Health Law's Kaleidoscope

Health Law Rights in a Global Age

Belinda Bennett

ASHGATE

APPLIED LEGAL PHILOSOPHY

Health Law's Kaleidoscope

Health Law Rights in a Global Age

BELINDA BENNETT
Faculty of Law, University of Sydney, Australia

ASHGATE

Published by
Ashgate Publishing Limited
Gower House
Croft Road
Aldershot
Hampshire GU11 3HR
England

Ashgate Publishing Company
Suite 420
101 Cherry Street
Burlington, VT 05401-4405
USA

Ashgate website: http://www.ashgate.com

British Library Cataloguing in Publication Data
Bennett, Belinda
Health law's kaleidoscope : health law rights in a global age. - (Applied legal philosophy)
1. Medical laws and legislation 2. Medical innovations - Social aspects
I. Title
344'.041

Library of Congress Cataloging-in-Publication Data
Bennett, Belinda.
Health law's kaleidoscope : health law rights in a global age / by Belinda Bennett.
p. cm. -- (Applied legal philosophy)
Includes bibliographical references and index.
ISBN 978-0-7546-2631-2
1. Medical laws and legislation. 2. Medical ethics. 3. Human reproductive technology--Law and legislation. I. Title.

K3601.B46 2008
344.04'1--dc22

2007031216

ISBN 978 0 7546 2631 2

Printed and bound in Great Britain by MPG Books Ltd, Bodmin, Cornwall.

Series Editor's Preface

The objective of the Applied Legal Philosophy series is to publish work which adopts a theoretical approach to the study of particular areas or aspects of law or deals with general theories of law in a way which focused on issues of practical moral and political concern in specific legal contexts.

In recent years there has been an encouraging tendency for legal philosophers to utilize detailed knowledge of the substance and practicalities of law and a noteworthy development in the theoretical sophistication of much legal research. The series seeks to encourage these trends and to make available studies in law which are both genuinely philosophical in approach and at the same time based on appropriate legal knowledge and directed towards issues in the criticism and reform of actual laws and legal systems.

The series will include studies of all the main areas of law, presented in a manner which relates to the concerns of specialist legal academics and practitioners. Each book makes an original contribution to an area of legal study while being comprehensible to those engaged in a wide variety of disciplines. Their legal content is principally Anglo-American, but a wide-ranging comparative approach is encouraged and authors are drawn from a variety of jurisdictions.

Tom Campbell
Centre for Applied Philosophy and Public Ethics,
Charles Sturt University, Australia

Preface and Acknowledgements

During my teaching and research of health and medical law, I have found that the same themes continue to arise, even across issues that seem to be quite diverse: the meaning of individual choice and rights, the relationship between the individual and the community, and the role of law in an increasingly globalized world. These themes arise against a backdrop of rapid developments in medical science, the globalization of health and health law, and the growing acknowledgement of the links between health and human rights. This book has developed out of my quest to identify and analyse these synergies and connections and their relevance to contemporary health law.

As always, my work has benefited from the generosity of friends and colleagues who have read drafts, discussed ideas and helped me to refine my work. In particular my thanks go to Terry Carney, Michael Freeman, Isabel Karpin, Derek Morgan, Patti Peppin, Kerry Petersen, Don Rothwell, Sally Sheldon, George P. Smith II and the anonymous reviewers of previously published work. I would also like to thank the Faculty of Law, University of Sydney for its continued support of my research. Some parts of this book have been presented at seminars and I am grateful to the seminar organizers and participants for their comments and suggestions. I am also grateful to Roslyn Moloney for her research assistance on Chapter 5 and to Claire Deakin for her research assistance as I finalized the manuscript. The manuscript was completed in March/April 2007 while I was a visitor at the Law School at Chinese University of Hong Kong. My thanks go to Mike McConville, Robyn Martin, Alexandra Lo and the staff at the Law School at Chinese University of Hong Kong for their hospitality. My work has also benefited enormously from my interaction with my undergraduate and postgraduate students in health and medical law at the Faculty of Law, University of Sydney. Their continued enthusiasm is always a source of inspiration. I am grateful too to John Irwin, Alison Kirk, Emily Jarvis, Carolyn Court and the staff at Ashgate Publishing for their continued support of this book. Finally, my thanks and gratitude goes to my family. Without their continued support and encouragement none of this would have been possible.

Research for Chapters 1 and 5 was supported by a grant from the Australian Research Council for a Discovery Project on 'Globalisation and Biomedicine: The Harmonisation of Local and Global Regulatory Demands' (DP0452853) (Chief investigators: Don Rothwell and Belinda Bennett). Chapter 1 was previously published as 'Rewriting the Future? Biomedical Advances and Legal Dilemmas'. This article was published in the *Journal of Law and Medicine*, Vol. 13, No. 3 (2006): 295–303, © Lawbook Co., part of Thomson Legal & Regulatory Limited <www.thomson.com.au>, reproduced with permission.

Earlier versions of parts of Chapter 2 were previously published as 'Gamete Donation, Reproductive Technology and the Law', in Kerry Petersen (ed.), *Intersections: Women on Law, Medicine and Technology* (Dartmouth Publishing, 1997): 127–44 and as 'Reproductive Technology, Public Policy and Single Motherhood' in the *Sydney Law Review*, Vol. 22, No. 4 (2000): 625–35 © *Sydney Law Review* and authors; published by Thomson Legal and Regulatory Ltd <www.thomson.com.au> for the Faculty of Law, University of Sydney. I am grateful to Ashgate Publishing, to the *Sydney Law Review* and to Thomson Legal and Regulatory Ltd for permission to use this material.

Earlier versions of parts of Chapters 3 and 8 were published in 'Written in Code: Diversity and the New Genetics', in Michael Freeman and Andrew D.E. Lewis (eds), *Law and Medicine: Current Legal Issues 2000*, Vol. 3 (2000): 189–203. This material is used here by permission of Oxford University Press. An earlier version of this work was presented at the Feminist Legal Academics Workshop (F-LAW) in Sydney, February 1999; as a seminar at the Faculty of Law, University of Sydney, March 1999; and at the Law and Medicine Colloquium at the Faculty of Law, University College London, July 1999. Earlier versions of parts of Chapter 4 were published as 'Prenatal Diagnosis, Genetics and Reproductive Decision-making' in the *Journal of Law and Medicine*, Vol. 9, No. 1 (2001): 28–40, © Lawbook Co., part of Thomson Legal & Regulatory Limited <www.thomson.com>, reproduced with permission, and as 'Choosing a Child's Future? Reproductive Decision-making and Preimplantation Genetic Diagnosis' in Jennifer Gunning and Helen Szoke (eds), *The Regulation of Assisted Reproductive Technology* (Ashgate Publishing Ltd, 2003): 167–76. An earlier version of Chapter 4 was presented as the Willis Cunningham Memorial Lecture at the Faculty of Law, Queen's University, Canada in January 2006. I am grateful to the Faculty of Law at Queen's University for making this presentation possible.

An earlier version of Chapter 5 was presented at seminars during March 2005 at the Faculty of Law, University College Dublin; University College Cork; the Law School, University of Limerick, and at the Faculty of Law, University College London. Earlier versions of Chapter 6 were presented at the Faculty of Law, University of British Columbia in January 2006 and as a seminar in the Kirby seminar series, University of New England Law School in Armidale, New South Wales in May 2006.

The quote on page 77 from *Year of Wonders: A Novel of the Plague* by Geraldine Brooks is reprinted by permission of HarperCollins Publishers Ltd. © Geraldine Brooks, 2002.

Contents

Introduction

According to Thomas Friedman (2005), the world is flat. This flat-world phenomenon is part of the third era of globalization that we live in. While Globalization 1.0 shrank the world from large to medium size, lasting from Columbus's voyage to the Americas in 1492 until 1800 and was about countries globalizing, version 2.0, which lasted until 2000, shrank the world from medium to small and was driven by multinational companies (ibid.: 9–10). Globalization 3.0 is, according to Friedman, about individuals working and competing globally and is transforming the world from small to tiny, while simultaneously flattening its playing fields (ibid.: 10). Although this flattening is occurring at a dramatic pace, Friedman argues that flatness is not a uniform phenomenon. For large numbers of the world's people, the world is not flat and, may not become so (ibid.: 461). Many people live in the unflat world where people are too sick, too poor, or too disempowered to enjoy the benefits of flatness (ibid.: 461–94).

While these forces are undoubtedly transforming relationships between countries, businesses and individuals, the processes of globalization are also undoubtedly impacting upon the regulatory laws and frameworks that set the stage for those interactions. Just as globalization reveals a tension between the universal and the particular, so too law is increasingly embedded in global regulatory developments and debates while simultaneously being driven towards increasing specialization and diversification. In general, law is a jurisdictionally-based discipline and it is this focus on the local that often occupies a central place in legal analysis and debates. In the flattening world of globalization, the global takes on a new significance that demands the transcendence of law's traditional local focus.

Health law is not immune from these broader trends. In the past quarter-century, health law has grown out of its infancy and has developed into an area of growing significance. This development has been influenced by a number of factors including the growing recognition of patients' rights within health care (Darvall 1993), the impact of medical science and technology, developments within the discipline of law, and the impact of globalization, bioethics and human rights on contemporary debates about health. Increasingly, health law is about the legal and ethical challenges posed by the complexities of modern life and death. Law is often looked to as the solution to the hard questions of our time and is forced into the role of arbiter and decision-maker for the imponderable (Smith 2006: 15–16). Law faces the seemingly impossible task of finding a path through an ethical landscape that is dotted with quicksand that traps the unwary. In general, our response to these challenges is to turn to the traditional tools of law reform: to seek the views of the community and experts and to craft laws that represent a balancing of the various interests and viewpoints.

This book is about the ways in which developments in globalization and in medical science and technology open new possibilities for our future – both positive and negative – and about the challenges we face in responding to those possibilities. It is a book about the choices we will be required to make as the future becomes the present and it is about the connections and intersections between the lives of individuals and communities within both local and global spaces. In short, it is about the ways that different aspects of our lives intersect with the lives, rights and interests of others to form a rich kaleidoscope of contemporary life and it is about the patterns and connections that we can choose to make.

Chapter 1 sets the scene by arguing that regulatory debates around biomedicine are characterized by a number of common themes. These include the positive and negative possibilities of advances in medical science in areas such as genetics, assisted conception, and stem cell research. On the one hand, there are the potential therapeutic benefits to individuals and communities that will flow from advances in each of these fields. However, these developments also present reasons for caution with fears often articulated about the directions science may take us. Indeed, the dystopian possibilities of the future are a regular theme in popular culture. Another theme is that of globalization and its relevance to questions of regulatory choice in response to new technologies. Finally, there is the challenge of articulating common values both at the local level in terms of the need to address diverse community viewpoints, and more globally as we seek to develop a common language for bioethics. Chapter 1 argues that an appreciation of these issues is essential if we are to be able to respond to new and emerging challenges.

Chapter 2 explores the changing nature of the family in contemporary society through an analysis of rights in relation to assisted conception. Through discussion of the rights of single and lesbian women to access assisted conception services, and changing views over the rights of children conceived using donated gametes to information about their biological parentage, we can trace the impact of new technologies and social trends on the core social institution of the family.

Chapter 3 focuses on debates over cloning technologies. The chapter analyses the debates over reproductive and therapeutic cloning and the argument that cloning is antithetical to human dignity. The cloning debate also reveals the difficulties that exist in crafting laws for new technologies since legislative definitions can quickly be rendered irrelevant if new advances in medical science do not fit within existing statutory definitions. Finally, this chapter questions the link between genetics and identity and argues against biologically deterministic definitions of the body and identity.

In Chapter 4, the themes of assisted conception, genetics and cloning come together in an analysis of the meaning of reproductive rights in a posthuman world. This chapter asks us to consider whether it is ethically acceptable for prospective parents to use preimplantation genetic diagnosis to choose between embryos on the basis of their characteristics and explores the idea of whether there should be limits to choice. The chapter returns to the theme of human dignity, that was explored in the context of cloning within Chapter 3, and considers the whether human dignity is compatible with posthuman reproduction.

The relationship between health rights and health tourism is explored in Chapter 5, which marks a return to the theme of globalization. The ease of international

travel opens new possibilities for interaction between citizens of the world's wealthy countries and those of the world's poorer countries. The chapter uses four examples to illustrate these interactions: (1) the global movement of health professionals, both in terms of migration of skilled health professionals from poor countries to wealthy ones, and also the movement of researchers to jurisdictions with favourable regulatory environments; (2) the relationship between international trade and travel and infectious disease; (3) fertility tourism in which individuals and couples travel internationally in order to access assisted conception services that are unavailable or too expensive in their home countries; (4) transplant tourism in which individuals in need of organ transplants travel internationally, typically from wealthy countries to poorer ones, to receive an organ donation. In each of these examples, there is the potential for individuals to interact across global spaces in ways that may be either beneficial or exploitative. The globally commercial nature of health care services presents significant challenges for countries seeking to regulate these practices and effectively demands the development of global legal solutions.

Chapter 6 explores the theme of the interaction between people in global and local spaces in the context of pandemic influenza. This chapter analyses the threat from an outbreak of pandemic influenza and the role of global preparedness. The role of the revised International Health Regulations as a regulatory framework for international health is also discussed. Finally, this chapter considers the implications of pandemic influenza in terms of individual and community rights through discussion of a reconceptualization of public health law and ethics based on an embodied and relational understanding of public health. In this chapter, it is clear that individuals and communities are linked in the global world and that the health of individuals and communities, wherever they are located, is a common concern.

Autonomy is a constant theme both in contemporary Western thought and in health law and bioethics. Chapter 7 analyses the concept of autonomy in health law. The conceptualization of autonomy as a form of 'self-ownership' is examined through a discussion of whether the body can actually be owned, that is, whether it can be property. The debates around human tissue are contrasted with those relating to the status of embryos derived from assisted reproductive technology (ART). In the case of ART embryos, there is a clear reluctance to apply property concepts to embryos, which are regarded as being worthy of special treatment because of their potentiality to develop into people. This focus on the potentiality of embryos is evident in the debates about stem cells, even though embryos destined for research are destined never to realize their potentiality. At the end of this chapter, I revisit the issue of autonomy through a consideration of the relational aspects of pregnant embodiment and feminist theories of relational autonomy.

Finally, in Chapter 8, I seek to tie together some common themes and consider whether there are common lessons that cut across the diverse range of issues addressed in this book. This book is not a recipe book seeking to provide instructions for crafting the specific detail of legislative reform. Rather, it is a plea for a new, more connected vision of health law which acknowledges differences, diversity and rights, while making connections both within and across the rich landscape of contemporary health law.

Chapter 1

Rewriting the Future?

Medical science has rewritten the future. A relatively small number of discoveries have transformed our ways of thinking about illness, disease, treatments and cures. In the space of one generation, the world around us has been transformed. Caught in a whirlwind of change brought about by the processes of globalization, the speed of the computer age and developments in biomedicine, both the context and possibilities of our lives seem to have become elastic, stretching and moulding into contours that were previously unimaginable. The future shock of our times leaves us with a sense that our communal lives have lost their anchor point, casting us into a realm where everything seems to be negotiable.

It is against this backdrop that governments around the world have pondered the question of regulation: whether regulation of biomedicine is necessary and if so, what form it should take. In many respects, these should seem straightforward questions with achievable answers. Yet in fact, it seems that in many countries regulatory problems have defied ready solutions. Developments in genetic science, assisted conception, stem cell research and cloning technologies, for example, have all sparked major debates about the legal and ethical implications of medical science and have challenged many of our traditional understandings of birth and life. Law reform commissions, parliamentary committees and a range of other organizations have all sought to resolve the seemingly impossible question of the best way to address these issues.

This chapter addresses the points of commonality between new technologies and our responses to them. This is not to suggest that all new technologies have some essentialist, core features, but rather that there are points of commonality in our responses to biomedicine that cut across the discourses surrounding individual technologies within contemporary biomedicine. The approach adopted here involves developing an understanding of the debates over scientific possibilities and their implications (both positive and negative) for human society, the practical limitations to domestic regulatory options posed by globalization, and the challenges of articulating shared values in a pluralistic society. In exploring this approach we may be able to develop both an understanding of the sense of regulatory *déjà vu* that permeates current biomedical debates,[1] and an understanding of the core values that are worthy of legal protection. Furthermore, an appreciation of these discourses and their interaction is vital to an understanding of the regulatory challenges of our time.

---

1 Margaret Brazier has noted (1999: 167) that 'again and again, as new medical developments emerge, we debate the same issues in different disguises'.

The Language of Possibilities

Contemporary debates about advances in medical science are laden with the language of possibilities. Each new advance seems to open a new range of possibilities, with new ways of thinking about our future.

Genetic science is already in the process of transforming our understandings of who we are and why we are the way we are. Major advances in knowledge of the genetic bases of disease have already been achieved, for example, with the identification of the genetic mutations associated with predispositions to breast cancer, early-onset Alzheimer's disease, familial adenomatous polyposis (FAP) and other conditions.[2] The combination of genetic science and computer science opens the possibility of collating vast amounts of genetic information and being able to process and sort that information quickly and efficiently. The storage of information within genetic databases means that information can be utilized for population-wide research on the causes of illness and disease. With this research comes not only the possibility of identifying new genetic contributors to disease, but also ultimately, perhaps, the development of new treatments.[3] Using a form of 'genetic archaeology', scientists will be able to dig down to humanity's roots, tracing mitochondrial DNA back through the generations so as to provide a genealogy of contemporary humanity and new insights into human evolution (Karpin and O'Connell 2002; Tutton 2004).

The quest is on to utilize genomics to explain the human condition, to develop pharmacogenetics so as to target pharmaceutical treatments more effectively, and to understand the workings of stem cells so they can be used to develop therapeutic treatments for conditions as diverse as Parkinson's disease, diabetes and spinal cord injury. The future for modern therapeutics for the human body seems to lie at the genetic level, creating a dynamic between genetics conceptualized in universal terms (a common heritage of humanity) and genetics conceptualized as a blueprint of individual health or disease.

Assisted conception technologies have already reshaped the terrain of the possible. Since the birth of the world's first IVF baby in England in 1978, thousands of couples have used assisted conception in their quest to have a child of their own. The technologies of assisted conception, the ability to store gametes and embryos and the potential for donor gametes to be used at a later date have meant that parenthood has been fractured into genetic and social parentage. This has not only opened up new possibilities for the infertile to have a child of their own, but has also opened up the possibility that the very meaning of infertility could be reconceptualized to include not only the clinically infertile, but also a range of other women, including single women and lesbian couples, who wish to utilize the technology to conceive a child.

Cloning and stem cell technologies represent another frontier of medical science. Both areas are very new, with human embryonic stem cells only isolated in 1998, and the age of modern cloning dating to the birth of Dolly the cloned sheep in 1997.

---

2 For discussion, see Australian Law Reform Commission, (2003: Chapter 2).

3 For an analysis of the legal and ethical issues associated with human genetic databases, see Australian Law Reform Commission (2003: Chapters 18–20).

While both technologies are still in their infancy, and therapeutic applications may still be decades away, these technologies too seem set to transform our understandings of the possible, and therefore to transform our future.

The isolation of human embryonic stem cells in 1998 represented a significant breakthrough in stem cell research. Embryonic stem cells are pluripotent, meaning that unlike other cells in the human body which become specialized or committed to developing into particular types of tissue, stem cells retain their ability to develop into a range of different tissue types. Stem cells have also been identified in adult tissue but to date they appear to be more difficult to work with and less flexible in their ability to develop into different tissue types (House of Representatives Standing Committee on Legal and Constitutional Affairs 2001: para. 2.43ff). The potential to combine some of these technologies with cloning technologies suggests that one day it may be possible to grow new tissue to treat illness or disease.

Each of these technologies seems to offer the potential of a future full of possibilities and hope. Indeed this is the promise of modern biomedicine: to unlock science's mysteries and to develop new and effective therapies for the conditions affecting humanity. This is not to suggest that medical scientists exaggerate the realistic possibilities of their science. Indeed, the limits of current knowledge and the time lag between current research and clinical applications are typically stated very clearly (Braude, Minger and Warwick 2005; Bubela and Caulfield 2004; Byrne and Howells 2003). Rather it is simply to acknowledge that developments in genetics, assisted conception, stem cell research and cloning technologies seem to open previously unimaginable doors and that the landscape beyond, when described in terms of its possibilities, is readily captured in the public's imagination. The language of possibilities is, after all, generally about the opening of those doors and what might, one day, be found on the other side.

Risk and Negative Possibilities

While scientific advances hold out exciting possibilities for the future, the discourses around these possibilities are tempered by concerns over the potential for science to generate negative, rather than positive outcomes, and the need to regulate so as to impose limits on scientific researchers. This then is the flip side to the debates about possibilities: the negative possibilities inherent in technological change.[4] There is a concern that 'mad science' may create a high-tech but undesirable future characterized by eugenics, in which people's options are limited by their genetic make-up, an idea portrayed strikingly in the movie *GATTACA*, or in which reproduction becomes completely high-tech and divorced from natural reproduction, as in the novel *Brave New World* (Australian Law Reform Commission 2003, para. 3.64). As the House of Lords Select Committee on Science and Technology noted (2000, para. 2.2), there is an apparent crisis of trust. While people appear to have an appetite for popular

4 I am indebted to Sally Sheldon for suggesting this way of characterizing the debate around limits.

science, the paradox is that this is accompanied by increasing scepticism about the pronouncements of scientists on science-related policy issues of all types.

The concern over negative possibilities and risk is perhaps hardly surprising given that risk is a central feature of contemporary society (Beck 1992). Beck describes risk society as one in which '[q]uestions of the development and employment of technologies...are being eclipsed by questions of the political and economic "management" of the risks of actually or potentially utilized technologies' (ibid.: 19). A risk society is, as Anthony Giddens points out, not necessarily more dangerous, or riskier than earlier societies, but rather one that is 'increasingly preoccupied with the future (and also with safety)' (Giddens 1999: 3). In the public and regulatory debates surrounding genetics, stem cell technologies, cloning and assisted conception, we can see very clearly the preoccupation with the future that characterizes risk society.

As we live increasingly in a risk society, so the language of risk is used increasingly to guide our decision-making about the future. It is used to make insurance decisions, in actuarial calculations, in financial assessments, to make decisions about safety, and in an array of legal principles ranging from the calculus of negligence in tort law to the precautionary principle in environmental law (Steele 2004). Jenny Steele has argued that the use of risk in decision-making fits in with liberal legal theory's focus on individual autonomy: 'Risk in its positive, opportunity-creating sense is compatible with the richer liberal ideal of the autonomous individual who seeks to maximise his wellbeing through pursuit of a good life' (ibid.: 29). Decision-making on the basis of risk allows us to rely on a vision of the future that can be employed to achieve current goals, yet not only are we unable to determine the future (ibid.), but the future itself seems ever more uncertain (Giddens 1999: 4).

Concerns about risk reflect reservations about the direction in which science may ultimately lead society. At the same time, a range of more practical and immediate concerns have also arisen. While genetic science may reveal the genetic bases of some diseases, there are concerns that the information derived from genetic testing could be used by employers, insurance companies and others to discriminate against individuals on the basis of their genetic make-up (Australian Law Reform Commission 2003). Furthermore, the meaning of 'healthy' has been redefined by genetics, as the line between healthy and ill has been blurred with the creation of a new class of the pre-symptomatically ill – individuals who have a genetic predisposition towards a particular disease but are, and indeed may always remain, asymptomatic. As knowledge of genetics has increased, so understandings of the body and its medical, social and cultural significance, are all in the process of being rewritten.

Just as the discussions of positive scientific advances change over time with each new development, so the discussions of negative possibilities are not fixed or immutable. Within the context of reproduction, the regulatory debates are mediated by a complex array of debates surrounding the nature of the family, the status of the embryo and the rights and interests of children. In some cases, the discussion of negative possibilities appears to reflect concerns that science may accelerate changes that are already taking place in our social fabric. Thus opposition to expanded access to assisted conception services appears to reflect a more general concern about what may be regarded as the erosion of traditional family forms and values in society. The social reality of the contemporary family certainly includes the heterosexual nuclear

family but increasingly also includes families comprising single parents, lesbian and gay parents and families of blended relationships arising from the formation of new families through adoption or after divorce. While assisted conception has provided infertile couples with new reproductive options, the claims by single and lesbian women and others to also share in these possibilities has sparked debate over the meaning of 'family' in contemporary society. Public debates over whether access to assisted conception should be limited to heterosexual couples (either married or in *de facto* relationships) reveal the contested meanings of both 'family' and rights to health care in contemporary society.

The potential to link genetic technologies and assisted conception technologies in the form of pre-implantation genetic diagnosis, while simultaneously providing women and their partners with more information on the genetic make-up of their future children, may also appear to take us closer to the slippery slope in which parents choose in advance the characteristics of their children. In the context of these technologies, the question of whether certain forms of genetic testing or pre-implantation genetic diagnosis should be permitted becomes an important but vexed issue for regulatory authorities (Brownsword 2004b; Sheldon and Wilkinson 2004).

The nature and status of the human embryo has also become contested territory. Since developments in assisted conception and embryonic stem cell research both involve the use of human reproductive material for research, the discourses of scientific advance have been countered by discourses surrounding the embryo. Drawing on the belief that life begins at conception, these discourses have argued that such research should not be permitted and have conflated the discourses surrounding protection of the embryo in the context of abortion into the newer discourses surrounding the embryo in the context of stem cell research, resulting in a tangled weaving of the ethical and legal debates across these areas (Dolgin 2003).

Popular fear of eugenics and 'mad science' lend real weight to calls for limits to be placed on science. Some regulatory limits are appropriate to ensure, for example, that research is ethical. Some developments, such as reproductive cloning, the cloning of whole individuals, appear to be so lacking in support within the general and scientific communities that limits may seem appropriate, at least in the short term. In many other areas of biomedicine, however, including therapeutic cloning, pre-implantation genetic diagnosis, and other forms of genetic testing, the placing of limits is less certain and more contested.

Globalization and Regulatory Choice

No analysis of regulatory debates surrounding contemporary biomedicine would be complete without an analysis of globalization. Of course, globalization itself is not a new phenomenon. World religions and medieval trade networks provide an historical perspective on the processes of globalization, although it must be recognized that globalization may take different forms during different historical periods (Held et al. 1999: 13, 17). Yet the globalization of the late twentieth century and early twenty-first century is different from other periods of globalization because of the dislocation and intensification of space and wealth in the current global environment (ibid.: 327).

Globalization constantly dislocates and relocates our sense of space (Beck 2000: 46). National borders appear more permeable and less relevant in the globalized world of international trade and finance, transnational corporations, international media networks and global environmental concerns (Beck 2000: 11). Although the significance of the national appears to fade in significance in a globalized world, the momentum is not all entirely towards an international oneness. Rather, there is a dynamic between the local and the global ('glocalization') (Robertson 1995: 40) that reveals the cultural rewriting evident in contemporary Western society (Held et al. 1999: 373). At the same time as locality becomes globalized, so globalized markets seek to develop local connections (Beck 2000: 46). Within this dynamic Beck argues that 'local specificities are globally relocated and there conflictually renewed' (ibid.: 47). Globalization has been described as 'aterritorial' in the sense that it involves 'a complex deterritorialization and reterritorialization of political and economic power' (Held et al. 1999: 28).

In a regulatory context, this dynamic between the local and the global occurs at several levels: at an international level in the relationships between national and international laws and regulation; within federal legal systems in the relationship between state and national laws, or to use the example of the European Union, between national and EU laws; and at a more micro level in terms of the relationships between individuals and the broader community and in debates over the contrasts between generic (universal) characteristics and rights and characteristics or rights conceptualized in terms of diversity. Each of these dynamics plays a role in shaping regulatory options.

The economic forces of globalization are characterized by the increasing flexibility of movement of people, goods and services. Even health services are available increasingly in more than one locality and patients who are unable to access the health services they desire or need are able to travel to those services wherever they may be located provided they have the financial resources to do so. This phenomenon of 'health tourism', first identified in the reproductive context (Knoppers and LeBris 1991: 333), but now evident across many areas of modern medicine, raises issues of the harmonization of international laws, the value of moral pluralism (Pennings 2002) and the role of law in regulating these activities. Yet the challenges of formulating national regulation in the face of a globalized market for health services are not limited to the area of health tourism. Increasingly, globalization shapes the context of contemporary health care and health law across a wide range of areas (Bennett and Tomossy 2006).

Within the legal sphere, we can see how the development of transnational laws and norms leads on the one hand to a globalized form of law, yet on the other also leads back to a strengthening of the identification with local (national) laws (Chalmers 2003: 547). This dynamic is particularly evident in the regulatory debates within the European Union where there seems to be a heightened awareness of national approaches to regulatory issues within a supranational regulatory context (ibid.). However, this dynamic does present some significant challenges for national (local) regulatory tasks, for at the same time as supranational laws appear to be gaining in importance and the permeability of national borders increases, so too the continued relevance of national laws appears to be increasingly open to question.