



CONTESTED CELLS: GLOBAL PERSPECTIVES ON THE STEM CELL DEBATE — A CRITICAL INTRODUCTION

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INTRODUCTION: THE SOURCE OF CONTROVERSY

This book is entitled ‘Contested Cells’. We might have prefixed this with *essentially*, because many of the concepts seen as fundamental to the debate — for example, ‘dignity’, as used in reference to the human embryo — resist analytic and philosophical scrutiny, perhaps even to the degree that they have become meaningless in sensible debate; such protean usage may be nothing more than a pretext for equivocation. The result, for some, has been for the debate to become a political debacle. And furthermore, these disputes ‘cannot be settled by appeal to empirical evidence, linguistic usage, or the canons of logic alone’.¹ In the stem cell debates, disagreement is the rule, rather than the exception.

The potential for the clinical application of stem cells to revolutionise medicine — especially in the field of regenerative medicine — is generally not challenged. But an enduring issue concerns the morally acceptable sources of human stem cells — whether pluripotent or multipotent. The derivation of human pluripotent embryonic stem cells requires the destruction of nascent human life; and this technique has been followed by the creation of animal-human mixtures, or ‘cybrids’, which according

¹ J. Gray. On the Contestability of Social and Political Concepts. *Political Theory* 1977; 5(3): 331–348.

to some commentators, inevitably entails the illegitimate crossing of fundamental species boundaries.² These developments have raised wider concerns about our failure to respect the ‘dignity’ of human life, and the danger of an inexorable slide to reproductive cloning.

Another aspect of the debate is the contention that there is not even a need to do these experiments, because there are alternatives in the form of somatic stem cells. But this claim ought to be tempered by the current scientific uncertainty. For example, the question of whether induced pluripotent stem cells (iPS cells) are functionally equivalent to the ‘gold standard’ embryonic stem cells, remains to be answered.³ This means that communication of the science should be moderated to avoid ambitious claims, misinforming stakeholders, or manufacturing uncertainty (and the subsequent insistence on the legitimacy of precautionality has the tendency to encourage the prohibition of controversial science).

However, we should not forget that the stem cell debate is not only about embryo research; and, indeed, closing off this contentious path merely forces researchers down others. For example, some point to the inducement that must accompany the procurement of oocytes for research from women⁴; or the consequences of rampant technological advance, resulting, for example, in the commodification of stem cell lines. Stem cells economics may fuel an industry of irrepressible commercialisation, and this potentially threatens the integrity of transactions between scientists and donors.⁵

Another key ethical issue, considered in number of the following contributions, is the clinical translation of stem cell research ahead of reliable

² See: Kure, this volume.

³ A recent paper suggests that there are molecular differences between iPS cells and embryonic stem cells. It is unknown whether the differences in gene expression are biologically significant; M. Chin *et al.* Induced Pluripotent Stem Cells and Embryonic Stem Cells are Distinguished by Gene Expression Signatures. *Cell Stem Cell* 2009; 5: 111–123.

⁴ See: B. Capps and A.V. Campbell. Why (only some) Compensation for Oocyte Donation for Research Makes Ethical Sense. *Journal of International Biotechnology Law* 2007; 4: 89–102.

⁵ See: Mackenney & Capps, this volume.

clinical evidence.⁶ While often charging high costs for such treatment (thus revealing that they are not intended to be seen as clinical trials), practitioners (often part of global networks, and not always limited to regulatory havens, as one might expect) are reluctant to make available data for review and scrutiny, relying instead on patchy reports and hearsay. This risks patients' well-being by exposing them to potentially unsafe therapies, and is almost certainly exploitative of their sometimes desperate plight.⁷ Some countries are becoming acutely aware of these concerns, and are implementing new rules which are designed to curtail a growing business in unproven treatments. The availability of stem cells as lifestyle treatments may not be as much of a concern to the vulnerable or unwell; but it does risk a catastrophic error or unforeseen side-effect which becomes a setback for the reputation of validated science.⁸

In Part One of this volume, the reader will find a valuable collection of theoretical papers, which, when taken together, illustrate the connections — as well as the disparities — between different ideas of stem cell legitimacy. It is noticeable, for example, that many countries have been keen to advocate that there is an 'ethically right' way to conduct stem cell science. While this has taken countries in the direction of a number of regulatory paths, it also shows that few welcome a regulatory vacuum. The complexity of the regulatory responses also highlights that frameworks have been sophisticated enough to accommodate issues beyond the

⁶ International Society for Stem Cell Research. 2008. *ISSCR Guidelines for the Clinical Translation of Stem Cells*. 3 Dec.

⁷ A recent report describes a patient who developed glioneuronal neoplasms after undergoing repeated transplants of 'fetal neural stem cells' in Russia starting in 2001. The article, by an Israeli team who removed the tumours, reports that the growths originated from donor cells derived from two or more tissue sources. See: N. Amariglio *et al.* Donor-Derived Brain Tumor Following Neural Stem Cell Transplantation in an Ataxia Telangiectasia Patient. *PLoS Medicine* 2009; 6(2): e29.

⁸ New anti-aging 'stem cell' products available in the EU do not contain stem cells, or even parts of stem cells, because under European law, it is illegal for cosmetics sold to contain human tissue or human-tissue extracts. If they did, they would have to meet strict regulatory criteria as medicinal products, not cosmetics. While these products are mostly harmless, the marketing of these products is accused of being misleading (although most, on closer examination, claim to only 'harness' stem cell 'potential'.)

question of the status of the embryo. Within these regulatory responses, there is evidence that, even if new or foreseeable threats to ‘dignity’ or liberty remain conceptually befuddling in how exactly they are ‘threats’, there is a willingness to tackle regulatory issues as a matter of political accountability. These national developments require careful consideration in the global context.

The national perspectives, to be found in Part Two of this volume, recognise that unregulated practices threaten the wellbeing of donors and recipients alike. The challenge for international bodies, such as the United Nations, is to create for an environment which is supportive of regulative cooperation with respect to these specific groups, whilst striving to avoid issues seemingly destined for inevitable conflict. This, in turn, will require nations to submit to covenants which protect the interests of donors in non-embryonic areas of stem cell science, while allowing recipients of therapies to benefit from safe and proven technologies.

We now consider in more detail how these broad ethical and regulatory issues play out in the contributions to this volume.

PART ONE

CONTESTED CELLS: UNDERSTANDING THE ETHICAL CONTROVERSY

a) The Problems of Regulation

Stem cell science is just one aspect of a widespread technological transformation involving, among others, neuroscience, nanotechnology and reproductive medicine. This kind of progress drives technocratic solutions that permeate into all aspects of life, whether they are welcome or not. These technologies are a challenge to traditional regulatory frameworks found in many technologically-advanced countries. As Roger Brownsword explains: the changes that we are witnessing are ‘highly significant for the future of law and the way that we regulate social life’; and this sea change makes regulation an unwieldy concept.⁹ Time and again, our laws,

⁹ R. Brownsword. 2008. *Rights, Regulation, and the Technological Revolution*. Oxford NY: Oxford University Press: 6–7 and 130.

condemned as archaic, and often hard pressed to keep up, become wholly inadequate.

The first part of the collection begins with a case study, written by Anthony Hollander, which confronts the objectives of effective regulation. The case concerns a group of scientists, of which Hollander was a member, who successfully transplanted a human trachea grown from mesenchymal stem cells into a patient.¹⁰ Professor Hollander's chapter sets out the challenge for the researchers; he writes:

'...therapies will never reach clinical trial or commercial exploitation because the burden of meeting regulatory requirements is so heavy that resources will not be available. Patients may continue to suffer and some may die because a new treatment could not be exploited' [61].¹¹

Hollander clearly brings into focus the problem of overregulation; of the fastidious and protracted assessment of risk, and which sometimes means that opportunities — or even lives — are lost. Society's response to controversy inevitably swings to conservative-minded principles. This is not to say that research should be deregulated; but unnecessary delay and over cautiousness may hamper innovative research. Hollander writes: 'As a scientist I have been trained to pay attention to every detail, make no assumptions, test every theory to the limit of technical capability and even then to be aware that my hypotheses may be wrong' [58]. But, the urgency of the situation in this case meant that normal regulatory measures would have to be circumvented — not because of a maverick irresponsibility and disregard for time-wasting measures — but because 'we might, just might, make a real difference to this lady's life and surely it was worth trying' [59]. Hollander and his colleagues decided to 'plunge headlong into helping those who are suffering' [62]; and through numerous special permissions granted by the UK and Spanish regulatory

¹⁰ The transplantation is reported in: P. Macchiarini *et al.* Clinical Transplantation of a Tissue-Engineered Airway. *Lancet* 2008; 372: 2023–2030.

¹¹ Where a quote appears in the text followed by a page reference enclosed by square brackets, it should attributed to the proximate named author(s), and the page to his or her contribution in this volume.

authorities, were able to transplant the new organ successfully. Hollander's plea, therefore, is not to deregulate, but to ensure that regulators are skilled in ethical review; and that they appreciate that sometimes, specified risks are worth taking. This may require, given the circumstances, the bending of procedural oversight. It does not suggest the breaking of ethical norms, or the justification for reckless abandon. Sometimes, it takes a certain risk-taking vision to make the significant steps in medicine: if taking these risks are worth it when the patient benefits, the patient only suffers when progress is blocked.

The problem, as Hollander acknowledges, is that while evaluators have no choice but to work within the regulatory framework that has been established in law, the challenge is to appraise translational research effectively. His observations, from the view of a scientist, imply that sometimes the bar for research approval is set too high with respect to proving the benefits; furthermore, the bureaucratic hurdles can be complicated and time consuming. However, throughout this book, the plight of patients being misled and harmed through exposure to treatments which lack scientific validity is highlighted. These cases appear principally to be a phenomenon of 'regulatory havens' which harbour unscrupulous clinicians. The difference between these jurisdictions and regulated countries is stark. Within a provisionally effective ethical regulatory framework, no patient is exposed to experiments that are not valid in principle. Nor are they forced, coerced or tricked into taking part. But there are concerns when loopholes, a lack of interest, or economic motivations, permit scientists and doctors to bypass normal scientific and ethical oversight.

Hollander and his colleagues did not operate in an ethical vacuum, and in fact were more than honest in their attempts to expedite the process. Throughout, the patient was well informed and a willing participant, albeit in an experimental procedure. (This, in itself, is not uncommon in medical innovation.) It is possible, therefore, that the kinds of risks that Hollander talks about can only plausibly happen where there are *strong* regulatory frameworks and a *willingness* to monitor research. In this context, an ethical bar is set, either through national, regional or international measures. Sometimes getting over it may be perceived as requiring an unreasonable or unattainable absence of risk. But, scientists and doctors within regulated environments operate within a culture of responsibility to

patients and their peers (a high calling indeed), and the requirement for proper scientific validation. Risks, therefore, can be taken only within a framework of evaluation and oversight (because one can only know the extent of these risks after impartial due consideration). All research involves a degree of risk; and the challenge for those that are responsible for approving research is to weigh it appropriately: what this amounts to changes from case to case, and patient to patient. This balancing requires skill, and while many countries create an environment to promote adept ethical review, others have failed to ensure levels of proficiency and accountability.

International Regulation

The regulatory challenge means different things to different countries. The essay by Donald Chalmers helpfully describes some of the most important developments in this respect. The ‘embryo question’ continues to resist straightforward solutions (compromise, not surprisingly, is still elusive), and it is now part and parcel of the regulation of the wider reproductive enterprise, that includes human cloning, fertility medicine, genetic selection (PGD), and chimera and hybrid research. Chalmers notes that there are predominantly three kinds of control to be found: *strict regulation*, *licensing schemes*, and *guidelines regulation schemes*. All of these characterise a default ‘restrictive tilt’: that countries favour either *regulated* permission (the tilt is against prohibition) or prohibition (*vice-versa*) of embryo research. The corresponding laws tend to be complex in their coverage of a myriad of activities and techniques, and as a result, legislative interpretation has become intricate, and sometimes, bewildering in its ambitions. If countries bring the stem cell controversy under a *permissive* regulatory umbrella, a list of permissible activities will be drawn up; also stipulating what activities will continue to be categorically prohibited. A *prohibitive* tilt will ban the derivation of cells within national borders. In these countries, the laws are often straightforward in stipulating that embryo research is not permitted, thus implicitly prohibiting other related technologies. Sometimes they remain naive to the problems of tying up loose regulatory ends — for example, addressing the migration of patients to more permissive states; and by embracing progressive change to a

degree, one wonders as to the legitimacy of the policy (for example, policies seem contradictory in their moral consistency in banning embryo research while promoting their ambitions for the import of embryonic cells from other jurisdictions).

The default of this ‘tilt’ depends on each country; and in closer examination, it is evident that there are a number of cultural and historical factors that determine this. There is a good deal more to know about each country’s regulatory mix — there are few laws which evince a blanket prohibition or open permission — and instead an enquirer will find a patchwork of measures. One has to do some leg work to find out the terms on which research is permitted or prohibited, and then translated into the clinics (an area which is critically underdeveloped in most regulatory schemes, suggesting that most are confident, but perhaps unduly so, in current clinical regulations to adapt to stem cell science).

Chalmers concludes that the *International Society for Stem Cell Research (ISSCR) Guidelines for the Conduct of Human Embryonic Stem Cell Research (December 21st, 2006)* are a central contribution to the future development of responsible stem cell applications and therapies as stem cell research moves gradually into the clinic. The problem with any international guidance, however, is that it requires countries to assimilate common norms; a point taken up by Daniela Cutas and Christian Munthe in the next chapter. They argue that effective global or multinational regulation of stem cell research will imply some degree of imperialism; that is, to achieve effective international regulation, involved parties will have to be willing to accommodate (either permissive or prohibitive) regulations within their own laws. They explore this phenomenon in the context of extraterritorial jurisdiction and embryo research.

The authors note that extraterritorial jurisdiction is acknowledged in the ISSCR Guidelines as ‘Responsibility for Conduct’ of researchers.¹² However, because researchers will be expected to work between jurisdictions, the Guidelines instruct them to ‘assume the responsibility for compliance with local statutes and adherence to guidelines’.¹³ It is also likely that the translocation of clinicians and patients to other jurisdictions

¹² ISSCR, *op. cit.* note 6, para. 5.1.

¹³ *Ibid.*: para. 5.2.

will expose them to diverse, and sometimes bewildering, laws. As some have argued, the solution to impending accidental transgressions, and to facilitate cooperation, is to harmonise international regulation under a universal set of rules; but this is suggestive of a common ethical framework underlying those laws, as well. Cutas & Munthe argue that ‘the prospect of a globally harmonised regulatory framework [is] considerably more vulnerable to the existence of very restrictive views’ [97]. And they note further: any moral reasons for the ‘consistent legal application of the moral view underlying the restrictive legislations would imply that the ES cell research is, as a matter of fact, a case of genocide’ (emphasis in original) [105]. This does not mean that we can easily discount ideas of a prohibitive nature:

‘Since logic dictates that, on the basis of such a [prohibitive] moral evaluation, ES cell research amounts to genocide, ES cell research would look like a classic example of the sort of act where ...extraterritorial jurisdiction is often seen as acceptable within international law’ [97].

But they further argue that it ‘becomes a deeply problematic feature [of extraterritorial jurisdiction] in cases where deep and wide disagreement exists as to whether or not certain activities belong to one of these types’ [98]. Cutas & Munthe are right to say, that, given the evidence, restrictive measures would require an unjustifiable transgression into the sovereignty of liberal pro-embryo research countries. Moreover, a restrictive position would ‘risk setting in motion a chain of events that would jeopardize international financial and political stability on a scale considerably larger than merely the ES cell area and, possibly, with vast effects in terms of life and health’ [118]. They conclude that the restrictive use of extraterritorial jurisdiction potentially ‘clouds the vision of a global substantial regulation of ES cell research and rather inspires international conflict’ [116].

The concerns that Cutas & Munthe raise are similar to those which were expressed by the European governments that objected to the proposed ethical stance of the European Union’s *Tissues Directive*.¹⁴ In the

¹⁴ *Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells* (Final Act OJ L 102 7.4.2004 48).

early drafting of the Directive, the *Liese Report* attempted to guide the ethical debate towards a harmonised conservative position, and therefore restrict embryo research that was being conducted, legally, elsewhere.¹⁵ The restrictive tone of the Report was eventually dropped; and the final position taken echoes the view of the *European Group on Ethics and New Technologies* (EGE) that ‘It is not only legally difficult to seek harmonisation of national laws at Community level, but, because of lack of consensus, it would be inappropriate to impose one exclusive moral code’.¹⁶ The result was a set of minimal standards stipulated by the *Tissues Directive*, but which reflected inherent regulatory pluralism by remaining neutral about controversial research, stating:

‘This Directive should not interfere with decisions made by Member States concerning the use or non-use of any specific type of human cells... including embryonic stem cells. If ...any particular use of such cells is authorised in a Member State, this Directive will require the application of all provisions necessary to protect public health...’.¹⁷

And furthermore, it was stated that the ‘Directive shall not prevent a Member State from maintaining or introducing more stringent protective measures [which] include the prohibition or restriction of imports of human tissues or cells.’¹⁸ Thus, the Directive set out rules which were easily transferable to established national legislatures, focussing on safety and consent issues predominantly, but which would also act as a guide for new states joining the Union.

The problem becomes more acute when countries collectively become global in their ambitions, such as those of the United Nations (UN).

¹⁵ See: B. Capps. 2005. The Human Embryo, Stem Cell Research, and the European Union. In *Crossing Borders. Cultural, Religious, and Political Differences Concerning Stem Cell Research: A Global Approach*. W. Bender, C. Hauskeller & A. Manzei, eds. Münster: Agenda Verlag: 435–467.

¹⁶ The European Group on Ethics in Science and New Technologies. *1998 Ethical Aspects of Research Involving the Use of Human Embryo in the Context of the 5th Framework Programme*. No. 12, 23rd November. Strasbourg. European Commission. p. 10, para 2.4.

¹⁷ *supra*. note 14, recital 12.

¹⁸ *Ibid*. Article 4(2).

Calvin Ho's contribution to this volume considers the UN's 2005 *Human Cloning Declaration* to have been largely a failure as a gesture of moral or legal authority.¹⁹ He notes that, during the UN cloning debate, the view that there was no real distinction between therapeutic cloning and reproductive cloning, since both involved the use of a common technological process: 'proved attractive to many countries (especially those with a predominantly large Catholic population) without having first arrived at a national position on the subject' [125]. A number of compromise approaches were proposed which were 'not greeted with much enthusiasm' [125]. The impasse remained, despite the observation that reproductive cloning represented an 'imminent threat and prompt response on the part of the international community would be politically expedient' [126]. Ho suggests a number of economic, socio-political and ethical arguments that may have been behind the prolonged wrangling. Noting also that the problem for large, diverse fora, such as the UN, is that there is a substantial group of member states which are largely disinterested in the technology (the remoteness of the issues of human cloning in many developing countries where far more urgent medical and health concerns need to be prioritised); thus weakening the pro-therapeutic and anti-cloning coalitions alike.

Ho remarks, however, that the Declaration did have the effect of motivating countries to get their domestic laws in order. Ho points to the fact that the 'absence of a sufficiently generic "immutable mobile" or "boundary object" that could be easily transplanted from one sociopolitical setting' [123] was a root impediment to progress in the UN:

'The notion of human dignity was itself too vague to inspire action, and also too ambiguous to enable consensus to be forged across a community with varied, and in some respects conflicting interests and concerns' [123].

For Ho, however, this ought not to be considered as necessarily fatal for cooperative international law. His analysis locates shared ethical premises

¹⁹ A/Res/59/280 (23 Mar 2005).

in the separate adjudication work on cloning of the Bioethics Advisory Committee (Singapore) and the Human Fertilisation and Embryology Authority (UK). Both tended to use the ideas of ‘tolerance, compromise and regulation’ [153] as valid responses to questions about effective societal coherence (what has been called the ‘Warnock Strategy’, after the UK philosopher, Mary Warnock)²⁰; and Ho argues that, although their approaches were somewhat different (holistic and incremental respectively), this points to the existence of the ‘immutable mobile’. The question both bodies asked was: How would it be possible to legitimise a permissive tilt — if this seems as rightly being ethical — given the wide disagreement in society (and that a proportion of the population was known to object to embryo research)? Legitimation, in both cases, appeared as a kind of ‘social contract’: ‘in exchange for permitting a limited amount of embryo research the state would assure its strict regulation subject to the very highest standards of public accountability’.²¹

Would such an approach have been applicable to the UN Declaration? Was there a way to countenance both the willingness to ban reproductive cloning, and, to allow those countries that wanted to permit therapeutic cloning to do so within a robust national legal framework? If they could have, instead of concluding the Fifty-Ninth General Assembly with the rather toothless *Declaration on Cloning*, a potentially powerful tool to stop reproductive cloning may have resulted, all the while assuring the global public that therapeutic cloning, where legal, would be subject to the very highest standards of public accountability.

Given the failures of international law, what, then, could be the point of regulatory harmonisation? One should note, for instance, that a number of states had already enacted bans on reproductive cloning by the time the UN’s Declaration had been ratified; and that most countries that were obdurate in rejecting the outright international ban had set high standards of oversight for therapeutic cloning. Moreover, the inevitable

²⁰ S. Franklin & C. Roberts. 2006. *Born and Made: An Ethnography of Pre-implantation Genetic Diagnosis*. Princeton, NJ: Princeton University Press: 197–198; Cf. Department of Health & Social Security. 1984 (reprinted 1988). *Report of the Committee of Inquiry into Human Fertilisation and Embryology*. London: Her Majesty’s Stationary Office.

²¹ Franklin & Roberts, *ibid*, p. 197.

consequence it would seem, as pointed out by Cutas & Munthe in the previous chapter, is an impasse when international law instruments are used in ways to compromise sovereign interest. We may, however, postulate at least three reasons for the specific calls for regulation in this field of research: 1) It gets important issues onto the agendas of states yet to address them. Granted that some states have more immediate concerns, the international forum serves to redirect attention and awareness, and may provide a future environment constructive for collaborative action in this respect. 2) It provides the means for states to try again to gain legal ground on issues they feel strongly about. For example, there are a number of European states which may have considered the permissive tilt of the EU as an abject moral failure; international condemnation may have (although it was unlikely) reversed this trend, or at least resolved ambiguities (where EU law remained silent) in favour of prohibition. 3) Anyone who thought that prohibiting reproductive cloning would face few obstacles, ought to have noted the considerable obstacles that the European Union and Council of Europe had to overcome when creating laws in medicine and science. But, what was forthcoming in these European fora were minimal standards of research, and these have been seen as instrumental in protecting the rights of donors and recipients, and guiding acceding states towards an agreed level of regulation (which in some states was altogether absent at the time of accession).

In the final analysis, the ‘embryo question’ — obliging a jumble of political, religious, and scientific answers, and dispersing into many aspects of technology that force us to look at what it means to be ‘human’ — faces considerable hurdles when transposed onto the global setting. Ho finds some hope, in that countries have ‘developed in ways that have meaning within their local context, and it is also within this context that the political and socio-cultural impetus and resources in resolving conflicts over meaning are found’ [152]. It is these local solutions that are thematic in Part Two of this volume.

b) The Enduring Ethical Debate in Translational Research

The six papers in this section of the volume turn away from the specific problems of regulation to the particular challenges of translational

research. Put in rather general terms: while regulators continue to struggle with several fundamental ideas concerning, principally, the status of the embryo, clinical translation will require a nuanced appreciation of the potential developments in stem cell science.

Clare Williams and Steven P. Wainwright begin this section with an empirical investigation of the ways in which ethical dilemmas and reasoning occur in the translational research and clinical setting. They recapitulate some of their recent work in empirical ethics: exemplar of the specific approach of ‘sociology *in* bioethics’. This method ‘explores the links between bioethics, medicine, science and society and aims to ground more abstract philosophical ethical debates in empirical case studies which explore and describe the embodied ethics of “real actors” in particular social worlds’ [157]. Williams & Wainwright are critical of the ‘disembodiment’ of bioethics by one-sided philosophical debates [163]; their point is that this kind of approach to ethics has tended to dominate technology debates. Enquiring of the opinions of various actors in the stem cell debate — in this case, scientists — can show that significant ethical details may be obscured by policies focused on legitimacy alone. The narrow set of explanations used — perhaps, in the final analysis, only assuring to a few like-minded of an established and worthy doctrine — fail to account for the interest of those actually involved.

These philosophical based arguments, Williams & Wainwright maintain, bring to the fore ‘ethical issues that encompass issues such as: the use and destruction of embryos; informed consent; commercialisation and the commodification of bodies; the “threat” of reproductive cloning; animal rights and species integrity; [and] resource allocation’ [168]. But they argue that this prevailing way of doing bioethics — a ‘view from nowhere’ [168] — misses the point; and they present their own data — asking scientists how they see themselves as ethical, as well as expert, actors, by drawing the boundaries of ethical scientific activity — to bear out this out. They attest that scientists, although bound by the formal legal and ethical framework, are reflective and prepared ‘to venture into ethical argumentation and thereby enter the foothills of normative as opposed to merely conventional ethics’ [167]. This fact leads their challenges to ‘normative bioethics’, and is supported by ‘Our scientists’ refusal to create embryos for research, even though this is legal in the UK

and is something that is promoted by many bioethicists' [167]. An important supposition of their work is that:

'scientists must nevertheless demonstrate their commitment to "ethics" as the audiences of science include various public and regulatory constituencies who, in one way or another, lend the whole bio-scientific enterprise legitimacy' [159].

Their work does indeed shed a different light on the stem cell debate. Returning to Hollander's chapter in this volume, for example, we can immediately locate the 'ethical reflection and rectitude' [167] that Williams & Wainwright found in their studies. The rules of 'ethical' research may be deep rooted in a long history of normative debate, but in the urgent context described by Hollander, they may have become merely hindrances — indeed, the rigid imposition of these rules might well have cost Claudia Castillo her life. Williams & Wainwright's 'descriptive empirical ethics' is important in that it uncovers the inevitable loopholes and weaknesses of regulatory structures by asking of those who spend every day working within them.

Williams & Wainwright's paper is a reflection upon the 'dysfunctional marriage' between sociologists and philosophers. Much like the authors, we do not see that the social science and philosophical approaches ought to be mutually exclusive: the task, Williams & Wainwright declare, is to appreciate how they both are tasks fundamental to bioethics practice. Their position is that the former approach embodies a philosophically dominated bioethics field. But, this is also suggestive of (but does not go as far as) the 'Anti-theory' movement, which advocates that we can do without normative ethics altogether, and that our moral guides ought to be a kind of Humean reflection; that is, ethical solutions ought to be about empirically informed knowledge of sentiment and custom, rather than principles formed from intellectual reason.²² Stuart Toddington comes to

²² Cf. A. Baier. 1989. Doing Without Moral Theory. In *Anti-Theory in Ethics and Moral Conservatism*. S. Clarke & E. Simpson, eds. Albany, NY: State of New York University Press: 29–48.

the philosophers' defence in this respect: the central problems of the methodology of social science require for their resolution the resources of an objective moral theory:

'a "fact" is not *given*, it is the *product* of a framework of assumptions comprising an explanatory or interpretative scheme. This has undermined the notion of "empirical proof"; quite obviously, the "proof" is a product of non-empirical assumptions which themselves stand in need of justification'.²³

Scientists' and clinicians' views about regulatory structures do not necessarily point to their inefficacy or otherwise; they are observations informed by individuals who have a stake in the permissions and restrictions of law. The law tells them what they may or may not do, restricting their freedom of action, and thereby curbing maverick, and sometimes, insidious inclinations. But, the goals, factual circumstances, and context of a particular regulatory regime may be very different from the aspirations of a particular scientist or clinician. Indeed, those that find the rule of law too restrictive will relocate to areas which are more conducive to what they want to do; or even move to regulatory havens, should their ambitions go further than any existing regulatory system. The risk of empirical ethics is to overplay cultural values and sub-cultural sensitivities as determinants of public-orientated regulatory regimes, thus leading to a disciplinary (and relativistic) understanding of legal jurisprudence. Law, thereby, becomes a pragmatic judgement of embodied actors, and only tells us about their own (the regulatee's) depiction of means to ends. But, if a regulatory regime is to avoid the thin ethics that the introduction of pragmatic solutions often leads to,²⁴ a prior requirement of any empirical

²³ S. Toddington. 1993. *Rationality, Social Action and Moral Judgment*. Edinburgh: Edinburgh University Press: x. (Italics in original).

²⁴ Cf. An approach that Robertson appears to support, when he argues (in respect to the creation of inter-species forms): 'when doing so serves important human needs... [as] the question of breaching species barriers is... less a matter of principle than a question of pragmatics and context'. J. Robertson. A Response to 'Crossing Species Boundaries' by Jason Scott Robert and Francoise Baylis. *American Journal of Bioethics* 2003; 3: W64–W65.

approach is for scientific facts to be delivered as neutral statements, thereby stripping them of moral underpinnings. It is worthwhile to find out what moral values different actors attach to their own statements of fact (the ‘realities of situation’); and understanding these values and principles is fundamental to our sociological awareness of events. But it is only by understanding the values themselves, out in the open and in their objective entirety as expressions of *moral* theories, that we can appreciate our complex social structures and then formulate ethical solutions.

Tamra Lysaght and Ian Kerridge likewise use an ‘empirical ethics’ approach to analyze the Australian stem cell policy, which developed in the years 2005 and 2006. Using their own qualitative data, they examine how science was deployed in the claims of participants: observing that the policymaking debate in Australia was typified by the preferential deployment of claims with sound scientific support. The authors claim: ‘Science has a special place in these and other policy contexts because it is posited as the most reliable and value-neutral source of truth and knowledge’ [202]. They noted that the authority figures, such as scientists, involved in the policy process were more likely to control the shape and direction of scientific research. Scientists, therefore, were able to obscure other ideas by making them unsuitable for serious consideration by policy makers (we could imagine that their targets would be those based in religion or culture). And by having the ear of politicians, for example, they could undercut intellectual debate by making other views nothing more than anecdotal; and thus, it would seem, would have the final, and determinant, say in stem cell policies. The authors conclude:

‘The preferential use of science claims in the Australian debate surrounding stem cell research meant that the status attached to scientific knowledge was greater than other ways of knowing and that the personal narratives and stories of those most likely to be affected by the outcomes of the policy episode were marginalised’ [202].

How concerned should we be that the ‘rhetorical power of science claims’ [202] is entrenched in the legitimation process? Legitimation signifies a broad range of public interests i.e. that there are good reasons to choose one policy over another; this, as Lysaght & Kerridge point out: ‘is because the

moral positions upon which the stem cell dispute is fought are fundamentally incommensurable' [203]. Thus, the *legitimacy* of regulatory purposes and practices become secondary, because they are a difficult set of more narrow justifying reasons. Societies who fail to acknowledge the importance of science *within* a framework of public understanding (in terms of what they understand and how it is perceived, and ultimately, accepted), risk the growth of public scepticism and cynicism in the integrity of science-based policy decisions, and moreover, the marginalisation of science expertise.²⁵ Any professed gap between 'the public' and science may be exploited by opportunisms and expediency; thus the principal driving force to *use* science and technology is a political agendum, rather than a justification of whether a technology, in terms of legitimacy, ought to be permitted or not.

Noticing this, the authors remind us 'that science is not value-neutral and does not occur in a political vacuum' [205]. Scientists themselves will have a certain idea of legitimacy which drives their research; they might advocate policies which promote interventions that promise to assist medical research, and in due course, to deliver therapies for major human disease. However, scientists' views also appeal to a specific moral reason and this brings us back to our commentary on Williams & Wainwright's chapter, where we argued that scientists, just as much as any other agent, are under the same obligations to 'persuade' the public as to the legitimacy of their position. That is, whether an adequate ethical justification is available to them to promote their opinions.

Researchers have a central role in ensuring that stem cell science stays within the bounds that are set up by the regulatory regime in which each one of them works; so to speak, the activities of researchers are to be legal, if not necessarily 'ethical', as long as their endeavours meet the immediate jurisdiction's criteria. Researchers' transgressions can have resonating effects on public opinion; witness, for example, the Hwang scandal. Hwang, however, did not only contravene South Korea's laws,

²⁵ See: Lysaght & Kerridge, this volume; see also: L.J. Virelli III. '*Political*' Science: Peer Reviewers as Agents of Administrative Legitimacy. SSRN 2008. Revised (and published) as: 'Training the Elephant in the Room: Scientific Peer Review and Administrative Legitimacy'; last revised March 24, 2009; *Administrative Law Review* Fall 2009. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1259801 [Accessed 08 Sep 2009].

but also long standing, universal standards of ethics. Hwang, from his luminary status, was able to coerce junior colleagues to donate oocytes; and if we learn anything from this affair, it is that society must be watchful of other exploitative practices driven by the 'business of science'. In their contribution, Jonathan Mackenney and Benjamin Capps consider the micro-event of procuring cells for stem cell work, focusing in particular on the future of research on induced Pluripotent Stem cells (iPS cells). There have been claims that iPS cells are an 'ethically clean' alternative to contentious embryo research and cloning technologies currently used. To create these immortal cell lines, the raw material needed is procured by a simple biopsy, for which consent can easily be given. What instead has happened, however, is a culture of routinely procuring cells for research without asking the patient; this is easily done by hiding the intention to appropriate cells within the medical procedure. The justification for this is the trumping of consent requirements by the 'good of science'. But this typically utilitarian grounded vindication exploits the intimate access to the body that is generated by an ongoing physician-patient relationship. The authors argue that this research practice ought not to endorse, nor be intentionally conflated with, medical goals: if patients are not told about the research aims, or are led to believe wrongly that excised tissue is for medically indicated procedures only, then they cannot be said to have consented to its use in research (regardless of the research's propinquity to the medical procedure). Moreover, without authorisation (in any form), additional biopsies or collection of abandoned tissue entail an unacceptable level of deceit or misinformation.

The authors' argument stems not only from the non-consensual insult to the body, but also from privacy rights that endure in excised cells; and by virtue of these latter rights (rather than any proprietary rights) an interest continues in the fate of the cells, despite the transfer (consented to or not) of property. This privacy interest can be removed by first asking the patient for access to the cells, and secondly, authorising the endeavours of researchers in creating, and therefore owning, an immortal cell line. They do not argue for stringent informed consent, because, given the dynamic field of stem cell science, to give general information is not to deny the donor the facts, but truly due to the uncertainty of research aims and future technology. But, rather than duping patients about the fate of

cells taken during unrelated medical procedures, which is sure to foster distrust in researchers, an acquiescence to consent norms may develop enthusiasm on the part of the donor to willingly, rather than unwittingly, take part in research. By looking at the consent procedures of UK biobank, which are designed to develop an ongoing relationship with participants, Mackenney & Capps propose that a similar partnership ought to be created between the research community and the public, which not only benefits, but also contributes to, scientific endeavour. Such a partnership may be particularly important given the physical and psychological status of patients who donate not for personal gain, but who want to contribute to the endeavour of treating those with similar illness.

James Yeates' chapter sets out to address the omission of nonhuman animals from the discussion of the ethics pertaining to stem cell therapies. He notes that, while the advent of stem cell technologies has been against a backdrop of concern about the use of increasing numbers of nonhuman animals in the laboratory context, there has been relatively less said about animal welfare. Yeates, in this respect, asks whether it is acceptable to 'inflict' suffering on nonhuman animals in the testing and development of clinical stem-cell therapies [242]. This chapter focuses on the *interests of the animals themselves*. By using a novel deployment of John Rawls' approach in Justice as Fairness, Yeates argues that life has instrumental value for animals (leaving open the question of whether their life might additionally have intrinsic value to them). He states:

'Life is instrumentally valuable for an animal because it permits it to have "positive" ends: enjoyable, eudaimonic states... Thus life is valuable to an animal if it affords sufficient positive value to outweigh any negative value: this is a life worth living. The desirability of a state of positive welfare is categorically valuable and this affords an instrumental value to life' [242].

The application of this Rawlsian framework reveals that a number of veterinary relationships established by UK and EU law can be considered unfair to the animal itself; they contribute to a 'Life Not Worth Living' (LNWL). As Yeates remarks, Rawls did not overtly extend Justice as Fairness to the veterinary context (but neither did he include sick humans

in his distributive theory, instead hypothesising the idealised participation of healthy individuals in the Original Position). This, Yeates argues, opens up the Original Position beyond its strictly epistemic conditions; and this way into Rawls' theory allows the moral consideration of the severity and duration of suffering of animals. This is a level of welfare that we ought to avoid inflicting upon sentient animals, and should their lives fall below this, there is a moral duty to end such an existence. Instead, what society should aim for is providing 'Lives Worth Living' (LWL) for animals. Thus, the principles of justice as fairness would prescribe that all animals should have a guaranteed minimum opportunity, regardless of context and species, to ensure intra-contextual and intra-specific fairness. These rules potentially permeate into all aspects of animal welfare (pet ownership, husbandry and animal research). And specifically:

'Stem cell therapies cannot be legitimately used to provide further companionship for an animal's owner, increase performance of sports animals or increase productivity of farmed animals, if that requires the animal having a LNWL. Animals with diseases should be euthanased if the treatment cannot avoid their having a LNWL. ...The main fear with novel therapies is that they are implemented by clinicians enthusiastic about the novelty and progress, rather than about the interests of the animal itself' [274].

Such a framework can be extended to animal research, thus limiting the human 'benefits' that come at a cost to animal interests. Yeates' framework adds further philosophical strength to Russell & Burch's 3Rs — Replacement, Reduction and Refinement.²⁶ And while stem cell science raises the prospect of ever more animals being employed in research and therapy; it may, conversely, foster opportunities to decrease the unfair suffering of animals by using *in vitro* grown human organs and tissues as an alternative.

However, the application of Justice as Fairness, Yeates readily admits, risks foregoing significant benefits to humans: 'under Justice as Fairness

²⁶ W. Russell & R. Burch. 1959. *The Principle of Humane Experimental Technique*. London: Methuen.

the benefits to other subjects would not legitimise keeping any subjects with a LNWL, any more than any other system which lowered the maximum for the benefit of any better-advantaged citizens' [276]. He does add the following caveat: 'If subjects are considered as individuals extended in stages through a lifetime, then short periods of LNWL might be balanced by periods of LWL. This would effectively be a refinement, but one focusing not on lessening pain but on increasing positive experiences as counterbalance' [276].

Yeates' chapter takes a different path from those more common arguments which see the conflict between human beings and animals as irreconcilable until we acknowledge that non-human beings have a place in our moral framework. This latter view has drawn attention to the inconsistency of denying a moral role to biological characteristics such as race or sex, while at the same time attributing a moral role to another biological characteristic such as species. These arguments tend towards a concept of a 'person', who is self-aware or sentient, and therefore brings some non-human animals into the moral community, while sometimes excluding human beings at the fringes of life.²⁷ The evident complexity of social structures, however, undermines simplistic 'balancing of interests' arguments (of the kind presented in modern Millian ideas), and fails to acknowledge that decisions made by thinking beings presuppose the circumstances of their own bonds and relationships to non-sentient human beings. That is not to say that human and non-human moral entitlements cannot be relationally similar, but this requires a deeper understanding of the conditions of agency and our responsibilities to other non-agents.²⁸ The corollary, of course, is that there is something special about human beings — their 'dignity' perhaps — and this reserves the moral sphere for only human beings, including those which are non-sentient (a point that Yeates touches upon in his concluding remarks: 'An embryo, without basic neural structures cannot suffer, and therefore *ceteris paribus* cannot have a life worth living' [276].) Yeates, in this respect, successfully

²⁷ Cf. P. Singer. 1975. *Animal Liberation: A New Ethics for our Treatment of Animals*. New York: New York Review/Random House.

²⁸ D. Beylveid and R. Brownsword. 2001. *Human Dignity in Bioethics and Biolaw*. Oxford NY: Oxford University Press.

disassociates the ‘animal debate’ from the embryo question, and draws much needed attention to the improvement of animal welfare.

Returning to the Embryo Question

The ‘embryo question’ asks: what is it about a being that makes it worthy of moral status? The implications of this question are the background of Joseph Kure’s chapter, in which he analyses the notions of human-animal biological mixtures. His chapter is a thought-provoking search for the ontological status of these beings, and specifically a clarification of what we are really talking about when we call a thing a ‘chimera’ or ‘hybrid’ (what has been called an ‘admixed embryo’ in UK law, to differentiate from ‘true chimeras’ — the fertilisation of a human egg with animal sperm or *vice versa*). His focus is on the research interest in these entities, writing that ‘repeating the humanzee experiment is not a project that many researchers want to try, or one that would get support from an ethical review board given its questionable scientific merits and the moral concerns’ [289].

The interest in creating human-nonhuman mixtures has been driven by the lack of human oocytes for research; the immediate solution, so some scientists claim, is to use those from animals. The controversy of such a move is well captured in Kure’s essay. He traces the origin of the chimeric being back to antiquity, and notes the awe that these beings held in various cultural and historical contexts. Even modern science struggles with the intangible status of such beings: ‘it is difficult to apply our classification and categories for novel beings or “in-between” species, that do not occur in nature, and which do not fall under the (well) defined categories used in biology’ [306]. The apparent breakdown of the distinction between human and inhuman, human and animal, has been a familiar topic in the media. In the horror genre, for example, the beings are a feature of disgust, but also curiosity, possessing a ‘half-hypnotic fascination’.²⁹ But the animals portrayed with human characteristics, such as speech and recognisable

²⁹ As an exemplar of the characterization of ‘monstrous hybridity’ from H.P. Lovecraft’s ‘The Shadow Over Innsmouth’, first published in 1936, by Everett, PA: Visionary Publishing Co. Chapter IV. Available online at: <http://www.hplovecraft.com/writings/fiction/texts/soi.asp>. [Accessed 08 Sep 2009].

human facial expressions, are often creations that we welcome as friendly companions; and even the ‘good guys’ when pitted against the environmental excesses of human ascendancy. But if these beings are not ‘human’, then what are they? Inevitably, this uncertainty is played upon to create a format for their oft expected ‘anti-human’ character; or to surprise us when a non-human displays, unexpectedly, human virtues. However, while the distinction between the living and breathing human-animal creatures found in text and celluloid are far removed from the cellular entities imagined in stem cell science, the tendency is to incite deep-seated ideas of repagination. As one commentator stated:

‘There is a lot of innate wisdom in the “yuck” factor, or repugnance as it is also known. My Question is: what will they actually create? It is simplistic or deliberately deceptive to say that they are simply making stem cells. In order to obtain stem cells they surely have to go through the blastocyst stage; they have to create a “something” from which to derive the new cells. What is this something? It must be human to be of any use to researchers’.³⁰

We can split this objection into two parts: objection to transferring human genetic material into the nonhuman; and creating human-animal beings to then be destroyed in stem cell research.

The principal goal of stem cell scientists at present is to transfer the genetic coding of human beings into enucleated animal oocytes to create ‘cybrids’ (through interspecies somatic nuclear transfer).³¹ The aim here is not the creation of postnatal beings, but to develop stem cells genetically related to the donor they were cloned from; this has been called ‘therapeutic cloning’ because of the possibility of deriving matched cells

³⁰ J. Quintavalle, quoted in: I. Sample. 2006. Stem Cell Experts Seek Rabbit-Human Embryo. *The Guardian*. Friday 13 Jan.

³¹ They would carry mitochondria of both human and animal origin. The first report of such an entity was reported in: Y. Chen *et al.* Embryonic Stem Cells Generated by Nuclear Transfer of Human Somatic Nuclei into Rabbit Oocytes. *Cell Research* 2003; 13: 251–263; also see: S. Minger. Interspecies SCNT-derived Human Embryos — A New Way Forward for Regenerative Medicine. *Regenerative Medicine* 2007; 2: 103–106.

for treatment. One justification is to address the current paucity of oocytes available for use in human embryonic research, and meet the inevitable demand that clinical transition will create. Scientists are also attempting to create modified embryos and cells which mimic the genetic defects found in humans.³²

The recombinant procedures scientists employ to move DNA from one cell to another are adapted from processes found in nature, and which have been used in research and therapy for some time. Genetically modified bacteria are used to produce human insulin to treat diabetes, and clotting factors to treat haemophilia (these are ‘cellular hybrids’, because daughter cells will have identical human-bacterial genomes).³³ Pig heart valves have already been introduced into humans. But on a much larger scale, the future may see human organs developing inside animals, forming a chimeric being with two distinct cell populations: the human organs within the animal vessel.

While these experiments do present certain risks, for example, the chance that animal viral vectors may be encouraged to cross over into human infection,³⁴ conceding the repugnance of such experiments is more problematic. The ethical question is whether a human genome, or parts thereof, relocated into an animal cell really does warrant the aforementioned response? Genetic modification has always tended to incite a degree of trepidation: witness, for example, the rejection of GMO crops.³⁵ The response continues to be indicative of the permeation of the precautionary principle (and scientific scepticism) into regulatory policy. But for some, it is too easily appropriated by those who have their own moral or

³² For example: P. Catalina *et al.* Genetics Stability of Human Embryonic Stem Cells: A First-Step Towards the Development of Potential hESC-Based Systems for Modeling Childhood Leukemia. *Leukemia Research* 2009; 33: 980–990.

³³ G. Walsh. Therapeutic Insulins and their Large-Scale Manufacture. *Applied Microbiology and Biotechnology* 2005; 67: 151–159; S. Pipe. Recombinant Clotting Factors. *Journal of Thrombosis and Haemostasis* 2008; 99: 840–850.

³⁴ National Health and Medical Research Council. 2005. *Statement on Animal-to-Human Transplantation (Xenotransplantation) Research*. 10 March/Final report and advice to the National Health and Medical Research Council; Sep 2004.

³⁵ L. Levidow. Precautionary Uncertainty: Regulating GM Crops in Europe. *Social Studies of Science* 2001; 31: 842–874.

political agenda in relation to objectionable biotechnology.³⁶ However, while precaution may in some circumstances unjustifiably restrain the free hand of scientists, it also allows policy makers to avoid foreseen (or merely hypothesised) threats and irreversible damage — a factor often overlooked by those overly optimistic about science.³⁷

The second objection reflects the still deep-rooted controversy concerning the status of the human embryo. For some, this technology means creating ever more of human lives from an unlimited supply of animal oocytes, and this compounds the unacceptable destruction and commodification of human life. There has been little headway in resolving this issue; with religious doctrine and philosophical ideas of potentially and proportionality, being pitted against utilitarian-type arguments grounded in sentience, and human rights arguments derived from the concept of agency.

However, there is also a concern that these human-animal beings — cloned and genetically modified — will possess, in some way, human attributes. In this respect, *The UK Academy of Medical Sciences* stated:

‘If the concept of “human dignity” has content, it is because there are factors of form, function or behaviour that confer such dignity or command respect. Either hybrid creatures would also possess these factors or they would not. If they do possess these factors, they would also have a specific type of dignity analogous or identical to human dignity that other creatures lack; if not, they would not’.³⁸

We can surmise that the *Academy* is suggesting that human-animal mixtures would fall into either the animal or human category — not both.

³⁶ H. Somsen. 2008. Cloning Trojan Horses: Precautionary Regulation of Reproductive Technologies. In *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes*. R. Brownsword and K. Yeung, eds. Oxford: Hart Publishing: 221–242.

³⁷ Cf. S. Holm & T. Takala. High Hopes and Automatic Escalators: A Critique of Some New Arguments in Bioethics. *Journal of Medical Ethics* 2007; 33: 1–4.

³⁸ Academy of Medical Sciences. 2007. *Inter-Species Embryos: A Report by the Academy of Medical Sciences*. Jun. London: Academy of Medical Sciences: 29.

And if it made it into the latter, then the being would have the status of any other human being and any rights that follow. Arguments for fundamental human rights can be categorised into two broad camps: the ‘dignity’ view, and the ‘agent’ view. The former, which is prominently voiced, so it is argued, in many international conventions, stresses that human beings, by being virtue of being *human*, have rights. But, on this view, it would seem that no non-human being could ever have rights. While this claim raises the familiar charge of ‘speciesism’, we are left also with the perplexing question of how much ‘human’ is *human* enough.

The agent view narrows the focus of rights to the capacities of a being that is capable of self-regarding law; that is, a capacity for rational constraint of their conduct. When this normal capacity dips, then rights are withheld proportionally. On this view, rights are claims made by those who can, and not claims made on behalf of those who cannot.³⁹ While this view leaves us with the troubling question of what we can do to non-rights holders, it does mean that we have to take the potential agent status of human-nonhuman animals seriously. But, we do not know yet whether a mouse with a brain containing human neurones is a cause for concern in this respect: will it be able to think ‘human’? So far, we have made few strides in affording rights to any non-human animals, which nevertheless show characteristically significant capacities of agency. And this does represent a far reaching ethical question: whether societies are comfortable with a potential widening of the circle of rights holders? If these anomalous beings are seen as ‘persons’, then are we willing to welcome them into our current framework of human rights? We suspect that the inherent difficulties in granting *human* rights to all human beings, the failure to recognise the fundamental interests of *all* human agents throughout the world, and the continued exclusion of all other beings from this moral framework, makes this unlikely. Since it is doubtful that we will be able to settle on how much ‘humanness’ makes a being a ‘person’, such beings, if ever created, are likely to become objects of experimentation and imprisoned in the laboratories from whence they came.

³⁹ D. Beyleveld. 2000. The Moral Status of the Human Embryo and Foetus. In *The Ethics of Human Procreation*. H. Haker & D. Beyleveld, eds. Aldershot: Ashgate: 59–85.

Teoh Chin Leong's chapter examines the role that religion can play in public discourse. He approaches the task from the ground up, using the ideas of Robert Audi about the cultivation of an ethics of citizenship: a substantive *and* procedural framework for reducing resentment, alienation and divisiveness, and increasing cooperation, harmony and respect.⁴⁰ Teoh argues that Audi's theory is a plausible account of how religion ought to be incorporated into public policy debates. Teoh's chapter is a convincing account of the development of what he sees as a false dilemma driving a wedge between substantive ethics and proceduralism (we pick up on proceduralism again, below). He sees as more important to human flourishing, given a 'presumption of undecidability' that contributes to the separation of religion and secular beliefs,⁴¹ an idea of *virtue-based process legitimacy*: 'In a procedural account of ethical citizenship, it is the principles, values, virtues, attitudes and dispositions that accompany civic engagement that are important... these traits or virtues ...help to (procedurally) guide and facilitate fruitful dialogue amongst discoursing parties in an open, civil and respectful manner'.⁴² This, Teoh claims, ought to facilitate cooperation between religious institutions and the drive for political order and public policy; however, he laments the absence of such virtues in 'newspapers, public talks, letters to the forum, on the internet or in public and interest group debates' [341]. In criticising two examples from the stem cell debates, one rooted in religious doctrine, the other from a 'pro-embryo research' commentary, Teoh argues that the '*spirit* of public debate and inquiry' [355] are lost to dogmatic (both religious and secular) beliefs. Instead of such biased discussions, Audi's three principles of *secular rationale*, *secular motivation* and *theo-ethical equilibrium*, ought to be the starting point for a 'civically-conscious discourse ...[and should] promote our flourishing goals whilst ensuring the moral legitimacy of ethical debate and public policy' [356].

⁴⁰ R. Audi. 2000. *Religious Commitment and Secular Reason*. Cambridge, UK; New York: Cambridge University Press.

⁴¹ R. Ashcroft. Fair Process and the Redundancy of Bioethics: A Polemic. *Public Health Ethics* 2008; 1: 3–9: 3.

⁴² Teoh, this volume [340–341].

Teoh's chapter concludes Part One of this volume; his observations on the virtues and the procedures of policy making, ideally set up the following chapters on global perspectives in stem cell research. Although the subsequent papers, representing various national approaches to the stem cell issue, are focussed on the grand design of regulating this controversial issue(s), it is worth while considering the characters, whether good or bad, that contribute to policy decisions: politicians, civil servants, and experts representing religion, culture or science; and how their dispositions and roles are integrated with ideas of public good or interest. Policies become 'ethical' or objectionable not only on the basis of their procedural validity, but also on the logic of substantive justifications, and the skills of those who make them. The public's confidence in these decisions depends, in part, on the conviction that they are made by virtuous players, and based on good reasons. And, whether one argues that the fact of plurality requires mechanistic frameworks to guide our public ethics, or bemoans the presumption of undecidability which discourages the real 'bioethics' task of finding normative resolution, communities will continually collide with contested issues that require some kind of ethical solution. Therefore, they will need people willing and capable to meet this calling. In the following Part Two, the reader will find examples of the ethical 'solutions' used by different countries in the stem cell debate.

PART TWO

GLOBAL PERSPECTIVES

The five papers found in Part Two of the volume represent unique perspectives on regulatory developments in seven countries active in stem cell research, and one where this kind of science is less developed (for reasons that will become apparent). In stem cell science, there are four distinct regulatory categories depending on the origin of stem cells: 1) somatic stem cells (either donated, or from 'waste' and 'discarded' tissue); 2) foetal stem cells from abortuses; 3) cord blood cells; and 4) embryonic stem cells. In this latter category would also be included the further controversies of chimera-derived stem cells, and those created through therapeutic cloning. Very little is said in the proceeding chapters about the *regulation* of first kind of stem cells; and with very few exceptions, the clinical transition 'from bench to bedside' has

attracted relatively little regulatory notice. This is because although iPS cells feature as a newly conceived cell type, their regulation has tended to fall in line with existing measures to regulate cells and tissues.⁴³ This is not without its controversies, as discussed by Mackenney & Capps in this volume, and referred to earlier in this introduction.

Foetal Stem Cell Regulation

With respect to the second category of cells, regulation has appeared to remain fairly static. Although the potential isolation of foetal stem cells has originated a good deal of controversy, the regulation of such research has tended to be conceptually fixed to the kind of rules first promulgated by the *Polkinghorne Report* in the UK.⁴⁴ The Report was principally about deflating any possible influence that imminent foetal research may have on the decision to terminate a pregnancy. The consent of the pregnant woman was central, and the ethical debate concerned who should ask, and at what point — before or after the termination — it would be acceptable to do so. At the time, the Report came under criticism, principally on its implication that commodification of unborn life was permissible, and because of the inexorable ethical inter-relational concerns of foetal use and abortion.⁴⁵ More recently, the Polkinghorne guidelines have been questioned as appearing disconnected from modern medical science. For example, in ‘excluding clinical investigators from the clinical care of women undergoing pregnancy termination the [Polkinghorne] guidelines codified distrust of clinicians who undertake research’.⁴⁶ This situation is potentiality inhibiting progress in modern foetal medicine, because it suggests that obstetricians cannot be associated with foetal research; and, some argue, that the requirement for separation is unnecessarily hampering the collection of stem cells at the

⁴³ See, for example, the EU’s Tissues Directive, *op. cit.* note 14.

⁴⁴ J. Polkinghorne. 1989. *Review of the Guidance on Research Use of Foetuses and Foetal Material*. HMSO: London.

⁴⁵ J. Keown. The Polkinghorne Report on Fetal Research: Nice Recommendations, Shame About the Reasoning. *Journal of Medical Ethics* 1993; 19:114–120.

⁴⁶ J. Kent & N. Pfeffer. Editorial: Regulating the Collection and Use of Fetal Stem Cells. *British Medical Journal* 2006; 332: 866–867.

time of termination — there are, it is claimed, ethical ways to connect this process.

Cord Blood Regulation

The use of cord blood-derived stem cells⁴⁷ has been thought by some to avoid the ethical constraints found in other sources, because it utilises an otherwise routinely discarded ‘waste product’ of maternity hospitals. For some time, cord blood has successfully been used for treatment of a number of childhood diseases.⁴⁸ This kind of allogenic, non-directed donation grew into a tradition of public, rather than private, banking of cord blood. However, because of progress in isolating and expanding its stem cell content, cord blood has become of increasing ‘bio-value’ as an autologous resource. Thus, the growing industry in private banking of cord blood has become a notable ‘health insurance policy’ for children worldwide. The UK’s *Royal College of Obstetricians and Gynaecologists* summarised the current situation:

‘There is substantial speculation about the use of cord blood non-HSC in treatment of a variety of acute and chronic conditions but there is increasing evidence of the use of fetal-derived stem cells in the treatment of neurological disease⁴⁹ and a number of preclinical studies in animal models, which suggest an improvement in cardiac function following infusion of umbilical cord stem cells for acute myocardial infarction.⁵⁰ There has also been a report of the infusion of cord blood

⁴⁷ C. McGuckin *et al.* Production of Stem Cells with Embryonic Characteristics from Human Umbilical Cord Blood. *Cell Proliferation* 2005; 38: 245–255.

⁴⁸ E. Gluckman. Hematopoietic Stem-Cell Transplants Using Umbilical-Cord Blood. *New England Journal of Medicine* 2001; 344: 1860–1861.

⁴⁹ S. Dunnett & A. Rosser. Cell Therapy in Huntington’s Disease. *Neurotherapeutics* 2004; 1: 394–405.

⁵⁰ B. Kim *et al.* Cell Transplantation Improves Ventricular Function after a Myocardial Infarction: A Preclinical Study of Human Unrestricted Somatic Stem Cells in a Porcine Model. *Circulation* 2005; 112 (9 Suppl): 196–204; J. Leor *et al.* Human Umbilical Cord Blood Cells: A New Alternative for Myocardial Repair? *Cytotherapy* 2005; 7: 251–257; H.E. Broxmeyer. Biology of Cord Blood Cells and Future Prospects for Enhanced Clinical Benefit. *Cytotherapy* 2005; 7: 209–218.

stem cells in a patient with longstanding spinal injury.⁵¹ Commercial cord blood banks are citing such preliminary research as further potential uses in their literature. In addition, websites are now offering cell therapy using cord blood cells ahead of formal clinical trials'.⁵²

However, the *Royal College*, along with other groups, have repeatedly voiced their reservations about the emergent trend of unregulated private banking.⁵³ The principal concerns are twofold. Firstly, there are concerns that the practice of collection — driven by extraneous economic interests — places the health of the neonate secondary to obtaining cord blood of sufficient volume and quality. It is also important to note that should external contracts be established for collection, this risks dividing the duties of the attending physicians, because it is not clear what their role is in the agreement between the mother and the collection/storage bank (which may be based in another jurisdiction).⁵⁴ Secondly, while it may well be prudent to store cord blood for future use, the *clinical* prospects of this future are not evident. There are no treatments currently available beyond those developed in the late 1980s; and there are no reputable scientific reports to support the imagined clinical targets of regenerative medicine. At present, banks can only

⁵¹ K.S. Kang *et al.* A 37-Year-Old Spinal Cord-Injured Female Patient, Transplanted of Multipotent Stem Cells from Human UC Blood, with Improved Sensory Perception and Mobility, Both Functionally and Morphologically: A Case Study. *Cytotherapy* 2005; 7: 368–373.

⁵² Royal College of Obstetricians and Gynaecologists. 2006. *Umbilical Cord Banking. Scientific Advisory Committee. Opinion Paper 2* (revised Jun 2002).

⁵³ The *European Group on Ethics in Science and New Technologies* therefore advised that: 'The legitimacy of commercial cord blood banks for autologous use should be questioned as they sell a service, which has presently, no real use regarding therapeutic options. Thus they promise more than they can deliver. The activities of such banks raise serious ethical criticisms'. European Commission. 2004. *Ethical Aspects of Umbilical Cord Blood Banking. No. 19*. 16 Mar. Strasbourg: European Commission: 20.

⁵⁴ Where hospitals believe that they will be able to provide this service safely to those who demand it, we suggest that they should make it clear to prospective parents that this agreement will be conditional upon the clinical and logistical demands on the service locally at the time.

offer the facilities for storage, because the technology for treatment does not exist beyond clinical trials; and therefore, the chances of cord blood being used for treatment remains as remote for most patients.

Thus, one might point to the fact that the *promise* of technology shapes how people prospectively (on their own terms) need it. The result is optimism and hope that drives a credulous population to expend resources to bank cord blood, but has the consequence that blood units are locked away from public use (and life-saving allogenic use). Moreover, if one looks to the future of cord blood banking, the focus on 'for-profit' banking, rather than developing public programmes, creates a culture of 'private insurance' to benefit those who can pay. The complaint is therefore one of justice; and some argue that regulatory oversight is necessary for this burgeoning industry.⁵⁵

Embryonic Stem Cell Regulation: Political Tension and the Law

The fourth regulatory category has come under most ethical scrutiny. As was evident in the first part of this volume, many of the current questions come back to the controversies of embryo research; the concerns about cloning or creating chimeras, the commodification of human life, and debate about fundamental principles such as dignity. With the USA becoming the first country to approve human embryonic stem cell trials in humans, the urgency of sound regulatory oversight is pressing;⁵⁶ and this has taken many countries beyond embryo questions, to those of comprehensive regulatory coverage of translational aspects of stem cell science.

⁵⁵ R. Steinbrook. The Cord-Blood-Bank Controversies. *The New England Journal of Medicine* 2004; 351: 2255–2257.

⁵⁶ The trial is currently on hold because of the risk of rogue cells that may trigger tumours. Geron Corporation had been given Food and Drug Administration approval for Phase I trials of a cryopreserved formulation of human embryonic stem cell-derived oligodendrocytes. The new cell-based drug, GRNOPC1, will be primarily assessed for safety by injecting it into patients with functionally complete spinal cord injury. The drug has been shown to enhance re-myelination in rats. For full coverage, see: <http://www.geron.com/GRNOPC1clearance/> [Accessed 08 Sep 2009].

Geoffrey Lomax's contribution raises the tension within national law in a particular context: the separation of state and federal law in the USA. During his first term in office, Ex-President Bush was vocal in his opposition to embryo research. In his 2001 address, he described: 'Like a snowflake, each of these embryos is unique, with the unique genetic potential of an individual human being',⁵⁷ and from then established the restrictive federal policy to limit funding to 60 existing cells lines 'where the life-and-death decision has already been made'.⁵⁸ But, given the autonomous legislatures of individual states, this also set up, as Lomax remarks, an "'extraordinary tapestry", in which scientific and political threads are delicately intertwined'. Lomax's enlightening critique focuses on the distribution of authority between federal and state governments. He argues that to meet the administrative challenges encountered by sovereign states in stem cell research programs, procedural mechanisms:

'...combined with the formation of inter-jurisdictional networks within the sphere of publically funded stem cell science programming, has served to enhance legitimacy and advance effective governance' [360].

This leads to the intriguing question as to whether such a model for responsible governance of controversies involving science and technology *through state action*, constitutes a '*rejuvenated federalism*' [360]?

Lomax's contribution invites us to look more closely at the curious phenomena which may focus regulations towards a particular objective. He describes how the procedural turn strongly influenced the *California Stem Cell Institute's* policies (more on this later). It was one of many states to initiate stem cell programmes at the time, given the prospect of adapting to federal policies in respect to their own legal peculiarities. However, many states recognised the technical challenges posed by policy interaction and the potential for border issues, leading to the formation of the *Interstate Alliance on Stem Cell Research*. The result was, perhaps remarkably, given

⁵⁷ President George W. Bush's Address on Stem Cell Research. *CNN*. 9 Aug 2001. Available at: <http://edition.cnn.com/2001/ALLPOLITICS/08/09/bush.transcript/index.html> [Accessed 08 Sep 2009].

⁵⁸ *Ibid.*

the controversial issues at stake, cooperation between participating states; and concurrently, the alignment of state regulations with various (but not all) federal standards, such as those referring to patents. The embryo question, not surprisingly, was not one of the issues to become part of the regulatory consensus. We can take regulation to mean the ‘sustained and focussed attempt to alter the behaviour of others according to standards or goals with the intention of producing a broadly identified outcome or outcomes’.⁵⁹ In this frame, state and international cooperation is seen as shifting many different outlooks to focus in the same regulatory direction. In the USA, states responded to a restrictive federal policy. This created a patchwork of stem cell policies, and led to a characteristic decentralising of regulation. The only alternative for permissive states was to keep out of federal legitimation; but in doing so, rather ironically, that ultimately led to a welcome, cooperative research environment. Lomax argues that the states’ willingness to engage in a coordinated stem cell policy forum may have been instrumental in an enlightened federal policy; albeit that George W. Bush’s personal beliefs were, until now, a barrier to continued debate at this level. But, far from damaging the regulatory focus, the alignment of regulatory frameworks reflected ‘the ongoing desire to ensure broad health and economic benefit from stem cell research’ [370]. It was notable, according to Lomax, that states became ‘laboratories for democracy’ [369], were attentive to local ‘justice-related concerns’ [369], and were a ‘source of policy innovation’ [369]. In the global debates, where there are broadly similar border issues, the driving force for international harmonisation is a *lack of regulation*. But, the basic idea of an ‘enlightened federal approach’ is one that ought not to be lost in the international debates. We can take note, for example, that the EU (for example, see the comments we made on the *Tissues Directive*, above) has seen an increasing grouping of member states’ policies; and, arguably, this ought to be the focus in further international initiatives.

The introduction of the *Food and Drug Administration’s* Guidelines for Human Stem Cell Research was the most recent development in

⁵⁹ J. Black. 2005. What is Regulatory Innovation? In *Regulatory Innovation: A Comparative Analysis*. J. Black, M. Lodge & M. Thatcher, eds. Cheltenham: Edwards Elgar: Chap. 1: 11.

the USA, after President Barack Obama's executive order to remove Bush's previous policy. The similarity of these guidelines to many states' laws arguably showed the remarkable consistency within the USA with respect to the broader issues of stem cell science. According to Obama, these guidelines should address concerns of 'responsibility, scientific worth, and legality', suggesting that it was no longer the embryo question — for Obama at least — which was central to the American debate.⁶⁰ The *Dickey-Wicker Amendment* as part of the 2009 *Omnibus Appropriations Act*,⁶¹ however, introduced exclusions into the guidelines: principally, the prohibition on federal funding to derive embryonic stem cells. It remains to be seen whether the *Stem Cell Enhancement Act 2009*, or some other legislative action, will lead to more permissive federal regulations (the guidelines are a step in this direction).⁶² In this respect, Lomax concludes that the FDA has 'initiated efforts to promote communication and exchange between the agency and its stakeholders with the goal of facilitating development of safe and effective therapeutic products [374].'

The Procedural Fix

Lomax's paper brings into focus the mechanics of the (Californian) procedural approach. The idea of procedural justice (a theory within politics) is often distinguished from those of substantive justice (the 'business' of ethics). The procedural idea can be narrowed to the processes of politics itself,⁶³ or to a wider objective that also integrates comprehensive moralities.⁶⁴ Procedural ethics is referred to by Jasanoff as 'regulatory science': the use of techniques, processes and artefacts that

⁶⁰ M. Majumder & C. Cohen. Future Directions for Oversight of Stem Cell Research in the United States: An Update. *Kennedy Institute of Ethics Journal* 2009; 19: 195–200.

⁶¹ Public Law 111–8, Division F, Title V, sec. 509.

⁶² The 2005 introduction of the Act (H.R.810) was vetoed by Bush in July of that year.

⁶³ Cf. S. Hampshire. 1989. *Innocence and Experience*. London. Penguin Books.

⁶⁴ Cf. J. Rawls. 2005. *Political Liberalism*. Columbia University Press: 2nd Revised Edition.

further the task of policy development. This involves validation (employing, for instance, expert advice, and peer and scientific review) and 'persuasive efforts to protect the public against risks, emanating from scientific institutions and their products'.⁶⁵ The system described by Lomax is one built upon the constitutional charge granted to public officers to set policy, issue regulations, and adjudicate decisions that carry the force of law (or are transposed into law by governmental approval). Importantly, what legitimises the authority of bodies, like the *Californian Stem Cell Institute*, according to Lomax, is that officers are subject to a principled set of ground rules that must guide them as public policy agents.

Most national solutions to legitimate policies on the stem cell issue have tended towards some kind of 'procedural fix': (we only mention the key points due to space) they implement rules of transparent discussion, removing coercion and manipulation, so that policymakers are able to filter valid and justifiable paths for regulation and operative policies; or at least find those options which are suitable for political consumption. No one substantive solution ought to take precedent from the outset (otherwise making the process rather opaque, and perhaps disingenuous); but instead, the framework employs a set of principles which focus all efforts towards a legitimate and conciliatory policy outcome. The framework expects that agents freely enter the debate, and that each recognises what they must do if they reasonably expect their view to be considered; moreover, they cannot back out of the agreement if they don't get their way.⁶⁶ The proceduralist's claim is that the ethical validity of the framework ought to be readily conceded, and that outcomes, even when they are objectionable to ones' own views, are 'acceptable' because of the justness of the process. For advocates of the procedural fix, it has been necessary to consider not only how jurisdictions can optimise regulatory procedures, but also to understand the proper normative content that validates them.

⁶⁵ S. Jasanoff. 2005. *Designs on Nature: Science and Democracy in Europe and the United States*. Princeton, NJ: Princeton University Press: 230.

⁶⁶ Cf. D. Gauthier. 1986. *Moral by Agreement*. Oxford NY: Oxford University Press.

Roger Brownsword, perhaps with a hint of disparagement, concluded that a procedural strategy to overcome a 'legitimacy crisis' is dependent upon each protagonist judging that the:

'constituency's ethical commitments are better served by an adjustment of position and by reaching accommodation with one another rather than by unreflectively standing one's ground'.⁶⁷

This is a claim that many have been unwilling to let proceduralism get away with. The principal objections are that the focus on process integrity is flawed; and proceduralism cannot meet the 'ethical' standards it virtuously broadcasts, because the outcomes are 'right' answers only in the sense that they meet a broad range of public interests. It therefore fails to impart *legitimation* to the claims of regulatory action.

With respect to the first objection, the critical enquirer questions the relative effectiveness of the procedures themselves; and is largely suspicious of the circumstances of ideal deliberation.⁶⁸ Detractors will point to the unavoidable imbalances in all conditions of discourse because of their particular sensitivity to political influence. This is because the course of action chosen is designed to achieve a set of predetermined (political) goals, and often to sustain the trajectory of the current regulatory tilt. Practitioners of the procedural art can adapt and combine leading ideas to get the 'best' results; but, as Frank Michelman argues, often the process remains legitimate only as long as certain outcomes are vouchsafed or excluded as a concluding possibility.⁶⁹ To be sure, getting the procedures right is no easy task, and ensuring political transparency is a constant challenge. But, it is not inevitable that a well thought-out procedural system is bound to

⁶⁷ Brownsword, *op. cit.* note 9, p. 130.

⁶⁸ In this regard, T. McCarthy, in *A Theory of Communicative Competence (Philosophy and Social Science 1973; 3: 135–156)* considers that Habermas' criteria necessary for the 'Ideal speech situation' is practically unattainable. See: J. Habermas. 1970. *Towards a Theory of Communicative Competence*. In *Recent Sociology No. 2*. H. Dreitzel, ed. New York: Macmillan: 114–148.

⁶⁹ F. Michelman. *Constitutional Legitimation for Political Acts. Modern Law Review 2003; 65: 1–15.*

fail (and thereby promulgate unabridged ‘unethical’ politics); or moreover, is merely a tool for political intrigue. Skilled policy-makers can use guiding principles of proceduralism, such as transparency, accountability, and consistency, to make deliberation fair and accessible, just as well as they can manipulate them for disingenuous ends.⁷⁰ This charge is not particular to proceduralism; in any high stake circumstance — including in the ‘business’ of bioethics — there is scope for pacts, tradeoffs, deceit, insincerity, and duplicity.

A more profound anxiety, however, is found in the second objection: political aspirations cannot be taken beyond their contextual limits, because they are achieved by forgoing rigorous ethical argumentation.⁷¹ Ultimately, therefore, they must be rejected as ideas of *ethical* regulation. Richard Ashcroft suggests that the exclusion of ethical debate does little to reassure the ‘public that the issues have been thought out, or that this has been done in a reasonably just or ethical way’.⁷² Moreover, proceduralism cannot meet the ‘high calling of ethics’, because it fails as a ‘litmus [test] to tell us which political acts are legitimate (respect-worthy, even if wrong) and which are not’.⁷³ It is, therefore, a politically disingenuous way to ignore the conflict to be found at the heart of modern pluralistic democracies; it merely ‘...hopes to vault people past their real,

⁷⁰ B. Capps. Authoritative Regulation and the Stem Cell Debate. *Bioethics* 2007; 22: 43–55.

⁷¹ It is easy to achieve a desired outcome by establishing the pre-agenda; see, for example: House Committee on Oversight and Government Reform, *Political Interference With Climate Change Science Under The Bush Administration* at (Dec. 2007) (revealing that ‘the Bush Administration has engaged in a systematic effort to manipulate climate change science and mislead policymakers and the public about the dangers of global warming’); G. Harris. White House is Accused of Putting Politics Over Science. *N.Y. TIMES*. 10 Jul 2007 (reporting claims by former Surgeon General Richard H. Carmona that ‘top officials in the Bush administration repeatedly tried to weaken or suppress important public health reports because of political considerations’); and E. Blackburn. Bioethics and the Political Distortion of Biomedical Science. *New England Journal of Medicine* 2004; 350: 1379–1380 (who alleges the stacking of the President’s Council on Bioethics by the Bush Administration in 2001 to silence pro-embryo research voices).

⁷² R. Ashcroft. Fair Process and the Redundancy of Bioethics: A Polemic. *Public Health Ethics* 2008; 1: 3–9, p. 7.

⁷³ Michelman, *op. cit.* note 69, p. 6.

unliquidated disagreements'.⁷⁴ These arguments focus on the legitimacy of these endpoints; and they raise doubts about whether an adequate ethical justification is forthcoming from a purely procedural approach — even if it is legitimate. *Fair* procedures, on their own, cannot create *just* endpoints; nor can they say anything creditable about the ethics of public policy.

The procedural turn is about instituting coherent sociality. This is achieved by legitimising regulatory policies which, it is argued, generate an idea of mutual public recognition (we all support a given policy because we were all part of its establishment). Moreover, procedural ethics considers that it is possible to do this without destabilising the local (or even international) community. Justifying this approach can be achieved by locating it in an idea of 'public ethics'; or specifically, a moral theory that purports to show how *community values* can *transcend pure self-interests* when considered within a system of public policy.⁷⁵

The *legitimacy* of proceduralism is found within a theory that bridges private and public.

'The public', in this sense, refers to a collection of private individuals who may or may not be congruous in their collective goals; each member represents a sovereign agent with powers of self-determination and governance. This is the source of democratic plurality and the inevitable conflict of interests. Private ethics begins with the opinions, viewpoints, convictions and beliefs of an agent's dialectic rationality; they are often then to be aired only within private dialogue or the cosy theatres of bioethics. It is an ethics which signifies 'integrity, gentleness, disposition to sympathy, a fastidious sense of honour'.⁷⁶ Public ethics, however, concerns ideas which are grounded in the circumstances created by communities and public life. It is about: 'tenacity and resolution... largeness of design and purpose ...habits of leadership'.⁷⁷ Public

⁷⁴ Ibid: 7–8.

⁷⁵ Capps, *op. cit.* note 70.

⁷⁶ Hampshire, *op. cit.* note 63, p. 177.

⁷⁷ Ibid.

decisions are often expedient and extensive, and not always popular or welcome, meaning that often they are only possible where there is a disassociation between 'the public interests' and personal beliefs or sentiments. The latter cannot be definitive of public policy, since we cannot *expect* others to share them, nor can the agent's approbation or affirmation of a set of relevant facts be a measure of the appropriateness for public policy. Personal ethics may be specifically directed to private gain or goals, sometimes reprehensible or unintelligible, and which are often parochial with respect to those who share a close existence. They are based on our approval of facts that we are comfortable with, which often lacks considerations of justice or reflectivity of public purposes; and sentiments that we are used to, rather than those which are remote, unfamiliar, and 'public'. This is not an abandonment of ethics (it is, however, a rejection that private ethics is a suitable endpoint for public policy), but an ethics suited to the expedient political world. 'The public interest' concerns the obligations of collective and impersonal choices which are necessary for the governance of the state — grounded in, what one might call, *political instinct*.

But, this does not sanction a Machiavellian 'princely fox', unable to uphold the virtues of a good citizen if he is to do his political duty; not least because his moral obligations are tainted by a desire to avoid dishonour — a seat of glory that requires the fox to maintain the dignity of office by cover-ups and corruption.⁷⁸ But nor does it seem wise to turn to the 'saintly' to make such decisions: they are naive and inexperienced of the demands of office, finding solace in provincial interests and relying on skills honed in the familiar surroundings of academic debate. The capable public official is aware of his or her own conviction, and accomplished in the political virtues. However, policy-makers are, at the same time, private individuals and public officials; and their interests in one will inevitably influence and overlap with the other (and there is nothing to oppose private virtues informing public dealing too). But the subjectivism that this entails means that the public have to be confident in the *authority of reason*, and specifically, a theoretical con-

⁷⁸ M. Hollis. 1996. *Reason in Action*. Cambridge NY: Cambridge University Press: 139.

struction of *reasonable* public decision-making.⁷⁹ The role of the public official is one open to the elements of public criticism: their public decisions cannot be made for personal advantage. To justify public decisions, and thus impart a public moral obligation, evidence, opinions and judgement must meet rigorous scientific authentication and ethical scrutiny. Officers are licensed to do a certain job (and the privileges that go with this), but the public expect checks and balances — that procedures are in place to scrutinise their public conduct. Furthermore, procedural mechanisms, which grant individuals privileges and entitlements to make policy, also require that individuals have rights to take part in the debates of their choosing and to be listened to; thus, it ensures that all members of the community are under the same ethical obligations to exercise their rights so as not to deceive or wilfully misrepresent information to insidious ends.

The Notion of Respect and Global Values

The next four papers document how individual countries have implemented regulations in stem cell research. There appear to be a number of common ideas which can be found in both Asian and Western bioethics arguments; principally, this is a symptom of a procedural way of conducting deliberative bioethics.

We begin with the recent developments in the UK. The UK is one of the few countries that have found it necessary to review existing statutory laws, because they have become increasingly disconnected from scientific developments. The *Human Fertilisation and Embryology Act 1990* brought embryo research under comprehensive oversight — the problem, which has become increasingly evident as a result of persistent legal challenge, is that novel technologies have strained the operation of the Act. This detachment has been compensated through a number of interpretive measures. Notably, in *Royal College of Nursing of*

⁷⁹ Seymour Martin Lipset argues that government legitimacy ‘involves the capacity of a political system to engender and maintain the belief that existing political institutions are the most appropriate and proper ones for the society’. *Political Man: The Social Bases of Politics*. London: Heinemann: 2nd edition, 1983: 64.

the United Kingdom v Department of Health and Social Security, Lord Wilberforce made a seminal speech on purposivism,⁸⁰ which has been subsequently used to reattach Parliament's policy or intention at the time of drafting the Act, to current issues outside current law.⁸¹ But purposivism has a tendency to become a tool for the presiding legislative tilt: that it will be interpreted in terms of the current political leaning, rather than that of the time of drafting. As Brownsword writes, 'what constitutes gap-filling and second guessing [of Parliament's intention] largely hinges on whether the present case can be subsumed under the same genus of the covering policy, which in turn depends on whether the court judges that a liberal or restrictive approach is called for'.⁸² The precarious stability and need for constant reattachment gathered momentum, resulting in the review of 1990 Act.⁸³

Natasha Hammond-Browning and Søren Holm discuss the review of the 1990 Act in respect of the prospect of creating hybrid embryos. The 2008 Act, unlike its predecessor, explicitly mentions 'human admixed embryos', which refers to the 'human end' of chimeric entities (entities with a predominantly human genetic content and not created by fertilisation nor intended for postnatal life).⁸⁴ Hammond-Browning & Holm suggest that such a term is misleading: 'The *legal* name for such embryos does not truly acknowledge the animal contribution, however small that may be, since it does not make it clear what the human is "admixed" with' [386]. They further note that the legislation now requires chimera research to be 'necessary and desirable' for the purposes of licensing by the *Human Fertilisation and Embryology Authority*; and that the Act will not justify the issuing of licences for hybrid embryo research where a viable

⁸⁰ [1981] AC 800.

⁸¹ See: *R. v Secretary of State for Health ex parte Quintavalle* (on behalf of the Pro-Life Alliance) [2001] EWHC 918 (Admin) (Crane J), [2002] EWCA Civ 29, [2003] UKHL 13.

⁸² Brownsword, *op. cit.* note 9, pp. 172–173.

⁸³ Department of Health. 2006. *Review of the Human Fertilisation and Embryology Act*. Cm 6989.

⁸⁴ Lord Darzi of Denham 15 Jan 2008. House of Lords Hansard (Debates) Vol. 697, Col 1195 HL. Such embryos cannot be implanted in a woman's or animal's womb. 'True chimeras' can be legally created by the mixing of hamster sperm with human oocytes for fertility purposes, and not research.

alternative exists. Looking to the future, the authors raise the issue that ‘whilst it may be desirable and necessary to use hybrid embryos for research, it is debatable whether it is desirable to use such embryos for use in *human* clinical trials or treatments’ [389]. With the advent of iPS cells — which do not involve gametes or embryos in the derivation process, and their derivation is therefore outside of the remit of the HFEA — the answer is possibly not. Chimera-derived cells to be used in clinical implantation will face similar concerns as those voiced in debates on xenotransplantation: safety concerns, inefficiency, and less contentious alternatives may make hybrid research in the clinical contexts obsolete. However, while the UK’s Act does cover the derivation of chimera cells, there is little said in respect to their clinical use.⁸⁵

In their contribution, Renzong Qiu and Xiaomei Zhai describe how the ‘cloning and stem cell debate in China is taking place at a time when the country is in transition from a monolithic society to a more or less pluralistic civil society’ [396]. This creates a complex regulatory response, which assimilates China’s historical cultures with periods of adaptation to external philosophies and its modern integration into the international community. The commitment to investment in the biotech industry has concurrently initiated a need to address the ethical, legal and social implications of the scientific discovery; and this has resulted in a number of regulations to protect the interests of human participants in research and

⁸⁵ The EU Tissue and Cells Directive, as transposed into UK law by the *Human Tissue (Quality and Safety for Human Application) Regulations 2007* ‘sets standards of quality and safety for the donation, procurement, testing, processing, storage and distribution of human tissues and cells’. While this sets high standards for *human* cells, there may be concerns that the animal content of may disqualify chimera cells from this oversight. Clinical use will come under the remit of *Regulation on Advanced Therapies* (Regulation (EC) 1394/2007). This regulation recognises the unique character of stem cell-derived therapies; and that they lie at the border of the traditional pharmaceutical area and other fields (e.g. medical devices). The inclusion of animal engineered components in human cells is covered, but the effectiveness and extent of this has been questioned; see: European Commission. 2005. *Tissue Engineering and Beyond: Summary of the 2005 Public Consultation on the Draft Proposal for a Regulation on Advanced Therapies*. Enterprise and Industry Directorate-General; Consumer Goods; Pharmaceuticals. Brussels. European Commission. November.

patients in clinical practice. In respect to stem cell research, there has been a distinguishing permissive tilt strongly influenced by a Confucian pro-life precedent that saving lives (*renzheng*, or humane policy) is an ethical imperative: the peoples' *minsheng* (well-being) is the driving force justifying the acceptability of embryo research and therapeutic cloning. The authors trace the political solution to the embryo question in China by reference to the 'spirit' of graduated priority, which may be found in Confucian thought: the person is formed from their achievements and by fulfilling certain roles. The embryo, accordingly, appears at the beginning of this process — and is considered as a potential or proportional person to be extended respect according to the distance and difference between their ontology and actual persons.⁸⁶ Given the benefits of research, it is justifiable to use such embryos to derive stem cells. *Rén* (benevolence) may be shown to the embryo, even if it is used in research, by showing it respect; this may include a proper committal subsequent to use.

The Chinese government explicitly banned reproductive cloning in 1998. It is a country that has enthusiastically embraced stem cell research, and the '*Ethical Guiding Principles*' from December 2003, issued by the *Ministry of Science and Technology*, permit research on human embryonic stem cells, embryo research up to 14 days, therapeutic cloning, human foetal research and induced parthenogenesis. The Guidelines also reaffirm that gametes and tissues must be voluntarily donated in accordance with the principle of informed consent; and that research institutions proposing to experiment with human embryonic stem cells must establish an ethical committee to review the research, prohibit the implantation of human embryos used in stem cell research, and prohibit the buying and selling of human eggs, sperm, embryos and foetal tissue. The Guidelines address an oversight, which was revealed when a reputable Shanghai team announced that it had generated stem cells by transferring nuclei from human skin into rabbit eggs.⁸⁷ These Guidelines, according to Qiu & Zhai, lack legal clout; and moreover, there is no system for

⁸⁶ Cf. D. Tsai. Human Embryonic Stem Cell Research Debates: A Confucian Argument. *Journal of Medical Ethics* 2005; 31: 635–640.

⁸⁷ The goal was to develop a way of generating embryonic stem cells that did not require scarce human oocytes; Chen, *op. cit.* note 31.

overseeing compliance with the Guidelines or for inspecting stem cell research facilities. China's policy of well-being has led to further regulations that came into effect on the 1st of May, 2009, and that designate all forms of stem cell therapy as 'category three' medical technologies: those deemed 'ethically problematic', 'high risk' or 'still in need of clinical verification', and thus under Ministry oversight (including the requirement for submitting clinical-trial protocols).

Satoshi Kodama and Akira Akabayashi describe the circumstances in Japan which led up to the *Law Concerning Regulations Relating to Human Cloning Techniques and Other Similar Techniques*, enacted on 6th June 2001. Once again, the idea that the human embryo is morally distinct from a person is central to a permissive tilt. The embryo is described as the 'sprout of human life', thus suggesting its *potential* to become a moral being: 'the harm in violation of embryos that are no more than a sprout of life is minute relative to that of foetuses or humans'.⁸⁸ In expanding this concept, Ryuichi Ida is quoted in the chapter as remarking:

'an embryo is not just a "thing" either; if it divides, it will naturally become a person. This is why we used the expression "sprout of human life", and thus in a sense it describes an intermediate stage on the way to becoming a person... If the embryo was deemed to be human life, then to take it to an extreme, these researchers would be committing murder' [432].

The 2001 law has two roles: it specifically bans reproductive cloning; and it required the *Ministry of Education* to produce national guidelines for the creation of 'Specified Embryos' for research purposes. On 23 July 2004, Japan's *Council for Science and Technology Policy*, the Government's eminent science and technology policy body, approved the final report of its *Bioethics Expert Panel* on human embryo and stem cell research. The report recommended a change in Japanese policy to allow the creation of human embryos using therapeutic cloning techniques.

⁸⁸ From Kodama & Akabayashi, this volume [430].

The Potentiality Argument

The gradualist idea that appeared in both China and Japan is common in Western political ideas of embryo status as well; and has been seen as the ‘compromise’ position between ‘pro-life’ (the embryo has full moral status) and ‘pro-choice’ (the embryo has no moral status solely by virtue of its own characteristics) positions. Gradualist arguments in the Western context have tended to come under criticism because they must rest on the metaphysical ideas of potentiality and proportionality. These have been seen variously as vulnerable to *reductio ad absurdum* arguments: that potentially reaches back to limitless ‘what ifs’. Far more difficult is the challenge that *mere* potentiality cannot be morally relevant because a being’s status at a certain time depends on the being’s properties *at that time*; properties that the being has yet to actualise cannot matter in a morally relevant way and cannot serve as a surrogate for actuality. If a being has full moral status by virtue of being a person, then a potential person can only have potential moral status, not actual moral status. Proportion, on the other hand, opens up the propositional risk that agents can have degrees of *higher* status, and this suggests a distinctly un-egalitarian idea of moral status.

This, at first, appears to be very different from the Confucian understanding of potentiality and proportionality. The latter suggests the relational aspects of *becoming a person*, and these are observations which are far more accessible to Confucian cultures than Western epistemology. Moreover, in Kodama & Akabayashi’s paper, the Western idea of dignity is seen as being ‘out of place when considered from an Asian, or Japanese, perspective’.⁸⁹ (But the authors themselves conceive that: ‘Accepting the Western idea of human dignity and at the same time making ambiguous the Western dichotomy of things and persons, the *Committee* made it possible for ethics and science to reconcile with each other, at least for the time being’ [439].)

However, within the Confucian approach we see that relating ideas to personhood leads to a concept of ‘respect’. In Japanese law, practices which contradict the prescription that ‘All people shall be respected as

⁸⁹ From Kodama & Akabayashi, this volume [427].

individuals' are prohibited — but, this does not rule out embryo research — embryos 'require careful handling, but they are still at a different stage than fetuses or post-natal humans' [430]. This idea — that the embryo does not meet the criteria of a full 'person' — is found in Western thought; as is the notion that such being may still be respected. Thus, the idea of respect may be surmised as the *use* of the human embryo so that it does not become an object or mere thing, but as a locus of diminished, but important moral value. The *respect* is not so much shown in what the embryo *is*, but what we do to it. This means that it ought to be treated in a certain way, and even, if appropriate, afforded some legal protection.⁹⁰ Thus, working back, when such protection is translated into an idea of 'respect', it requires that research is subject to strict oversight and that certain limits are in place (supported by criminal sanctions).

However, some critics focus on the fact that 'protection' is ill defined, and is ultimately vacuous because it inevitably results in the destruction of the embryo. Qiu & Zhai articulated an idea of respect to suggest that it could be shown if research is performed only when there are laudable scientific goals.⁹¹ Likewise, Kodama & Akabayashi quote the Japanese *Subcommittee on Human Embryo Research*, which states: stem cell research requires 'a swift response in Japan and is the source of high hopes for regenerative medicine'.⁹² Moreover, the call for strict rules for conducting research also suggests a level of respect towards embryos; essentially confirming that they cannot be used except under certain specific conditions.

It is perhaps remarkable that the stories of regulative struggle in China and Japan, as given here, have been preceded by similar struggles elsewhere, especially where the legislative tilt has been permissive; and it is likely that states lacking regulation in this area, and willing to make the same legislative step, will face similar difficulties. The problem for international law, as skilfully shown in the chapter of Cutas & Munthe, is where

⁹⁰ M. Warnock. 1985. *A Question of Life: The Warnock Report on Human Fertilisation and Embryology*. Oxford: Basil Blackwell Limited: 62.

⁹¹ Cf. House of Lords Select Committee (Sel Com.). 2002. *Stem Cell Research*. HL Paper 83(j) London: HMSO, February.

⁹² From Kodama & Akabayashi, this volume [431].

different legislative tilts (permissive and prohibitive) come into contact. While this idea of respect has been used to move forward from national debates to regulatory action, it remains to be seen whether 'respect' can be taken into multinational fora, and where regulatory progress in regard to these controversies is notably absent. To illustrate this point further, the Singapore *Biomedical Ethics Advisory Committee* stated that 'respect' is about allowing different views to be expressed (given the multicultural circumstances of the city-state), and for due consideration to be given to them.⁹³ In the end, a global policy may be about a position which may be tolerated in a pluralistic world, created by 'considered weighing and balancing of the spectrum of views held'.⁹⁴ Although the BAC were writing about the pluralism within Singapore itself, in many areas — notably human rights — the weighting of interests has been successful to a degree; and an international balance, promulgated by regional groups such as the EU, and the wider influence of the UN, has been achieved.

But it is noticeable that many appear unconvinced that an adequate level of harmonisation at this level is possible⁹⁵; others lack confidence in those who are responsible for the international community's advocacy of rights are able, or even willing, to assert themselves properly. We also are mindful that a concept of 'respect' will probably creep into the same unhelpful niches of our human rights frameworks as has dignity; but by foreknowing the difficulties that a vague and inconsistent use of dignity has caused, can we avoid such indeterminacy happening again? Can we in fact respect individuals, as rights holders, while leaving the embryo question to one side? (In this regard, it was perhaps a mistake to include the embryo in the Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the*

⁹³ C. Ho, B. Capps & T.C. Voo (in press). Stem Cell Science and Its Public: The Case of Singapore. *East Asian Science, Technology and Society: An International Journal*.

⁹⁴ Bioethics Advisory Committee, Singapore. 2002. *Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning*. Jun. Singapore: BAC: 21.

⁹⁵ I. De Melo-Martin. Forthcoming. Human Dignity in International Policy Documents: A Useful Criterion for Public Policy? *Bioethics* (online early) 10.1111/j.1467-8519.2009.01737.x.

Application of Biology and Medicine, given all but one of the Articles referred to agent-relevant capacities.) Can a weakened idea of respect be sensitive to variations in cultural values, or flexible enough to allow rudimentary progress in international law? Now, of course, we are at risk of embarking on an equally difficult task, and too ambitious one for this introduction, of spelling out what we mean by ‘rights’ (and what it means to be respected in having one’s rights claims recognised) — but given the almost universal assent to documents which are unambiguous in their agent targets (such as the Declaration of Helsinki and the conditions of volunteering for research), this might be an opportunity to explore at another time. A conceptual idea of ‘respect’ is unlikely to supplant dignity in our international language, as it is deeply ingrained and would require the onerous task of reorganising current institutions. Many would be unwilling to abandon our current intentional framework given its achievements in some areas; others would dismiss this as reinventing the wheel, and it is likely to be seen by some as further muddying of the conceptual water of international law. While it is unlikely that any core concept — no matter how well, or even intentionally vaguely, defined — will reach out to all cultures and all corners of the globe, we speculate that, just maybe, and with hard work, a breakthrough may be found.

The Complexity of National Legislation

Peter Sýkora considers the unusual case of two closely related countries developing very different regulatory approaches: Slovakia, in which embryo research is banned; and the Czech Republic, where it is permitted. Sýkora analyses the reasons for the juxtaposed biopolicies. The two countries have employed different strategies to address the then ‘bioethical deficit’ in their healthcare legislation. The reason for this may not be merely different religious and secular developments, because, as the author argues, a probable key factor was the impact of national research lobbies.

Slovakia has prohibited stem cell research using human embryos through general and criminal provisions. The origins of the prohibition stemmed from the *Health Care Law*, which, Sýkora argues, was used to protect the embryo as a ‘vulnerable’ person, including it in a list of

excluded populations from research. Sýkora adds that at the time, and subsequently, there has been little explanation or comment on the issues in the health care reforms; and indeed, more weighty issues — health care reform itself and criminal jurisprudence — overshadowed any potential attempt to engage in bioethical debate. Thus, the *in vitro* embryo is protected as a vulnerable person (the embryo lacks any definition in Slovak law), and despite the law not actually recognising such a status (as stated by the Slovak Constitutional Court). The *Penal Code* (2006) further strengthens the prohibition on embryo research by listing a number of banned activities, including any human cloning. Furthermore, the *Code* makes a prohibitive extraterritorial claim (a first in Slovak history) on Slovakian researchers, effectively ruling out any international collaboration that involves human embryos. Within the European Union, Slovakia has continued to formally support ‘anti-embryo’ initiatives.

The Czech Republic, in stark contrast, adopted legislation in 2006 which permitted the procurement of human embryonic stem cells from surplus embryos. It prohibited the creation of research embryos, reproductive cloning and chimera/hybrid research; and outlined in some detail the definitional aspects of embryo research (including defining the embryo). Unlike Slovakia, the law was passed after direct parliamentary debate, with an argument that prohibition would mean the ‘continuation of [the Czech] excelling reputation in this research field would end’ [456].

The reasons for these divergent policies, Sýkora argues, were not only about the religious circumstances of each country (‘Catholic Slovakia’ and ‘atheistic Czech Republic’ [457]): he also points to a more obvious pro-science culture in the Czech Republic, and one which was organised into an effective lobby to promote research and the use of hES cells. (These issues, Sýkora suggests, were for the most part ignored by the major scientific groups in Slovakia; and in general there was a lack of awareness or interest shown by the public). Furthermore, the Czech Republic had earmarked considerable funding for biotech industry, and it was not going to be prevented from injecting capital into promising embryonic stem cell research. This pro-science environment was, Sýkora argues, instrumental in pushing a pro-embryo research agenda. (And quoting Michael Mulkey’s *The Embryo Research Debate*, he suggests that the pro-science lobby groups — which overcame a prominent anti-abortion sentiment — were an

essential component of passing the UK's permissive *Human Fertilisation and Embryology Act*, and again were important in the revision of the Act in 2008; this time, overcoming opposition to chimera/hybrid research.)

Peter Sýkora's chapter highlights an important aspect of a country's legislative tilt: that a developed and organised scientific organisation has a major role in centralised policy. His contribution is further evidence that understanding the legislative tilt of a country — a necessary step in reconciling international harmonisation — requires a careful analysis of the complexity of background details informing that position. One can see, for example, how a particular pro-science environment was created in Singapore: the need to establish a legal and regulatory climate that enabled this relatively new investment initiative to flourish was identified early on in the policy process, and the involvement of leading scientists on high-level advisory bodies was actively pursued to this end.⁹⁶ One can also see how a country's particular circumstances can dampen scientific enthusiasm: Germany, for instance, despite having a highly-developed scientific infrastructure, was unable to support the controversial aspects of stem cell science — the reasons for this may be as a result of a pre-existing conservative ruling thesis (that protects the human embryo as a human being), and which takes precedence over the freedom of research due to reservations still engrained from past scientific atrocities.⁹⁷ While it is relatively easy to characterise the two main 'permissive' and 'prohibitive' countries in the stem cell debates, we do disavour to their history and culture if further contextual elements are lost in 'the vote'.

CLOSING REMARKS

During the editing of this volume, it became clear to us that the final text would be much more than a rehearsal of the familiar aspects of the

⁹⁶ K. Wong & T. Bunnell. 'New Economy' Discourse and Spaces in Singapore: A Case Study of One-North. *Environment and Planning A* 2006; 38: 69–83.

⁹⁷ D. Beyleveld & S. Pattinson. 2001. Embryo Research in the UK: Is Harmonisation in the EU Needed or Possible. In: *Embryo Experimentation in Europe: Bio-medical, Legal, and Philosophical Aspects*. Bad Neuenahr- Ahrweiler GmbH: Europäische Akademie zur Erforschung von Folgen wissenschaftlich-technischer. M.B. Friele, ed. *Entwicklungen*: Gray Series: 58–74.

‘embryo question’. In this comprehensive critical introduction, we have attempted to draw together the several issues beyond the dualistic ‘yes’ or ‘no’ solution to stem cell research; in this book, the reader will find original articles considering translational issues, which — of foremost concern — are about the possibility of scientific and medical advancement which could eventually save lives. But, let us not forget the complex relationships that develop as a consequence of this shift, such as the possible threat to the integrity of transactions between scientists and donors, as well as questions about the reputation of scientists and clinicians. In particular, one will find nuanced scrutiny of the root causes behind regulatory tilts in the respective countries, and how these could in turn affect international harmonisation efforts in stem cell science. Importantly, one will appreciate how culture (such as the pro-science Czech republic) and philosophy (China and Japan), as well as history (Germany), and even public assessment of the scientific community as the ‘benchmark’ of evidence for parliamentary uses, can shape policies regarding stem cell science. We conclude on a general note on the place of contention in bioethics and biotechnology.

The stem cell debates have persisted throughout a particularly intense period in growth of innovative biotechnology and global bioethics. The future for stem cell regulation will depend in part on how the disparate disciplines found in ‘bioethics’ — law, philosophy, social science — influence the course of governance development in the stages of translational medicine. All the while, scientific endeavour and market forces will be pulling regulators in diverse, sometimes conflicting, directions. The legitimacy of bioethics has extensively permeated zones of governance; it is no longer the case that bio-medical controversy can be negotiated within specific cultural and political contexts of the state, because each nation’s position within a regional and global economy, ensures that they cannot operate independently. The creation of complex international networks has created a need for greater integration and harmonisation; but while questions still hang over the competency and effectiveness of institutions of global governance, the push to reform has predominantly come from meeting the standards of the global markets, rather than universal ethical norms.

The papers in this volume should initiate a sustained, focused and forward looking debate about aspects global governance; and we think that

they are a valuable contribution to redressing the balance between the economic imperatives of stem cell science, and the contemporary social and ethical thought about the best conception of an ordered and just global community. Moreover, the unique international perspectives presented in this book provide a snapshot of where global regulation might be heading.

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Our sincere gratitude also goes to the contributors to this volume, who spent their time and effort in the careful preparation of their papers. Each author was a pleasure to work with, and wrote a thoughtful essay for this volume. In this introduction, we have begun a critical analysis of the contributions, and with the intention of this representing the beginning of further debate, we look forward to responses and further discussion with the authors. We hope our readers will also find in this rich collection of papers a stimulus to further thought about the complexities of the stem cell controversy.

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