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The Governance of Genetic Information

Who Decides?

Edited by Heather Widdows and Caroline Mullen



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THE GOVERNANCE OF GENETIC INFORMATION

This volume maps the areas of ethical concern in the debate regarding the governance of genetic information, and suggests alternative ethical frameworks and models of regulation in order to inform its restructuring. Genetic governance is at the heart of medical and scientific developments, and is connected to global exploitation, issues of commodification, commercialisation and ownership, the concepts of property and intellectual property and concerns about individual and communal identity. Thus the decisions that are made in the next few years about appropriate models of genetic governance will have knock-on effects for other areas of governance. In short, the final answer to 'Who decides?' in the context of genetic governance will fundamentally shape the ethical constructs of individuals and their networks and relationships in the public sphere.

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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. 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.

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WHO DECIDES?

Edited by
HEATHER WIDDOWS
and
CAROLINE MULLEN



CAMBRIDGE
UNIVERSITY PRESS

CAMBRIDGE UNIVERSITY PRESS
Cambridge, New York, Melbourne, Madrid, Cape Town, Singapore,
São Paulo, Delhi, Dubai, Tokyo

Cambridge University Press
The Edinburgh Building, Cambridge CB2 8RU, UK

Published in the United States of America by Cambridge University Press, New York

www.cambridge.org

Information on this title: www.cambridge.org/9780521509916

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First published in print format 2009

ISBN-13 978-0-511-62966-2 eBook (Adobe Reader)

ISBN-13 978-0-521-50991-6 Hardback

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P R E F A C E

Heather Widdows and Caroline Mullen worked together as the lead investigators of the Property Regulation in European Science, Ethics and Law (PropEur) project, an EC funded project that ran for three years and finished in 2007. This volume is not an outcome of that project, but it was the experience of working on the project that provided the inspiration for it. In particular, the dearth of critical theorising which spoke to practice became abundantly clear, as did the need for comprehensive thinking which crossed disciplines and governance jurisdictions and interrogated the foundational assumptions of such governance. It is hoped that this volume, which was conceived as a concept volume with all its chapters commissioned, goes some way to addressing this gap. While it may not definitively answer ‘Who should decide?’, it does challenge existing practices and suggest alternatives.

We would like to acknowledge the Philosophy Department at the University of Birmingham for welcoming the PropEur project, and particularly to thank Helen Harris, Donna Dickenson, Dita Wickins-Drazilova and Louise Jelf, for their work on the project. The editors would also like to thank Phil Champion and Matthew Hilton.



Introduction

HEATHER WIDDOWS AND CAROLINE MULLEN

The governance of genetic information is relevant to issues of health, welfare, privacy and of personal and communal identity. This volume seeks to map this complex and difficult terrain and move beyond it by making positive suggestions for the restructuring and design of ethical frameworks for governance in this area. It sets out the key areas of ethical concern in the governance debate in a way which clarifies the significant features of genetic information and the problems of how it is ascribed, controlled and regulated in order that the complexities of genetic governance can be understood. This book seeks not merely to describe the areas of controversy and ethical dilemma but to drive the debate forwards and break new ground. It offers suggestions and alternatives, in terms of ethical frameworks and models of regulation, which it is hoped will inform the theory and practice of good governance. Accordingly this book intends to speak not only to academics, but to practitioners, participants in research and, perhaps most importantly, to policy makers. For genetic governance is not merely an interesting philosophical problem – although undoubtedly it is this – but more importantly it is an issue at the heart of medical and scientific developments and governance and one that touches on governance in general and globally. For example, issues which are connected to the governance of genetic information include issues of global exploitation, issues of commodification, commercialisation and ownership, conceptions of property and intellectual property and concerns about individual and communal identity and notions of public good. Thus the decisions that are made in the next few years about appropriate models of genetic governance will have knock-on effects for other areas of governance; in particular they will profoundly affect views about the proper units of ethical concern and ethical priorities. In short, the final answer to ‘Who decides?’ in the context of genetic governance impacts on governance more generally and thus fundamentally shapes the ethical constructs of individuals and their networks and relationships in the public sphere. In order to address these most important questions

of governance this volume is divided into three sections: 'Problematising governance of genetic information'; 'Ethical frameworks of governance'; and 'Redesigning governance'.

Section One: Problematising governance of genetic information

This first section of the volume problematises the governance of genetic information, highlighting the key issues of controversy and concern which must be addressed if comprehensive and effective governance mechanisms are to be developed. The chapters in this section, by Neil Manson, Søren Holm and Caroline Mullen, serve to set the scene and map the central concerns of this volume. Each of these chapters focuses on one key aspect of genetic governance and problematises it, revealing its complexity and thus the challenge of such governance.

In the first chapter of the section, 'The medium and the message: tissue samples, genetic information and data protection legislation', Manson systematically examines what is meant by genetic information and the scope of the governance of genetic information. In so doing he seeks to clarify the underlying tensions and dilemmas which surround the acquisition, possession and use of genetic information. Manson begins with the regulation regarding the storing of human tissue containing genetic information. He asks whether the current consent-centred forms of regulation are appropriate means of regulating such tissue (and while his focus is on the UK his argument is applicable to all forms of consent-centred regulation). Having set the scene Manson critically assesses what, if anything, is ethically valuable and significant about human tissue and genetic information and explores what it is that we are seeking to protect. Manson interrogates the nature of information by asking a series of questions, 'What is personal data?', 'What is information?', 'What is genetic information?', suggesting that information is not as simple as is often assumed in the genetics debate. In so doing he reveals the similarities and dissimilarities between these categories in order to critique current practices of genetic governance.

In the light of such discussion he criticises current regulatory practices of data protection which he considers are based on misleading assumptions regarding the similarity of genetic information and other types of information and which have resulted in a distorted and inappropriate expansion of consent-thinking. He concludes by suggesting that clarity about what is at stake in the ethics of communication and information in the

genetic debate aids assessment of current governance mechanisms. His hope is that even though such analysis is out of fit with current regulatory practices, it is nevertheless useful in the eventual construction of a robust and justifiable system of governance.

The nature of genetic information and current consent-based thinking having been problematised, the second chapter in the volume, 'Me, myself, I – against narcissism in the governance of genetic information' by Holm, considers whether it is the individual, the family, or society who should be considered to be the decision-making actors within the governance of genetic information. The first option, which grants rights only to the individual, is the most commonly endorsed position in current (Western) practice. Holm argues that this position, which gives the individual primary legitimacy to control the information, is only able to account for some of the moral concerns of the governance of genetic information. For example, the individual has commitments and obligations to others, including family members, which may override individual concerns but which are invisible on the individual model. The second position is the traditional understanding that the family is the unit of ethical concern rather than the individual. Holm is critical of this view for a number of reasons, which include confusions between biological and social understandings of family, and practical difficulties of establishing family decision-making mechanisms. Holm maintains that the third position, although rarely addressed directly, nevertheless underlies arguments about using patient information and by-products for research. He argues that any claim for the state to control genetic information would also apply to other types of information and that to restructure the current system so profoundly would need to produce significant benefits to be justifiable. He argues that there are areas where the state has a strong claim for control of health information, but that these are limited. Holm therefore concludes that none of these actors should be granted primary and sole control, but appropriate governance requires more complex mechanisms with sensitivity to differing specific circumstances.

The final chapter in this section, 'Decisions, consent and expectations of the individual' by Caroline Mullen, brings together themes from Manson's and Holm's chapters as she considers the current emphasis on the individual in governance. Mullen addresses the choices available to the individual donor and the constraints on those choices when considering whether or not to participate in genetic research. She explores what moral considerations individuals might be expected to take into account when deciding whether or not to participate in research and what, if

any, obligations the donor has to participate in such research. Mullen's starting point is the current focus on informed consent – which suggests that ethical standards rest on the question of whether the individual is able to give informed consent when deciding whether to participate in research. She maintains that this focus on informed consent excludes further considerations of whether people have responsibilities to consider benefits to others that might arise from research.

Mullen asks whether the potential risks and benefits of medical genetic research challenge this standard of informed consent. Having outlined current presumptions regarding the expectations and responsibilities of the individual, Mullen proceeds to consider arguments that medical research benefits all and thus we have a duty to participate in research (at least when it is not overly burdensome). She suggests that if we follow such reasoning, then there is a general obligation to support genetic health (given its prospect of helping to improve basic health which, she argues, should be prioritised). However, Mullen claims that this obligation to participate in medical genetic research is not straightforward. The reasoning which leads to the claim that we should have concern for one another also suggests that we should interpret this responsibility with respect for people's differing circumstances and with regard to issues of distributive justice. Furthermore, Mullen argues that in some instances there is no obligation to participate in research (and even an obligation not to): for example, when research is presented as an alternative to measures being put into place which might better meet basic health needs. Therefore, what we can expect of potential participants in medical genetic research is not that they recognise a simple obligation to contribute, but that they give consideration to the relative benefits of the research to themselves and others. While she maintains that it is ultimately for the potential donor to judge the relative value of research, she argues that in making this decision they should take into account forms of democratic debate and institutions which are accountable to such democratic processes.

Section Two: Ethical frameworks of governance

The first section of the volume served to problematise and map the key issues in the governance of genetic information. The second section begins to address them. It suggests possible ways that current systems of governance can be adapted, modified or restructured in order to meet the dilemmas presented in the first section. Thus it begins to offer suggestions as to how ethical frameworks should be constructed and interpreted

if comprehensive and equitable systems of genetic governance are to be established. The chapters in this section by Heather Widdows, Roger Brownsword and Sarah Wilson all speak to the key tension of genetic governance: that of balancing the rights of individuals and the rights of communities, or in other terminology the need to respect and protect the individual (which, as we saw in Holm's and Mullen's chapters, is the current focus of ethical concern) balanced against the public good. In an effort to address this fundamental tension, Widdows, Brownsword and Wilson all put forward alternative frameworks and, despite the differences in the solutions they suggest, all argue that the over-dominance of the individual (found particularly in current practices of bioethics) must be reassessed if good models of genetic governance, which are capable of tackling the relevant forms of injustice, are to be established.

In the first chapter of this section, 'Constructing communal models of governance: collectives of individuals or distinct ethical loci?', Widdows explores the recent move from individual models towards communal models of ethical governance. She draws on thinking about group rights to explore what conception of groups is necessary for an effective ethical framework. In particular, she is concerned with whether it is sufficient to regard groups as collectives of individuals – with their moral status and attendant rights dependent on the rights of individuals – or whether a more robust conception is necessary to establish the ethical protections required. Widdows begins with the conviction that whether or not one's ethical framework is capable of taking account of group interests and rights fundamentally affects the ethical issues that can be recognised and addressed. Accordingly she suggests that these conceptual concerns about groups and their rights speak directly to the practice and policy concerns of governance addressed in this volume: from the structure of benefit-sharing and stakeholder models to political concerns regarding what counts as participation; to questions of ownership rights and decision-making powers in genetic governance; to traditional bioethical concerns regarding what counts as harm in research. For Widdows, whether and how effectively these practical concerns of governance can be addressed depends on the prior ethical framework that one adopts. Thus whether and how groups feature in ethical frameworks profoundly impacts upon what is good governance.

Widdows argues that any effective ethical framework must include groups as ethical loci as well as individuals. Moreover, in her examination of groups she argues that in the context of genetic governance, group models which rely only on collectives of individuals are not always sufficient

to prevent harm and protect interests in all instances. To illustrate this she uses examples of research on indigenous groups and argues that in these cases the group interests do not equate directly to the interests of existing group members; thus robust conceptions of groups and their rights are necessary. Despite advocating the inclusion of robust group models in any ethical framework, Widdows is well aware of the criticisms of such corporate models (in particular the need to protect individuals); thus she advocates the use of collective models where possible and suggests that for many groups, such as participants of biobanks, this model is sufficient to provide protection and ensure that rights and entitlements are adequately recognised. She concludes that any effective framework for ethical governance must accommodate the individual and groups of varying constructions in order that all the ethical pertinent features of any situation can be clearly recognised and addressed.

In the next chapter of this section, 'Rights, responsibility and stewardship: beyond consent', Brownsword, like Widdows, addresses this key fault-line of genetic governance; that of the balance between the community and the individual, between private rights and the public good. He is dissatisfied with the current over-individualised practice of consent, however; his alternative approach is based on a reassessment of the ethic of individual rights. He argues that if implemented properly, such an ethic is capable of recognising both communal and state obligations as well as the rights of the individual. Brownsword begins with the current focus on the individual and the criticism of this 'sovereign individual' from a public good perspective. Brownsword is wary of advocates of both positions and suggests that, rather than dismissing the individual, we should temper the narrative of consent by considering the ethic of individual rights which lies behind it. He argues that if implemented correctly this ethic is capable of supporting the healthcare interests of the community as well as the individual. In order to do this, Brownsword first interrogates the notion of consent; what it is intended to protect and the way it functions. He examines its function in data protection law: as procedural justification, as agent relative and as authorising the negation of a right. Brownsword clearly shows the attraction of consent as a simple governance mechanism which does not require justificatory reasons. Yet he warns against the 'tick box', 'sign here' 'routinisation' of consent which reduces it to a mechanical or perfunctory procedure. Conversely, he rejects views which over-emphasise consent and denies both that robust consent is always necessary and that it is capable of justifying *prima facie* wrongs. He argues that it is absurd to suggest that for an action to

be legitimate the consent of all who are affected is required. Indeed, he suggests that to assert this is to commit the 'Fallacy of Necessity' in relation to consent and he illustrates his argument with cases throughout.

Brownsword then proceeds to examine the responsibilities and obligations that an ethic of rights lays on individuals in a community of rights. In his picture an ethics of rights is not simply a matter of consent but of positive obligation to others in the community, balanced by stewardship responsibilities of the state. Brownsword argues that there are positive responsibilities or, in other words, duties of assistance, in a community of rights. Brownsword outlines the conditions of positive rights and applies this framework to UK Biobank. He argues that in a community of rights there are positive obligations to participate and these are matched by obligations on UK Biobank, for example, for feedback in certain instances: an obligation which cannot be rescinded by UK Biobank's denial of responsibility and participants' consent. In addition, Brownsword argues that a community of rights also requires rights-holders to accommodate the state's stewardship duties, including those pertaining to legitimate public health interventions. In sum, for Brownsword larger healthcare goals and the public good are justified not by the abandonment of an ethic of rights but by its full application which includes obligations and responsibilities to others.

In the final chapter of this section, 'Who decides what? Relational ethics, genetics and well-being', Wilson introduces a relational approach, drawing on the ethics of care as a supplement to the current individualist model. Wilson shares concerns about the individual model of current governance with Widdows and Brownsword, and is particularly keen to establish a framework which prioritises issues of social justice (like Widdows she is concerned with the issues of commodification, biopiracy and profiteering which are not adequately addressed in the liberal model). Wilson begins from the same starting point as Widdows, noting the emerging (or converging) rhetoric of community and social solidarity in governance of genetic information; for example, as found in rhetorics of the genome as the common heritage of mankind, of public goods and of benefit sharing. Wilson explores this communal turn using one philosophical framework, that of 'relational ethics' which draws on feminist ethics and particularly the 'ethics of care'.

The care perspective regards individuals as embedded, interconnected and interdependent selves, in contrast to the separate, individually autonomous individual of traditional political and moral theory and bioethics. Wilson argues that a perspective of care is useful

in offering an alternative to individualist accounts and in providing a more comprehensive ethical framework which allows a greater number of significant ethical issues to be addressed. For example, if one applies a traditional liberal (and bioethical) model to genetic enhancement, the ethical issues are those of individual choice, recreational autonomy, parental rights and the rights of the child. From a relational perspective this liberal reading ignores key ethical issues such as those of social justice, access and inequality, as well as concerns about the social constructions of persons (particularly women) and their relationships. Accordingly the individualistic model is judged to be ethically reductionist, competitive, overly abstract (ignoring the relational and emotional context) and over-simplistic (rejecting complex frameworks for binary ones). A care approach to genetic enhancement raises ethical issues which are simply not visible on liberal individual models such as the inherent values of the technological mechanisms, the underlying objectives of genetic enhancement, possibilities of exploitation and issues of commercialisation. Wilson argues that the ethics of care's ability to address issues of injustice and inequality is particularly important in the global context and in differentiating the burdens placed on the vulnerable (for example, women and children).

Having discussed the benefits of the ethics of care as an alternative ethical framework of governance in the context of genetic enhancement, Wilson returns to the issue of genetic information and the communal turn. Wilson explores the key features of this communal turn, particularly reciprocity, mutuality and solidarity. She interprets and expands on such concepts from an ethics of care perspective, providing examples of how such an ethical framework might be brought to bear on key issues of genetic governance. In the final section Wilson introduces principles of gender equity to flesh out her alternative approach to governance and develop an account which relates social justice and institutional justice. She concludes that principles drawn from such an account, namely those of antipoverty, antiexploitation, antimarginalisation and antiandrocentrism, could be used to develop this perspective and develop more comprehensive governance mechanisms.

Section Three: Redesigning governance

Having considered the key issues of the governance of genetic information in the first section of the volume and possible constructions of comprehensive ethical frameworks in the second section, the third

section of this volume will make suggestions about how such frameworks should be redesigned. The three chapters in this section by Kathryn Hunter and Graeme Laurie, by Andrew Edgar and by Ruth Chadwick and Heather Strange, are all concerned with the design of governance mechanisms and the ways in which they should be constructed in order for comprehensive and good practices of governance to be implemented. These authors address differing aspects that should be considered in designing governance: Hunter and Laurie focusing on participation in UK Biobank; Edgar on the role of public debate in determining the governance of biobanks; and Chadwick and Strange on the need for different voices in a harmonisation of governance mechanisms. Taken together, and in conjunction with the second section of the volume, a number of robust models are offered for the redesign of current practices of genetic governance.

In the first chapter of this section, 'Involving publics in biobank governance: moving beyond existing approaches', Hunter and Laurie ask what constitutes effective public involvement in biobanks deemed so necessary for good governance? They address this issue in the context of UK Biobank and the calls for greater participant involvement in its governance mechanisms. Hunter and Laurie outline UK Biobank's status, purpose and governance mechanisms and recount its attempts at public engagement and the criticisms thereof. They proceed to explore how such criticisms can be met and more effective forms of public participation in governance established. Hunter and Laurie first explore and assess Winickoff's claims that public engagement must move from consultation to representation and his 'shareholder' model.¹ The shareholder model is intended to address the lack of agency of donor collectives in biobank governance. Donors would have the option to become members of a Donor Association which would have membership on the UK Biobank Board of Directors and the Ethics and Governance Council. Despite praising Winickoff's model, Hunter and Laurie are not convinced either that it does meet the agency gap or that it addresses the problems of maintaining trust. They suggest that the model faces both practical and conceptual problems, including: lack of fit with a public body such as UK Biobank; issues of effective representation; and contradictions between notions of shareholding and partnership.

¹ D. E. Winickoff, 'Partnership in U.K. Biobank: a third way for genomic property?', *Journal of Law, Medicine & Ethics*, 35, 3 (2007), 440–56; and 'Governing population genomics: law, bioethics, and biopolitics in three case studies', *Jurimetrics*, 43 (2003), 187–228.

In the light of such debates and drawing particularly on the discourse of deliberative democracy, Hunter and Laurie suggest an alternative 'stakeholder approach'. The stakeholder model intends to go beyond representation to participation with emphasis on inclusion, accountability and ongoing engagement. The stakeholder model then (like UK Biobank) is committed to participants, users and society, with this wider commitment to society being fundamentally important. Hunter and Laurie go on to address aspects of the practical functioning of such a model, such as identifying stakeholders and considering the nature of stakeholder involvement. In conclusion, they endorse the stakeholder model on the grounds that it meets deliberative democratic goals of participation, involvement and inclusion and thus is in fit with the aims of UK Biobank and moreover has the added advantage of being able to develop and adapt over time.

The second chapter of this section, 'Genetic information and public opinion' by Edgar, is concerned with the role of public debate in the development of biobanks, and introduces the importance of taking seriously public understanding and knowledge, and in particular cultural factors, if good ethical governance is to be achieved. Edgar explores the process of public debate regarding the collection and use of genetic information, focusing on the development of DNA biobanks. Edgar maintains that while public consultation and involvement are crucial to legitimate such projects, achieving any effective participation is problematic.

Edgar begins by describing the rise in biobanks and the ethical issues which are widely understood to arise in such developments (such as informed consent, privacy and data misuse) and the further complexities arising from the communal nature of genetic information. He argues that these issues create a need for public acceptance if genetic research and technologies are to be legitimately sustained, and suggests that recognition of the need for public acceptance has motivated the use of public consultations over the development of biobanks. However, Edgar argues that the conduct of these consultations has been problematic, and he suggests this stems in part from unwarranted assumptions about public understanding of science. In turning his attention to public debate on genetic science, he challenges the view that the sole potential for difficulty in gaining public acceptance stems from limitations in public understanding of scientific processes and knowledge. He considers how public policy on genetic science may rely either on 'golem science' (that is, science about which we cannot yet have confidence) or on 'reflexive historical science' in which the effects of science will be influenced by human

decisions. Edgar suggests that in either case, public debate can go beyond expression of subjective opinions and holds the potential to contribute to the development of knowledge.

To elaborate on this claim, he draws on Habermas's notion of the public sphere and his model of decision-making under ideal conditions. Edgar argues that Habermas provides a positive account of decision-making and offers a critical tool that can be developed for application to debates about the exploitation of genetic information and thus serve as a tool for governance. He applies this model to genetic information, highlighting the difficulty of public debate in this context. In so doing he argues that there is a tension in the debate on genetic science between the Habermasian validity claims of 'truth' and 'rightness'. Analysing the emergence of the public engagement on science, he suggests that the Habermasian approach is useful in highlighting the necessity of real public dialogue on values, while nonetheless recognising that some positions are more defensible than others. Moreover he argues that the Habermasian model takes account of ideological distortions, thus permitting the inclusion of cultural understandings and popular perceptions of genetics. It is this aspect of genetics that Edgar concludes with – that of the cultural power of genetic discourse which makes it such a complex issue for public deliberation. He concludes by arguing that the task of the expert is less of a knowledge conduit and more of a facilitator and interpreter of dialogue as the complexity of the debate is negotiated.

In the final chapter of this section, 'Harmonisation and standardisation in ethics and governance: conceptual and practical challenges', Ruth Chadwick and Heather Strange remind us of the need to take account of wider jurisdictions and the global context in issues of genetic governance. Chadwick and Strange address the calls to harmonisation at both scientific and ethical levels which have increasingly beset the governance of genetic information and particularly the governance of biobanks. Chadwick and Strange problematise the notion of harmonisation and question the assumptions that lie behind it. Chadwick and Strange consider what harmonisation of ethical frameworks might mean in the global sphere and what benefits it might bring. They consider different models of the harmonisation of ethics and ethical agreement – those of the human rights model, the ethical agreement model and the cultural dialogue model – and argue that harmonisation must be an ongoing process and more than an end-point for scientific progress.

Chadwick and Strange suggest that what has been achieved in places of apparent harmonisation is not actually harmonisation but is instead