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Lee, Robert; Morgan, Derek

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Regulating Risk Society: Stigmata Cases, Scientific Citizenship & Biomedical Diplomacy

ROBERT G LEE AND DEREK MORGAN*

1. *Stigmata Cases and Legislative Landscapes: A Survey from England & Wales*

Several years ago we wrote an essay¹ in which we reflected upon the case of a woman wanting to make use of the emergent technologies of assisted conception. What was unusual was that her husband had died and she wanted to use medical skill to recover sperm in order to try to become pregnant; to make use of his gametes posthumously. We contrasted that case with the long dying of a young man who had lain in a persistent vegetative state for four years, where the question was not access to, but curtailment of medical technology. Her name was Blood;² his Bland.³

We argued that every legal system needs its Diane Blood, in the same way that it needs its Tony Bland.⁴ They have the necessary ingredients to mark them as what we called a 'stigmata' case. We suggested that such cases would be ones that:

1. are relatively novel and ethically controversial;
2. raise the balance of personal interests and public interest;
3. force us to ask of the very basis of medical practice — not how, but why; goals, rather than methods, being their primary concern;
4. offer an opportunity to take stock, to re-examine the existing boundaries between the anomalous and the routine; between the normal and the pathological;

* Cardiff Law School.

1 Derek Morgan & Robert G Lee. 'In the Name of the Father *Ex Parte Blood*: Dealing with Novelty and Anomaly' (1997) 60 *Mod LR* 840.

2 *R v Human Fertilisation and Embryology Authority. ex parte Blood* [1997] 2 All ER 687 (hereinafter *Blood*).

3 *Airedale NHS Trust v Bland* [1993] 1 All ER 821 (hereinafter *Bland*).

4 Indeed, most common law systems provide their examples; for discussion in the Australian context, see Belinda Bennett, 'Posthumous Reproduction and the Meanings of Autonomy' (1999) 23 *MULR* 286, discussing inter alia, *AB v Attorney-General (Vic)* (Vic Supreme Court, Gillard J, 21 July 1998); Roger Magnusson, 'The Sanctity of Life and the Right to Die: Social and Jurisprudential Aspects of the Euthanasia Debate in Australia and the United States' (1997) 6 *Pacific Rim L & Policy J* 1, but still unable to address the strange absence in Australia of a 'right to die' case, for which the debates concerning the *Rights of the Terminally Ill Act 1995* (NT) may stand as a surrogate. Magnusson reminds us that the certification of insanity has, at least until very recently, still been used to coax patients refusing food as a consequence of their wish to die, to relent, at 45. Counselling usually follows soon after; recognition of advance refusal is often not that far behind.

5. require courts to develop a social, even a moral vision with which to respond to the dilemmas created by the social and cultural revolution of contemporary medicine.

Thus, we argued that there is a sense in which advances in modern science had delivered Tony Bland and Stephen Blood not only to the ward of the hospital, but also to the precincts of the court. Both cases involve what would until recently have been thought to be unthinkable, the inconceivable. Stigmata cases, like *Blood* and *Bland*, then, are part of the meditation of a culture upon itself.

What we failed to remark upon in that essay was power. While we reflected on goals, rather than methods, we did not take the opportunity — obvious now in retrospect — to remind ourselves that *Blood* and *Bland*, like other stigmata cases, illustrate how markedly power is being enhanced. This is power which lies not particularly, or necessarily, in the hands of the individuals concerned, but in the hands of their physicians. As that power is enhanced, the more dependent — potentially the more disenfranchised — we become, as we see ‘the gradual gathering into the discrete ambit of one professional — the doctor — of an ever-widening range of human issues’.⁵ Stigmata cases raise issues, often otherwise latent, of ‘who’s in charge?’ as the case of *Re A (conjoined twins)*⁶ illustrates quite starkly.

In this essay we want to pick up on this analysis, but expand our reach and enquiry beyond ‘stigmata cases’ and to reflect upon the role of law in the regulation of biomedicine and its associated and parasitic technologies more generally. First, however, we set the context of regulation by exploring and explaining the background to legislative regulation of reproductive medicine, and particularly human fertilisation and embryology in the UK.⁷ We then develop two further themes. We explore what Ulrich Beck and others have nominated as ‘risk society’⁸ and its impact upon the regulatory agenda. Because one of the features of risk society is that it is global, this leads on to our second theme: the important question of national regulation in the age of global ‘procreative tourism’⁹ and scientific exchange. The ability to procure something biomedical somewhere in the world then prompts a question of the sense of the national regulatory framework and the role of courts in giving it effect.

Examining legislative responses in the UK, we need to observe that with the exponential advance of reproductive technologies comes a capacity to re-form, not

5 Sheila McLean, *Old Law, New Medicine: Medical Ethics and Human Rights* (1999) at 1.

6 *Re A (children) (conjoined twins: surgical separation)* [2000] 4 All ER 961 (hereinafter *Re A (conjoined twins)*), in which it *appears* to be the court that is ‘in charge’ but where in effect, that is a charge that is delegated to the doctors involved. For a rigorous analysis and enlightening discussion and criticism of the case, see Soren Holm & Charles Erin, ‘The Manchester Conjoined Twins: An Ethical Analysis’ [2001] *Jahrbuch für Wissenschaft und Ethik* 6.

7 We aim to do no more than this — for a full account of the legislation, see Robert G Lee & Derek Morgan, *Human Fertilisation and Embryology: Regulating the Reproductive Revolution* (2001).

8 Ulrich Beck, *Risk Society: Towards a New Modernity* (1992).

9 A term first coined by Bartha Knoppers & Sonia LeBris. ‘Recent Advances in Medically Assisted Conception: Legal, Ethical and Social Issues’ (1991) 17 *American J of L & Medicine* 329 at 333. Although now somewhat dated, the fundamentals of the approach which they adopt is still illuminating.

only the social, but even the natural world.¹⁰ The apparent public concern in the regulation of such technologies is signalled by stories in the media on a weekly, if not daily basis. Such stories involve the private lives of the individuals concerned, but the interest in them goes beyond the prurient and becomes public, in the truest sense of having a capacity to affect us all.¹¹

Indeed, in health care systems that are publicly funded, what might otherwise be seen as purely private choices about what one might purchase and from whom, are inevitably subject to public scrutiny. Thus it is that, in a matter so apparently intimate, Sheila McLean has rightly argued that human reproduction is more than a merely private matter.¹² In Britain, little infertility treatment provision is available through the National Health Service, but it is regulated no less heavily, and possibly more intrusively, than other health care services which are the subject of public provision. One reason for this lies in the patient's ultimate objective in accessing the treatment, which is to seek the birth of a child following reproductive assistance. However, this cannot constitute a full explanation for the regulation, not least since the same legislation¹³ is used to regulate other matters not immediately connected with the birth of children. Equally, for the most part, little effort is made elsewhere to regulate reproductive intentions.¹⁴

This is not to suggest that the regulation in Britain is overly restrictive; indeed, it is now generally accepted that in comparative terms, the British legislation in this area can be classed as 'liberal'.¹⁵ That this is so may owe much to the place of Britain in the history of reproductive technology — a matter perhaps of public acknowledgement and achievement. The first 'test tube' baby was a British baby, just as the first cloned mammal was a British sheep. This may have particular consequences on a number of fronts. Louise Brown's birth helped position IVF in the UK as a positive intervention, just as, some years later, 'Dolly' became a celebrity media star, although the images are no more or less benign than that of the average sheep. The celebration of the scientific achievement influenced responses to what we might allow in relation to reproductive assistance.

However, whatever scientific satisfaction there might have been in the technological development of IVF, questions about regulation soon followed. For the most part, the debate carried on through the *Warnock Report*¹⁶ was less

10 A theme that we return to below in the section on risk society.

11 For an extended, careful reflection on this, see Valerie Hartouni, *Cultural Conceptions: On Reproductive Technologies and the Remaking of Life* (1997); Marilyn Strathern, *Reproducing the Future: Essays on Anthropology, Kinship and the New Reproductive Technologies* (1992); Janet Dolgin, *Defining the Family: Law, Technology and Reproduction in an Uneasy Age* (1997).

12 Sheila McLean, 'Reproductive Medicine' in Clare Dyer (ed), *Doctors, Patients and the Law* (1992).

13 *Human Fertilisation and Embryology Act 1990* (UK); see Derek Morgan & Robert G Lee, *Blackstone's Guide to the Human Fertilisation and Embryology Act 1990 Abortion and Embryo Research — the New Law* (1991).

14 Hugh LaFollette, 'Licensing Parents' (1980) 9 *Philosophy & Public Affairs* 182.

15 See Derek Morgan & Linda Nielsen, 'Prisoners of Progress or Hostages to Fortune?' (1993) 21 *J of L, Medicine & Ethics* 30.

16 Department of Health and Social Security, *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (London: HMSO, 1984) (hereinafter the *Warnock Report*).

concerned with the restriction of the new infertility treatments than their administration. This may have been a peculiarly British debate, conducted at a particular moment in history. The conservative government of Margaret Thatcher had no inclination to expand welfare provision and saw no need to incorporate these new treatment services within a National Health Service into which it already wished to engender greater competition and efficiency. If the technologies were not to be made available through the National Health Service, then how would one regulate clinical standards within private services?

What was missing in this debate, unforeseen, and possibly unforeseeable, was a developing global bio-economy.¹⁷ Represented here in the space of not much more than a decade is the shift from medicine to science and from science to business. The birth of the first test tube baby heralded the coming of many more, but it also was an indicator of radical shifts in what biomedicine might achieve. Some indication of this is given by the Human Fertilisation and Embryology Authority's statement of its role: 'underlying all of its activities ... [it aims] to safeguard all relevant interests — patients, children, doctors and scientists, the wider public and future generations'.¹⁸

The issue is not now so much about what doctors might do, but rather what scientists might enable them to do. It is idle to argue that the 'end-of-pipe'¹⁹ solutions in regulating the profession and provision of medicine are satisfactory. What scientists place on the reproductive menu, those hungry for the intervention will expect someone to deliver.²⁰ The physician becomes the waiter in the biomedical café. The traditional professional structures of medicine are falling under the sustained pressures of the information age. This allows the trans national corporation to promote products or services worldwide to a patient community with the means, not merely to receive it, but to seek it out.²¹ In this context, the regulatory agenda has become filled with questions of competition law, intellectual property rights, licensing and registration. Ulrich Beck has suggested that we may be on the edge of a second modernity.²² While the post-modernist challenged

17 For an introduction to the bio-economy, see, among many sources, Stan Davis & Christopher Meyer, *Blur: The Speed of Change in the Connected Economy* (1998); Stan Davis, *Lessons from the Future: Making Sense of a Blurred World* (2001) at 179–183.

18 Human Fertilisation and Embryology Authority, *Eighth Annual Report and Accounts* (London: HMSO, 1999) at 1.

19 We borrow this term from environmental policy to describe attempts to regulate in the aftermath of impacts rather than to control processes or products pro-actively: see, for example, Christopher H Schroeder, 'American Regulatory Policy — Have We Found the Third Way?' (2000) 48 *U Kansas LR* 801.

20 Consider one small, immediate example: Dr Severino Antinori, head of a reproductive medicine clinic in Rome, has announced his ability and intention to produce a cloned human being by the end of 2003. *Time* (Europe) vol 158 (February 2001) carried a news feature indicating the possible uses to which such technology might be put and families willing and wanting to avail themselves of it.

21 See below n29.

22 Ulrich Beck, *What is Globalization?* (2000).

scientific rationality,²³ in the second modernity, the trans-national enterprise may wrest back control, evading the grasp of any single jurisdictional regime. This is a theme to which we will return.

For now it is sufficient to indicate that while work on the public understanding of science has pursued an important goal of opening up to enquiry the essentially social processes of scientific consensus, there remains much to do in terms of completing the project of what we have called 'scientific citizenship', which *additionally* involves a critical examination and elucidation of the scientific understanding of the public. An important element of what we mean by this consists in the cold-calling deliveries that bio-medical research can sell to society, presenting the achievable as the acceptable, and naturalising that element of nature that has been changed. The House of Lords Select Committee on Science and Technology observe of this that 'society's relationship with science is in a critical phase'.²⁴ On the one hand, there has never been a time when the issues involving science were more exciting, the public more interested, and opportunities more apparent. Yet, the 'public unease, mistrust and occasional outright hostility' which the Committee notes, 'are breeding a climate of deep anxiety among scientists themselves',²⁵ is then discussed throughout as almost exclusively an issue of the public understanding and acceptance of science, and not, also, vice versa. Thus, the Committee's comprehension of what it calls 'democratic citizenship' is essentially uni-directional: 'Although scientists are a minority of the population, democratic citizenship in a modern society depends, among other things, on the ability of citizens to comprehend, criticise and use scientific ideas and claims.'²⁶ But there is no concomitant requirement that scientists be able to comprehend, criticise and observe ethical or philosophical claims. And while the Committee recognises that the 'applications of science raise, or feed into, complex ethical and social questions, which government and industry must handle in ways which command public confidence'²⁷ so as to mediate 'resistance, whether well-founded or misguided, on the part of the public whether as citizens or as consumers, [which] may inhibit technological progress,'²⁸ this is not accompanied by a reciprocal responsibility for scientists to limit or abandon their visions of progress at public insistence. It is to this theme that we now turn.

23 There is an excellent account and collection of this literature in Paul A Komesaroff (ed). *Troubled Bodies: Critical Perspectives on Postmodernism. Medical Ethics and the Body* (1995). especially in the essay by Paul Redding. 'Science, Medicine and Illness: Rediscovering the Patient as a Person': see Alan Hyde. *Bodies of Law* (1997).

24 House of Lords Select Committee on Science and Technology. *Third Report: Science and Society* (London: HMSO. 2000) at para 1.1.

25 *Ibid.*

26 *Id* at para 1.11.

27 *Ibid.*

28 *Ibid.*

2. *Risk Society and the Regulatory Agenda*

In the face of this transformative capacity of biomedicine, we might look to regulatory structures (including law) to give voice to a real scepticism about scientific 'progress'. Certainly, earlier accepted notions of scientific detachment and value neutrality are no longer accepted as axiomatic. There are clear calls for the operation of scientific endeavour to be made formally accountable and (at least in theory) dependent upon democratic assessment. Moreover, this is not just in terms of whether a particular application of science might be 'good' or 'bad', but whether this scientific enterprise can itself be properly considered good. But the regulatory process more often takes the form of a debate as to whether the scientific application should be considered to be a 'good', not in any moral sense, but in the economists' sense of the word.²⁹

In posing questions about the why and the wherefore of modern biomedicine, we wish to reflect upon 'scientific citizenship' in the 'risk society'. This latter concept is derived from and developed by Ulrich Beck and his intellectual interpreters, such as Anthony Giddens. One of the most remarkable metamorphoses of the 20th century is that from what nature could do to us, to what we can do to nature. According to Giddens,³⁰ this transition marks one of the major points of entry in 'risk society' that suggests a society that increasingly lives on a 'high technological frontier' that no one completely understands; this generates a 'diversity of possible futures'.³¹ 'Risk society' is not simply a world that has become more hazardous. Rather, it is a society increasingly preoccupied with the future (and also with safety), a world 'which we are both exploring and seeking to normalise and control'.³² The origins of the risk society can be traced to two fundamental transformations: firstly, the end of nature; and, secondly, the end of tradition.³³ Each is connected to the increasing influence of science and technology, although not wholly determined by them. To live after the end of tradition, says Giddens, is to be in a world where life is no longer lived as fate. Almost any modern 'medical' news story, and much modern medical litigation, turns on this very fact, as claims of entitlement to posthumous use of sperm, disputes about the care of patients in (or said to be in)³⁴ a 'persistent vegetative state' and judgments about conjoined twins³⁵ serve readily to illustrate.

29 For an analysis of health care as an economic good and the possible legal consequences of the political recognition of health care as a public or a private good, see Robert G Lee, 'What Good is Health Care' in Richard Mullender (ed), *Dilemmas in the Common Law* (2001).

30 Anthony Giddens, 'Risk & Responsibility' (1999) 62 *Mod LR* 1.

31 *Id* at 3. We translate this to mean scientific and other developments that could fundamentally alter, for example, social relations, although, as Marilyn Strathern has suggested, in ways that we cannot be sure will be positive or negative: above n11.

32 Above n30.

33 *Ibid*.

34 For example, *Northridge v Central Sydney Area Health Service* (2000) NSWLR 549.

35 *Re A (conjoined twins)*, above n6.

The principles of 'reflexive modernisation' within science are such that progress necessarily implies unplanned excess, any harmful effects of which are unintentional:³⁶ 'nothing succeeds like success, nothing also entraps like success'.³⁷ Historically, as a professional power, scientific medicine has secured and expanded for itself a fundamental advantage against political and public attempts at consultation and intervention.³⁸ As the boundaries of medicine and technology become blurred,³⁹ there is a danger that the fruits of this insulation will be reinforced and encompass an even wider community. Recall the importance of this observation: if the costs of progress are unintentional, they are equally unforeseeable. Beck's thesis is that there has been a 'revolution of the lay public's social living conditions without its consent'.⁴⁰ The divergence of diagnosis and therapy in the current development of medicine results in a dramatic increase of so-called chronic illness, 'illnesses that can be diagnosed thanks to the more acute medical and technical sensory system, without the presence or even the prospect of any effective measures to treat them'.⁴¹

But, with our modern concern for autonomy and individual choice, this has important implications for law, as Margot Brazier and Nicola Glover have recently reiterated.⁴² Medical law must confront 'challenges deriving both from how we regard [ill] health and how we seek to respond to its demands', a task made more pressing because 'medicalising choices to grant such choices respectability is a recurring theme of the law's relationship with medicine'.⁴³ Trumping ethical debates about, say, novel fertility treatments, by claiming that infertility is a disease, thereby legitimating any process offering a cure, represents (amongst other things) a real challenge if not threat to law; 'unless the law can settle upon some coherent and defensible definition of illness, the elasticity of concepts of illness may snap'.⁴⁴

36 Above n8 at 209.

37 Hans Jonas, *The Imperative of Responsibility: In Search of an Ethics for the Technological Age* (1984) at 9.

38 Above n8 at 210; Illich, *Limits to Medicine* (1976).

39 Porter, *The Greatest Benefit to Mankind* (1997) at 8.

40 Above n8 at 206: see also above n37 at 18–19.

41 Above n8 at 204.

42 Margot Brazier & Nicola Glover. 'Does Medical Law Have a Future?' in Peter Birks (ed), *Laws Futures* (2000) 371–388 at 376.

43 *Id* at 377.

44 *Ibid*. Although we do pursue the argument here, it may indeed be very difficult to prevent that break from occurring.

These developments of modern technology have set in motion processes which undermine the 'idea of democracy from inside'. Central issues of public policy⁴⁵ affecting the future of society, formerly the subject of public debate to shape the political resolve, are obviously bypassed by developments that cannot be foreseen because they are unintended. Technology is thus becoming the instrument of an uncontrolled 'sub-politics' of medicine, where there is neither parliament nor executive to examine the possible consequences of decisions before they are taken.⁴⁶ Too often, the daily orders of this sub-politics read more like an 'obituary for decisions taken long ago'⁴⁷ rather than their calling card. This Beckian notion of undermining the idea of democracy from within had been foreshadowed by an Australian lawyer nearly 20 years ago. Michael Kirby, cautioning of the dangers of the law failing to keep up with science, argued that because science and technology are advancing rapidly:

If democracy is to be more than a myth and a shibboleth in the age of mature science and technology and more than a triennial visit to a polling booth, we need a new institutional response.⁴⁸

Failure to articulate such an approach would have, in an extraordinary anticipation of Beck, profound democratic consequences. Kirby warned that to fail to appreciate the phenomenal gravitational pull of science and technology and to chart a consequent response, or even an anticipatory framework, would entail societies resigning themselves:

... to being taken where the scientists' and technologists' imagination leads. That path may involve nothing less than the demise of the Rule of Law as we know it. It is for our society to decide whether there is an alternative or whether the dilemmas posed by modern science and technology, particularly in the field of bioethics, are just too painful, technical, complicated, sensitive and controversial for our institutions of government.⁴⁹

German philosopher Hans Jonas in a different but compelling analysis, argued that modern technology, which has produced an 'ever-deeper penetration of nature and propelled by the forces of market and politics, has enhanced human power beyond anything known or even dreamed of before'.⁵⁰ Accordingly, the enormously

45 Ulrich Beck, *Ecological Politics in an Age of Risk* (1992) at 203, cited in Julia Black, 'Regulation as Facilitation: Negotiating the Genetic Revolution' in Roger Brownsword, William Cornish & Margaret Llewellyn (eds), *Human Genetics and the Law: Regulating a Revolution* (1998) at 29 n2.

46 Jonas, above n37 at 21 illustrates how the 'most ambitious dream of *homo faber* ... show most vividly how far our powers to act are pushing us beyond the terms of all former ethics' and 'demand an answer *before we embark*'. [Emphasis added.]

47 Above n8 at 203.

48 Michael Kirby, *Reform the Law: Essays on the Renewal of the Australian Legal System* (1983) at 238.

49 Id at 238–239.

50 Above n37 at ix.

enhanced power which modern science and technology has helped to bring to human beings and their dominion of the world brings with it a change in responsibility: responsibility that is a 'correlate of power and must be commensurate with the latter's scope and that of its exercise'.⁵¹ In his analysis, this means that we need to construct and identify a metaphysically based theory of responsibility — one which addresses the responsibilities of humankind to itself, to distant posterity and to all terrestrial life.

The imperative in identifying this theory of responsibility is to enable us 'to discriminate between legitimate and illegitimate goal-settings to our Promethean power'.⁵² The enlarged nature of human action — enlarged in magnitude, reach and novelty — raises moral issues beyond inter-personal ethics and requires reflection. Responsibility is centre stage and calls for lengthened foresight — what Jonas calls a 'scientific futurology'.⁵³ This responsibility should be informed by a 'heuristics of fear',⁵⁴ which will help to disclose what is possibly at stake; what values and traditions we may pass up; what approaches and opportunities we ought in all conscience to deny ourselves. In short, '[w]hat we must avoid at all cost is determined by what we must preserve at all cost'.⁵⁵

Easy dependence upon the professional sense of responsibility, as Maclean has identified, will become more elusive as a new breed of providers of reproductive technology emerges.⁵⁶ Increasingly, developments will be funded, findings unveiled, possibilities mooted, results replicated and then (and only then) regulatory responses sought. Previous structures of cooperative and corporatist workings may fall under the competitive pressures of a global market. Regulation within domestic markets will become more problematic as providers of services can engage in regulatory arbitrage and operate from their chosen base in an increasingly global market. Access to technology will become easier than ever as infertility treatment providers and purchasers explore the tentacles and trappings of the world wide web.⁵⁷ As always with the internet, it appears to allow the opportunity to access global markets increasingly free from the regulation of any single jurisdiction.

The advent of 'risk society' 'presumes a new politics because it presumes a re-orientation of values and the strategies relevant to pursuing them'.⁵⁸ For Giddens, this leads to the so-called 'third way' in politics. More generally, this is what gives rise to Hobsbawm's 'general concern with ethics'.⁵⁹ Ethics, in the limited sense of a concern with different values, has become the paradigm form of social inclusion

51 Ibid.

52 Ibid.

53 Ibid.

54 Ibid.

55 Ibid.

56 Above n5 at 163.

57 For two of the many examples, see: <www.eggdonorfertilitybank.com> and: <www.thespermbankofca.org>.

58 Above n30 at 5.

59 Eric Hobsbawm, *Age of Extremes: The Short Twentieth Century 1914–1991* (1994).

in the risk society. Ethical debate, perhaps more than politics, is becoming the paradigm form of participation. The primary responsibility of law, then, while controversial remains significant; law has a central role in stimulating and contributing to ethical debate. This underlines the important requirement that courts develop a moral point of view, as we have argued it must do in 'stigmata' cases. This entails that the court should not, because it cannot, disguise its judgments as no more than a positivistic exercise concerned only with its own internal, self-referential logic. As much was recognised by Hoffmann LJ in *Bland*,⁶⁰ arguably misapplied by Lords Mustill and Browne-Wilkinson in the same case⁶¹ and — with disastrous effects for the court's legitimacy — denied by Ward LJ in *Re A (conjoined twins)*.⁶² We return to this discussion in our conclusion.

3. *Procreative Tourism and Biomedical Diplomacy*

In the 1980s and early 1990s debates in reproductive medicine were about how and in what appropriate way(s) to respond to biological infertility and where, if judged appropriate, to bound the commons of assisted conception. Remarkable transformations in science and medicine have occurred since. The news of that decade has been populated with postmenopausal women⁶³ and posthumous pregnancies;⁶⁴ surrogate mothers⁶⁵ and homosexual fathers,⁶⁶ tourism, whether

60 Above n3 at 850.

61 Id at 885 (Lord Mustill), 879 (Lord Brown-Wilkinson).

62 *Re A (conjoined twins)*, above n6 at 969.

63 See Fleur Fisher & Ann Sommerville, 'To Everything there is a Season? Are there Medical Grounds for Refusing Fertility Treatment to Older Women?' and Inez de Beaufort, 'Letter From a Post-Menopausal Mother' in John Harris & Søren Holm (eds), *The Future of Human Reproduction: Ethics, Choice and Regulation* (1998) at 203 and 238 respectively.

64 A survey of over 300 fertility clinics in the United States and Canada found that more than a dozen had already harvested sperm from dead men and stored it for possible later use. Three times as many had been asked to perform such a procedure: Philip Cohen, 'Clinics Admit They Take Sperm From Dead Men' (1996) 152 *New Scientist*.

65 In varying guises and disguises. A Californian couple are seeking a surrogate mother to carry a child for their dead daughter: she survived a brainstem tumour but developed lymphoblastic leukaemia two years later. She underwent fertility treatment, eggs were collected and fertilised by donor sperm and frozen. She died two years later in late 1996. She had wanted at least one of her frozen embryos to be used to establish a pregnancy and her parents were seeking to oblige: *Daily Mail* (25 January 1997). A British woman, Edith Jones, hoped to become the UK's first 'surrogate grandmother' acting as a surrogate for her own daughter who has no womb: *Mail on Sunday* (6 August 1995). Similar stories are reported from South Dakota, USA: 'Surrogate Granny Has Twins' *The Times* (14 October 1991) at 11; and South Africa: Sue Reid, *Labour of Love: The Story of the World's First Surrogate Grandmother* (1988).

66 Sometimes run together. Witness the birth in late 1999 of Aspen and Saffron Drewitt-Barlow to their gay fathers Tony Barlow and Barrie Drewitt, who had found a surrogate mother in California to carry the pregnancy after a donated egg was fertilised with sperm provided by one of them. On arrival in Britain, the babies were refused entry at Heathrow airport: Helen Carter, 'Gay Couple's Twins denied Entry to UK' *Guardian* (3 January 2000) at 5. An immigration battle appeared imminent before the Home Office relented.

procreative,⁶⁷ surrogacy, very occasionally unintentional,⁶⁸ abortion and sperm,⁶⁹ sex selection⁷⁰ and genetics; virgin births⁷¹ and multiple births;⁷² the appearance of social infertility and, latterly, circumvented fertility, at least in sheep⁷³ and pigs.⁷⁴

Concern with, and demand for, reproductive medicine has become a global matter. The existence of a number of specialist clinics has revealed a global market for assisted conception. With the facilitation of travel and the phenomenon of speed, the ability to avail oneself of the services available at the reproductive tourist office makes the franking of the stamp on the ethical envelope more interesting. Where technological development results in the blurring of national boundaries, the increasingly difficult task of one country insulating itself from events elsewhere in the world has given rise to the possibility of what has been called 'procreative tourism' and ethical dumping:

[t]he possibility of a coherent and comprehensive policy, or of legislation encompassing all of these new technologies in each state, may never be forthcoming and may not even be desirable where it would run contrary to basic human rights and freedoms. Furthermore, even if internal domestic agreements were to be achieved, today's modern "global village," with its means of

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- 67 The season of procreative tourism was publicly inaugurated by the birth to a 59 year old British woman, refused treatment services in the UK, of twins in an Italian clinic. For a careful consideration of some of the possible consequences of treating reproduction as an item of the consumer market see Margaret Jane Radin, *Contested Commodities* (1996).
- 68 One particular case from a Manhattan IVF clinic concerns Donna Fasano and Deborah Rogers who attended the clinic on the same day. Mrs Fasano became pregnant with twins; Mrs Rogers did not. Mrs Fasano later discovered that she had been an unintentional host surrogate to Mrs Rogers' child when she gave birth to the babies; one was white, the other was black. Mrs Fasano is reported to have handed the black child to his biological parents and lawyers have been consulted: Philip Delves Broughton, 'Mother in Embryo Mix-up to Give Up Baby' *Daily Telegraph* (31 March 1999).
- 69 So called 'transport IVF' — where sperm is collected from a donor in one centre and transferred for fertilisation use to another.
- 70 Considered in Derek Morgan, *Issues in Medical Law & Ethics* (2001) at 129–151.
- 71 For an illustrative example of this early furore see Sue Jennings, 'Virgin Birth Syndrome' (1991) 337 *The Lancet* 559.
- 72 Mandy Allwood, pregnant with eight fetuses which all died, is paralleled by Zoe Efstathiou, a Cypriot woman pregnant with 11 fetuses after fertility treatment who decided that seven should be aborted by selective reduction: Celia Hall, 'Birth Drup: Wife Expects 11 Babies' *Daily Telegraph* (20 December 1996) at 3.
- 73 I Wilmut, A E Schnieke, J McWhir, A J Kind & KHS Campbell, 'Viable Offspring derived from Fetal and Adult Mammalian Cells' (1997) 385 *Nature* 881; 'Dolly', the sheep, was born following a technique which involved nucleus substitution into an egg and not an embryo. Dolly had been preceded at birth by Morag and Megan, but they had been born following the use of an embryonic or foetal cell. All had been preceded by over 270 unsuccessful attempts to perform the technique: see Ian Wilmut, Keith Campbell & Colin Tudge, *The Second Creation: The Age of Biological Control by the Scientists who Cloned Dolly* (2000).
- 74 Dolly has since gained a number of piglet cousins; the birth of Millie, Christa, Alexis, Carrel & Dotcom was heralded in the British press in March 2000. For a consideration of some of the ethical problems and legal issues to which cell nucleus replacement does and might give rise, see Derek Morgan, 'Identity Issues: The Strange Case of Nucleus Substitution' in Martin Richards, Andrew Bainham & Shelley Day Sclater (eds), *Future Bodies* (forthcoming).

transportation and communication. would allow citizens to practice "procreative tourism" in order to exercise their personal reproductive choices in other less restrictive states.⁷⁵

Procreative tourism may be inevitable, even in the face of concerted efforts to harmonise or approximate individual states' laws. Not every state will be committed to a regulatory model based upon advance determination of what is to be permitted. This may be because of an instinctive political commitment to regulation primarily through the market, or because of an inability to reach a political commitment of any complexion. This seems to be particularly the case in federated systems of health regulation, such as Australia, Canada and the United States, but it applies also in political unions such as Europe. This can produce curiosities such as the Italian situation, where recent regulation would have introduced one of the tightest regulatory structures in Europe, if not the world, but where, in the absence of agreement on that legislation, anything goes. An answer, and one pursued by, for example, the Council of Europe, might lie in what we call 'biomedical diplomacy'. It is an important task for biomedical diplomacy to chart how presently different planes or planets might interact to live together in one system. The task is to examine and evaluate the way(s) in which they might operate together to co-construct the 'bioeconomy'.

However, there are a number of reasons why this provides a daunting challenge. To begin with, part of the reason why it is commonly said that assisted conception techniques and medical technology generally outstrip ethical and legal debate is precisely because there exists no consensus about the complex ethical issues which arise. Throughout Europe, to take a continent that has at least some common legal framework, the moral and legal pluralism reflected in approaches to regulation of biomedicine is evident. In truth, this pluralism typically operates at the margins of what might be called the ethical stationery. The depth and breadth of agreement far outweigh and outpace moral disagreement, whether the supporting reasoning is of a broadly consequentialist or deontological kind. Nonetheless, at the margins of this ethical page the lines become less clear, the text blurred and the meanings most ambiguous, oppositional and most evidently contextual. It is in these margins that legal script becomes most franked with national stamps, and yet in the envelope of responses there are some common scripts to be discerned. But it is those very margins that provide the points of departure for the procreative tourist.

The challenge for any state is to obtain all the advantages of the reproduction revolution and avoid the disadvantages: to avoid becoming prisoners of the planned or unplanned excesses of progress, and to try to control these developments and guide them in the directions wanted. An initial problem is trying to second-guess unwarranted consequences where they are unplanned; another is to agree upon which consequences are unwarranted and how they are best avoided

75 Above n9. For a critical analysis of one particular case of globalisation and the effect of that on a national regulatory scheme. see above n1. We write, obviously, against a westernised background where relatively common assumptions about travel and tourism can be made.

or minimised. Yet even at a national level such agreement may be marked by pragmatism and compromise. Margot Brazier, writing of the *Human Fertilisation & Embryology Act 1990* (UK), has complained that there is 'little conceptual depth underpinning British Law', and that as a result 'we debate the same issues in different disguises'.⁷⁶

The *Human Fertilisation & Embryology Act* has several purposes. The first is to regulate certain infertility treatments which involve keeping or using human gametes and to regulate the keeping of human embryos outside the human body. The second purpose is the statutory regulation of embryo research, which is now permitted until the appearance of the 'primitive streak'; for the purposes of the legislation that 'is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed', excluding any period of cryopreservation.⁷⁷ Thirdly, there is a prohibition on the creation of hybrids using human gametes, the cloning of embryos by nucleus substitution to produce genetically identical individuals, and genetic engineering to change the structure of an embryo. The fourth purpose is to effect changes to the *Abortion Act 1967* (UK).

The major contribution made by the Act was the creation of the Human Fertilisation and Embryology Authority (hereinafter HFEA), a regulatory body with a wider range of responsibilities, and more varied range of powers and duties than the voluntary predecessors following the publication of the *Warnock Report* in 1984. HFEA has power over public and private institutions to scrutinise and license, to approve and discipline, and to sanction and censure the provision of assisted conception services and the work which it is said will take forward in this area the experimentation upon live human embryos.

The Authority's engine has four cylinders:

- i) the provisions of the Act itself;
- ii) regulations and directions made under the Act;
- iii) the Authority's code of practice — a sort of highway code for infertility treatments; and
- iv) ethics committees (although whether they should properly be seen as a part of the transmission system, or as a part of the braking system is debatable).

HFEA is primarily a licensing body. It is concerned with three main areas of activity:

- i) the storage of gametes and embryos;
- ii) research on human embryos; and
- iii) any infertility treatment which involves the use of either donated gametes or embryos created outside the human body.

Different parts of the Act apply to the collection, storage and usage of such gametes. Where a clinic performs artificial insemination using gametes from the

⁷⁶ Margaret Brazier, 'Regulating the Reproduction Business' (1999) 7 *Medical LR* 166 at 167. A similar complaint informs the recent work of McLean, above n5.

⁷⁷ *Human Fertilisation & Embryology Act 1990* (UK) s3.

couple alone, or where it undertakes a procedure such as GIFT — gamete intrafallopian transfer — using the couple's own gametes, then the licensing conditions of the legislation do not apply. There are some provisions of the Act to be attended to, but not the full blown licensing scheme.

In addition, HFEA is charged with:

- i) maintaining a register of information concerning donors, treatment services and children born following licensed services;
- ii) publicising services which centres and HFEA itself provide;
- iii) producing advice and information to centres and publishing a code of practice to which centres should adhere or aspire; and
- iv) providing information to donors, to potential patients and to children born following regulated services.

The ability of HFEA to react pragmatically to societal developments replaces commitment to a coherent and clearly articulated policy. In cases where control is difficult or impossible, such considerations may lead to accepting technologies despite their ethical drawbacks.

Having said that, there are a number of fronts upon which regulatory bodies — such as HFEA — are to be applauded precisely for their pragmatism. For the most part in the UK, issues involving perplexing cocktails of ethics, law and public morality have been resolved in a manner which has served private access to assisted conception services whilst maintaining broad public support for this provision. Indeed, the lack of any dogmatic stance has allowed the development of liberal policy without causing widespread offence or opposition. While there may be doubts as to its capacity to switch across cultures, the model presented by HFEA has been widely admired in other jurisdictions. Where more (politically) dogmatic stances have been struck, for example, in those States of Australia which have introduced legislative oversight of assisted conception, one effect has been, and we suspect will continue to be, the opening up of state legislation and state regulatory bodies to judicial challenge based upon federal and Commonwealth laws of general application.⁷⁸

This should not blind us, however, to the considerable tasks that will face bodies such as HFEA in the future, and which suggest that a commitment to little more than pragmatic good sense may not always be sufficient and, certainly, will provide few foundations for the biomedical diplomatic initiative. If this pragmatism is typical of regulatory enterprise in this area, then the product of

78 Such as the successful challenges in *Pearce v South Australian Health Commission* (1996) 66 SASR 486 to the *Reproductive Technology Act* 1988 (SA) and in *McBain v State of Victoria* (2000) 99 FCR 116 to the *Infertility Treatment Act* 1995 (Vic) based on s22 of the *Sex Discrimination Act* 1984 (Cth); on which see the comment by Belinda Bennett, 'Reproductive Technology, Public Policy and Single Motherhood' (2000) 22 *Syd LR* 625. The state government has sought to amend the 1995 Act to restore the pre-existing provision and a review by the High Court of the decision of Sundberg J has been sought. The dubious legality of similar provisions in s23 of the *Human Reproductive Technology Act* 1991 (WA) is reviewed in Stella Tarrant, 'Western Australia's Persistent Enforcement of an Invalid Law: section 23(c) of the *Human Reproductive Technology Act* 1991 (WA)' (2000) 8 *JLM* 92.

national systems will be dependent on their history, and will tend inevitably to variation. Hopefully, however, history will not govern all. Wise government does not always legislate at the first opportunity,⁷⁹ and the global nature of the reproduction revolution makes the lack of attention to concerted international legislation perhaps less surprising than would be its presence.⁸⁰ Indeed, there is sometimes a temptation to believe that legislative attempts to secure recognition of one particular view at the expense of others is the enforcement of moral majoritarianism. Thus, legislation is sometimes asked to portray or reflect a weakened and expansive ethical or moral conception. The Danish Council of Ethics perceptively observes:

... this relationship between ethics and legislation makes it necessary to pose two questions in connection with concrete legislation: Does the legislation live up to that minimum of humanity which the society wishes to preserve and does it allow real freedom for the individual to observe stricter standards than those contained in the law?⁸¹

In addition, the Danish Council advocates that the legislation concerning these problems must take its point of departure in Danish conditions. This means that there may be deviations in relation to the legislation of other countries. The Council argues that the acquisition of knowledge can in some instances raise ethical questions, and it is important that such questions be discussed internationally in order, if possible, to create consensus. But this does not exclude national regulation. An important issue, of course, is whether adoption by, say, Denmark of its own legislation means a greater possibility of influencing the supranational law, or whether it retards that possibility.

Another way of addressing the problem posed for biomedical diplomacy by the processes of national regulation is to consider further the subject matter. When we come to speak of health and illness, we necessarily address a package of conceptual questions.⁸² These include political questions, such as the role and responsibility of the state in securing, promoting or damaging the health of its citizens and those whom it affects directly and indirectly, intentionally and accidentally, through the extraterritorial effects of its behaviour,⁸³ and those of gender, race and ethnicity.

79 Arthur Caplan. 'Introduction' in Dianne Bartels, Reinhard Priester, Dorothy Vawter & Arthur Caplan, (eds), *Beyond Baby M: Ethical Issues in New Reproductive Techniques* (1990) at 5-6: 'Where matters of morality and medicine are concerned, society is best served not by policies based on fear, ignorance, prejudice, or raw emotion, but by the emergence of moral consensus.'

80 Rebecca J Cook & Bernard M Dickens. *Considerations for Formulating Reproductive Health Laws* (1998) at 11.

81 Danish Council of Ethics, *8th Annual Report: Assisted Reproduction — A Report* (Copenhagen: Danish Council of Ethics, 1995).

82 Christopher Boorse, 'On the Distinction Between Disease and Illness' (1975) 5 *Philosophy & Public Affairs* 48; L Nordenfelt, 'On the Relevance and Importance of the Notion of Disease' (1993) 14 *Theoretical Medicine* 15.

An appreciable task for comparative public policy making is to fashion a response to these forces of globalisation, which include 'procreative tourism' and other 'reprogenetic' migration, telemedicine⁸⁴ and other cross-border and jurisdictional questions, such as biotechnology and patenting and the differential impacts which this relationship has in more and less developed countries and regions of the world.⁸⁵ This is the first and perhaps most central task for biomedical diplomacy. It is one to which the study of medical law, as a part of a humane reflection on science, must both urgently attend and be dedicated. If our understanding of medicine's task is to be driven by our understanding of the human values at stake, medical (or health care) law admits of at least a descriptive and a conceptual approach. Margot Brazier has expressed one voice of concern in precisely this regard: 'unless the law can settle upon some coherent and defensible definition of illness, the elasticity of the concepts of illness may snap',⁸⁶ and the concept of medical law with it.

4. *Regulating Biomedicine — Utility or Futility?*

Thus far we have expressed concerns that within risk society, biomedicine and its advance may create more confusion and uncertainty than it resolves, and that this may amount to a change in the 'lay public's social living conditions without its consent'.⁸⁷ But we have also argued that the regulatory task may be fraught with difficulty not merely in the jurisdiction attempting the task, but especially across jurisdictions as transnational provision of the fruits of the biomedical endeavour is increasingly common. If the price of an airplane ticket goes much of the way towards guaranteeing the procreative tourist access to services restricted elsewhere on grounds of age, taste, health, or child protection, then what price the effort of regulation?

Alan Hunt has described these regulatory choices as involving moral politics.⁸⁸ choices made at the interface of the political and the moral. If this is so, much of what is expected of regulating biomedicine has as great a political as moral dimension. In regulating the bioeconomy, we also need to discuss what it is that is

83 Peter Townsend & Nick Davidson (eds), *Inequalities in Health: The Black Report* (1982); Bernard Williams, 'The Idea of Equality' in Peter Laslett & W G Runciman (eds), *Philosophy, Politics and Society. Second Series* (1962) at 110–131; Robert Nozick, *Anarchy, State and Utopia* (1974) at 233.

84 Laurence C Kennedy, 'Medicine, Law and the Internet — Professional Survival in the Cyberage' (2000) 11 *Computers & Law* 31.

85 In less developed regions, the role being played and to be played by the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (to be in place by 2006) — allowing individual states to take into account public interest arguments — will be central. The response is the legal challenge mounted in Transvaal by the South African Pharmaceutical Manufacturers Association and 39 other applicants to the effect that South Africa's patent law is inconsistent with its Constitution.

86 Above n42.

87 Above n8 at 206.

88 Alan Hunt, *Governing Morals: A Social History of Moral Regulation* (1999).

being regulated and by whom or by what. Is the advent of the bioeconomy merely another stage in the description of the physician–patient/family relationship; or are we now fundamentally concerned with business regulation? And, increasingly, regulation is understood to be undertaken in, and as part of, the changing economic constitution of western liberal democracies. These decisions, then, are political in that they relate both to wider structural questions within society, and also in their capacity to generate argument between interest groups with strong affiliations to particular sides of the argument and government. Regulatory flexibility may be opportune in delimiting the extent to which government need stray into this realm of ‘moral politics’.⁸⁹ An example of this from Britain is the hasty washing of hands by the politicians when the permitted storage period for embryos lapsed under the *Human Fertilisation and Embryology Act 1990*. Any action to be taken was very much left to the regulator. Similarly, the delegation of regulatory discretion means that it is the regulator that faces the challenge from those disappointed by the boundaries drawn. Cases like *Blood* seem only to confirm that, in the future, it may be courts rather than governments that will regulate the regulator.

The mechanisms employed here can be seen as a part of a wider and well-documented move towards discretionary regulation.⁹⁰ Now, rather than Weberian formal rationality there is an obvious shift to substantive rationality with ever more discretionary regulation pursuing policy goals.⁹¹ Not surprisingly, judges have reacted to this tendency to replace formal rules with wider administrative discretion to act by an increasingly active commitment to the development of powers of judicial review. The curiosity of these forms of discretionary regulation is that at the same time there is a significant extension of state power into the realm of the private, including the essential identities that we bear. Yet this power is not exercised formally by government, but by agency; and this power is articulated not in the language and mechanisms of traditional rule making and enforcement, but is expressed in the vocabulary and manners of administrative discretion. There is at the same moment much more at stake and yet a concession of the regulatory ground.

The exposure of regulators to a field of moral politics vacated by government may produce compromise rather than control. Indeed, the work of the HFEA has been described by Sir Colin Campbell, former Chair, as an attempt ‘to balance views of scientists with those of patients, ethicists, members of the public and

89 The previous Labour administration of the 1960s has been portrayed as a reformist liberal party specifically in this arena of moral politics. This can be exemplified in a number of ways, of which the following are only symbols: removal of censorship on theatre performances; limited legalisation of the act of abortion; greatly restricting the use and availability of capital punishment; decriminalisation of certain acts of homosexuality; the first fundamental reform of the family law and the opening gambit in the emancipation of children from the otherwise all-encompassing arm of paternalism.

90 Peter Cane, *An Introduction to Administrative Law* (4th ed, 1999); Robert Baldwin & Christopher McCrudden, *Regulation and Public Law* (1987).

91 Max Weber, *Economy and Society* (1978).

others'. This accords implicit weight to the desires of scientists (and note the mention of scientists rather than physicians), in spite of the claim that 'complex science and ethics can be considered impartially, and the public reassured that social policy controls science and not vice versa'.⁹² Ruth Deech, Campbell's successor, later commented that 'there are no clear paths forward and no consensus yet'.⁹³ This echoes the increasingly widespread unease referred to earlier that pragmatism replaces principle in the exercise of regulatory discretion.

Taken in the round, these shifts to regulatory discretion also imply more law, more types of law and more sites on which it operates. Gunther Teubner has identified this as part of the 'juridification' of social spheres,⁹⁴ Marc Galanter has claimed that it is evidence of 'law abounding'⁹⁵ and Richard Susskind has described it as 'hyper-regulation'.⁹⁶ Galanter's hyper-regulated world is characterised by more laws, more lawyers, more claims and more players of the law game. Societies spend more on laws and lawyers. Legal institutions, including courts and firms, increasingly operate in rational, business-like manners and lawyers and judges are more entrepreneurial and innovative. Law, as Jennings has also suggested,⁹⁷ is plural, de-centralised and issuing from more sources; more rules are being applied by more actors to more varied circumstances. More law, more pervasive law, and more information about law, also means that law is less autonomous, less self-contained, more open-textured, and responsive to methods and data from other disciplines. Legal outcomes are more contingent and changing. Outcomes are increasingly negotiated rather than decreed,⁹⁸ such that, in this field we witness law increasingly operating through indirect symbolic controls rather than through imposed coercion.⁹⁹ This we believe is the essence of Campbell's claim to negotiated balance.

Paralleling Hobsbawm's 'crisis decades' and Beck's description of this period as a 'secret farewell to an epoch of human history', Galanter has observed in strikingly similar fashion that:

92 Colin Campbell, 'Legislation and Regulatory Bodies: the Interface Between Law and Ethics' (1995) 46 *Northern Ireland LQ* 365.

93 Ruth Deech, 'Family Law and Genetics' in Brownsword et al, above n45, 105 at 123.

94 Gunther Teubner, 'Juridification: Concepts, Aspects, Limits, Solutions' in Gunther Teubner (ed), *Juridification of Social Spheres: A Comparative Analysis in the Areas of Labor, Corporate, Antitrust and Social Welfare Law* (1987) at 3.

95 Marc Galanter, 'Law Abounding: Legislation Around the North Atlantic' (1992) 55 *Mod LR* 1.

96 Richard Susskind, *The Future of Law: Facing the Challenges of Information Technology* (1996).

97 Jennings, 'Possibilities of Consensus: Towards Democratic Moral Discourse' (1991) 16 *J Medicine & Philosophy* 447.

98 There is an excellent illustration and application of the meaning of this part of Galanter's argument in Black, above n45 at 29.

99 That this is hardly a novel phenomenon nor one newly observed can be gathered from, for example, Kait Erikson's elegant study *Wayward Puritans: A Study in the Sociology of Deviance* (1966).

law itself is being transformed. ... As law expands and penetrates the world, it changes in the process. Its institutions flourish but lose their autonomous, self-contained quality. On every front we can observe the boundaries of the legal world becoming blurred and indefinite.¹⁰⁰

The nature of law in the 'risk society' has changed. And not only in the sense suggested by Eser that law may have different functions: the instrumental, the symbolic, the protective and the declaratory (though this is important, and we will return to it). Nor is it simply, as suggested by John Griffith, that this expanded law produces more gaps between intended, unintended, foreseen and unforeseen consequences of law making.¹⁰¹ Rather the nature of law is different in that, as more areas of social life become 'legalised', it thereby disqualifies other versions of truth.¹⁰² Biotechnology and biomedicine is a highly topical illustration of this.

5. *Who Gives a XXXX? Should We Bother Trying?*

All of this may seem pretty bleak. Despite our continual resort to legal regulation, it strains to cope with the speed of change in scientific medicine, and the spread of its global reach. Writing in another time, and in another context, Antoine de Saint-Exupéry, memorably captured this nonetheless in the idea that:

Everything around us is new and different — our concerns, our working habits, our relations with one another. Our very psychology has been shaken to its foundations, to its most secret recesses To grasp the meaning of the world of today, we use a language created to express the world of yesterday.¹⁰³

Why then stick with the regulatory task? There are many gaps after all in most regulatory structures, so that even if we try, through lack of foresight we may fail. Why not leave the task to the market? Let innovators decide whether people will express their desire for the latest biotechnology through their willingness to pay. Let public doubt or disapproval express itself in the rejection of the opportunity to buy.

One answer to this is that the issues ought to be subject to wide ethical debate — of what the good life consists, and how it is to be achieved or maintained.

One response of the law is in the realm of the colloquial — the ability of law to provide a forum within which such matters may be addressed. This colloquial response is itself part of the process of mediating what we have labelled elsewhere the naming, blaming, claiming and declaiming inherent in biomedical law.¹⁰⁴ This lays a particularly heavy burden and responsibility upon legislators but perhaps

100 Above n95 at 17–18.

101 See John Griffiths, 'Is Law Important?' (1979) 54 *NYULR* 339.

102 See, in a different context, Carol Smart, *Feminism and the Power of Law* (1989) at 23; Margaret Davies, *Asking the Law Question* (1994) at 253; Stephen Bottomley & Stephen Parker, *Law in Context* (2nd ed, 1997) at 66.

103 Antoine de Saint-Exupéry, *Wind, Sand and Stars* (1939; 1975 Pan ed) at 39–40.

104 Above n7 at 1.

especially on courts which are then called upon to examine the nature of these regulatory responses, and, it must be added, their obverse, legislative silence. This responsibility may be seen and may be keenly sought in what we have called 'stigmata' cases. These are those cases in which (and through the use and expansion of the mechanism of judicial review, increasingly)¹⁰⁵ courts will be used as an arm of regulation in moral politics. This will require that they develop and declare an explicit moral framework to their decision-making. The 'stigmata' cases that we have earlier identified — *Bland*,¹⁰⁶ *Blood*,¹⁰⁷ and *Re A*¹⁰⁸ do not yet indicate that at least English courts are well versed in this vocabulary, at least not beyond an unadulterated utilitarianism — the very language of modern bioethics.¹⁰⁹ And as Lords Mustill and Browne-Wilkinson recognised in *Bland*, it is far from evident that the lexicon of law rather than the vocabulary of values will of itself be sufficient to carry their voice in this colloquy, to sustain their vote in this parliament of moral politics.

Law, of course, is not something that is separate from other social structures and practices, but is a part, indeed itself a constitutive part, of them;¹¹⁰ 'legal discourse is never entirely insulated from popular discussion of issues of law and justice.'¹¹¹ Law regulates social behaviour not just as a set of rules imposed from 'outside' but by being internalised in that behaviour. Law, as Clare Dalton has memorably written,

... like every other cultural institution, is a place where we tell one another stories about our relationships with ourselves, one another, and authority When we tell one another stories, we use languages and themes that different pieces of the culture make available to us, and that limit the stories we can tell. Since our stories influence how we imagine, as well as how we describe, our relationships, our stories also limit who we can be.¹¹²

105 For an excellent contribution review of past and suggested future developments see Cameron Stewart, 'Judicial Review of Treatment Decisions — A Further Role for the Courts' (1999) 7 *JLM* 212; Cameron Stewart, 'The Future Impact of Administrative Law on Medical Decision-Making', paper presented at continuing legal education seminar entitled *Medical Decision-making: New Issues in Liability and Review*, 10 November 1999, Faculty of Law, University of Sydney.

106 Above n3.

107 Above n2.

108 *Re A (conjoined twins)*, above n6.

109 Anne Maclean, *The Elimination of Morality: Reflections on Utilitarianism and Bioethics* (1993).

110 Austin Sarat & William Felstiner, *Divorce Lawyers and their Clients: Power and Meaning in the Legal Process* (1995), as recently recognised although not articulated by Lord Phillips MR, Peter Gibson & Latham LJ in *R v Secretary of State for the Home Department, ex parte Mellor* [2001] 2 FCR 153.

111 Jeremy Webber, 'Constitutional Poetry: The Tension Between Symbolic and Functional Aims in Constitutional Reform' (1999) 21 *Syd LR* 260 at 262.

112 Clare Dalton, 'An Essay in the Deconstruction of Contract Doctrine' (1985) 94 *Yale LJ* 997 at 999, citing Gerald Lopez, 'Lay Lawyering' (1984) 32 *UCLALR* 1.

This much is clear from the judgment of Ward LJ in *Re A* and Hoffmann LJ in *Bland*. While in the former, Ward LJ observed that ‘this is a court of law, not of morals’ he proceeded to support his judicial reasoning within an explicitly moral framework.¹¹³ In *Bland* Hoffman LJ came closest of any of the judges to recognising the nature of the task with which the courts were confronted:

This is not an area in which any difference can be allowed to exist between what is legal and what is morally right. The decision of the court should be able to carry conviction with the ordinary person as being based not merely on legal precedent but also upon acceptable ethical values.¹¹⁴

How far short of that the House of Lords fell in their speeches is at least perceived by some of the judges there.

These colloquial and constitutive canons are a reason, perhaps *the* reason, to persevere in the regulatory task. However falteringly, however late, these stories are told on the legal stage. The audience listens, hoping as Hoffmann LJ perceived, to comprehend what it is that the courts are engaged in. The story may be of the woman wishing to have a baby using the sperm of her dead husband, of the tragedy of conjoined twins and the agony of their parents, of the suggestion to terminate the life of a man injured at a football match who has never woken up. Simple stories, these are not always told in the formal language of the law but in the more prosaic terms of the tabloids. But the issues are clear enough, and views are formed. In many senses those views may be clearer than those presented by the law. Was the *Blood* case about free movement rights in the European Union, or something essentially more important than that? On this view, law is a mediating institution, not usually the media itself. It is often the stage on which complex matters of scientific medicine are played out as morality plays to the attentive gathered audience. At least in the stigmata cases, law is an institutional mechanism for offering explanations and rationalisations for scientific citizenship, rather than the explanation itself.

The challenge which lies for law in this era of scientific citizenship — the age of the bioeconomy — and one of the key tasks of biomedical diplomacy, is to debate and decide on the very relationship between medicine and law, one which Sheila McLean has portrayed as at best ambivalent, at worst one that infantilises patients through a ‘comfortable alliance’.¹¹⁵ ‘The decision whether or not legal intervention is appropriate and whether it comes in the best possible form has been reached by *ad hocery* rather than on the basis of mature reflection.’¹¹⁶ Indeed, Boaventura de Sousa Santos has cautioned us to characterise the present character

¹¹³ *Re A (conjoined twins)*, above n6 at 969.

¹¹⁴ Above n3 at 850 (Hoffmann LJ).

¹¹⁵ Above n5 at 162–163, 180–181.

¹¹⁶ *Id* at 162.

of law as the alter ego of science rather than its conscience. Sheila McLean has argued that law itself must come to bar and be judged according to whether it appears to be 'controlling or conceding' the future.¹¹⁷

It is not the mechanics of the law's response which are so important as its content — a content informed by concern for liberty, for the protection of the vulnerable and for the reinforcement of ideals.¹¹⁸

We are engaged in nothing short of a continuing intellectual revolution in modern scientifically based medicine. That revolution demands a revisitation of old institutional forms and responses, including those of law itself. Otherwise we will be confronted with Kirby's vision of the democratic deficit in scientific citizenship; the demise of the rule of law and the inarticulate reign of the possible.¹¹⁹ Scientific citizenship requires that courts develop a moral vision and vocabulary so that we shape the moral economy of the emergent bioeconomy.

117 *Id* at 161–181.

118 *Id* at 180.

119 Above n48.