Key Themes in the Policy Debate on Human Genetic Research and Genetic Databanks: An Evaluation

Introduction

Genetic research has reached the point where the human genome has been ‘cracked’ and its potential is beginning to be unlocked. It is a time of great promise and opportunity. Genetics is now seen as central to the prevailing model of health, but there is also an awareness that there are risks associated with these advancements. Progress must therefore be measured, and risks must be mitigated by ensuring adequate safeguards. Given that biotechnology is now at the forefront of the public debate, it is timely to be reviewing the underlying directions and themes.

This paper seeks to identify and explore key themes in the contemporary policy discussion on human genetic research and databanking from international statements and other literature, including concepts of common heritage, solidarity, human dignity, equality/equity, benefit sharing, non-discrimination, and international co-operation. From the outset, it should be acknowledged that there are other issues embedded within, and interconnected with these themes, so the discussion inevitably broadens out to encompass other related matters. This paper also endeavours to highlight links between some of these themes, and also some tensions which exist between them.

Through this exploration of key themes, the paper aims to assess what value these notions bring to the debate, and the influence they have on substantive areas of law and practice. In particular, the paper examines the capacity to give practical effect to these ideas in promoting genetic research for the improvement of health care, and the responsible use of genetic information. The paper uses large-scale human genetic databanks as a case study to interrogate some of these matters, in particular to demonstrate the inadequacy of a framework based purely on individual rights, and the need for broader principles, drawn from these themes to frame the issues.\(^1\)

Key Sources Contributing To the Policy Debate: International Instruments

A number of international instruments have featured significantly in the policy debate seeking to protect human and patient rights. UNESCO (United Nations Educational, Scientific and Cultural Organisation), through the work of its International Bioethics Committee, has played an important role, and particularly relevant is the Universal Declaration on the Human Genome and Human Rights (1997). UNESCO has since produced the International Declaration on Human Genetic Data (2003), and the Universal Declaration on Bioethics and Human Rights (2005.) At the regional international level, the Council of Europe, Convention on Human Rights and Biomedicine (1997) is a noteworthy instrument. There are also a number of pertinent HUGO (Council of the Human Genome Organisation) statements, including: the Ethical, Legal and Social Issues (ELSI) Committee Statement on the Principled Conduct of Genetic Research (1996), Statement on DNA Sampling: Control and Access (1998), the Statement on Benefit Sharing (2000), and the 2002 Statement on Human Genetic Databases.

Whilst these instruments have no binding legal force, either internationally or under domestic law, they represent important international norms and provide grounds for individuals to challenge laws that run counter to these instruments. Indeed, there is a growing tendency for courts to look at declarations in international law as a guideline. Taken

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together with other national statements and codes, they provide a set of core values, which although not unanimously agreed upon, represent a high degree of international consensus.

Key Sources Contributing To the Policy Debate: Commentators

The themes from the various international statements have been augmented through their critical analysis by commentators, including philosophers, sociologists and lawyers. Influential contributions to the policy debate in the literature internationally include the work of Caulfield and Brownsword on human dignity; Harris and Sulston advocating genetic equity; Chadwick and Berg's writings with respect to solidarity and equity; Knoppers and Fecteau's input on global public goods; Laurie and Hunter's paper on benefit sharing and public trust; the work of Harris on participation in biomedical research as a moral duty; and Parker's arguments in support of a more communitarian understanding of autonomy.

Assumptions Underpinning Key Themes

Reading these themes together, certain underpinning assumptions can be identified in the context of genetics. Firstly, the themes recognise the special status of genetic information, being sensitive, personal, familial, and therefore shared information. Notably, however, recognition of these features is not necessarily tantamount to endorsing genetic exceptionalism, but rather calls for a more nuanced response. Secondly, they are premised on genetic data being a rich resource; a public good, which, through research, can benefit humanity if used wisely. At the same time, they acknowledge the significance of the information that genetic data can reveal, and the potential to cause harm if misused. These underlying presuppositions are in fact explicitly spelt out in some instruments. A good example is Article 4 UNESCO International Declaration on Human Genetic Data (2003) which provides: ‘Human genetic data have a special status because: ‘and then goes on to refer to their predictive nature, familial implications, and their capacity to include information of unknown significance, and calls for due consideration to be given to the sensitivity of human genetic data, and an appropriate level of protection for these data. Building on this premise that genetic data are special, the instrument proceeds to set out special requirements and obligations pertaining to this area.

Relating these above assumptions to the key themes under consideration: Our common genetic heritage creates a special bond with concomitant obligations (common heritage, solidarity), and demands that individuals are respected (human dignity), treated fairly (equality/equity, non-discrimination, benefit sharing from an individual perspective), and that opportunity for access to this valuable resource and its outputs are shared (international co-operation, benefit sharing from a wider community perspective).

Consideration will now be given to each of these key themes in turn.

Common Heritage

Linked with the theme of solidarity, common heritage speaks of the shared status of the human genome (sometime also discussed in terms of common humanity, communitarism, and shared future). For example, Article 1 of the UNESCO Universal Declaration on the Human Genome and Human Rights (1997) regards the human genome ...‘in a symbolic sense as the heritage of humanity’. This

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7 J. Harris, Scientific Research is a Moral Duty (2005) 31 Journal of Medical Ethics 242-248.

9 For discussion of public goods see Knoppers and Fecteau op cit. n 5 and note also the HUGO Statement on Human Genetic Databases (2002) which defines global public goods as ‘those whose scope extends worldwide, are enjoyable by all with no groups excluded, and, when consumed by one individual are not depleted for others.’
emphasis on a shared or common heritage helps to highlight the value of genetic research and suggests that the collection of human genetic material, especially for large-scale human genomic databanks, should be perceived as global public goods for the benefit of present and future generations. This, in turn, sets up arguments about equality of access internationally, and the need for sharing of resources, knowledge and benefits, and fostering of international co-operation. Express support for this idea can be found in some international statements, for example, HUGO Ethics Committee Statement on Human Genomic Databases (2002) which encapsulates it in the following terms:

'Human genomic databases are global public goods:

a. Knowledge useful to human health belongs to humanity.

b. Human genomic databases are a public resource.

c. All humans should share in and have access to the benefits of databases.'

Moreover, this emphasis on solidarity and common heritage is consistent with concepts of non-ownership of genetic material, and non-commercialisation which are ventilated in a number of statements, for example, UNESCO Universal Declaration on the Human Genome and Human Rights (1997) which declares in Article 4 that 'the human genome in its natural state shall not give rise to financial gains.' However, this view should not be allowed to become a guise for exploitation, and the importance of full disclosure to individuals about potential uses cannot be overstated.

Further, this communitarian perspective suggests a move away from the paramouncy given to individualism and autonomy.

Solidarity

The Oxford Dictionary defines solidarity as 'unity or accordance of feeling, action etc among individuals with common interest; mutual support or cohesiveness within a group.' In its more general sense, social solidarity indicates an obligation on society to provide assistance, including medical assistance; it is also open to be interpreted as raising issues of distributive justice and the concept of equal rights for all. The promotion of solidarity, particularly with regard to those vulnerable to, or affected by genetic disease, is explicitly referred in the UNESCO Universal Declaration on the Human Genome and Human Rights (1997), Article 17, as well as in the preamble of this instrument and of the UNESCO International Declaration on Human Genetic Data (2003).

The notion of solidarity springs from the prior theme of common genetic heritage, and the idea that we all share the same basic human genome. The concept of genetic solidarity highlights the social or public interest or common good, and also focuses attention on the mutuality of interest in medically based genetic research. In turn, this links with the ideas of reciprocity, mutuality and citizenship. Tensions, however, also exist between this notion and traditional principles of individual autonomy, and the relationship between these principles may need to be renegotiated to find an appropriate balance between respect of persons/individuals, and genetic solidarity/common good.

Human Dignity

Human dignity is well recognized in international human rights law and in numerous international instruments and ethical statements. Article 1 of the UNESCO Universal Declaration on the Human Genome and Human Rights (1997) states that: 'The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity'; Article 2 provides that everyone has a right to respect for their dignity, irrespective of their genetic characteristics. The concept of human dignity is a broad, open-textured one, and open to a number of sometimes competing interpretations. It is linked with the principles of respect for persons, individual autonomy and self-determination. It can be seen as a capacious umbrella for quite a number of other principles, including the need for consent, privacy and confidentiality, whether to be informed about the results of genetic testing, also the need for genetic counselling to be available so that individuals can make informed choices. Some of these principles

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13 Chadwick and Berg, op cit. n 4.
are expressly included within international instruments. Indeed, UNESCO documentation specifically states that in order to ensure respect for the dignity of the human person, the Universal Declaration on the Human Genome and Human Rights solemnly proclaims the confidentiality of genetic data, and seeks to protect the individual against the disclosure of data that belongs to them. More broadly, it speaks of the need for public consultation, engagement and social dialogue with communities regarding the direction of policies in this area.

Writers Caulfield and Brownword focus on the importance of human dignity to our conceptions of consent. They note that in this context, human dignity is used is its traditional human rights sense. They go on, however, to express concern about it being hijacked in other settings and deployed as a general condemnation, and blanket justification for regulatory restraint, for example, in the campaign against the use of embryonic stem cells in research.

It is interesting to explore the interaction between themes on this issue of consent, and possible tensions arising. In particular, the topics of solidarity and common heritage pull away from too strong or exclusive a focus on individual rights. There is some disquiet that the current approach to consent is highly individualistic, lacks social cohesion and de-emphasises the common good. Whilst consent and privacy are clearly important values to further human dignity, they must be interpreted in the wider framework of relevant interests. This underscores the importance of recognizing the plurality of interests in this field which need to be kept in balance.

Equality and Equity

Equality, which can be defined as 'the condition of being equal,' is, for example, part of the preamble of the UNESCO Universal Declaration on the Human Genome and Human Rights (1997) which refers to the UNESCO Constitution and the 'democratic principles of dignity, equality and mutual respect of men.' John Harris and John Sulston have promoted the idea of genetic equity which they delineate in the following terms:

'Humans are born equal, they are entitled to freedom from discrimination and equality of opportunity to flourish; genetic information may not be used to limit that equality.'

However, others such as Fukuyama, might postulate that the notion of natural rights and inherent rights is in fact challenged by genetic science, in that it cannot be said that 'all are born equal'. This theme of equality/equity has clear linkages with the themes of solidarity and also non-discrimination which this paper turns to next.

Non-discrimination

Article 6 of the UNESCO Universal Declaration on the Human Genome and Human Rights (1997) states that: 'No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.' (Note also the UNESCO Declaration on Human Genetic Data, Article 7, and the European Convention on Human Rights and Biomedicine, Article 11).

Non-discrimination in this context of genetic data and research encapsulates the idea that no person shall be unfairly discriminated against on the basis of his or her genetic characteristics. However, this concept is not inconsistent with the possibility of legitimate uses of personal genetic information in the making of some decisions. This suggests that the notion of genetic equity, as defined by Harris and Sulston (that genetic information may not be used to limit equality) may be somewhat naïve and misplaced, if it is taken to mean no differentiation in any circumstances, as equal treatment cannot be guaranteed in all cases.

Importantly, however, this principle of non-discrimination and the foregoing theme of equality and equity highlight the proposition that in the process of ensuring public benefit from the developments in genetics, which may require some relinquishment of personal rights such as privacy, we

15 Caulfield and Brownword, op cit. n 2.
18 Harris and Sulston, op cit. n 3.
20 For further discussion, see M. Otlowski, Exploring the Concept of Genetic Discrimination (2005) 2 Journal of Bioethical Inquiry 165-176.
must strive to ensure adequate protection for individuals through appropriate regulation.\textsuperscript{21}

**Benefit Sharing**

Also significant in this era of growing commercialisation is the subject of benefit sharing. Whilst not specifically provided for in the UNESCO Universal Declaration on the Human Genome and Human Rights (1997), some aspects of the Declaration give support to the concept of benefit sharing: for example, Article 12 under ‘research on the human genome’ states that the benefits from advances in biology, genetics and medicine concerning the human genome shall be made available to all, with due regard for the dignity and human rights of each individual, and Article 18 refers to the idea of cooperation between industrialised and developing countries. Benefit sharing is, however, expressly mentioned in Article 19 of the UNESCO Declaration on Human Genetic Data (2003) which provides:

‘In accordance with domestic law or policy and international agreements, benefits resulting from the use of human genetic data....or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community.’

Benefit sharing is clearly linked with some of the foregoing themes, in particular, the idea that the human genome is the common heritage of the human race, and therefore, the benefits that accrue from genetic research should benefit all people. Laurie and Hunter argue that promotion of benefit sharing allows retention of the normatively appealing gift model, by redressing the imbalance of power between subject and researcher.\textsuperscript{22} By instilling some reciprocity in the relationship, benefit sharing promotes public trust. There is an emerging recognition that a more equitable approach to the distribution of benefits from genetic research is needed, to ensure some return of benefits to the community from which the research participants were drawn, for example, through profit-making organisations dedicating a percentage of annual net profit to health infrastructure and/or humanitarian efforts.\textsuperscript{23}

As commentators point out, there is currently scant evidence that this issue is being taken seriously\textsuperscript{24}; and that more than ‘mere gestures’ towards public benefits are required.\textsuperscript{25} Nicol argues that benefit sharing should not be seen by stakeholders as a threat to the commercial success of their endeavour, but as an important component of its success, particularly for enhancing public trust.\textsuperscript{26} It also needs to be understood that benefit sharing does not equate to paying research participants for their involvement, nor to commodification of human tissue, but it does, in a significant way, recognize the important contribution that participants, their social groupings and the public at large make to the research endeavour.\textsuperscript{27} Clearly, there is scope for more to be done to give tangible meaning to this concept.

**International Co-operation**

Turning to the final theme of international co-operation, Article 18 of the UNESCO Universal Declaration on the Human Genome and Human Rights (1997) stipulates that:

‘States should make every effort... to continue fostering the international dissemination of scientific knowledge concerning the human genome, and genetic research and in that regard to foster scientific and cultural co-operation particularly between industrialised and developing countries’.

(See also the UNESCO Declaration on Human Genetic Data, Article 18).

Developments with regard to globalisation have created an imperative for international frameworks, for co-operation and harmonisation of operational parameters (including terminology). International linkages are necessary to ensure worldwide access-

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\textsuperscript{22} Laurie and Hunter, op cit. n 6.


\textsuperscript{25} Williams, op cit. n 1.

\textsuperscript{26} Nicol, op cit. n 24.

\textsuperscript{27} Ibid.
bility of resources in furtherance of the themes of common heritage, solidarity and benefit sharing.

Relevant in this regard is the Public Population Project in Genomics (P3G), led by Bartha Knoppers, which is seeking to secure greater uniformity and achieve internationalisation. The P3G is a non-profit, international consortium to promote collaboration between researchers in the field of population genomics. It has the aim of facilitating data management for public population genomics projects to encourage co-operation between projects (transfer/sharing etc) and to foster the creation of an open, public and accessible knowledge database.

There are concerns, however, about lack of attention beyond the first world. There is growing support for the view that more focus is needed on addressing diseases of global significance to advance global health, justice and recognition of common goods. This theme is well highlighted in the UNESCO Universal Declaration on Bioethics and Human Rights (2005). A significant inclusion within that Declaration is Article 14 which sets out the principle of social responsibility, introduced to counter developments with regard to commercialisation and patenting. It calls for a new agenda in bioethics to respond to fundamental issues such as poverty, illiteracy and water problems. This is very much linked with the foregoing point, and the need to promote benefit sharing: substantially more must be done to ensure that the benefits of advancements in the area of genetics are shared with the whole world community for the advancement of global healthcare, including access to knowledge and resources.

Summing up the Key Themes

As the foregoing review has shown, there are in fact a number of interconnected themes in the policy debate which have potentially significant implications for genetic research. Given this plurality of interests, it becomes readily apparent that individual concepts and interests cannot be validly considered in isolation. Rather, a more holistic approach is required which takes account of this diversity, and where appropriate, balances competing considerations.

Human Genetic Databanks: A Case Study

Against the background of these interlocking themes, human genetic databanks will be used as a case study to illustrate the multi-dimensional nature of the interests involved and their interaction. Large-scale human genetic databanks are useful as a case study, as they raise multiple policy issues, presenting tremendous opportunities as well as challenges. This stems from their scale (involving unprecedented numbers of participants, as well as large investment of public resources), complexity of structure (set up over an extended period of time with long-term activities and objectives), and prospective and open-ended projects which, by their very nature, are broad and indeterminate in their research purposes.

Moreover, human genetic databanks contain genetic information (typically both genetic samples, as well as family history and other medical information); indeed, the linking of identifiable information is a key feature of such collections. Human genetic databanks are also characterised by a range of stakeholders (individual participants, their families, communities, researchers and their research organisations, commercial bodies and governments). Another dimension, to do with the scale of large population-based collections, is the fact that the databank might include information on a significant proportion of, or even an entire population, thus raising societal, in addition to ethical, issues. For the foregoing reasons, it is well accepted that human genetic databanks present challenges for regulation, and there have been repeated calls for stronger governance and a clear policy.

31 Ibid.
framework. Consequently, this area provides fertile ground to explore the practical relevance of the identified themes.

The large-scale human genetic research databanks that are being established, such as Biobank in the United Kingdom, have a strong research focus, indeed research as a core purpose. Drawing on the principle of solidarity, they involve input from individuals through altruistic donations. However, the value of such databanks derives from the collective nature of their data. This harks back to the notion of common heritage. Pooling data in this way can benefit communities and ultimately, humanity through enhancing our understanding of genetic diseases, particularly the interactions between genes and environment, and thereby improve public health. Also significant is the potential of such resources as the basis for developing pharmacogenomics or individualized medicine. Accordingly, given the quasi universal nature of their benefits, human genetic databanks can be viewed as a type of public good.\(^{35}\) This, in turn, points to the desirability of free and open communications, treating such databanks as a public access resource,\(^{36}\) and for benefit sharing: indeed the shared nature of contributions supports recognition of communal, as distinct from individual, benefits.

These big picture considerations, such as solidarity and common heritage, help to encourage and justify peoples’ involvement. They call for an affirmation of communitarian values. But there is also another aspect to an individual’s involvement which looks to their legal rights and the need to safeguard their interests. This individualised perspective is influenced by concerns for protecting human dignity, ensuring individuals are dealt with equitably, and are protected from unfair discrimination resulting from their participation.

The emergence of large-scale human genetic databanks has led to re-evaluation of the focus on and frequent pre-occupation with individual rights. The challenge is that optimizing advances in the public good may require some reassessment of individual claims, so as to achieve an effective balance between collective and individual interests. More emphasis needs to be given to the common endeavour, our objectives and the commonality of interests rather than seeing it simply as a irreconcilable conflict of interests (individual interests in privacy versus researchers’ interest in access.) At the same time, we must not be simplistic in our understanding, or underestimate the complexities. In particular, we should be aware of viewpoints which challenge the idea of commonality of interests on the basis that there is no one public, but rather diverse publics.\(^{37}\)

**Human Genetic Databanks: Consent To Future Unspecified Use?**

The issue of consent to future unspecified use of data collected for genetic databanking has been very contentious internationally. In particular, there is debate as to whether the consent of a participant to collection of their data for unspecified future research counts as valid informed consent, or whether participants must be recontacted again in the future, once specific research projects are developed, to obtain specific consent for participation in each distinct project.\(^{38}\) Researchers contend that insisting on specific consent in each case is unworkable for the sort of large-scale databanks proposed.\(^{39}\)

It is instructive to make reference to the key policy themes identified in this paper to ascertain what light, if any, they shed on this issue. The identified concepts help to support the need for balance and for a holistic view to be taken, not just focused on the individual in isolation, but having regard to the plurality of interests, in order to arrive at a workable interpretation of consent. Arguably, there has been an overemphasis on ‘informed’ consent, in the course of which, sight has been lost of the important values that it represents, namely autonomy, respect and protection. Consent requirements must be interpreted consistently with human dignity requirements, and the idea of respect for individu-

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35 Knoppers and Fecteau, op cit. n 5.
36 Ibid.
39 ALRC/AHEC, op cit. n 21 at p 422.
Whilst this analysis has focused on consent, it also need to adopt a more moderate, less absolutist view of privacy. Privacy interests should not be seen in purely individualistic terms. Rather, there must be recognition that there are collective or public values in privacy. So in framing the analysis, it is preferable to acknowledge competing public interests; namely in promoting research, and in protecting privacy.

Human Genetic Databanks: Other Issues

Aside from matters of consent and privacy, as noted earlier, human genetic databanks test a number of the themes which this paper examines, a few of which are addressed further below.

Benefit Sharing

There is unlikely to be any direct benefit to individuals from donating genetic samples; indeed depending on the project, participants may not receive any individual feedback, as is the case with the UK Biobank.42 In light of the emphasis in the international instruments on equity and benefit sharing, a strong case can be made for some form of benefit coming back to individuals or their communities to compensate for their involvement. Under current arrangements for UK Biobank, the extent of benefit sharing will be the free dissemination of information arising from the project in the public domain. Whilst this is not insignificant, it is disappointing that a more proactive stance has not been taken to this important issue.

Governance Framework

Important questions also arise about the appropriate governance framework of human genetic databanks. Relevant in this regard are the proposals for use of a 'gene trustee model' for human genetic databanks to oversee and regulate access to the databank to ensure protection of privacy and confidentiality. This model involves separation of any identifying information from all potentially sensitive data and genetic material held in a human genetic databank. Its advocates maintain that by fostering public trust, such a model can help to maximise the capacity of such databanks for the common good.43 The potential merit of this model

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40 Harris, op cit. 7. Note also the House of Lords Select Committee on Science and Technology, 4th Rept, Human Genetic Databases: Challenges and Opportunities, 2001 at para 9.4.

41 See for example, HUGO (Human Genome Organisation) Ethics Committee Statement on Genetic Databases 2002 Article 4 and the Australian NHMRC (National Health and Medical Research Council) National Statement on Ethical Conduct in Human Research, para. 2.2.14(c).


was endorsed by the ALRC/AHEC Inquiry. The Essentially Yours Report recommended that the NHMRC issue guidelines making use of an independent intermediary a condition of registration of human genetic databases, or approval by a human research ethics committee of research involving a human genetic research database. In considering governance models and regulation of human genetic databanks, there are also important questions to be decided as to whether a legislative framework is appropriate, or some other, less interventionist, model.

Access, Commercialisation and Ownership

Difficult issues have also emerged with regard to access and ownership of the resource. In relation to access, should such databanks be conceived as a public resource that is available to all researchers? What about access by commercial entities for research aimed at pharmaceutical development? Related to this is the question: on what conditions should access be allowed? One only needs to be posing these questions to appreciate the relevance of key themes such as international co-operation, benefit sharing and equity to the satisfactory resolution of these problems. More fundamentally, questions have been raised as to the appropriateness of commercially oriented human genetic databanks as distinct from not-for-profit initiatives.

The work of the Human Genetics Commission in the United Kingdom provides some evidence of the relevance of the key themes identified in this paper influencing practice in this area, and of the imperative of balancing commercial and other interests in the development and use of human genetic databanks. The Inside Information Report contains a strong statement that ‘large-scale population genetic databases established with and supported by public funding, constitute a national asset, with the consequence that national benefit and interest should be taken into account in determining the terms upon which access is to be granted to such databases’. It goes on to express support for equitable research access and to speak of the importance that databases are seen and understood to be bringing at least some benefits to public-domain knowledge, rather than being solely designed for commercial exploitation.

Against a background of growing commercialisation of the new developments in genetics, it is unsurprising that human genetic databanks, with their rich potential, present particular challenges. Where there is some prospect of commercialisation arising from the research using the human genetic databanks, how is this to be addressed? What is to be disclosed to participants? A strong case can be made for full disclosure such that information about the possibility of commercial exploitation must be revealed to participants, including the fact that they are not entitled to directly share in any profits as such, but may participate in some form of more general benefit sharing.

Although there has been considerable consternation with respect to ownership issues, the basic legal principles are in fact fairly clear: Legal ownership of the databanks and sample collections rest with the organisation responsible for the collection. For example, in the case of Biobank, legal ownership will reside with UK Biobank Limited. Significantly, however, UK Biobank Limited sees its role as one of stewardship; maintaining and building the resource for the public good in accordance with its purpose, and does not propose to exercise all rights of ownership, such as sale of samples.

Global Considerations and the Need for International Co-operation

As some of the earlier questions about access and ownership have intimated, there are also global considerations entailed with human genetic databanks. Efforts are required to foster international co-operation, so the potential value of human genetic research databanks can be maximized. In this context, benefit sharing needs to also be considered, not only in terms of individual participants and their communities, but also in terms of how we can promote within the developed world, wider sharing of resources with less privileged countries. To this end, the newly emerging biobank projects should be giving serious consideration to how benefit sharing in this wider sense can be addressed.

References:

44 ALRC/AHEC, op cit. n 21, Recommendation 18-3.

There are other important policy implications of publicly-funded large-scale human genetic research databanks. The investment of substantial public resources in such databanks has led to calls for careful scrutiny of, and deliberation about the relative value to science, society and state of such developments.49

Evaluation and Conclusion

On one, somewhat cynical view, the themes the subject of this paper are simply motherhood, rhetorical statements, not intended to be binding or to create real rights, and in practice, they achieve little. Whilst it is important that we acknowledge the limitations of the large objectives on which these concepts are based, they are nevertheless significant. Their importance lies in recognising (as per the language of the instrument preambles), and aiming for these objectives: this is part of a process of standard-setting and articulating what we, as a civilised community, believe in and strive to work towards. Accordingly, a more constructive interpretation of these themes is that although these instruments do not create binding legal duties, they provide an important and influential reference point for governments and commentators on the direction for international progress in human biotechnology. Further, they represent important values underpinning a democratic, liberal society, providing context and content, and thereby adding a degree of quality and depth to the debate about appropriate parameters for genetic research. These guiding themes help to broaden the focus from a purely individualistic, somewhat reductive approach50 to encompass also important social, policy and cultural issues. Moreover, they are useful in raising the standard and helping to shape the future of genetic research globally. Indeed, Knoppers suggests that the Human Genome Project has provided us with an opportunity to develop a global health ethic.51 In light of the concepts that they embody, these themes clearly have the potential to contribute to public trust in genetic research, provided that they are given real meaning and not just paid lip-service to, which would be likely to have quite the opposite effect.

It must be made clear, however, that advocating fuller, more inclusive debate does not amount to undermining the important values which individual interests such as consent and privacy protect. The central role and protective function of these principles must be maintained; rather, what this paper proposes is that there be some reinterpretation and mediation of the issues, so that the essence of the principles can be upheld, but within a more holistic and flexible framework.

In conclusion, it is important that these aspirational themes are taken seriously, and not just treated as rhetorical statements to which lip-service is paid. There are no doubt many challenges ahead. For commentators, key national bodies, policymakers, legislators, and states, the challenge is to give serious attention to these guiding themes in developing law and policy in this area, and for researchers, and their research organisations, both in the public and private arenas, to draw on these ideas to help to shape best practice in genetic research.

49 See, for example, the US Secretary's Advisory Committee on Genetics, Health and Society, Draft Report on Policy Issues Associated with Undertaking a Large US population Cohort Project on Genes, Environment and Disease, May 2006.

50 Williams, op cit. n 1 at p 61.

JIBL is a scholarly journal dealing with the legal implications of the latest developments in the sphere of biotechnology and genetic engineering. Its intention is to serve commercial advisors and decision-makers within the enterprises. Naturally, the legal institutions' need for information dealing with matters of patent law and copyright (law courts, solicitors operating nationwide/international) will be taken into account as well. High-quality scientific essays, combined with to-the-point abstracts giving a quick yet comprehensive insight into aspects of the law concerning biotechnology and genetic engineering. These contents will be supplemented by a summary of the latest developments in the fields of law and science (medical studies, research). The journal will be concluded with reflections from the points of view of different countries. Further elements include an introductory editorial and a personality report.

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