Genetic Data and the Law

Research using genetic data raises various concerns relating to privacy protection. Many of these concerns can also apply to research that uses other personal data, but not with the same implications for failure. The norms of exclusivity associated with a private life go beyond the current legal concept of personal data to include genetic data that relate to multiple identifiable individuals simultaneously and anonymous data that could be associated with any number of individuals in different, but reasonably foreseeable, contexts. It is the possibilities and implications of association that are significant, and these possibilities can only be assessed if one considers the interpretive potential of data. They are missed if one fixates upon its interpretive pedigree or misunderstands the meaning and significance of identification. This book demonstrates how the public interest in research using genetic data might be reconciled with the public interest in proper privacy protection.

Mark Taylor is a senior lecturer at the University of Sheffield and Deputy Director of the Sheffield Institute for Biotechnological Law and Ethics. His primary research interest concerns the legal and ethical issues raised by scientific developments in genetic testing and screening technologies.
This series of books was founded by Cambridge University Press with Alexander McCall Smith as its first editor in 2003. It focuses on the law’s complex and troubled relationship with medicine across both the developed and the developing world. In the past twenty years, we have seen in many countries increasing resort to the courts by dissatisfied patients and a growing use of the courts to attempt to resolve intractable ethical dilemmas. At the same time, legislatures across the world have struggled to address the questions posed by both the successes and the failures of modern medicine, while international organisations such as the WHO and UNESCO now regularly address issues of medical law.

It follows that we would expect ethical and policy questions to be integral to the analysis of the legal issues discussed in this series. The series responds to the high profile of medical law in universities, in legal and medical practice, as well as in public and political affairs. We seek to reflect the evidence that many major health-related policy debates in the UK, Europe and the international community over the past two decades have involved a strong medical law dimension. With that in mind, we seek to address how legal analysis might have a trans-jurisdictional and international relevance. Organ retention, embryonic stem cell research, physician assisted suicide and the allocation of resources to fund health care are but a few examples among many. The emphasis of this series is thus on matters of public concern and/or practical significance. We look for books that could make a difference to the development of medical law and enhance the role of medico-legal debate in policy circles. That is not to say that we lack interest in the important theoretical dimensions of the subject, but we aim to ensure that theoretical debate is grounded in the realities of how the law does and should interact with medicine and health care.

Series editors
Professor Margaret Brazier,
University of Manchester
Professor Graeme Laurie,
University of Edinburgh
Professor Richard Ashcroft,
Queen Mary, University of London
Professor Eric M. Meslin,
Indiana University

Titles in the series
Marcus Radetzki, Marian Radetzki and Niklas Juth
Genes and Insurance: Ethical, Legal and Economic Issues

Ruth Macklin
Double Standards in Medical Research in Developing Countries
Donna Dickenson
*Property in the Body: Feminist Perspectives*

Matti Häyry, Ruth Chadwick, Vilhjálmur Árnason and Gardar Árnason
*The Ethics and Governance of Human Genetic Databases: European Perspectives*

Ken Mason
*The Troubled Pregnancy: Legal Wrongs and Rights in Reproduction*

Daniel Sperling
*Posthumous Interests: Legal and Ethical Perspectives*

Keith Syrett
*Law, Legitimacy and the Rationing of Health Care*

Alastair Maclean
*Autonomy, Informed Consent and the Law: A Relational Change*

Heather Widdows and Caroline Mullen
*The Governance of Genetic Information: Who Decides?*

David Price
*Human Tissue in Transplantation and Research*

Matti Häyry
*Rationality and the Genetic Challenge: Making People Better?*

Mary Donnelly
*Healthcare Decision-Making and the Law: Autonomy, Capacity and the Limits of Liberalism*

Anne-Maree Farrell, David Price and Muireann Quigley
*Organ Shortage: Ethics, Law and Pragmatism*

Sara Fovargue
*Xenotransplantation and Risk: Regulating a Developing Biotechnology*

John Coggon

Anne-Maree Farrell
*The Politics of Blood: Ethics, Innovation and the Regulation of Risk*

Mark Taylor
*Genetic Data and the Law: A Critical Perspective on Privacy Protection*
Genetic Data and the Law

A Critical Perspective on Privacy Protection

Mark Taylor
For Poppy
The European Convention for the Protection of Human Rights and Fundamental Freedoms 66
Research and proportionate interference 73
Research and data protection 74
The Data Protection Directive (95/46/EC) 76
What is personal data? 78
Multiple data subjects and biological samples 80
Personal data and norms of exclusivity 82
Legitimate data processing 83
Supplementary material? 85
Other principles of data protection 87
Rights to access and to object 89

SECTION II INTERNATIONAL LEGAL STANDARDS APPLICABLE SPECIFICALLY TO GENETIC DATA 93
Transactional variable 94
Relational variable 96
Reflections 97

PART II THE CRITIQUE 101

5 DATA IN COMMON 103
Terminology 104
Family members (and other affected individuals) 106
Structure 107

SECTION I DATA SUBJECTS AND GENETIC DATA IN COMMON 109
Defining data subjects 110
Can data ‘relate to’ more than one individual? 111
Can genetic data ‘relate to’ more than one individual? 113

SECTION II WHY MIGHT RECOGNISING MULTIPLE (GENETIC) DATA SUBJECTS BE PROBLEMATIC? 116
English law and secondary data subjects 119
Durant v. FSA [2003] 120
Passing the threshold 121
Problems with not recognising multiple data subjects 122
Inadequate protection 122
Alternative responses 124

SECTION III ADDRESSING THE BALANCE 126
How should data be understood to ‘relate to’ another individual in order for that data to be personal data? 127
Expanding the exemptions 129

6 ANONYMITY 131
Structure 131

SECTION I TERMINOLOGY 134
SECTION II DATA PROTECTION AND ANONYMOUS DATA 138
The burden of compliance and the UK implementation of identifiability 140
Can a data controller meet responsibilities to an anonymous data subject? 142
Notification 142
Access and objection 143
Reasons to protect anonymous data 145
Contents

Zorro’s mask and re-identification 146
Fresh association 149
Anonymity and failure to protect group interests 150
Private data cf. identifiable data 151
Are we overprotecting identifiability? 153
Reflection 155

7 Human tissue 157
    Structure 160
    SECTION I HUMAN BIOLOGICAL MATERIAL, SAMPLES, DATA AND INFORMATION 161
    SECTION II PERSONAL DATA, BIOLOGICAL SAMPLES AND NORMATIVE EXPECTATIONS 164
    Normative expectations 165
    Convention on Human Rights and Biomedicine 167
    The Declaration of Helsinki 169
    International Declaration on Human Genetic Data 172
    International guidance on the use of genetic data within biobanks 174
    SECTION III THE FINITE NATURE OF DATA – A RELEVANT DISTINCTION? 175
    Advantages to treating biological samples as ‘personal data’ 176
    Reflection 178

8 Genetic discrimination 180
    Structure 182
    SECTION I TERMINOLOGY 183
    Three kinds of genetic discrimination 185
    SECTION II PROBLEMS OF DISTINCTION AND DEFINITION 188
    An alternative approach? 190
    Drawing a distinction within different kinds of discrimination 191
    Drawing a line within primary genetic discrimination 192
    Drawing a line within secondary or tertiary genetic discrimination 193
    SECTION III IMPLICATIONS FOR REGULATORY REFORM 197

Part III The consequence 199

9 Potential, promise and possibility 201
    Personal information and privacy protection: a dysfunctional relationship 202
    The limits of personal information 203
    The interpretive pedigree of recorded information 204
    Consent 206
    Anonymisation 210
    Implications for reform: short term 211
    Implications for reform: medium term 216
    Implications for reform: long term 219

Index 222
Preface

This book represents a collection of thoughts that date back to the completion of my doctoral studies in 2004. Given its genesis, this seems an appropriate time and place to thank publicly my Ph.D. supervisor, Professor Roger Brownsword, for the extremely generous, illuminating, and supportive, advice he offered me during that period and has continued to offer me since.

Since I wrote my Ph.D. thesis on the subject of genetic discrimination and contractual freedom, I have weaved, or perhaps stumbled, my way towards a broader position on the regulation of genetic data in research. I am especially keen to encourage a critical evaluation of the weight placed upon the idea of ‘personal data’ in the area of privacy protection. Frankly, I think it is a concept that has been forced to shoulder a disproportionate burden of work and it has made a rather convenient vehicle to transport us from some difficult questions. Rather than continue to pretend that this concept, and the regulatory frameworks that orbit it, are up to the task of fully protecting privacy, and also striking the right balance between the (at times) competing interests engaged by research uses of genetic data, we should recognise both its strengths and its weaknesses, and strengthen weaknesses where we can, while, at all times, ensuring that apparent strengths do not undermine our ability to qualify particular protections where appropriate.

The position that I seek to describe in what follows is one that has been reached through linking together thinking stimulated by many different people and involvement in a number of different research projects. Some of the ideas have already found expression, in piecemeal fashion, through a number of articles over the past several years. While it is impossible personally to acknowledge everybody that has progressed my thinking in this area, I sincerely hope that they each realise I appreciate my indebtedness to them and am truly grateful for their support, their insight, and, quite often, their challenge. It would not have been possible to bring together a number of the ideas that have found previous published expression without the generous agreement of the
editors of the respective journals. Although most of the ideas have inevitably been developed and revised before inclusion here, there are, at times, particular recidivist paragraphs or sections that have escaped reform. They are reproduced here in their original form and I am grateful for the permission to do so. To some greater or lesser extent, Chapter 5 draws upon an argument first presented in M. J. Taylor, ‘Data protection, shared (genetic) data and genetic discrimination’, Medical Law International 8(1) (2006), 51–77. Chapter 7 draws upon the section I authored for a paper written with Professor Deryck Beyleveld, and published most recently as D. Beyleveld and M. J. Taylor, ‘Patents for biotechnology and the data protection of biological samples and shared data’, in Jean Hervég (ed.), The Protection of Medical Data: Challenges of the 21st Century (Louvain-la-Neuve: Anthemis, 2008), 127–48. A shorter version was earlier published as D. Beyleveld and M. J. Taylor, ‘Data protection, genetics and patents for biotechnology’, European Journal of Health Law 14(2) (2007), 177–87. Chapter 8 draws upon an argument first described in M. J. Taylor, ‘Problems of practice and principle if centring law reform on the concept of genetic discrimination’, European Journal of Health Law 1(4) (2004), 365–80; and Chapters 2 and 9 both contain thoughts first expressed (by me at least) in M. J. Taylor, ‘Health research, data protection and the public interest in notification’, Medical Law Review 19(2) (2011), 267–303. I am also glad to acknowledge that the idea for the cover picture, an anatomical theatre as a metaphor for the public examination of ‘internal’ aspects of human life occurring when research uses genetic data, was an idea used by Professor Giuseppe Testa in a seminar while visiting the University of Sheffield.

I am particularly grateful to colleagues and students, past and present, who have helped me to clarify and further my thinking on these issues. Specific and heartfelt thanks must be extended to Professor Deryck Beyleveld, Professor Roger Brownsword, Dr Fiona Douglas, Jamie Grace, Dr Richard Kirkham, Dr Ruth Stirton, David Townend and Daniel Wand. Special mention must go to Professor Graeme Laurie who has been typically generous with both his comments and his encouragement. Each of these individuals has, in various ways, been crucial to bringing these ideas forward in their current form. In should be made clear, however, that none of them is responsible for any errors that remain in the final version. Finally, I should thank Dr Natasha Semmens and Mrs Natasha Taylor. For me, together, they represent every reason to do anything.