into account structural factors in their deliberations, often on the basis of what they regard as 'good', for instance, what they consider to be patient safety and science quality. Even if this decision-making process would lead to harm, I do not refer to it as regulatory violence. But when regulation is created for reasons, say, of international or other 'selfish' competition (for instance, based on individual gain, fame or profit), then the harm done to patients and the public at large can be viewed as regulatory violence, even when the harm done was not intended. This is because it was foreseeable.

Globalisation, under regulatory capitalism, tends to pit nation-states against each other, whereby what is medically beneficial for a country has largely come to depend on how government policies weigh up international opportunities and interests against biomedical capacities and health conditions at home. Since state regulators have absorbed the sovereign power to regulate experimental violence (that is, to allow biomedical experimentation for legitimate reasons, Chapter 1) from professional medical communities, they can decide what are 'reasonable' scientific and public health targets and 'reasonable' sacrifices by patients in support of medical progress, through, for instance, clinical trials. The bodily violence necessitated by controlled clinical translation (Seyhan 2019) in the context of regulatory violence is rationalised within the

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framework of the strategic policy-making of the state and implemented through discourses of hope and the hyping of obtained success. It concerns not just the sacrifices made by patients, who might participate in clinical trials out of a sense of duty or altruism, but also the sacrifices of patients and other members of the public, as a result of the disturbance of the fine-tuning of the scales on which 'the reasonable risk for patients' are weighed against 'scientific needs' for reasons of competing political priorities.

Such forms of regulatory violence are not hard to imagine, as the setting of political priorities involves the consideration of the cost-benefit analysis of a whole range of economic, social and scientific factors, including the percentages of non-natural casualties 'reasonable' in the light of economic growth, the choices of targeting which healthcare issues associated with which populations and the decision to fund and invest into which scientific projects. Regulatory violence in politics, then, relates to the individual responsibilities of all those involved in regulatory policy-making.

Competitive Desire and the Costs-Benefits of Regenerative Medicine

Regulatory violence in nation-state politics is a result of competitive desire, or the desire to compete for what other countries possess and stand for, often wealth and power. The coveted actions of countries become models to follow in the hope that the adoption of their regulation and scientific infrastructures will yield the means for them to become as wealthy and powerful as their models. Competitive desire and regulatory capitalism feed the perspectives adopted by distant observers, such as policy-makers, regulators or entrepreneurs, who may justify the sacrifice of anonymous individuals statistically as collateral. The distancing mechanism of individual market exchanges leaves the vulnerable and other, often, random victims with little protection through communal support, while for most victims, judicial redress lies rarely within reach. In the context of regenerative medicine, competitive desire–based regulatory violence systematically sacrifices the health interests of patients in the quest for medical blockbusters. Using tax money for government investment into regenerative medicine and creating industry-friendly regulation, some might consider as financially and medically smart moves to promote the economy and to lower the population's healthcare bill. In this section, I first show how competitive desire is reflected in

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economic investment and state support, and in parliamentary discussion, after which I discuss how competitive desire may not actually deliver what is desired.

State Support for Regenerative Medicine

Policy-makers might consider regenerative medicine to be lucrative and expect it to have a promising future. Economic interest in the field has increased substantially: there has been much trade in the sector and a mounting dedication by governments to support it. According to the Global Regenerative Medicine Market Report – 2019 (GRMMR), the regenerative medicine industry saw venture capital investment expand from $200 million in 2010 to $14.6 billion in 2018, a growth of 7.300 per cent over an eight-year period (ResearchAndMarkets 2019). Subsequent investment, according to Custom Market Insight (CMI 2023) expanded from $14.6 billion in 2018 to $76.04 billion in 2023. Apart from venture capital, the construction of cell and gene therapy manufacturing facilities is undertaken by biotech companies, which are boosting their own production capabilities, as well as by contract development and manufacturing companies (CDMOs) (CMI 2023). The key drivers for the growing market of regenerative medicine, according to GRMMR, are high rates of clinical trials, accelerated pathways for product approvals, new technologies to support cell and gene therapy manufacturing and the potential for cell therapies to revolutionise healthcare.

Most of the initial infrastructural and scientific investment, however, is provided by the state, as industry is risk-averse at the 'early' stages of medical product development. Once successful, however, promising start-ups are bought up (Angell 1997). A top-ten list of 'take-over targets' by the website of GEN (Philippidis 2018) parades the gems targeted by pharmas. During 2018, for instance, merger and acquisition activity saw large pharma companies make investment in the acquisition of smaller regenerative medicine companies, such as the acquisition of June by Celgene for $9 billion and AveXis by Novartis for $8.7 billion (Hargreaves 2018). In terms of pluripotent cells, the hope is to upscale the production of hESCs and iPSCs using HLA-specific cell banks to create off-the-shelf therapies with genetic correction. Risk-averseness of industry means that scientists try to find ways to persuade governments to invest in upscaling to decrease treatment costs: if they do not, it is argued, only small companies would reap the profit from vulnerable patients (Cossu et al. 2018: 897). Observers, however, warn that, despite

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the considerable research that has gone into this (Thomas et al. 2008; Soares et al. 2014), consistent manufacturing is difficult to attain (Pigeau et al. 2018; Hargreaves 2019).

The early stage of experimental therapies using pluripotent stem cells is necessarily expensive, but investment is hoped to be offset by future benefits. Japan's experience illustrates some key dilemmas faced by countries when joining the race to 'clinical firsts'. Ironically, the regulatory policies and stimulation packages of the sector require the population – who pays part of it – to be extremely patient, trusting and tolerant. Nobel Laureate Shinya Yamanaka has frequently warned that the stage of developing human-iPS and ES-cells could take over thirty years, asking the Japanese population to support iPS for the long haul. The first iPS clinical trials in 2014, using $900,000 to develop and test the iPSCs, showed that iPSCs could improve the sight of a woman with AMD, but Yamanaka made clear that 'Regenerative medicine is not going to cure patients in the way they hope', as the cells did not reverse the condition (Normile 2017). In 2020, Yamanaka wrote how, over twenty years, scientists have been fighting against the practical challenges of tumorigenicity, immunogenicity and heterogenicity, even though the field shows immense promise with clinical therapies reaching clinical trials (Yamanaka 2020). Confidence in the future of iPS among Japanese citizens has been very strong, but for how long will they be prepared to wait and bear the cost? Why do governments continue to invest?

Competitive Desire in Governments

Without competitive desire, politicians are not likely to put their money on the horse of regenerative medicine: beating other countries to a clinical first block-buster in regenerative medicine could mean fame, profit and even economic growth. Japan's regulatory and investment policies for the life sciences, as we saw in Chapter 8, were soon followed by other countries, propelling forward the race to successful clinical applications. The competitive desire to gain an edge over rivals can be easily spotted in political discourses on science, their overhyped language often seems contradictory. Declaring Japan as world leader in regenerative medicine research, in 2012, Japanese Prime Minister Shinzo Abe promised to invest ¥110 billion (US$1 billion) and announced regulation that would *accelerate* the translation of iPSCs into clinical applications (Cyranosky 2019). Countries that want to be world leaders in regenerative medicine broker their regulation, provide financial facilities and

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create national expectations of success. But decision-making based on competitive desire is not confined to political strategies isolated from science and industry. References to world leadership, competitors in the field and requests for crucial investments and 'not over-rigorous' regulation to facilitate translational science constitute common parlance prevalent among scientists and regulators when considering funding. Examples from the House of Lords, UK, debating the regulation of regenerative medicine in 2013 illustrate this (House of Lords 2013: 11–15, *italics* are mine):

Sir John Tooke: We do *not want over-rigorous regulation* where it is not required because a trial is, for example, of *very low risk*. On the other hand, the area that we are discussing this morning is at the sharp end of medicine where *some of the risks are unknown and many of them are more considerable than the application of a conventional small-molecule pharmaceutical product*. So, in the *rush to get regenerative medicine into practice and into commercial exploitation, we must be aware of some of the risks that are present*.

Professor Robin Ali: We are leading here, yet we have not yet built up in the UK the leading infrastructure [for gene therapy] to be able to go on to the next phase, to capitalise on the proof of principle and to capitalise really on technologies and the clinical trials that have been done in the UK, because there has not been the long-term investment on a scale required to allow us to expand. We see that in the US: many institutions there have invested. France, too, there are big facilities for GMP manufacture of vectors. These countries are in a much better situation now to really expand and capitalise on the UK's success.

Lord Willis of Knaresborough: My question is really to Professor Tooke. There is an issue that comes to us every time we talk to researchers on the ground, which is really about regulation. Professor Ali quite rightly said that *having strong regulation is what makes us very effective in the long-run but going through that morass of regulation is hugely difficult*. Indeed, *it will get worse because European directives in particular, and some of the court judgements in Europe will create new problems.*

Lord Patel: *My interest is that we do not miss out, as we have done previously* – for example, in monoclonal antibodies or in gene therapy – *in regenerative medicine translation research*, so that when the science is ready to be translated, we have *all that is necessary in place to do the translation and we are not caught out by other countries such as*

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France, the United States and maybe even Japan and others being better at identifying what would be required and putting it in place so that they jump the gun in translation . . ..

It is not unusual for scientists and regulators to compare themselves with neighbouring and rivalling countries, forever lobbying for better infrastructures, the 'right' regulation and the appropriate investment for aspiring world leaders. Competitive desire underpins not just the acceleration of regulatory permissions and clinical trials but also the race itself. To many scientists and observers, academic competition is crucial for the healthy development of science (Merton 1957; Collins 1968), even if scientists dislike it themselves (Hagstrom 1974). But competitive desire inevitably ties in academic competition with the economic and international dimensions of competition; it threatens to leave behind the value of science in a rat-race for funding, clinical firsts, patents, publications and national ambition (Martinson et al. 2009; Fanelli 2010; Ioannidis 2011; Fang et al. 2015; Smith 2021), while it is exactly in the absence of competition that transformative discoveries often occur (Fang et al. 2015).

This we saw illustrated in Japan, where the realisation of high hopes requires long-term commitment and considerable investment of social and financial resources, at the expense of resources previously earmarked for other fields (Chapter 6). Apart from eating into the budget of basic science in the life sciences, investment into other areas of innovation, such as tissue engineering (e.g., scaffolds) and physiotherapy (e.g., older osteoporosis patients benefit more from physiotherapy than from stem cell injections [Iijima et al. 2018]), were at stake. Most governments are unable to sustain the large investments associated with regenerative medicine, especially when it comes to full-blown clinical research trials. Though governments sometimes co-finance clinical trials (see Hauskeller 2018), in the long-run, they have to rely on industrial investment. To make clinical trials more affordable and less onerous, scientists have argued for alternative forms of regulation (see Chapter 2). In Japan, the regulatory overhaul and the efforts invested into science-industry collaboration through AMED, indeed, led to an explosion of industrial investment. Here, the introduction of the PMD Act played a crucial role in forging the trust invested by industry in the government's commitment to continue investing in regenerative medicine.

More than ever, resources are concentrated on translational rather than on basic research, while scientific collaboration with industry

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changed the dynamic of academic research at the universities, which according to researchers has become plagued by administration, management, regulation, competition and secrecy (Chapter 6; also, see McCain 1991). While academic research is being usurped by industry, regulatory facilitation made clinical trials more affordable. Industrial investment, however, usually aims at patents and royalties, making treatment costly and yielding little immediate health gain. For this reason, the Japanese government negotiated reimbursement with national insurance companies to cover the expenses for therapies under development (Chapter 6): This move shifted payments for scientific experimental research to taxpayers and patients, the enablers of the development of future therapies. The brunt of the costs involved in competitive desire is carried by those who have little knowledge of its existence.

The Clinical Promise of Regenerative Medicine

Japan's experience is repeated in competitor countries. Government investments into therapeutic promise and scientific ambition raise public expectations and appeal to the public for support, forbearance and generosity. It is no wonder that, as we saw in Chapter 7, many health organisations (HOs) place high hopes on regenerative medicine and are keen to work with industry, while at the same time they harbour suspicion, doubt and scepticism of its success. Considering the great investment into infrastructures, clinical trials and commercialisation, the adjustment of regulations, the high expectations of clinical applications and considerable public sacrifice, an important ethical question is whether regenerative medicine does what it promises: do the financial and regulatory investments justify returns in terms of patient health and high-quality science? A more pertinent question here is whether the answer to this question is of any relevance to the competitive desire that drives the investments in the first place.

Responses to the first question are ambiguous: according to Cossu et al. (2018), results in terms of therapies in the field of regenerative medicine vary from clinical efficacy for previously incurable and devastating diseases to, more usually, modest or no effect. Competition in what are internationally accepted as legitimate clinical trials is afforded mainly by HICs, and their research outcomes have highly uncertain routes to the market. Competitive desire also infects scarce-resourced LMICs, and, hence, thousands of research projects are conducted in medical schools and commercial clinics around the world. But there is little evidence that

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regenerative medicine can address polygenic and acquired, that is, most, disease conditions any time soon (Cossu et al. 2020). At best, in their drawn-out experimental stage, even with safety measures, regenerative therapies expose patients to risk, as outcomes are hard to predict. Though life scientists see great potential for regenerative medicine to reduce suffering and to lower heath spending for increasingly widespread conditions, such as heart failure (Lesyuk et al. 2018), the realisation of these 'estimations' have been expected for decades.

For governments' public health policies, the cost-effectiveness of treatment is a crucial factor in deciding to fund the development of regenerative medicine for medical purposes at home. Although the ability to tackle widespread conditions through regenerative medicine, such as heart disease, diabetes, stroke, Parkinson's disease and spinal cord injury, would save millions in healthcare and social care in the long run, the costs of regenerative medicine are high and would have to be paid at the time of treatment. In HICs, the costs associated with regenerative therapy are likely to be borne by the health services, but currently only a handful of rare diseases have been successfully treated (Cossu et al. 2018). As we saw in Chapter 7, efforts to accelerate the development of regenerative therapies, though supported by some HOs and their governments, are not welcomed by all. Some HOs actively oppose the brokerage of down-regulation. For example, in the US, a group of ten health organisations, including the National Organization for Rare Disorders (NORD) and the Michael J. Fox Foundation for Parkinson's Research (MJFF), opposed a bipartisan bill that would let FDA grant five-year conditional approval of regenerative medicine products. The organisations worried that the bill would compromise patient safety and that it would be difficult for the FDA to withdraw products that receive the conditional approval under the Reliable and Effective Growth for Regenerative Health Options that Improve Wellness (REGROW) Act (Wilson 2016). The case shows that that some regulation does not inspire confidence, even among the patients that advocate the clinical translation of regenerative medicine.

Academic studies make much of the great cost-effective potential for chronic and life-limiting illnesses such as DMD or Crohn's disease, with high, recurring costs of care and low health-related quality of life. We already saw in Chapter 7 that many HOs for DMD do not prioritise regenerative medicine. Many people with DMD are not prepared to spend their lives commuting to hospitals to submit themselves to the medical regimes of clinical trials on the off-chance that they improve their condition; many do not desire to become 'normal' (Kato and

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Sleeboom-Faulkner 2018). Nevertheless, numerous studies that calculate the costs of disease advise funding bodies on the development of therapies on the basis of forms of cost-benefit analysis that take little notice of what health improvement actually means to the patients themselves (e.g. Landfeldt et al. 2014). When governments decide to support the development of regenerative treatment for DMD with an eye on saving costs, in terms of national insurance, this would still require a huge amount of upfront investment, which would be unaffordable in most countries.

Crohn's disease (CD) is an example of a condition that has become the target of regenerative-therapy hyping, using phrases such as 'giving patients a new immune system' and 'radically changing the course of the disease' (see Queen Mary University of London 2018). Early trials of stem cell interventions in CD have had mixed results, with some short-term successes but also a significant incidence of side effects, including the death of one patient (Queen Mary University of London 2018). Research into the decision-making and expectations of people with severe CD to have autologous haematopoietic stem cell treatment (Cooper et al. 2017) indicates that decisions are influenced by participants' histories of battling with their condition, a frequent willingness to consider novel treatment options despite considerable risks (also see Lindsay et al. 2017; Qiu et al. 2017) and, in some cases, a high expectation of the benefits of trial participation influence the decision to join a clinical trial. Not surprisingly, potential therapeutic mis-estimations occur, whereby the research participant underestimates risk, overestimates benefits or both (Cooper et al. 2017). Partly, this is due to the difficulty for patients to recognise that clinical trials are not just about trying to improve patient conditions but also about acquiring scientific knowledge and sharing them in publications (Cooper et al. 2017). Similar to what we saw in Chapter 7 in relation to treatment priorities, this indicates among HOs for DMD and SCI, the process of decision-making about having treatment is shaped by the physical, socio-economic, cultural and relational aspects of a person's life.

All in all, government decision-making around regenerative medicine based on cost-benefit analysis and clinical outcomes is not straightforward. First, it makes false assumptions about what are costs and what are benefits. The costs do not just constitute those of financial investment but include harm related to the process of developing experimental medicine such as unknown side-effects, the investment of false hopes, spending time on commuting to hospitals and the medical regimes imposed on patients when undergoing a clinical trial. Second, people living with a

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condition may develop an identity associated with the lifestyle afforded by it. Many accept and like their identity, and do not desire or are not able to become what goes as 'normal' (Kato and Sleeboom-Faulkner 2018; Chapter 7). Third, the effort invested into regenerative medicine closes the doors for other medical research. This 'inverse care law', which favours distributional analysis of scarce healthcare resources (Cookson et al. 2021), is put strongly by Cossu et al. (2018): 'If policy-makers do opt for high-risk, expensive, but potentially revolutionary regenerative therapies with some tangible effects, they need to balance this against foregoing other, perhaps less-ground-breaking, cheaper research options with tangible effects for the wider population of patients.' And, lastly, even if regenerative medicine can alleviate a number of conditions, we do not know if its production will be feasible and affordable, as this involves questions of upscaling. The long-term effects of upscaling on the body and individual therapies of the live cells on the body may necessitate research over generations, before we know its 'full' biological 'costs' and 'benefits'.

Lowering the regulatory thresholds to accelerate clinical research in regenerative medicine involves risks and substantial costs. But it is doubtful that costs and benefits of medicine and health can be expressed adequately in financial terms. Patient experiences and decision-making indicate controversy about what is needed, depending on the condition in question, means and socio-cultural environment. It is an open question as to whether regenerative medicine can address widespread conditions cheaply, and where investments should be drawn from traditional scientific approaches, especially in countries with scarce resources. In fact, it is doubtful that governments can easily redirect funding. Because past investments are too large to fail, some might deem it necessary to change the 'social contract' between regenerative medicine and the public, as discussed by Cossu et al. (2018).

Social Contracts and Competitive Desire

As we saw, state regulators have taken responsibility for research regulation on the basis that, morally, patients need to be protected from the bodily violence that unscrupulous medical interventions can wreak and, politically, to ensure that there are rules in place that guard the quality of scientific research. Under regulatory capitalism, however, regulatory frameworks do encourage investigators, funding bodies and commercial investors to accelerate the process of clinical translation and marketing

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for economic reasons. To promote regenerative medicine, as explained below, there are calls from scientists and science observers for the public to play a more active role in the 'social contract between science and population' (Cossu et al. 2018). The social contract, served to unite individuals into a 'political society' (the state), using rules and regulations agreed by the political majority to prevent and mediate conflict (Locke 2007 [1690]: 101–114). As I argue below, under conditions of global regulatory capitalism this social contract is fatally challenged, because, first, competitive actors anticipate breaches of regulations, putting them at a disadvantage, and, second, industry pressurises regulatory institutions to change regulations or make international deals that avoid home rules.

Social Contracts

The social contract upon which basis medical progress is made, the social license by which scientists are permitted to conduct research, according to Cossu et al. (2018: 904), needs to change so as to involve the public in the development of regenerative medicine: 'The social licence [between scientists and public] is more passive than the arrangement that is needed if cell and gene therapy is to be harnessed for mainstream use' (Cossu et al. 2018). Although researchers risk losing their license to conduct research if they do not follow regulatory guidelines, such as applying for permissions and following regulation, Cosu et al. argue, few expectations are made of the public. In this context, other ethicists have argued that the public has a moral obligation/duty to participate in clinical trials, because everyone would benefit from scientific research (Harris 2005; Chan and Harris 2009). Cossu et al. refrain from going this far but instead argue that a good governance framework would increase 'the sense of mutuality between the public and scientists' and also enhance 'the sense of a common project that will take time to come to fruition'. But by not taking into account the intimate ties of science with the state and industry in specific (Guston 2000), and regulatory capitalism in general, I argue that this proposal overestimates its ability to cultivate a sense of mutuality that is meaningful.

The proposed social contract involves efforts from both scientists (competence, openness, acknowledging and addressing concerns, transparency, trustworthiness, providing accurate information) and targeted patient engagement and publicity initiatives. Although the desired qualities in scientists are commendable, they are clearly not new and they do

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not address issues of disagreement on the use of cell therapies, the affordance of particular forms of governance, the secrecy entailed in competition and working with industry and the aversion to public scandal. It is not difficult to see how a social contract based on engagement with the public, as has been the case in Japan (see Chapter 6), can motivate patients to queue up for participation in clinical trials and support a multi-decade project. While Japan's RMP Act since 2014 guarantees researchers and industry the means and availability of patients to achieve regenerative medicine, taxpayers and patients foot the bill and expectations had to be vastly downscaled. It is clear that acquiring public support is in the interest of innovative scientific undertakings. As political scientist Brian Salter (2007) pointed out, if public support is gained for a particular scientific field then the authenticity of the future market becomes more tangible; and if translated into political support, then the winning of scarce scientific resources becomes more likely. To be politically effective, Salter concludes, advocates must be seen to act responsibly, rationally and with due discretion, that is, to conform to the values advocated above.

Apart from the question of its use as political strategy, there are various interlinked issues that arise when requiring the public to actively engage in regenerative medicine as a part of the social contract between science and public. First, for public engagement with and participation in science to be of value to a democratic consultancy, that is, as a tool of democratic decision-making about scientific development, it must not be a way to subject it to a particular scientific project through which it can come to harm. This is why it is important to know who benefits from support to a particular project in the first place (Leach et al. 2005). This brings us to the second issue of why a particular scientific project is privileged: it is not clear whose interests are served by the social contract proposed by Cossu et al. (2018). Although more mutuality between scientists and public may be desirable, 'mutuality' implies a different kind of power relation compared to the dependence relation inherent to 'patient engagement' and 'patient participation' that are envisaged by Cossu et al. Furthermore, the proposed social contract does not consider the direction in which science is developing: as we saw above, the focus on regenerative medicine is driven not just by concerns for particular medical health issues but also by profit, career and other motives linked to competitive desire. It is not clear to what extent regenerative medicine is a desirable solution to the conditions on its target lists (Chapter 7).

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A third issue is whether a social contract can have predictable effects in the global context of regulatory capitalism with its endemic practices of brokering regulation for endings that have little regard for social contracts. Under global capitalism, investment into science digs wherever it can satisfy a future market, rather than where urgent problems are to be resolved (Busch 2000). Scientists, responsible for the scientific aspects of their work, should not also be the regulators of their work, especially not when they are in economic, political and cultural competition with scientists in other jurisdictions. In other words, the proposed social contract ignores the important fact that regulation in the current world, the main mechanism for protecting patients (and scientific development) against uncontrolled experimentation, leads a socio-political life of its own – both nationally and globally.

Competitive Desire and the Sacrificeable

In market economies, transactions involve a distancing mechanism that leaves the seller and buyers free of any ties of duty: you pay and you receive – that is it. This core feature of market economies based on competitive desire contrasts with the ongoing, circular relations of exchanges, which are subject to the social contracts of gift economies (Anspach 2017). Gift economies are far more relational compared to market economies and include a range of social codes that ensure socio-political continuity. But they can be plagued by upheaval, in particular as a result of the obligation to retaliate mis-behaviour or to make sacrifices to end violent cycles of revenge (Girard 1986). Philosopher Paul Dumouchel argued in this context that market economies universalise the category of 'sacrificeable' victims (Demouchel 2015) but on a larger scale: not just among those who risk their mental and physical health in the course of their employment but also among those who suffer from conditions and are wanted for experimental research. The victims are those whose (mal)-treatment, death or bankruptcy will not result in vengeance. It is well-nigh impossible to know whether severely ill patients die as a result of 'immature' treatment, and those that pay their life-savings for non-effective or maleficent interventions usually do not have recourse to justice. Who is in a position to blame the state for its regulatory facilitation of innovative treatments? Who can sue a clinic that raised unrealistic hopes but gave no guarantees? What are unrealistic hopes?

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Even when accompanied by a list of ethical conditions, ethics review and systems of supervisory control, the strengthening of the social contract between scientists and public/patients may have dire consequences: not taking into account the impact from the capitalist market, international competition and regulatory practices exposes 'the public', that is, 'patients' and 'volunteers' to the risk of being sacrificed at the altar of the progress of regenerative medicine. Despite the authority of international stem cell organisations, such as the ISSCR and the ISCT and the publication of research ethics on their websites (ISCT 2015; ISSCR 2016), the international arena of regenerative medicine is not likely to adhere to their guidelines. Similar to tribal gift economies, the global space of regenerative medicine is characterised by the absence of an overarching state (Blanc and Bessière 2001; Anspach 2017): there is no transcendental authority. In societies dominated by gift exchange, sometimes transactions occur with foreigners that are similar to market exchange: without mutual obligations. As put by Anspach, 'in such transactions, one has the right to cheat, steal, or wage war' (Blanc and Bessière 2001).

Similar frictions between local social contracts and deals with 'outsiders' occur in regenerative medicine. There are practical limitations to a social contract of a public engaged with the clinical trials needed for the translation of regenerative medicine in a global context of regulatory capitalism. The market mechanisms that necessitate a social contract between public and science cannot be easily controlled where national healthcare systems become part of industrial projects with global interests. The consideration of proposals for public engagement with regenerative medicine has to take into account the friction between global competition and the local investment of tax money into clinical trials, of which physical risks and hopes are shouldered by research participants. This has implications for how the social contract between science and public would work in practice.

Clinical Trials and Access to Patient Populations

The reign of regulatory capitalism raises the question of whether public engagement between science and patients leads to a co-optation of the latter into clinical research trials and, if so, on what basis. Currently, populations and patients are a lucrative subject of data collection for clinical trials. Clinical trials are popular among populations with scant healthcare access, the elderly population of ageing societies and patients that have run out of available options for treatment (Gwanade 2015;

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Haslam 2022). Under conditions of global competition, the knowledge of regulatory infrastructures and patient pools are important to clinical researchers, the organisers of clinical trials, as well as to highly profitable Clinical Research Organisations (CROs) (Petryna 2007; Montgomery 2012; Sleeboom-Faulkner 2016). Conversations with dozens of stem cell scientists from Asia and Europe indicate a range of factors that play a role in determining where research trials are located and in deciding which disease conditions to target (see Chapter 5 and 7). These factors relate to the profiles of research and health infrastructures, disease populations and to their socio-economic environment. Knowledge of research infrastructures and research populations is crucial to the quality of research and to estimating profit margins. Important infrastructural criteria include local regulatory requirements; the time and costs of obtaining research and marketing permissions; access to research funding; the availability of medical, linguistic, scientific and technical expertise; the reputation of collaborating research and medical institutions; the certification of laboratories and clinics and the sensitivity of the local media to stem cell provision and public attitudes (Sleeboom-Faulkner 2016).

The socio-economic environment and attitudes towards clinical trials of potential patient populations are just as important. Thus, to optimise research conditions, the organisers of multi-centre stem cell RCTs may look for a locality with a particular patient pool positively oriented towards and expedient to clinical research. To optimise standard treatment, trial participants may need to be precisely instructed about procedures, drug regime, sanitary conditions and other necessities to render the clinical trial scientifically sound. This requires participants to understand the language in which they are instructed, enough knowledge of what clinical interventions are for, to adopt alien cultures of hygiene and diet, to be free for the duration of the treatment and to be able to afford the expenses associated with insurance, transport, and time off work or away from home (Sleeboom-Faulkner 2016). If particular conditions do not meet the scientific protocol of an RCT, the organisers may try to control or cancel out deviations of participating local patients by altering the conditions and habits of research participants to suit the needs of the trial. Thus, diets, housing and exercise regimes may have to be adjusted (Rothwell 2005; Will 2007; Geissler et al. 2008: 705; Montgomery 2012).

Features of populations and local conditions can also be internalised into an RCT. This is important as the efficacy of some clinical interventions are sensitive to socio-environmental conditions, such as poverty and pollution. Thus, research participants bring into the experiment their

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particular social conditions, many of which may be related to healthcare, gender, age, diet, medicine, hygiene and attitudes, which shape the reaction of the experimental body, and which may influence the development of the experiment and its results. The internalisation of undesired local traits and conditions may be unpreventable and can bias the experiment (Montgomery 2012). The internalisation of local conditions and traits, however, can make scientific sense in 'pragmatic trial' designs, for instance, when ethnic background, age, gender and environment are closely monitored and measured. Thus 'race' may be hypothesised to be sensitive to certain chemical components in drugs. However, if a particular population is known to lack healthcare access, such population could also become the target of patient recruitment for reasons of accessibility (Duster 2005; McCain 2005). Depending on the particular research design and aims, knowledge of the public can be manipulated for scientific and for exploitative reasons (Sleeboom-Faulkner 2016). We saw in Chapter 5, for instance, that collaborating with scientists in Thailand was attractive for its large patient pool, limited healthcare resources, relatively cheap scientific expertise, the country's attractive regulation and in need of expensive equipment.

Certain aspects of a population's conditions, then, are internalised into the trial design, not because they are expected to contribute to state-of-the-art research or to benefit patients but because other interests are at play, such as market-share, patentability and profit. Similarly, social knowledge about patients can also be important to decisions to collaborate or to locate therapy provision centres, including healthcare access, insurance, education, religious belief, wealth, living conditions and family situation, which may all be valuable for patient recruitment purposes (Patra and Sleeboom-Faulkner 2009; Sleeboom-Faulkner and Patra 2011; Sleeboom-Faulkner 2013). Furthermore, knowledge of a country's healthcare system, regulation, patient pool, communication system, expertise, jurisprudence, insurance system and science policy can be expedient to stem cell enterprises and CROs conducting RCTs (Angell 2004; Rajan 2006; Fisher 2009; Petryna 2009; Dumit 2012). The question is whether a social contract between science and public will be compromised by the pressures of competition and the race for clinical firsts.

In short, uncertainties about the aims of the social contracts between the public and scientific institutions and the unpredictability national and international political and financial pressures under regulatory capitalism make it necessary to take into account the possibility that knowledge, rather than utilised to serve the needs of patient health under

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agreed regulation, becomes commodification and sold to be used for commercial purposes under different regulatory arrangements. As under regulatory capitalism, patients are objectified as pools and scientific knowledge is commodified as assets, any social contract between science and public should be understood in the particular context of the community in which it evolves and through the wider pressures it is subject to.

Caring Solidarity: Visions of Creative Desire and Local Wisdom

Though countries are not drawn into competition willy-nilly, national-level social contracts between scientists and patients under global regulatory capitalism are unlikely to end regulatory violence. Instead, I suggest that fostering a vision of caring solidarity, driven by creative desire and embedded in local wisdom could avoid at least some regulatory violence and could help us integrate science with sustainable health approaches (e.g., Centre for Sustainable Healthcare 2020).

Creative Desire

Under regulatory capitalism, thinking in terms of national competition requires strategies that involve the objectification of other countries and the creation of the distance between peoples through comparison, it presupposes a rational individualism that relegates love, ethics and solidarity to the realms of the naïve, the sacred and idealism. Hard-nosed decision-makers usually do not like to be associated with these. Taking inspiration from Rebecca Adams' work on 'creative mimesis' and 'loving desire' (Adams 2000), however, it becomes possible to see, not just why competitive desire does not have to underlie all economic exchanges but also how a constructive, loving form of desire can serve as a fundamental generative principle of what I call 'caring solidarity', if rooted in local notions of wisdom and includes the virtues of prudence and social justice (explained in the section below).

Creative and loving forms of desire, like competitive desire, are generative, mimetic principles. Creative desire accounts for constructive, non-violent symbolic and material exchanges that form the basis for communities. Competitive desire, a principle that mimics and generates selfish behaviour based on envy, dominates creative desire in a world characterised by regulatory capitalism. In a world of regulatory capitalism, competitive desire can only temporarily be superseded by

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means of the law and regulations in a community, because international strife puts pressures on nation-states to adjust to the global dynamics of competitive desire. The damaging effects of competitive desire go beyond those of the escalation of regulatory violence. It affects the ways in which countries self-define as 'backward' or 'developed' and influences the political priority setting in matters of science and healthcare (Chapter 2). Viewing themselves through the eyes of the powerful, Othering leads to self-objectification and emulation. Therefore, scapegoating, competition and mimetic desire are more generative than realised at first glance: we are not just dealing with sporadic violations of regulations. Rather, we are confronted with systematic and strategic internalisation of regulatory conditions that not only puts some groups at a disadvantage and scapegoats them but also places them in a position in which mimesis leads people to objectify and misrepresent themselves. From this vantage point, the only way forward may seem to be the emulation of the 'successful' strategies of what are viewed as the more 'developed' countries.

A more constructive form of desire from a *non-victimised perspective* would avoid that victims identify with the victim position. It is the objectification of others rather than 'acquisitive imitation' (Girard 2016) that is the locus of violence in competitive desire. Following Adams in her revision of Girard's 'imitative desire', I suggest that powerful HICs address their health needs on the basis of 'caring solidarity': as we saw in Chapter 7, rather than imitating and vying for the biomedical aims and regulations of other communities, resources are better spent when matched with the aims of and health needs embedded in the livelihoods of their local communities. As we saw in Chapter 7, the medical challenges of HOs for DMD in India, Japan, Europe and the US are quite different.

The health needs of LMICs and/or less powerful communities, rather than adopting the health models of wealthy countries, may be more appropriately fulfilled according to local conditions and local aims. Only when regulatory conditions and biomedical solutions correspond to the means and livelihoods of local communities can they begin to realise the desires engendered by their cultural subjectivities rooted in local creativity, including their views, values, sensory perceptions and ways of living. A shift in thinking in terms of 'society' to 'community' could draw attention to the relational nature of healthcare.

The notion of community draws attention to the importance of meaningful relations regarding materials wealth. By only desiring the

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subjective integrity of the self-conception of others, rather than desiring their objects (that is, the paraphernalia of power, wealth and status), communities are able to acquire greater well-being and improve the relationality within and between communities. Only then, the subjective integrity of other communities, unlike objectified Others and their objects, are not envied and appropriated but valued as integrated modes of living. It may be objected that creative desire implies that material exchanges are not stimulated and regulated, possibly leading to isolated communities and clandestine and exploitative exchanges. But, as argued above, creative desire is a generative, mimetic principle: it can be understood most fruitfully in the wider context of mutually beneficial cycles of gift-giving and solidarity. This discussion, which underpins the vision of caring solidarity, I will pick up after introducing the considerations of prudence and justice.

The Considerations of Prudence and Justice to the Common Good

The prudence with which communities develop innovative health products and the fairness and equitability of the distribution of healthcare resources are crucial considerations to the acceptability of medicine to communities. I speak of considerations here, because the practices in which the notions of 'prudence' and 'justice' acquire their meanings vary; communities deliberate, attend and understand prudence and justice differently. I use these considerations as a heuristic way to think about what kind of medicine might serve local communities appropriately: how can communities invest into healthcare in a way that (a) avoids regulatory violence; (b) includes patient groups that are not best served by the promised fruits of regenerative medicine; (c) is embedded in the sociocultural lives of national and local communities, including non-human life, and (d) is morally bound to undertake action to accommodate differences between the abilities of people in need through mutuality and relations of care.

The considerations of justice and prudence are relevant, first, to determine the conditions under which health-care products are marketed in countries with differential powers to negotiate prices and questions of who foots the bill (the public, private individuals, charities?) and how (through taxes, crowdfunding, insurance?); and, second, to determine which approaches to health are ethical, fair and reliable enough to invest in, given the frequent over-claiming of the potential benefits of biomedical products under the pressure of competitive desire and a widespread

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confidence in a high-tech quick fix approach to health conditions. I discuss this through the work of biologist and theologian Celia Deane-Drummond, who reformulated some of these social issues in light of the 'common good' using a perspective of virtue ethics.

The example of 'the alleviation of suffering', a claim frequently made in proposals for regenerative medicine, genomics and high-tech applications in general, shows how without further specification regarding the number of people that might benefit from them and how much, the costs involved in therapy, how it is paid for and the potential harm to patients, there is potential for political corruption. In other words, the 'common good' referred to in claims of alleviation can easily be translated into public support for lucrative projects *without genuine deliberation about the likely benefits of the populations that will be affected by them*. In an age of over-diagnosis and overtreatment (cf. Haslam 2022: ch. 6), with movements to counteract this through organisations such as Too Much Medicine (BMJ 2023), Choose Wisely (Choose Wisely UK 2023) and Prudent Healthcare (IWA 2017), reflection on the 'common good' needs to be accompanied by *a critical evaluation of the motivation and attitudes* of those involved in research and marketing projects. Discussing the ethics of biotechnology, Deane-Drummond (2004: 92) proposes to embed the notions of *prudence* and *justice* in social and political discourses to examine biotechnological projects. The notion of *prudence*, here, refers to the everyday practice of wisdom as a means of assessing relations, attitudes and motivations. 'Prudence' sets the way virtues need to be expressed in given circumstances, moving through deliberation, judgment and action in the community (Deane-Drummond 2004: 93–94).

Applying 'prudence' and 'wisdom' to deliberations on the common good of a new biotechnology in a community may turn out to be a 'partial good' when it benefits a few people at the expense of many, when health gains are minimal against the substantial healthcare of others or when achieved in undue haste. In global contexts, a critical eye needs to be caste on international collaborations that happen to coincide with regulatory differences or stark differences in wealth between the collaborating communities involved. Prudence tells us to interrogate the motivations of those responsible for or supporting such collaborations, including scientists, companies, state officials. It may also be important to query the practice of tempting scientists in LMICs into international research collaborations that overstate the benefits of research and health outcomes to their community. Wider needs and available resources of the community have to be taken into account, as an exaggerated passion

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about a particular new biotechnology towards a 'health good' can lack sensitivity about its long-term effects on both. Thus, communities with scarce healthcare resources may want to prevent that they are spent on high-tech quick fixes that entail long-term burdens and possibly irreversible health effects for the community (Haslam 2022). It is for this reason that the WHO and UN have argued for Universal Health Coverage (WHO 2017, 2022).

A key question relates to the need to focus resources on particular areas of biotechnology, when rather than the health of the local or national community, it mostly benefits the health or pockets of a few and leaves a majority without adequate primary care (UN 2016). Clarity should be given about the long-term costs associated with the development of regenerative medicine and the functions of its regulation (including, its ethics procedures and its relevance to national economic policies). The relative cost expended by LMICs, and also in HICs, may be in no proportion to any health benefits reaped (UN 2016; Polak 2022). Countries have hoped to save health budgets by relying primarily on public health systems that determine drug-intake on the basis of epidemiological statistics (Dumit 2012), leaving communities with unaffordable high-tech and care poverty (WHO 2017; cf. Chapter 5). Other countries, such as Japan, have concluded that the only way forward is to shift resources within scientific research towards sustainable health, while stimulating self-help solutions rooted in local communities (Watanabe 2018; NIHN 2022). Rather than the expensive option of having its elderly population commuting to hospital to participate in clinical trials, Japan has been investing far more of their health budget into preventative and integrated healthcare: from 'cure-seeking medical care' to 'cure- and support-seeking medical care' (Iijima et al. 2021).

The effects of developing particular biotechnologies cannot be assessed by cost-benefit analysis alone and need to involve the *judgement of the community and action*. *Judgement*, here, involves memory (history and tradition, social context and culture), reason, understanding, ingenuity and its aptness; *action* involves building on deliberation and judgement and requires foresight, circumspection and caution (Deane-Drummond 2004: 93–94). *Foresight* tells us that a quick-fix of regenerative medicine will not resolve the world's health conditions, as many of these are related to socio-cultural, economic and environmental practices; circumspection involves a clear perception of the reality of the applications of regenerative medicine, for example, its safety, such as the ability to control injected cells; and, *caution* deals with the risks involved in interaction

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with other health and environmental factors, such as stress, consumption and pollution (NHS 2020; Nesta 2023; WHO 2023). As many risks cannot be easily quantified, such as long-term risks and the synergies with other environments (for instance, cellular mutations can cause cancer), risk-benefit analysis alone in biotechnology is clearly inadequate.

In this virtue ethics approach, *justice* links virtue with wisdom and prudence: it frames appropriate ethical action owed to the community. Different from notions of rights, which force claims on others to provide equal opportunities usable only by some groups, justice involves *morally binding action* to accommodate differences between all people through duties and obligations towards, for instance, the excluded, the impoverished, the other-abled and non-human animals. Thus, when patent rights on regenerative therapy are violated by countries that have come to depend on them during clinical trials, but cannot afford them, the expectation of payment is morally unjust (Doval et al. 2015): it would force the national community to use resources unjustly. Communities might decide to conduct more research into 'primary prevention' of medical conditions, such as those resulting from traffic accidents (spinal cord injury), working conditions (cardiovascular diseases, stress, cognitive decline), consumption (diabetes), modes of infection (HIV, STDs) and the living environments (cardiovascular diseases, cancer, stress) (EUSPR 2023). Alternatively, they might want to rely on societal research into what patients need/want before accepting company claims about patient needs. All in all, communities may want to re-evaluate the importance of primary care and social care. Higher appreciation of care work, care identity, the role of the environment and healthcare provided at the point of use (at home, work, in the local community), as provision rooted in the community might be preferable to overburdening hospitals with 'social care' (Haslam 2022: 202).

Deane-Drummond's distinction between commutative justice, distributive justice and legal justice (2014) is also useful when considering current social and political practices of regenerative medicine. *Commutative justice*, which refers to *what is owed between individuals following contracts*, requires mutual respect and honouring commitments and the need for compensation when failing. Patient recruiters for experimental regenerative therapies that are unclear about the high risks involved do not conform to commutative justice; *distributive justice* concerns the socially just allocation of resources by those in power. This involves the fair and even-handed sharing of costs and benefits across time. But without the consultation of the population about high-risk national investment,

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regenerative medicine fails to conform to distributive justice; and *legal justice* pertains to regulatory relations between individuals and society as a whole. It restrains industry and healthcare providers to act responsibly towards individuals and the environment. But where brokered regulation is incentivised by competitive desire, regulation for regenerative medicine does not achieve legal justice.

Considerations of prudence and justice put into perspective the cost-benefit and risk-benefit analyses of the utilitarian approaches used by governments: they link the political deliberation on approaches to health to virtue ethics–based action in practice. When governments, similar to multinational pharma, are caught up in the vortex of competitive desire, their investment and regulatory policies will deprive their populations of a meaningful say in the deliberations on what kind of healthcare to develop, not just the programmes currently favoured on the basis of economic gains. Thus, long-term commitments of considerable funding of regenerative medicine for financial gain deprives people of choice. Apart from the ubiquity of overhyped scenarios of regenerative futures (Brown 2003; Brown and Michael 2003), populations currently have little to go on when considering how current healthcare investment might affect human and non-human life. And once large-scale investment in infrastructures is in place, choices will be path dependent (Page 2006), that is, pre-structured in directions that are not easily diverted.

Fostering Caring Solidarity

We saw that competitive desire entails foreseeable regulatory violence in which the state as regulator plays a main role. State regulation is not corrected by some neutral transcendental authority that can guide countries. Investments into regenerative medicine continue, regardless of whether they are justified by the benefits they generate to patients and the protection offered to the quality of scientific research. Changing course now would threaten economies and with them, the investments, jobs, incomes and hopes of many. A more intensive involvement of the public by changing the social contract between public and science could accelerate possibly successful applications through a growth of potential experimental subjects. But this is also likely to increase investment in a health system that is closely linked with insurance companies and experimental medicine, leaving traditional health options under-resourced. Furthermore, its potential for regulatory violence in a global context

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would make international repercussions unpredictable and could generate further harm to patients.

An approach of 'caring solidarity' would ask how investment into health serves the community and how to avoid that scientific development is thwarted by competitive desire. In a 'caring solidarity' approach, solidarity refers to fairness and care to prudence. While the generative principle of competitive desire is based on rivalry and the imitation of others, the generative principle of 'creative desire' proposed by Adams (2000) is rooted in creative imitation based on desiring the well-being of others as they experience it. I link this intersubjective approach with Deane-Drummond's emphasis on the importance of developing biotechnology in the light of 'wisdom', which is based on local considerations of prudence and justice (Deane-Drummond 2014). In brief, under regulatory capitalism, competitors imitate those that they envy in terms of possessions, attributes and power (Girard 2000). But models do not have to be based on negative principles of competition; they can also be based on relational, altruistic cultural forms, valuing solidarity with the well-being and integrity of the self-conception of others. By imitating the loving desire that our models have for the subjective well-being of others, rather than imitating the acquisitive desire for the objects of those that we envy (Adams 2000), the desire to imitate becomes a beneficial generative principle, while also fulfilling self-interested needs through generalised solidarity in the community.

Similarly, the desire to compete does not necessarily have to lead to violence in the way it does under regulatory capitalism. Violence originates in the attitude that conceives of countries as profit-based independent competitors, regarding them as opponents to compete with, to colonise and to outperform. Here the models imitated are powerful and driven by the destructive desire for profit. Rather than following a capitalist model of competitive desire, which proceeds on the basis of the generation of misleading representations of others (through strategic boundary-making and scapegoating), participatory models of caring solidarity lead to long-term relationality rather than to short-term gain. Those who desire the integrity and well-being of others can become the models and generate the conditions in which we imitate those who know how to care, not out of Darwinian strife but out of the need to engage in exchanges that are directed by an awareness of limited means, locally, and, by a vision of a sustainable environment that supports all communities, globally.

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In the globalised world of regulatory capitalism, the economy dominates politics and incapacitates the ability of policy-making to offer and pursue any self-transcending aims that benefit, not the utilitarian whole but the humans and non-humans that need protection most. There is a need for an image of the future that is sufficiently positive to be desirable and at the same time credible enough to give rise to actions that can bring about its realisation (Dupuy 2014). Rather than a social contract, it is the truthful moral vision of how health can be sustained among human and non-human creatures on this planet that needs to be central to any political arrangement. And, rather than a fate depending on technological hyping in a world of competition and regulatory capitalism where ethics serves as a crutch and commercial lubricant for the legitimisation of our individual jobs, projects and causes, a shared vision is needed to reconcile economy and political reason as the conception of a common future. French philosopher, Jean-Paul Dupuy (2014) argued that a market needs to be regulated with an endpoint or cause in mind and that regulation needs to have a direction outside the goal of those of individual members of the community. It has to be directed towards a metaphysical desire of an eternally changing common endpoint, recognising the co-evolution and unfolding development of human and non-human species in their mutuality. Caring solidarity generated by our model's desire for the cultural integrity and well-being of other communities and species might help us reach Dupuy's endpoint.

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