Annual report of the Human Genetics Commission : 2006-2007

Human
Genetics
Commission

Human Genetics Commission

Sixth Report from April 2006 to March 2007

Chair's introduction

It is my pleasure to present this sixth annual report from the Human Genetics Commission (HGC) following yet another busy year, which has seen the Commission involved in vigorous debates on cousin marriage, forensic use of DNA, genetic discrimination and the creation of human-animal 'hybrid' embryos for research.

As well as these headline-grabbing debates, the Commission has been gathering information and providing advice on issues such as the use of genetic tests by employers, the impact of NHS budgetary restrictions on genetic services and the growth in commercial genetic testing services provided directly to the public. As a high-level advisory body the Commission has also been active in establishing and facilitating links with and between agencies and regulatory bodies, both in the UK and abroad, to promote more efficient and proportionate regulation and more open and accountable governance.

Whilst I think we can now say that the 'leap forward' in genetics anticipated in 1999, when the Commission was set up, has proved to be more of a gradual acceleration, the range of areas into which the Commission has been led demonstrates how, in one way or another, genetics now enters almost every aspect of our lives: from healthcare to employment, insurance, and law and order. In this report you will read in detail about all the Commission's various activities, but let me now pick out some highlights.

In May 2006, in the context of widespread media debate and after a very informative discussion in our plenary meeting, we produced a statement on cousin marriages. This statement sought to put the risk of inherited conditions that can increase in cousin marriages into the wider context of risks of common genetic conditions. It advocated better information provision about marriage within a kinship group, access to appropriate counselling and support, and a no-blame approach that enables at-risk couples to come forward for testing. This statement was widely welcomed, both within the communities that traditionally practise cousin marriage and among clinical geneticists and genetic counsellors.

In July we began podcasts of our plenary meetings. This new service allows anyone who visits our website to listen to audio recordings of these meetings. The service has proved a great success and we expect the number of downloads to continue to grow.

On 1 September a ban on testing a person's DNA without their permission, which the HGC had campaigned for since 2002, finally came into force as part of the Human Tissue Act 2004. In *Inside Information*, the HGC had concluded that there should be systems in place that promoted public trust about the ways that clinicians, researchers and ultimately the State handled personal genetic information. However, the Commission's examination of the current situation revealed a lack of sufficient legal safeguards that left open the potential for gross intrusions into people's privacy to go unchecked. The HGC's proposal of a statutory ban – combined with a limited set of exceptions – both resolves this concern and should actively promote public confidence.

In December we held our annual meeting of the HGC's Consultative Panel comprising people with experience of genetic conditions, either personally, as carers or though family members. The Panel discussed genetic services (in particular the success of the Government's initiatives in the NHS), the forensic use of DNA and genetic testing in employment (the HGC surveyed a range of employers about this in 2006). As always, discussions were lively and thoughtful, and the Panel's contribution continues to refine and enrich the work of the Commission.

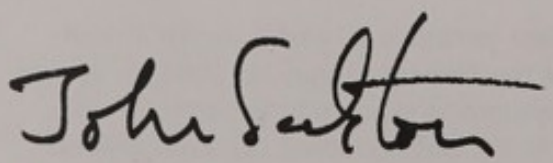
Chair's introduction

In December, too, we received a formal invitation from the Chair of the National DNA Database Strategy Board for a second Commissioner to sit on the Board to provide lay, ethical input. Throughout the year we have continued to develop our plans for a deliberative public involvement exercise in relation to the forensic use of DNA, and this will become a major theme of our work in 2007/08.

In January 2007, we held a follow-up meeting to assess progress against the recommendations we made in our 2003 report *Genes Direct: Ensuring the effective oversight of genetic tests supplied directly to the public*. The meeting involved experts and regulators from both the UK and abroad and was a great success, reaffirming the need for action on several fronts – in relation to regulation, service provision and marketing of direct genetic tests. Following this very positive meeting we will be producing a report, later in the year, on what we see as the outstanding issues to be addressed.

As 2006 gave way to 2007 we learned in more detail, too, of the Government's proposals for new legislation on human fertilisation and embryology – covering IVF fertility treatment and scientific research involving human embryos. The Commission has close links with the Human Fertilisation and Embryology Authority (HFEA), the regulatory body for these matters – and had recently published a major report in the area: *Making Babies: reproductive decisions and genetic technologies*. This set out the substance of our advice which helped inform the draft legislation. However, on one point, the HGC felt that the Government had been too cautious; namely, in ruling out the possibility of creating embryos in a laboratory using both human and non-human material for important scientific research, without a return to Parliament. After a lively debate at our February 2007 plenary meeting, in which the many facets of this difficult issue were examined, the Commission put its view to the Government and the HFEA. As the matter was publicly debated, it became clear that this view commanded significant support from a wide range of citizens and other organisations. I am pleased to say that when the final draft of the legislation appeared, the position had changed to, in principle, allowing the research to go ahead in very carefully controlled circumstances.

Finally, during the year from April 2006 we said goodbye to some old friends and welcomed some new ones. The year was a relatively stable one for the Commission's membership, following a tranche of new appointments the previous year. We did, however, say goodbye to Dr Sheila Adam who is replaced as the English Chief Medical Officer's representative to the Commission by Dr Anita Thomas. We also said goodbye to Dame Suzi Leather, Chair of the HFEA, who leaves to chair the Charity Commission for England and Wales. Shirley Harrison, who also chairs the Human Tissue Authority, has stepped in as acting chair of the HFEA. We wish both Sheila and Suzi well and welcome Anita and Shirley to the Commission.



John Sulston
Acting Chair, Human Genetics Commission, 2008[1]

[1] Baroness Helena Kennedy QC, who chaired the HGC from its establishment in 1999, stepped down in November 2007, before the completion of this report. Her immense contribution in setting the tone and direction for the Commission, and steering it resolutely on that course, will be recognised in the next report, due to be published later in 2008.

Contents

Our meetings held between April 2006 and March 2007

For the fourth year running we have continued our commitment to holding our four main plenary meetings in the public eye and in doing so this year we have visited both Wales and Northern Ireland. The minutes and audio podcasts of our meetings, as well as reports of proceedings, are published on our website (www.hgc.gov.uk) where you can also find details of our information-gathering sessions on a variety of subjects.

May 2006 – Belfast

In May 2006, we held our 24th plenary meeting, our second in Northern Ireland. Members discussed genetic discrimination, particularly in the workplace, and the revision of the UK Health Department Code of Practice on Paternity Testing. The Commission also agreed a statement on cousin marriage: this can be found at Appendix E and is also available on our website.

The following day, the Commission held a particularly informative and interesting information-gathering session on equality and human rights, given particular local relevance in consideration of section 75 of the Northern Ireland Act which relates to, amongst other things, the need to promote equality of opportunity between persons with a disability and those without and genetics in the travelling community.

September 2006 – Swansea

Our September meeting was held in Swansea. This was our second visit to Wales. The meeting began with a presentation from Dr Annie Proctor, a Consultant and Clinical Director in clinical genetics on the All Wales Medical Genetics Service, that concentrated on the difficulties in ensuring adequate provision of genetic services to all those living in the area.

During the plenary itself, the Commission discussed the review of the Government's genetics White Paper *Our Inheritance, Our Future* and the Department of Health's plan to carry out a public involvement event towards the end of 2007.

We also had a presentation from Dr Stuart Hogarth from Cambridge University on regulating direct-to-consumer genetic tests in the United States of America. Afterwards, the Commission discussed what lessons could be learnt for the UK as well as possible next steps that the Commission might take in following up its *Genes Direct* report.

The following day we held an important information-gathering session following on from the discussions of the previous day's plenary meeting on genetic service provision and genetic testing.

December 2006 – London

In December, we visited London. The meeting opened with a presentation by Dr Margaret Llewelyn, Dean of the faculty of law at the University of Sheffield, who provided the Commission with a brief overview of European patent law as well as an update on European developments in this area over the past few years.

Further items discussed during the main plenary session included the Commission's planned booklet on genetics and employment and the current state of funding for NHS genetic services. This latter

discussion led to a decision that the Commission would send a letter to the heads of all genetic services to seek their views on the impact of NHS financial constraints on genetic services. This letter can be found at Appendix E and is also available on our website.

The following day we held our Consultative Panel event for 2006. As always, this was a lively and informative event, which made a very real contribution to the work of the Commission on genetic services, the forensic use of DNA, and genetic testing in employment.

February 2007 – London

For our February plenary meeting we returned to London. The meeting opened with a presentation by Mr Phil Walker of the Digital Information Policy Unit at the Department of Health who spoke to the Commission about the introduction to the NHS of electronic patient healthcare records. Afterwards, the Commission discussed the issue of research on embryos created from both human and non-human material and the Scottish genetics White Paper review.

The following day the Commission held an information-gathering meeting on genetics research, which identified a number of areas for future consideration. The Commission agreed that it was important that the public should be able to find out the areas of research where funding is being directed and agreed to examine how this could be facilitated.

As always, the full minutes of these meetings as well as the audio podcasts of proceedings, notes and presentations from the information-gathering sessions are available on the Commission's website.

Key pieces of work

Cousin marriage statement

In May 2006 there was media interest over the issue of cousins who marry and the impact on public health and resources. The Commission considered at the time that there was a need for it to set out accurately the risks related specifically to recessive genetic disorders which can arise from a cousin marriage. At no point did the Commission seek to pass judgement on those who decide to engage in cousin marriage; rather, its intention was to state the real potential health risk that arises from recessive genetic disorders. The Commission felt that this risk was often misrepresented, or can be the cause of disproportionate concern.

The HGC's statement on cousin marriage can be found at Appendix E and is also available on the HGC website at: http://www.hgc.gov.uk/Client/Content.asp?ContentId=741

Genetics White Paper

In October 2006, the HGC submitted its response to the Department of Health's consultation on the three-year review of the genetics White Paper *Our Inheritance, Our Future: realising the potential of genetics in the NHS*. The Commission spent a considerable amount of time gathering evidence of the impact of the White Paper and suggestions for areas in which more remained to be achieved.

In the light of the information gathered, the Commission concluded that the assessment in the White Paper of the role that genetics could play in healthcare delivery during the funding period had been overoptimistic but the recommendations for investment were appropriate to realise the future potential. The Commission felt that the White Paper had made a positive impact on genetic services and had provided a welcome investment in laboratory equipment as well as in trained staff. It concluded that this should lead to a long-term improvement in genetic services within the NHS.

The Commission also noted that there was room for improvement in the mechanism to improve genetic education within primary care, particularly with the increasingly local focus of healthcare. Furthermore, the Commission expressed concern that benefits achieved as a result of White Paper investment risked being lost due to uncertainties about future support (for example, for trained operators to operate new equipment in genetics laboratories).

The full response can be found at Appendix E or on the HGC website at: http://www.hgc.gov.uk/Client/Content.asp?ContentId=769

Genes Direct follow-up meeting

In January 2007, the Commission organised a meeting to review progress against recommendations contained in its 2003 report *Genes Direct: Ensuring the effective oversight of genetic tests supplied directly to the public*. Specifically, participants in the meeting focused their attention on identifying regulatory gaps and making realistic and practical proposals for the HGC to take to the UK Government and wider European bodies where appropriate.

In addition to members of the HGC's own Genetic Services Monitoring Group, organisations with key roles in the international oversight of genetic testing, as well as key members of the UK Medicines and Healthcare products Regulatory Authority (MHRA) and other experts in the field contributed to the meeting.

In preliminary discussions concerns were immediately identified relating to the levels of scientific evidence given by manufacturers in support of their genetic tests, the quality assurance processes of genetic test providers and the lack of independent consumer information available.

The Commission will be taking this work forward throughout 2007 and aims to publish a report setting out its conclusions later in the year.

Citizens' Inquiry

This year the Commission established a working group to oversee a public dialogue project about the current and future use of DNA for forensic purposes, in particular the National DNA Database. The dialogue project will enable a small group of UK citizens to consider the key social and ethical issues involved, and to give their informed views on the issues. The findings of this Inquiry will form part of a report on the subject, which the HGC intends to publish in 2008.

The first task of the working group was to secure full funding for the project. After a number of setbacks, we are delighted that this was achieved in this reporting year and, as a consequence, look forward to working with our new project partners and funders – Sciencewise, the Wellcome Trust, the Economic and Social Research Council (ESRC) Genomics Forum, and the Policy, Ethics and Life Sciences Research Centre (PEALS).

Membership of the Citizens' Inquiry Working Group

Ms Alice Maynard, Human Genetics Commission (Chair)

Alice Maynard is Managing Director of Future Inclusion Limited. Future Inclusion helps organisations develop strategies to employ and provide services to people in parts of the community they find it hard to reach. She has facilitated a wide range of groups and activities, particularly with disabled people, and ran a Citizens' Jury of disabled people for Transport for London during the development of their Disability Equality Scheme.

Professor Stephen Bain, Human Genetics Commission

Steve Bain undertook his undergraduate medical education at St John's College, Cambridge, followed by clinical training at King's College Hospital, London. He qualified in 1983 and undertook junior medical rotations in London, the East Midlands and West Midlands prior to a Research Thesis in the Genetics of Type 1 Diabetes. He then held an MRC Lectureship jointly in Oxford and Birmingham prior to appointment as Senior Lecturer/Honorary Consultant Physician at Birmingham Heartlands Hospital in 1993. He was elected FRCP in 1996 and became Reader in Diabetic Medicine in 1998. In 2005, he became Professor of Medicine (Diabetes) of the Swansea NHS Trust and is currently Director of Research and Development for the Swansea NHS Trust.

Professor Sarah Cunningham-Burley

Sarah Cunningham-Burley is Professor of Medical and Family Sociology at the University of Edinburgh, where she has worked since 1990. She has been conducting research in the sociology of health and illness and family sociology for many years, mostly employing qualitative methods. Her research interests include sociological aspects of genetics and health, public engagement in science, young people, children and health, families, relationships and health. She is involved in teaching undergraduate medical students and postgraduate public health research students; she also supervises several PhD students.

Sarah is currently involved in research, with colleagues, on the social dynamics of public engagement in stem cell research and on public engagement within some of the projects under the Generation Scotland initiative.

Mrs Ros Gardner

Ros Gardner has her own successful consultancy, specialising in customer care excellence and complaint handling. As a professional keynote speaker on the subject of customer care excellence, Ros has spoken widely at conferences in Europe.

Ros is President of the Society of Consumer Affairs Professionals and a member of the National Speakers' Association (USA). She is also a Founder Director of The Professional Speakers' Association in the UK, and a member of the National Federation of Consumer Groups. She is a member of the School Teachers' Review Body.

Dr Tom Wakeford, Director of Co-Inquiry, Policy Ethics and Life Sciences Institute, University of Newcastle

Tom Wakeford is Director of the UK Beacon for Public Engagement at Durham and Newcastle universities, one of six four-year pilots designed to define how higher education institutions connect with people in the twenty-first century. He has led and/or designed 15 major public engagement projects on four continents since 1998. The Newcastle-based Policy Ethics and Life Sciences (PEALS) Research Centre, where Tom is based, has built partnerships on a range of participatory initiatives with organisations including the Royal Society, Unilever, BBC, Guardian, Sainsbury's, European Commission and UK research councils.

Mr Pat Wilson, Human Genetics Commission Press Officer

A former Government Director of Communications, Pat Wilson is Media Adviser to the HGC. He began his working life in newspapers and broadcasting before spending many years at the Department of Health as a press officer, chief press officer and Director of News. He was Director of Communications at the Welsh Office during the transition to the Welsh Assembly.

He is also Media Adviser to the Council for Science and Technology (CST) and was previously adviser to the Agriculture and Environment Biotechnology Commission (AEBC).

Professor Steven Yearley, Director of the Economic and Social Research Council (ESRC) Genomics Policy and Research Forum

Steve Yearley joined Edinburgh University in 2005 as Professor of the Sociology of Scientific Knowledge. He is primarily interested in social studies of science and in environmental sociology. Additionally, Steve has been closely involved – primarily through the Wellcome Trust – with work on social aspects of human genetics and with social science questions relating to bioethics.

Mr Carl Reynolds, Sciencewise

Carl Reynolds is an experienced mediator and facilitator working in the social and environmental fields. His role for Sciencewise is to ensure that public dialogue meets the conditions laid out in the Office for Science and Technology's Guiding Principles for Public Dialogue.

Key pieces of work

Carl is currently working on community cohesion and participation issues for the Department for Communities and Local Government (DCLG) and, for other clients, on reuse of materials from civil nuclear sites, conservation issues on northern English moorland and forest management in Sussex.

Carl provides advice on specification for work, tendering, commissioning and selection of contractors with the HGC team.

Mr Geoff Watts

Geoff Watts describes himself as a scientist who dropped out. After a stint in cancer research at St Mary's Hospital he moved to the Institute of Ophthalmology, the research arm of Moorfields Eye Hospital. He spent three years working on the effects of lasers on the eye and wrote a doctoral thesis – but then decided that laboratory research could 'cope without him'.

Journalism offered a way of keeping up with science but without the tedium of hours spent gazing down a microscope. He joined the doctors' magazine *World Medicine*, and freelanced for a variety of other publications.

During this time he began broadcasting, first on Radio 4's *Science Now*, then as sole presenter of the prize-winning *Medicine Now* – which ran for 17 years. He also presented countless other features and series on science and medicine for Radios 3 and 4, and for the World Service. He now presents the Radio 4 science programme *Leading Edge*. The rest of his time is given over to print journalism, training and lecturing.

HGC work plan 2007/08

In our last annual report, we set out our work plan until Autumn 2007. In doing so we announced a shift of emphasis from producing lengthy reports to following through on earlier recommendations and responding to issues as they arise and are identified by our monitoring groups. The reports from these groups contained elsewhere in this report show that there has been no shortage of issues arising to tackle.

During the latter half of 2007, the Commission will undergo a routine review carried out by an independent reviewer on behalf of its sponsor departments: the Department of Health, the Department of Trade and Industry, and the devolved administrations. The outcome of this review will have consequences for the HGC's future work, both in terms of how the Commission works and the areas to which it gives attention.

Our work for 2007/08 will therefore fall into four main categories:

- carrying forward and completing ongoing work;
- responding to new developments;
- public involvement; and
- reviewing and improving our effectiveness.

Carrying forward ongoing work

A major item of work in this category will be following through our work on genetic tests supplied directly to the public. As our examination of the area to date has indicated, this is likely to become a major growth area, with many new providers poised to enter the market. We aim, therefore, to continue to build on the relationships we have developed with experts and regulators and to facilitate the development and adoption of agreed standards of good practice with regard to the development and marketing of direct genetic testing services.

Our work on genetics and discrimination, which has involved a number of aspects – for example, in relation to the use of genetic information in insurance and employment – and which led to our response to the Equalities Review, will continue in 2007/08 as the Government's proposals for new consolidated anti-discrimination legislation are developed and debated.

We also intend to follow up our survey of the impact of NHS financial constraints on genetic services to see to what extent our findings of 2006/07 are repeated in the next financial year.

Responding to new developments

In 2007/08 we wish to preserve the ability to respond to developments which, by their nature, are less predictable. Developments in genetics science have brought us to a point where we can expect a greatly increasing level of translation into clinical practice and innovation in other areas (such as forensic identification, genealogy searching and insurance underwriting) which throw up ethical and juridical considerations.

One area where we foresee a number of issues arising is in connection with the Human Tissue and Embryos legislation, which the Government intends to bring forward to govern assisted conception, embryo research and the use of human tissue.

Public involvement

A major item in our work plan is the Citizens' Inquiry into the forensic use of genetic information. Having secured the external funding needed to get the project underway, we intend to look for an innovative approach which offers the possibility of genuine and ongoing engagement with citizens, especially from parts of the population who may be particularly affected.

We will also continue to conduct our business in an open and transparent way, holding our main plenary meetings and as many other events as possible in public and in a variety of locations around the four home countries to facilitate the broadest possible access to the Commission and engagement with our work.

Reviewing and improving our effectiveness

During the latter half of 2007 the Commission will undergo a periodic 'light touch' review. This is an opportunity to review what we have achieved, where we are as a Commission, and where we go from here. We expect the review to produce lessons for the Commission and for the advisory and regulatory environment in which we operate, and to help us to develop more effective ways of fulfilling our terms of reference, supporting and interacting with our stakeholders, and getting across our messages.

Consultative Panel

In 2001, the HGC set up a Consultative Panel of people affected by genetic disorders. The Panel is made up of about 100 people and acts as a sounding board for our reports and recommendations, as well as giving us insight into their concerns about genetic issues.

The Panel includes people who have experience of single gene, chromosomal or multifactorial disorders, which may have become apparent in either childhood or adulthood. Some are affected themselves or are carriers, some have experience as a parent of a child affected by a genetic disorder and some are carers for someone in their family who is affected. Membership has a wide age range and includes people who live in England, Scotland, Wales and Northern Ireland.

We established the Panel because we wanted to hear from people directly affected by a genetic disorder to help us make informed decisions. We need to learn from people who know about the reality of living with a genetic disorder, for example, about the experience of deciding whether to take a genetic test and whether, for example, they have concerns about insurance or employment issues. Our hope was that the Panel would help us to do this in a way that was both useful for the HGC and rewarding for those who participate.

Much of the Panel's work is by correspondence, with the views of Panel members being canvassed on the content of reports we are writing or issues we are discussing. Annual meetings are also held to allow Panel members to meet with Commissioners and to discuss selected issues in depth. We also produce a quarterly Consultative Panel newsletter, which informs Panel members about the Commission's activities and about the outcome of discussions at the plenary meetings.

The Panel has been a tremendously valuable resource for us. Since it was set up, members have assisted us with several consultations, meetings and the overall work plan of the Commission.

In December, the Commission held its third, day-long Consultative Panel event. Over half the Consultative Panel and nearly all HGC members attended the event. The meeting was an opportunity for the Panel, once again, to meet the HGC, as well as spend time with other Panel members and to hear about and discuss the Commission's forthcoming areas of work. The Commission was also keen to learn the Panel's views on how they feel that the Department of Health's White Paper has affected, if at all, their experiences of genetic services. Also discussed in some depth were individuals' concerns over the National DNA Database.

The meeting began with a couple of short presentations in the morning followed by group discussions in the afternoon. A summary of the feedback given by the Panel following those group discussions can be found at Appendix E. Overall, the event was a great success for all involved.

Business Committee and public involvement

Membership of the Business Committee during the reporting period

John Sulston (Chair)

Sarah Cunningham-Burley

Frances Flinter

Ros Gardner

Alastair Kent

Rosemary Leonard

Peter Sayers

The Business Committee was established to drive forward the work of the Commission. It is this group that shapes much HGC business and oversees its public engagement agenda.

The role of the Business Committee is:

- to provide a responsive executive structure so that the HGC can react to developments quickly and involve the membership as fully as possible;
- to liaise with lead members between plenary meetings and continue liaison with key organisations such as the Nuffield Council on Bioethics and the Wellcome Trust;
- to oversee external communications;
- to oversee press/communications arrangements and the HGC website content;
- to provide editorial oversight of the Consultative Panel newsletter and the HGC annual report; and
- to oversee all public involvement activities.

The Committee meets throughout the year and membership of the Committee entails a regular commitment on the part of Commissioners. It therefore operates a rolling membership and at some point, all Commissioners are expected to have served.

As well as maintaining the momentum of the Commission's work, the Business Committee takes the lead in involving the public in the Commission's work. This includes developing new and innovative ways of engaging with the public on a large scale, overseeing website content, agreeing plenary meeting agendas and setting up other public events. The Committee is also involved in engaging with the public on a much smaller scale by responding directly to queries and concerns from members of the public. It continues to be at the heart of all the Commission's work.

As part of the Commission's public involvement strategy a dedicated Citizens' Inquiry Working Group is taking forward the Committee's commitment to consider the implications of the forensic use of genetic information.

For more information on the Business Committee, visit the HGC website:
http://www.hgc.gov.uk/Client/Content.asp?ContentId=261

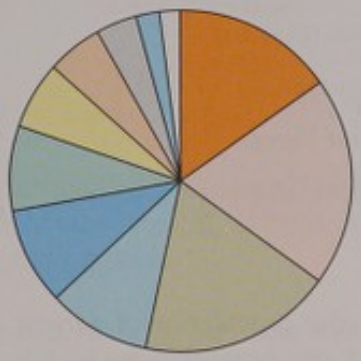
HGC website

One of the Business Committee's key roles is to oversee the content of the HGC website. Since its launch, the website has been seen as a key component of the HGC outreach and public involvement strategy. This year has been marked by a higher daily average number of browser visitors than last year with, again, an excellent spread of visitors from all across the globe.

Lead members for each working or monitoring group can edit and alter the content of their particular group's pages, although the majority of content updating has been handled this year by the Secretariat. The Secretariat is responsible, too, for the production and uploading of minutes, agendas and a whole variety of links and reports to ensure the content is vibrant and changing. The website has grown considerably in size over the year and its goal remains to be a trusted source, a point of reference for interested viewers both in the UK and abroad.

Visitors have steadily increased over the year, with some peaks as a result of press or media coverage, particularly in early March 2007.[2] The provision of sound recordings of each plenary meeting, in the form of MP3 files, have become a regular feature and their usage by the public is expected to grow considerably as people become more used to accessing content in this format.

Pages requested
Total 1,950,029

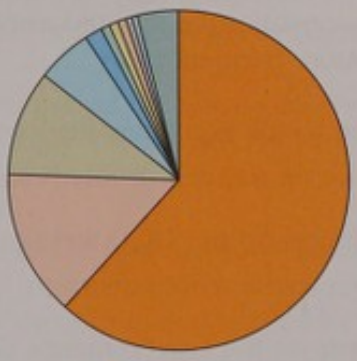


diary.asp	385,753
redir.asp	357,574
Content_wide.asp	191,222
Content.asp	179,724
redir.asp	158,614
diary.asp	120,506
Content_wide.asp	102,390
Content.asp	78,892
index.asp	40,630
document.asp	38,944
other	29,780

The most popular page was the diary page and attention has been paid to providing more content so that visitors feel that the visit has been worthwhile. Browsers are able to access HGC reports as Acrobat documents and the most popular this year has been our report on *Profiling the newborn*.

The spread of browsers across the world is again notable, with most overseas visitors accessing from the USA, China, Canada and Germany.

Countries



1. com (Commercial)	146,187
2. net (Network)	32,489
3. (no entry)	23,925
4. uk (United Kingdom)	12,400
5. cn (China)	3,705
6. ca (Canada)	2,451
7. de (Germany)	1,906
8. edu (Educational)	1,740
9. au (Australia)	1,599
10. it (Italy)	878
(all others)	9,011

[2] During the period December 2006 to February 2007, the server from which the website operates suffered a localised configuration error. This resulted in a failure to record the number of users visiting the site and for this period it appears in the usage statistics that there were no visitors, although the website remained fully functional throughout. The overall number of visitors is therefore likely to have been between 15 and 20 per cent higher than it appears.

HGC monitoring groups

Genetic Discrimination Monitoring Group

The Genetic Discrimination Monitoring Group was formed in 2003 with the remit to oversee the HGC's interest in the issue of genetic discrimination, particularly in the contexts of insurance and employment, and to monitor the work of other relevant bodies to ensure effective and efficient collaboration.

Following the agreement in March 2005 between the Government and the Association of British Insurers (ABI) to extend the Concordat and Moratorium on the use of genetic tests until 2011, the Genetic Discrimination Monitoring Group continued to focus its work on genetic testing and employment.

Membership during the reporting period

John Sulston (Chair)

Stephen Bain

Ros Gardner

John Harris

Michael Harrison

Iona Heath

Christopher Higgins

Alastair Kent

Rosemary Leonard

Alice Maynard

Lola Oni

Peter Sayers

Patrick Morrisson (co-opted)

Lord Sainsbury had requested that the HGC look into the prevalence of genetic testing in the workplace. In March 2006 the Group contacted 21 key organisations to ask if they were aware of any genetic testing being carried out in their fields, or, indeed, any other. This work was completed in June 2006, following which the Chair of the Commission wrote to Lord Sainsbury stating that the findings of the consultation were in line with the Commission's expectations and the findings noted in *Inside Information*, ie that employer-driven genetic testing is not occurring in the workplace. However, one of the responses received has given the Commission cause for significant concern. It reported anecdotal evidence of a case in which employers used sensitive health information in a way that is inconsistent with the Information Commissioner's Code (which states that employers should inform the HGC of any proposals to use genetic testing for employment purposes). Accordingly, the Commission recommended to Government that the time was right to begin considering appropriate safeguards to prevent genetic information being used unfairly. The Commission pledged to return to the subject on a more frequent basis.

The Group also responded on behalf of the Commission to the Equalities Review consultation being led by Trevor Phillips.

Further information on the work of the Group can be found on the HGC website or at Appendix E of this report.

Professor Patrick Morrison continued to sit as an observer on the Government's Genetics and Insurance Committee.

Identity Testing Monitoring Group

Since 2000, the Commission has taken an interest in the forensic use of databases. The Identity Testing Monitoring Group was formed in 2004 to look at issues relating to the commercial and forensic use of DNA for the purposes of establishing the identity of an individual.

The report *Inside Information: Balancing interests in the use of personal genetic data* was published in May 2002. Contained within were numerous recommendations which have been taken forward by this Group and the Commission.

Membership during the reporting period

Steve Bain (Chair)

Brenda Almond

Paul Debenham

Frances Flinter

Christopher Higgins

Rosemary Leonard

Alistair Kent

Lola Oni

Christine Patich

Peter Sayers

One such recommendation was:

"We recommend that, at the very least, the Home Office and ACPO establish an independent body, which would include lay membership, to have oversight over the work of the National DNA Database custodian and the profile suppliers."

Further, we recommended that *"In the short term the Home Office and FSS introduce an independent research ethics committee, to approve such research [involving information held on the National DNA Database."*

Following publication of the report, the National DNA Database Strategy Board invited the Commission to put forward one of our members to sit on the Board. In late 2006, following continued lobbying by the Commission for additional ethical oversight of the database, the Chair of the National DNA Database Strategy Board wrote to Baroness Kennedy QC to ask that HGC member Professor Stephen Bain, who already sat on the Board, be joined by a second HGC representative. This arrangement – two HGC members sitting as lay members on the Board – was formalised, so that it will continue even if the HGC remit were to change. Our second Commissioner, who now joins Professor Bain on the Board, is Professor Sarah Cunningham-Burley.

During this reporting period the Group responded to two consultations, one on the 'Standard setting and quality regulation in forensic science' and another to the Nuffield Council on Bioethics on the forensic use of bioinformation. The full responses can be found at Appendix E.

Following advice from the Commission's Identity Testing Monitoring Group, the Home Office agreed that it should set up an independent ethics group on the National DNA Database. The establishment and full funding for this group was agreed in this period.

Intellectual Property Monitoring Group

Membership during the reporting period

Chris Higgins (Chair)

Brenda Almond

Celia Brazell

Paul Debenham

Alastair Kent

John Sulstan

Mark Bale

Hugh Laddie (co-opted)

Margaret Llewelyn (co-opted)

Cameron Marshall (co-opted)

Jim Houlihan (co-opted)

The remit of the Group is to identify and monitor developments and issues relating to intellectual property and genetics and report these back to the HGC for information or to consider, as appropriate.

Due to developments in the area, such as BioBank, intellectual property policy and consideration of European patent rights relating to test cases on breast cancer genes, the Group co-opted additional members with legal expertise.

The issues considered include:

- ethics and gene patents;
- should genetic material be patentable;
- ethical concerns;
- application of the law;
- competition and access to information;
- informed consent, donor identification and confidentiality; and
- other issues: stem cells, incentives.

The Group held two meetings during the reporting period and in the intervals continued to keep in touch via email correspondence.

The Group sent a letter to the NHS voicing its concerns on the issue of NHS patenting and the need to establish priority setting and balance, and identified licensing in and out of the NHS as something that needs to be looked at in the future.

The Group investigated compulsory licensing in the UK and its use in other countries. Inquiries to the Department of Health were also made as to whether compulsory licensing has ever been threatened.

The Group reviewed and endorsed the OECD (Organisation for Economic Co-operation and Development) guidelines which define the general principles for patenting of genes. The Group planned to send the guidelines out to all research groups, especially genetic research groups (including, but not limited to, charities, research councils and the NHS) with a note that the guidelines should be adhered to by the organisation.

Databases Monitoring Group

Membership during the reporting period

Sarah Cunningham-Burley (Chair)

Stephen Bain

Celia Brazell

Angus Clarke

John Harris

Christopher Higgins

Lola Oni

The Databases Monitoring Group was first formed in 2003 to continue to monitor the development of UK BioBank and similar databases. The Group also considers some of the wider issues associated with research databases including:

- ensuring that content is informed and covers questions like feedback and intellectual property;
- ensuring strict confidentiality, by effective coding, anonymity or encryption and by controlling access by groups such as the police;
- maintaining public confidence, particularly ensuring that large public research databases remain a trusted public resource; and
- promoting realistic expectations of the pace of scientific and medical research and the role of partnerships between public and commercial research.

During this reporting period the Chair of this Group, Professor Sarah Cunningham-Burley, was recruited to sit as the second HGC member on the National DNA Database Strategy Board.

More details on the work of this Group can be found at:
http://www.hgc.gov.uk/Client/Content.asp?ContentId=258

Genetic Services Monitoring Group

Membership during the reporting period

Christine Patch (Chair)

Stephen Bain

Angus Clarke

Paul Darragh

Paul Debenham

Frances Flinter

Rosemary Leonard

Peter Sayers

Rosalind Skinner

Pritti Mehta (co-opted)

Prisca Middlemiss (co-opted)

The terms of reference for the Genetic Services Monitoring Group are as follows:

1. To keep under review and advise the Commission of new issues and developments in the following areas, including the routine exchange of information with other relevant bodies such as the National Screening Committee, the Genetics Commissioning Advisory Group and the Human Fertilisation and Embryology Authority:
   - strategic issues in the delivery of genetic services by the NHS and the private sector across the UK, including paternity testing services;
   - human genetic testing services supplied direct to the public;
   - significant new and evolving genetic tests and screening and associated technologies; and
   - codes of practice and guidance on the ethical, social and scientific aspects of human genetic testing services and their effectiveness.
2. To prepare draft documents and reports for the Commission as required and to contribute to the drafting and analysis of consultation documents and responses in relation to genetic services.

Following the plenary meeting held in May 2006 the Chair of this Monitoring Group, Christine Patch, wrote to the Department of Health to give the Commission's views on the revised Code of Practice on Genetic Paternity Testing. This included a number of suggestions clarifying some of the points raised in the first draft as well as issues that Commissioners believed should be included for a more complete document.

The Group planned over the year to follow up the HGC's report *Genes Direct: Ensuring the effective oversight of genetic tests supplied directly to the public* and to this end wrote to Ministers about the recommendations that were contained in the report. The response from Health Minister Andy Burnham MP on behalf of the Government can be read on the genetic services webpage at: http://www.hgc.gov.uk/Client/Content.asp?ContentId=260

The Group also held a meeting in which it reviewed the progress of the recommendations made in this report and to discuss the current oversight of genetic tests offered direct to the public. Planned work over the next year will be to create a follow-up report from these discussions.

Towards the latter part of 2006, the health charity Breakthrough Breast Cancer published a report entitled *Testing Times* that commented in some depth on the waiting times for those who require a breast cancer gene (BRCA) test. The Commission read the report with interest and as a direct consequence began a small consultation on the provision of genetic services as it was felt important

to clarify the extent to which problems in genetic service provision are wider than breast cancer alone. The Commission concluded that recent data from laboratories show that there were significant improvements being made to waiting times for tests and that technicians were working hard to clear any remaining backlog.

The Commission also responded to the Department of Health in relation to its review of the genetics White Paper. Further information about the Commission's response to this consultation can be found earlier in this report under 'Key pieces of work'.

Appendix A: HGC membership, April 2006 – March 2007

Chair
Baroness Helena Kennedy
Barrister and broadcaster

Vice-Chair
Sir John Sulston
Former Director of the Wellcome Trust Sanger Institute, Hinxton, Cambridge

Members
Professor Brenda Almond
Professor of Moral and Social Philosophy, Hull University

Professor Stephen Bain
Professor of Medicine (Diabetes), Swansea NHS Trust

Dr Celia Brazell
Director of Science and Technology, GlaxoSmithKline

Professor Sarah Cunningham-Burley
Professor of Medical and Family Sociology and Co-director at the Centre for Research on Families and Relationships, University of Edinburgh

Dr Paul Debenham
Director of Life Science, LGC Limited

Dr Frances Flinter
Clinical Director and Consultant Clinical Geneticist, Genetics Centre, Guy's and St Thomas' NHS Trust

Ms Ros Gardner
Ms Gardner runs a consultancy specialising in customer care excellence and complaint handling

Professor John Harris
Sir David Alliance Professor of Bioethics, University of Manchester

Mr Michael Harrison
Barrister

Ms Shirley Harrison (From December 2006)
Chair of Human Fertilisation and Embryology Authority and Human Tissue Authority

Dr Iona Heath
General Practitioner, London

Professor Christopher Higgins
Director of the MRC Clinical Sciences Centre and Professor and Head of Division of Clinical Sciences at Imperial College London

Mr Alastair Kent
Director, Genetics Interest Group

Dame Suzi Leather (Until September 2006)
Chair of Human Fertilisation and Embryology Authority

Dr Rosemary Leonard
GP and resident GP on BBC1's *Breakfast News*

Ms Alice Maynard
Managing Director of Future Inclusion Limited

Ms Lola Oni
Professional Services Manager Haemoglobinopathies, Brent Sickle Cell/Thalassaemia Centre

Dr Christine Patch
Genetic Counsellor Manager, Guy's and St Thomas' NHS Trust

Mr Peter Sayers
Former Chair of the Telecommunications Advisory Panel

Representatives of the Chief Medical Officers
Each of the four UK Chief Medical Officers are able to participate in the HGC or nominate a representative with observer status.

Dr Paul Darragh (Northern Ireland)
Consultant, Public Health Medicine, Eastern Health and Social Services Board

Professor Angus Clarke (Wales)
Honorary Consultant in Clinical Genetics, University of Wales College of Medicine

Dr Shelia Adam (England) (Until February 2007)
Executive Director of Public Health, North East London Strategic Health Authority

Dr Anita Thomas (England) (From February 2007)
Consultant in Acute Medicine, Plymouth Hospitals NHS Trust

Dr Rosalind Skinner (Scotland)
Principal Medical Officer of Public Health Medical Division, SEHD

Co-opted members
Professor Patrick Morrison (Discrimination Monitoring Group)
Consultant in Clinical Genetics, Belfast City Hospital Trust

Mr Geoff Watts
Journalist and presenter of BBC Radio 4's *Leading Edge*

Ms Prisca Middlemiss
Information Officer – Rare Chromosome Disorder Support Group and journalist

Dr Pritti Mehta
Equity and Access Programme Manager, Genetics Interest Group

Secretariat
Mrs Gwen Nightingale, Secretary (until December 2006)
Dr Peter Mills, Secretary (from March 2007)
Miss Sarah Connelly
Mrs Margaret Straughan
Miss Joanna Edwards
Mr Chris Lucas
Mr Pat Wilson (Press Officer)

Appendix B: How the HGC works (role, terms of reference, methods of working and Code of Practice)

The HGC's role

The Human Genetics Commission (HGC) is the UK Government's advisory body on how new developments in human genetics will impact on people and on healthcare. Its remit is to give Ministers strategic advice on the 'big picture' of human genetics, with a particular focus on social and ethical issues.

The HGC was established in 1999 following the UK Government's comprehensive review of the regulatory and advisory framework for biotechnology. Its role should also be seen in the context of other advisory and regulatory bodies in the framework for human genetics. The HGC does not direct these bodies or interfere with their lines of accountability, but works with them and helps form links between them. The HGC reports to Health and Science Ministers and works within the context of devolution settlements for Scotland, Wales and Northern Ireland. Government policy on human genetics is generally developed on a UK basis, but responsibility for NHS genetics services is the responsibility of each devolved administration.

Terms of reference

- To analyse current and potential developments in human genetics and advise Ministers on:
  - their likely impact on human health and healthcare; and
  - their social, ethical, legal and economic implications.
- To advise on strategic priorities in the delivery of genetic services by the NHS.
- To advise on strategic priorities for research.
- To develop and implement a strategy to involve and consult the public and other stakeholders and encourage debate on the development and use of human genetic technologies and advise on ways of increasing public knowledge and understanding.
- To co-ordinate and exchange information with relevant bodies in order to:
  - identify and advise on the effectiveness of existing guidance and of the regulatory and advisory framework as a whole, taking account of European and global dimensions; and
  - look at the lessons learnt from individual cases requiring regulatory decision to build up a wider picture.
- To consider specific issues related to human genetics and related technologies as requested by Ministers.
- To operate in accordance with best practice for public bodies with regard to openness, transparency, accessibility, timeliness and exchange of information.

Methods of working

A constant theme and priority within the Commission's work is actively to seek input from the public and other stakeholders and this involves a variety of consultation exercises and open meetings.

We work in accordance with best practice principles on openness and transparency. We also exchange information with other bodies in the advisory and regulatory framework, including meetings at secretariat level and between chairs.

We have established monitoring groups which involve both members and external participants, and which may co-opt input from individuals. We use email and telephone conferencing when this is useful, particularly for the work of the monitoring groups described below.

The HGC may commission work from individuals or organisations on a consultancy basis.

How we organise our work

The full Commission meets around four times a year, in different parts of the country. We usually meet over two days, holding an information-gathering session on one day, when we invite a number of people to talk to us about a particular issue, and the plenary meeting on the other.

In 2003, we set up a more flexible structure for the way the Commission carries out its work. We agreed to continue to focus the main areas of work in task-orientated working groups. We also identified HGC members to lead on a number of key issues and who work with monitoring groups to keep a watching brief on these areas and keep them high on our agenda.

Lead members are asked to:

- keep the HGC up to date on developments and make sure the issue remains on the HGC's agenda;
- advise on the need for meetings of the monitoring group and suggest specific pieces of work as needed; and
- lead on liaising with other relevant organisations and co-ordinating responses to consultations.

The following monitoring groups operated in 2006/07:

- Genetic Discrimination Monitoring Group
- Intellectual Property Monitoring Group
- Databases Monitoring Group
- Identity Testing Monitoring Group
- Genetic Services Monitoring Group

The work of the monitoring groups is described in the body of this report.

The **Business Committee** continued with its existing role to:

- provide a more responsive executive structure so that the HGC can react to developments quickly and involve the membership as fully as possible;

- liaise with lead members between plenary meetings and with key organisations such as Nuffield and the Wellcome Trust;
- have formal responsibility for all HGC public involvement work; and
- oversee external communications:
  - press office
  - website
  - newsletter/annual report
  - editorial oversight of briefing notes.

Working groups

The Commission decided that our working groups were very good models for taking forward large pieces of work and that we would continue to set up a specific group to deal with an individual area of work. This year we had one working group overseeing the arrangements for the HGC's Citizens' Inquiry in 2007. More information can be found in the main text.

Code of Practice for members

The HGC Code of Practice was prepared in line with Government policy on standards in public life, openness and accountability. Full details are available on the HGC website: www.hgc.gov.uk. The Chair, Vice-Chair, members and representatives of the Chief Medical Officers (collectively referred to as 'members') are expected to follow it in carrying out duties associated with the HGC. Co-opted members are also expected to follow the Code as it applies to the work they do on behalf of the HGC.

A copy of the Code of Practice can be found on the HGC website at:
http://www.hgc.gov.uk/client/content.asp?contentid=5

Appendix C: Register of members' interests

(This register provides details in respect of all HGC members for the period April 2006 to March 2007)

Professor Brenda Almond

Remunerated employment, office, profession, etc

Author, editor, lecturer (occasional, freelance)

Miscellaneous and unremunerated interests

President of Philosophical Society of England
Vice-president of Society for Applied Philosophy
Overseas Member of Austrian Academy of Sciences
Member of the Executive Committee and Council of the Royal Institute of Philosophy
Member of Societas Ethica (European Society for Ethical Research)

Professor Stephen Bain

Remunerated employment, office, profession, etc

Reader in Diabetic Medicine, University of Birmingham and Honorary Consultant Physician, Birmingham Heartlands Hospital, Birmingham, UK
Dr Bain has also received lecture fees from Aventis, Boehringer Ingelheim, Eli Lilly, GlaxoSmithKline, Merck Sharp Dome, Novartis, Novo Nordisk, Pfizer, Servier and Takeda. He has been awarded research and clinical grants by Aventis, Eli Lilly, Novo Nordisk and Sequana Inc

Miscellaneous and unremunerated interests

Member of West Midlands Multi Research Ethics Committee
Chairman of the Pan-Birmingham Diabetes Advisory Group and the East Birmingham and Solihull Local Diabetes Services Advisory Groups

Dr Celia Brazell

Remunerated employment, office, profession, etc

Director of R & D Policy, Office of the Chief Medical Officer, GlaxoSmithKline Research and Development

Registrable shareholdings

Aberdeen Technology Trust
Aggreko plc
The AIM Trust plc
Alliance & Leicester
Autonomy Corporation
B.A.A.
Bradford & Bingley
British Airways
Cable & Wireless
Fidelity American Fund
Fidelity UK Aggressive Unit Trust
Fidelity Special Sit Trust (1) & (2)
Gartmore UK Index fund
GlaxoSmithKline
HBOS
HSBC Holdings
Marks & Spencer
Northern Rock
Orange
Invesco Perpetual: Far Eastern Growth
Railtrack
Regus
ReNeurone
Rolls Royce
Schroders: Tokyo Fund
Scottish & Southern Energy plc
Scottish Power
Share plc
Tesco
Thus Group plc
Trafficmaster plc
Vodafone Group

Miscellaneous and unremunerated interests

Member of Department of Health Advisory Group for Genetics Research
Chair of Pharmacogenetic Group, European Federation of Pharmaceutical Industry Associations (EFPIA)
Member of Advisory Board of Cesagen
International Conference on Harmonisation (ICH): Chair and Rapporteur of E15-Harmonisation of Pharmacogenomic Terminology

Professor Angus Clarke

Remunerated employment, office, profession, etc

Professor of Clinical Genetics, Department of Medical Genetics, Cardiff University.
Salary sourced from NHS (60%) and HEFC (40%)
Recipient of research funds from the Wellcome Trust, Rett Syndrome Association UK, Jeans 4 Genes and the ESRC.
Author and editor of several books

Miscellaneous and unremunerated interests

Fellowships of Royal College of (1) Physicians of London and (2) Paediatrics and Child Health
Member of British Medical Association, NHS Consultants' Association, Clinical Genetics Society, British Society of Human Genetics, European Society of Human Genetics, European Society for the Philosophy of Medicine and Health Care
Chair of Medical Advisory Board, Ectodermal Dysplasia Society
Medical Advisor, Rett Syndrome Association UK and Rett Syndrome Association Scotland
Member, Editorial Boards of *Communication and Medicine, Genomic Medicine*
Supporter of Greenpeace, Religious Society of Friends, Oxfam, Christian Aid, Amnesty International

Professor Sarah Cunningham-Burley

Remunerated employment, office, profession, etc

Professor of Medical and Family Sociology, Division of Community Health Sciences (Public Health Sciences)
Co-director of Centre for Research on Families and Relationships, University of Edinburgh
Salary sourced from Scottish Higher Education Funding Council
Recipient of research funds from the ESRC and Scottish Executive, Office of the Chief Researcher and Education Department
Previously also Joseph Rowntree Foundation, Health Scotland, Chief Scientist Office (Scottish Executive)
Occasional remuneration in connection with professional services (eg examining, publications research consultancies)

Miscellaneous and unremunerated interests

Member of Scientific Committee for General Scotland
Member of British Sociological Association
Member of Society for Social Medicine
Trustee, Edinburgh Rudolf Steiner School, Signatory, Charter 88

Dr Paul Darragh

Remunerated employment, office, profession, etc

Consultant in Public Health Medicine, Eastern Health and Social Services Board
Non-executive member of Health Protection Agency Board

Miscellaneous and unremunerated interests

Director of Townsend Enterprise Park – training and workspace letter
Chairman of Townsend Social Outreach Centre – community development, youth work
Dun's Librarian – Royal College of Physicians (RCPI), Ireland
Member of Council of RCPI

Dr Paul Debenham

Remunerated employment, office, profession, etc

Director of Technology and Innovation, LGC Limited

Registrable shareholdings

Astra Zeneca
Syngenta

Dr Frances Flinter

Remunerated employment, office, profession, etc

Consultant in Clinical Genetics and Clinical Director of Children's Services and Genetics, Guy's & St Thomas' NHS Foundation Trust

Miscellaneous and unremunerated interests

Member of Clinical Genetics Society, British Society of Human Genetics, Evelina Appeal Committee

Mrs Ros Gardner

Remunerated employment, office, profession, etc

Managing Director of Ros Gardner Associates Limited
Member of the School Teachers Review Body
Council Member of the Nursing and Midwifery Council
Independent Complaints Mediator of the Criminal Records Bureau
Deputy Independent Complaints Examiner for the Dispute Service

Miscellaneous and unremunerated interests

Trustee of Alcohol Services to the Community
Lay Assessor, NHS Appointments Commission
Member of the British and Irish Ombudsman Association
Adviser for Thames Water Customer Assistance Panel
Founder Director of the Professional Speakers Association
Member of National Consumer Group
Member, Vice President and President of the Society of Consumer Affairs Professionals

Professor John Harris

Remunerated employment, office, profession, etc

Sir David Alliance Professor of Bioethics, University of Manchester
Visiting Professor of Philosophy, London School of Economics and Political Science
His research is currently supported by the European Commission, the British Embassy, Washington and the Greenwall Foundation
Ethical Consultant to Virgin Health Bank and Chair of one of their Ethics Advisory Boards
Since approximately September 2006 he has acted as an independent advisor to Cells Centre Ltd to provide an appreciation of the likely impact that the company will have within the NHS and public arena and on other matters connected with ethics and policy dimensions of its activities

Mr Michael Harrison

Remunerated employment, office, profession, etc

Barrister, London

Miscellaneous and unremunerated interests

Member of Gene Therapy Advisory Committee

Dr Iona Heath

Remunerated employment, office, profession etc

General Practitioner, Kentish Town, London

Miscellaneous and unremunerated interests

Nationally elected member of the Council of the Royal College of General Practitioners
Chair of the Ethics Committee of the *British Medical Journal*
Member of Medact and British Medical Association
Fellow of the Royal Society of Arts
Supporter of Oxfam, Amnesty International, Friends of the Earth, Medical Foundation for the Victims of Torture, Centre for Young Musicians, Little Sparta Trust

Professor Christopher Higgins

Remunerated employment, office, profession, etc

Director of Medical Research Council, UK: Head of Division, Imperial College London
Chair of Scientific Advisory Board, Microscience

Miscellaneous and unremunerated interests

Chair of Spongiform Encephalopathy Advisory Committee
Executive Council, Association of Medical Research Charities

Baroness Helena Kennedy QC

Remunerated employment, office, profession, etc

Board Member
Independent Newspapers
Member of the Bar

Miscellaneous and unremunerated interests

Advisory Council Member of the Foreign Policy Centre
Bencher of Gray's Inn Chambers
Board Member of British Museum, Tablet Trust
Chair of Arts and Business
Chair of the Board of Governors, Atlantic College
Chair of Standing Committee for Youth Justice
Fellow of the Royal Society of Arts, City and Guilds Institute, Institute of Advanced Legal Studies
Member of Academie Universalle des Cultures, Foreign Policy Centre Advisory Council, External Advisory Council, World Bank Institute
Patron of Charter 88, Liberty, Howard League for Penal Reform, Poets and the City
President of Civil Liberties Trust, The School of Oriental and African Studies
Trustee of KPMG Charitable Trust, Media Standards Trust
Vice-President, Association of Woman Barristers, Haldane Society

Political activity

Labour Peer

Mr Alastair Kent

Remunerated employment, office, profession, etc

Director of Genetic Interest Group
Non-Executive Director of Cambridge City Primary Care Trust
Member of Health Equality Europe

Miscellaneous and unremunerated interests

Chair of Public Engagement Committee, NHS LifeHouse
Member of Joint Committee on Medical Genetics, Association of British Insurers (ABI) Genetics Committee, Genetic Commissioning Advisory Group (DH), Genetics Commissioning Group (London NHS), Orphan Medicinal Products Committee (EMEA), Progress Educational Trust Advisory Committee
Justice of the Peace, Cambridge (until February 2006)

Dr Rosemary Leonard OBE

Remunerated employment, office, profession, etc

NHS General Practitioner
Paid Retainer Express Newspapers and the BBC
Regular contributor to *Woman & Home* magazine (IPC Magazines) and the Tesco Healthy Living Club Magazine

Ms Alice Maynard

Remunerated employment, office, profession, etc

Managing Director of Future Inclusion Ltd
Member of the Eastern Region Committee of Jephson Housing Association

Miscellaneous and unremunerated interests

Company Secretary of Equal Ability CIC
Associate of the Employers' Forum on Disability
Executive Committee Member of Milton Keynes Racial Equality Council
Member of the British Council of Disabled People, Greater London Action on Disability,

Milton Keynes Centre for Integrated Living, RADAR
Advisory Group Member of JMU Access Partnership, Milton Keynes Common Purpose
Supporter of Friends of the Earth, Amnesty International, ActionAid, Shelter, WaterAid, NSPCC and Ethiopiaid

Ms Lola Oni

Remunerated employment, office, profession, etc
Professional Services Manager Haemoglobinopathies, Brent Sickle Cell/Thalassaemia Centre, NW London Hospitals NHS Trust

Miscellaneous and unremunerated interests
Fellow of the Aspen Institute Nigerian Leadership Initiative
Member of NHS Sickle Cell and Thalassaemia Screening Programme Steering Group
Secretary to the First Martin Luther King Twelve
Trustee of the Martin Luther King Memorial Trust

Dr Christine Patch

Remunerated employment, office, profession, etc
Senior Research Fellow, School of Medicine, University of Southampton, funded by The Health Foundation
Honorary contract Specialist Nurse/Genetic Counsellor Wessex Clinical Genetic Service
Postgraduate Student, School of Medicine, University of Southampton (funded by NHS R&D training fellowship)

Miscellaneous and unremunerated interests
Joint chair of the Ethics and Public Policy Committee International Society of Nurses in Genetics
Member of British Society for Human Genetics, Association of Genetic Nurses and Counsellors, British Association for the Study of the Liver, Royal College of Nursing

Mr Peter Sayers

Remunerated employment, office, profession, etc
Director of IDM Ltd
Non-Executive Director of NHS Cheltenham and Tewkesbury Primary Care Trust

Miscellaneous and unremunerated interests
Director of New Harmony Press, Accessible Globe International Ltd
Company Secretary of Salt Marketing Ltd

Dr Rosalind Skinner

Remunerated employment, office, profession, etc
Principal Medical Officer in the Scottish Executive Health Department

Miscellaneous and unremunerated interests
Former clinical geneticist in the University of Edinburgh

Sir John Sulston

Remunerated employment, office, profession, etc
None, except for occasional freelance payments

Miscellaneous and unremunerated interests
Supporter of Oxfam, Amnesty, Greenpeace

Dr Anita Thomas

Remunerated employment, office, profession, etc

Consultant in Acute Medicine, Plymouth Hospitals NHS Trust
Board Member and Chair of Training Committe Postgraduate Medical Education and Training Board
Member of Scientific Advisory Committee, Food Standards Agency
Lead Assessor, GMC fitness to practise performance procedures

Miscellaneous and unremunerated interests

Chair of Chief Medical Officer's Venous Thromboembolism (VTE) Implementation Working Group
Member pf GMC Education Committee, UK Panel for Research Integrity in Health and Biomedical Science

Co-opted members

Dr Pritti Mehta

Remunerated employment, office, profession, etc

Equity and Access Programme Manager, Genetic Interest Group

Miscellaneous and unremunerated interests

Member of UK Genetic Testing Network Gene Dossier and Directory Working Group, NHS and Sickle Cell and Thalassaemia Screening Programme Information for Users and Professionals Subgroup

Professor Patrick Morrison

Remunerated employment, office, profession, etc

Consultant in Clinical Genetics, Belfast City Hospital Trust
Postgraduate Tutor and Director of the Belfast Postgraduate Centre

Miscellaneous and unremunerated interests

Director of Cancer Genetics, Northern Ireland Regional Genetics Service
Member of Northern Ireland Ethics Forum

Appendix D: Finance

The Human Genetics Commission is funded by the Department of Health, the Office of Science and Technology and the Devolved Administrations.

The majority of the HGC's operating budget (running costs) was spent on working in an open manner and public engagement, with approximately:

- £115,000 spent on plenary meetings, monitoring groups, information gathering sessions and the Consultative Panel;
- £15,000 spent on external communications, including the press office, the PR function, and the website; and
- £10,000 spent on printing and publishing.

Fees are payable to Commissioners at a rate of £148.59 per meeting, £180.40 per meeting for the Chair, and Commissioners are reimbursed for all reasonable travelling expenses.

Appendix E: HGC statements, consultation responses and other correspondence

Reply from the Chairman of the Medical Research Council to HGC letter of 10 March 2006 on the publication of HGC's report *Making Babies: reproductive decisions and genetic technologies*

Baroness Helena Kennedy
Chair
Human Genetics Commission
6th Floor North
Wellington House
133–155 Waterloo Road
London SE1 8UG

6 April 2006

Dear Helena,

Human Genetics Commission report *Making Babies: reproductive decisions and genetic technologies*

Thank you for your letter of 10 March drawing my attention to the recommendations of the recent report from the Human Genetics Commission. The report has done an excellent job in highlighting the ethical and scientific issues associated with this challenging area of research and I was pleased to see that in reaching its conclusions the Commission drew on the 2004 report from the MRC *Assisted Reproduction: a safe, sound future*. MRC remains committed to taking forward the recommendations identified in that report – in particular, developing appropriate systems that facilitate the long-term follow-up of children born following technological interventions such as ICSI and PDG. We shall achieve these aims only through working in partnership with the academic community and the appropriate regulatory bodies.

To this end we have recently funded a new MRC Centre of Epidemiology for Child Health, directed by Professor Carol Dezateux at the Institute of Child Health, London. Professor Dezateux has already begun to explore in partnership with the HFEA opportunities to develop and pilot systems that will enable the appropriate longitudinal studies to be carried out to assure a healthy long-term outcome for children and their mothers following these and other technologies. In a detailed response to the Department of Health public consultation on the review of the Human Fertilisation and Embryology Act last November, the MRC emphasised the need for enabling legislation to facilitate effective follow-up research. This reflected the conclusions of the 2004 MRC Report which noted that 'Current research into the potential adverse effects of ART in the UK is hampered by strict laws about data release, linkage to NHS systems... a lack of comprehensive accessible data sources suitable for routine follow-up, further research or clinical evaluation.' In our response we noted 'Current safeguards in law and professional guidance in relation to all medical information should adequately protect the public, while permitting ethical, high quality research.' MRC welcomes recommendation 26 of the Commission's report regarding amendment of this legislation and also recognises it has a role to play in facilitating research into the well-being of children born after HLA matching.

There is much that still needs to be done in improving the effectiveness of assisted reproduction and genetic screening technologies. The MRC remains committed to supporting both applied and underpinning research in this area and recently renewed, for a further 5 years, its support for the MRC Human Reproductive Sciences Unit in Edinburgh which undertakes leading-edge fundamental and clinical research in reproductive health.

I hope you find this response helpful.

Colin Blakemore

Reply from the Programme Director of the National Screening Committee to HGC letter of 10 March 2006 on the publication of HGC's report *Making Babies: reproductive decisions and genetic technologies*

Baroness Helena Kennedy
Chair
Human Genetics Commission
6th Floor North
Wellington House
133–155 Waterloo Road
London SE1 8UG

9 May 2006

Dear Baroness Kennedy,

Thank you very much for sending me a copy of your excellent report on Making Babies. The report is comprehensive and clear and provides, as always, helpful advice for the UK National Screening Committee.

The UK National Screening Committee supports all your recommendations and will seek to implement them through its work programme.

There is one particular issue which has arisen as we implement the sickle cell and thalassaemia screening programmes and this relates to the recommendation in paragraph 3.50. Obviously we fully support this recommendation but any professionals involved in direct work with parents and patients find the principle of openness and complete reporting a difficult part of their clinical practice.

In other screening programmes, for example in mammography screening or screening for diabetic retinopathy, we designed the report form so that the only report that was given was one relating to the screening programme to which the individual had been invited. For example, in the early days of breast screening radiologists wanted to record a very large number of different types of disorder discovered as an inevitable part of high quality mammography. However, by saying that we simply wanted them to report on whether or not the woman should move on to the next stage of screening, the problem was resolved. A similar problem occurs with fetal anomaly screening where people at present are reporting everything they see, and we are attempting to control this both by policy-making and by the design of the report form.

Until we have technologies that are precise, an approach would therefore be to say to women that we were inviting them only to be screened for X or Y, and prepare a report form that recorded the presence or absence of X or Y and contained no other information. Thus if other phenomena were observed, for example haemoglobin variants of unknown significance, it would simply not be reported. As has been pointed out, many anomalies are observed in clinical practice and are not reported. However, as we become more explicit and open in screening programmes, this has become an increasing issue which we have dealt with by reporting only on the results of the test to which the woman has agreed. This has arisen in haemoglobinopathy screening. It is also a hot topic for us in screening for Down's syndrome where many clinicians believe that because the pregnant woman has been exposed to the risks associated with amniocentesis or CVS karyotyping should be carried out, which as you know often reveals chromosomal problems of unknown significance, although there is a PCR test which is very precise and will identify only the trisomies of primary concern.

We would be pleased to discuss this with your officers in more detail.

Thank you again for this report.

Yours sincerely,

J A Muir Gray, CBE, DSc, MD, FRCP, FRCPSGlas, FCILIP
Programmes Director, National Screening Committee

HGC statement on cousins who marry

There has been much debate in the media recently about the practice of cousin marriage and its impact on public health and resources. This statement seeks to set out accurately the risks related specifically to recessive genetic disorders which can arise in cousin marriages.

Cousin marriage is a preferred and sustained practice in many parts of the world and there are members of some communities who believe that it has significant social, economic and community benefits. However, there is a potential health risk arising from recessive genetic disorders but this risk is often misrepresented, or can seem overly significant.

One recent media report estimated that British Pakistanis were 13 times more likely to have children with genetic disorders than the general population. Taken out of context, this figure implies that ALL British Pakistanis are equally at risk irrespective of marriage patterns, and fails to clarify that the risk relates specifically to recessive genetic disorders which can arise in cousin marriages. Other types of genetic conditions, including chromosomal abnormalities, sex-linked conditions and autosomal dominant conditions are not influenced by cousin marriage.

The absolute risk to first cousins having a child with a recessive genetic condition is about three in every 100 births, unless they have a family history of an autosomal recessive disorder, in which case the risk may be higher. When we also include the background risk of having a child with any type of congenital or genetic disorder, which applies in every pregnancy, the overall risk to first cousins rises to about six in every 100 births, ie double the risk in the general population. The great majority of pregnancies do not result in abnormalities.

In order to further contextualise this risk, the Genetic Interest Group (GIG) have made a useful comparison with another risk factor during pregnancy: increased maternal age. According to GIG, the effect of increased maternal age on the rate of Down syndrome, a specific type of chromosomal abnormality, can be compared with the increased risk posed by consanguinity. At 35 years of age, the risk of Down syndrome is four times that at age 25 and increases 15 times by the age of 40. The absolute risk at 40 years is one in every 100 births.

There are clear similarities between cousin marriage and increased maternal age. Both represent complex cultural trends. Both, however, also carry a biological risk. The key difference, GIG argue, is that cousin marriage is more common amongst a British minority population, whilst increased maternal age is more prevalent within the general population.

The NHS has responded to the risk of Down syndrome in cases of increased maternal age by committing significant resources to help address the problem. The national Down syndrome screening programme ensures that all pregnant women are routinely offered a screening test to identify those at increased risk of having a baby with this chromosomal abnormality. Overall, healthcare provision for women having children later in life has improved in order to reflect the cultural trend towards this. In a similar way, it is appropriate to offer genetic counselling to couples whose relationship is consanguineous, preferably before they conceive, in order to establish the precise risk of a genetic abnormality in their children, and to identify if any specific tests may be indicated.

Whilst we recognise that in a complex multiethnic society, it is not easy for the NHS to respond to the needs of all, the HGC agrees with GIG's assertion that, for communities where cousin marriage is the tradition, a similar response to that given to increased maternal age would be appropriate. We would therefore like to see the proper provision of education and information about marriage

within a kinship group. This should entail access to counselling and support, preferably in the individual's or couples' preferred language, and a no-blame approach that enables at-risk couples to come forward for testing.

If you are interested in this debate, you might like to visit the following web pages for further information:

www.gig.org.uk – this link is for the Genetic Interest Group (GIG), a national alliance of patient organisations with a membership of over 130 charities which support children, families and individuals affected by genetic disorders.

www.wellcome.ac.uk The Wellcome Trust is an independent charity funding research to improve human and animal health. Established in 1936 and with an endowment of around £11 billion, it is the UK's largest non-governmental source of funds for biomedical research.

If you would like specific advice, you should consult a clinical geneticist or genetic counsellor in your local NHS Regional Genetics Centre. To find out where that is, please contact the British Society of Human Genetics (www.bshg.org.uk) on telephone number – 0121 627 2634.

Reply from the Chair of Human Fertilisation and Embryology Authority to HGC letter of 10 March 2006 on the publication of HGC's report *Making Babies: reproductive decisions and genetic technologies*

Baroness Helena Kennedy
Chair
Human Genetics Commission
6th Floor North
Wellington House
133–155 Waterloo Road
London
SE1 8UG

1 June 2006

Dear Helena,

HGC report *Making Babies: reproductive decisions and genetic technologies*

I am grateful to be given the opportunity to comment on this report. I would also like to take this opportunity to thank you for inviting the HFEA to be involved and contribute to the review process.

I would like to comment on some of the points that you brought to our attention.

- *We recommend that women and couples contemplating PGD continue to be offered counselling to ensure they fully understand the implications of decisions they may be required to make at various stages of their treatment (page 46).*
  Under the requirements of HFE Act 1990 patients must be given a suitable opportunity to receive proper counselling before treatment and giving consent. Evidence suggests that patients benefit from counselling we therefore make the offer of counselling a condition of treatment licences and subject to regulatory inspection.

- *For the safety of mother and child, the HFEA has guidelines limiting the number of embryos that may be transferred in an IVF cycle to be implanted to two, except in certain conditions. The HGC would welcome developments in practice that would further reduce the number of multiple births (page 48).*
  The HFEA has launched a project to address the problem of multiple births following IVF in the UK and is working with clinics and professional bodies to identify ways of reducing the incidence of multiple births and associated complications. The number of embryos transferred in a treatment cycle is a key factor in this project.

- *We recommend that, in addition to systematic paediatric follow-up for all PGD children, there should be research into the well-being of children who are born after HLA matching (page 51).*
  In the Guidance issued by the HFEA relating to preimplantation tissue typing, centres offering preimplantation tissue typing are expected to demonstrate that they have arrangements in place for contacting patients to invite them and their families to take part in long-term follow-up studies, including long-term medical and psychosocial follow-up of children born after HLA matching.

- *We suggest that in situations where PGD is being used, and where there are both carrier and unaffected embryos of equal quality, parents should be able to request which they prefer to be implanted (page 52).*
  There is no guidance on the issue of replacing carrier over unaffected embryos. This is a matter that the HFEA currently leaves to be discussed by clinicians and the patients involved in each case. We will give consideration to your suggestion when the HFEA next has the opportunity to review the guidance on PGD.

- *We recommend that arrangements are strengthened to ensure that all those considering using donor gametes receive information about the importance of making children aware of their genetic origins and that counselling is available to support parents to do this (page 59).*
  The HFEA has stated that on balance it believes that it is in the interests of donor-conceived offspring to have access to information about their origins and donor (see response to the DH consultation on Donor Information on our website). We have produced guidance for those providing treatment with donated gametes which seeks to ensure that they are appropriately prepared for donor parenthood and aware of the importance of sharing information with their child/children about their origins from an early age. Our information for patients reflects a similar outlook (see, for example, the HFEA *Guide to Infertility* and information leaflets). However, the HFEA considers that any measures which would force people to tell their children carry the risk of being counter-productive and may, for example, encourage parents not to report birth outcomes to clinics so that they may be recorded on the HFEA Register.

- *We believe that all children born by donor-assisted reproduction should have the opportunity to find out their genetic origins and that it should be open to any couple from the age of 16, provided that they both consent, to enquire of the HFEA whether or not they appear to be related as a result of gamete or embryo donation (page 59).*
  Whilst the HFEA believes that access to origins information is important for donor-conceived people, the evidence is that that information would better come from the donor-conceived child's parents and that making it available from a third source risks interfering with parenting decisions and family relationships. We therefore support the current position that donor-conceived people should only have a right to access information about donors from the HFEA at 18, although the HFEA would ordinarily exercise its discretion to disclose non-identifying information about a donor to a parent of a donor-conceived child to assist them in their parenting decisions. The HFEA also interprets the provision for disclosure of information to those wishing to marry broadly, so that, with the consent of both parties involved, it will respond appropriately to those who wish to know if they are closely related to each other as a consequence of donor-assisted conception.

- *We endorse the conclusion of the HFEA SEED review that there should be no prescriptive guidance on the selection of donors for any particular recipient, but we suggest that the HFEA produce guidance on factors that may need to be taken into account when a donor is selected (page 60).*
  We intend to produce guidance on factors that may need to be taken into account as part of our ongoing review of existing guidance.

- *We support the Department of Health in its investigation of possible avenues for regulating commercial operations involving sperm donation which are currently outside the HFE Act (page 64).*
  We also support the Government's proposal to regulate the operation of suppliers operating via the internet or other media involved in the procurement of gametes.

- *We recommend that the HFEA should explore ways in which clinics in the UK can be prevented from preparing or otherwise colluding with individuals intent on seeking treatments which are permissible abroad, but prohibited within the UK.*

The HFEA continues to explore the ways to ensure that the interests of patients and the health and welfare of children born as a result of assisted conception are protected where the means to do so fall within our remit. We have recently produced updated information for those considering looking abroad for treatment which identifies many of the potential difficulties which should be taken into account.

I hope you find these comments useful. Please feel free to get in touch if you require any further information.

Yours sincerely

Dame Suzi Leather
Chair

Letter to Science Minister Lord Sainsbury of Turville on genetic testing and employment

The Lord Sainsbury of Turville
Parliamentary Under-Secretary of State for Science and Innovation
Department of Trade and Industry
1 Victoria Street
London
SW1H 0ET

5 June 2006

Dear David,

Genetic Testing and Employment

I am writing in response to your request last year asking the Human Genetics Commission (HGC) to carry out a review of the prevalence of genetic testing in the workplace. This has been an interesting topic that has sparked debate in many of those organisations that we contacted.

After careful thought, the Commission decided that the best way to complete this task would be to write to a range of relevant employment and genetic organisations to ask them whether they were aware that genetic testing was occurring in the workplace. The Commission wrote to 21 organisations and received 18 replies. We noted that although many of the employers' federations were not aware that genetic testing was occurring in the workplace, they did not have up to date information on this matter. It was disappointing that the CBI consciously chose not to respond to our request, and that some other responses were vague.

The information that we received does little to change the Commission's earlier conclusion that employer-driven genetic testing is not occurring in the workplace. We concluded this in our 2002 report *Inside Information* and asked employers considering offering testing to submit information to us. The Genetics White Paper asked us to monitor the situation. If genetic testing in this way was widespread, it is likely that this would have already been brought to our attention. The Information Commissioner's statutory Employment Code now sets out that employers should inform the Human Genetics Commission of any proposals to use genetic testing for employment purposes. Having established that genetic testing is not generally occurring in the workplace, if this mechanism is effective, the Commission should be alerted if it is planned to be used in the future.

However we did receive one response, from the British Society of Human Genetics, that gave us some cause for concern. It provided anecdotal evidence of a case where employers used sensitive health information, for example the results of genetic tests that potential employees have already taken, in a way that is inconsistent with the Information Commissioner's Code. This anecdote is reminiscent of comments that the HGC has received in the past, where employers used pre-existing genetic information that is provided on a pre-employment health questionnaire in a way that does not seem relevant to making a decision whether a person will be suitable for employment. For example, we are aware of a case where a police force would not admit a successful recruit because he carried the Huntingdon's Disease gene, even though the family history and clinical opinion suggested that he would not develop the condition until well after retirement age. This person later found employment with a different police force, who had a fairer and more enlightened policy on this issue.

With this point in mind, it gave me some reassurance to note in your original letter that "the Government wishes to ensure that once genetic testing has advanced to the stage where the use of test results by employers has become a realistic proposition, there are appropriate safeguards to prevent such information being used unfairly". The Commission believes that the Government now needs to consider how such safeguards can be implemented to protect those who have already taken tests, prior to seeking employment. A little information is a dangerous thing and it is important that, even if the use of genetic information is permitted in certain areas, employers understand what it means, or refer the issue to a suitably qualified occupational health physician or a clinical geneticist.

Your letter also made reference to the Commission for Equality and Human Rights (CEHR). I agree that it will have an important role to play in this area and I look forward to the HGC inputting into their formative stages. It is reassuring to know that even though issues relating to human genetics and equality may not be explicitly covered by statute, that the CEHR will be able to act in this important area.

The Commission continues to believe that genetic discrimination in employment and genetic discrimination more broadly are important issues and the issue will be an important area of work for us over the coming year. We intend to continue to feed into Trevor Phillips' Equalities Review and will also respond to the Government's Discrimination Law Review green paper in the Summer. We plan to build on this recent request for information and produce an easy to understand information leaflet on genetics and employment, covering all the relevant issues, from both an employee and employer perspective. In light of our findings, one of the key issues for the Commission to cover in this document is how companies can conform to the Information Commissioner's requirements for genetic testing and sensitive information.

Following the information that we have uncovered, we feel that this is an issue that should be returned to on a more frequent basis and the Commission will be taking this forward in its next stage of work. Even after the trawl for information that we completed, the Commission still feels that its evidence base in this area is poor and wants to work at this.

Please do not hesitate to contact me if there is any further work you would like the Commission to do in this area.

Yours sincerely,

Baroness Helena Kennedy
Chair, Human Genetics Commission

HGC letter to BBC complaints department regarding dramatic depiction of non-consensual DNA testing

BBC Complaints
PO Box 1922
Glasgow
G2 3WT

8th June 2006

Dear Sir/Madam,

New Tricks episode: 5th June 2006

I am writing to you as Chair of the Human Genetics Commission (HGC), the Government's advisory body on human genetics.

I was very concerned to hear about the episode of New Tricks that was transmitted on 5th June 2006. In this episode the police character Gerry was contacted by a character called Emily, who claimed to be his daughter. To corroborate this claim, Gerry took a sample of Emily's DNA from a wine glass she used and had it analysed against his DNA, without seeking her consent.

Unfortunately the programme did not make clear that analysing DNA in this way, without consent is wrong. It also didn't make clear from September 2006, it will be a criminal offence to have human material with the intention of conducting a DNA analysis without consent. The HGC recommended this new legislation on non-consensual DNA testing in its report *Inside Information*, published in May 2002, because of the evident concerns that people could obtain human material and test it via companies who do not have adequate safeguards to protect privacy in place. The Government accepted this recommendation and included provision for this in the Human Tissue Act 2004. The Act will be fully implemented in September 2006 and the offence will be punishable by a 2 year jail penalty.

Although the programme often gives a tongue-in-cheek slant on crime solving with the detectives using unconventional methods, portraying a DNA analysis in this way was irresponsible. When this episode of New Tricks is repeated in the UK after September 2006, will it make it clear that the non-consensual analysis of DNA is illegal and will be punishable by up to 2 years in prison? The BBC is a trusted source of information for many viewers and as such it is important for you to provide the full picture in your stories; it is not acceptable to suggest that such analysis should be permitted.

I enclose a copy of *Inside Information* and look forward to receiving a response to this issue.

Yours faithfully,

Baroness Helena Kennedy QC
Chair, Human Genetics Commission

Reply from Science Minister Lord Sainsbury of Turville to HGC letter of 5 June 2006 on genetic testing and employment

Baroness Helena Kennedy
Chair of the Human Genetics Commission
6th Floor North
Wellington House
133–155 Waterloo Road
London SE1 8UG

14 June 2006

Dear Helena,

Genetic Testing and Employment

Thank you for your letter of 5 June, reporting on the outcome of the short review by the Human Genetics Commission that I requested last September on the prevalence of genetic testing in the workplace.

I note that as a result of this review, the Commission's earlier conclusion, that employer-driven genetic testing is not occurring in the workplace, remains essentially unchanged. And I also note the mechanism that we now have, through the Information Commissioner's statutory Employment Code, which should alert you to any plans by employers that would change the current position.

In the broader context, as you mention in your letter, the Government is taking forward the Discrimination Law Review and establishment of the Commission for Equality and Human Rights and an independent Equalities Review has been established to investigate the underlying causes of inequality in British society. I am grateful for the input you have already made or plan to make shortly to these activities. We have made a commitment to consider the issue of legislating against the use of genetic tests in employment and insurance as part of the Discrimination Law Review.

Unfair genetic discrimination in employment and more generally is an important issue, even though there is little evidence for this in the UK at present. I therefore welcome your plans to continue to closely monitor this in future and to provide easy to understand information to employers and others.

I am most grateful for the work of the Commission on this review.

Best wishes,

Lord Sainsbury

HGC letter to Department of Health officials regarding the revision of the UK Health Departments' Code of Practice and Guidance on Genetic Paternity Services

Dr Mark Bale
Head of Genetics
Department of Health
Rm 611, Wellington House
133–155 Waterloo Road
London
SE1 8UG

16th June 2006

Dear Mark,

Revision of the UK Health Departments' *Code of Practice and Guidance on Genetic Paternity Services* (March 2001)

Thank you for seeking early input from the Commission on the revised Code of Practice on Paternity by sharing the first draft with us. As you know, the whole Commission discussed the draft at length at our plenary meeting last month, which was held in Belfast.

You had asked us to focus our discussion around some key questions relating to the content. Unfortunately, as is sometimes the case, our discussion took a looser form, and not all of the questions were addressed directly. However, I hope you will agree that Members raised a number of useful points, which will need further consideration when you come to revisit the draft.

The first message that I think came across from our discussion actually arose from misunderstandings about what the Code was for and to whom it was addressed. For example, Professor Christopher Higgins and Dr Frances Flinter raised the issue of circumstances when information about paternity was uncovered inadvertently, for example, when a routine genetic test on a patient was undertaken. The Code makes no mention of circumstances such as these, presumably because its primary audience is private paternity testing providers and those who commission their services. However, it is telling that there was a degree of confusion amongst Members who were medical practitioners, which led to a concern that NHS medical practitioners who may in the course of their work inadvertently uncover information about paternity, might fall foul of the Code. In order to avoid confusion in the field, it would be helpful if the Code was absolutely clear that it is only addressed to NHS practitioners insofar as they might commission, or aid in administering, a private 'over the counter' or internet paternity test.

The second point made by the Commission relates directly to page 12 of the draft, which contains the following statement:

"In the case of children, it is generally accepted that it is probably best for a child to grow up knowing who their biological father is. In other words, that it is in the best interests of the child that paternity is established as early in the child's life as possible. However, this may not always be the case and any assessment about the child's welfare must be based on the individual needs of the child in question."

Several Members disputed the validity of this statement and said that it was not, to their knowledge, supported by empirical evidence. Professor John Harris commented that to assert that it was generally accepted that it was in the best interests of the child to know who their biological father was, was to place a moral obligation on a mother to test a child if she did not know for sure who the father was. The Group agreed that it was important that the Code did not suggest that it was a moral or cultural imperative that people had a right to know their biological history. We would therefore ask that you revisit the statement and, if necessary, remove it from the text.

On the issue of additional safeguards for 'peace of mind' tests, one of our Members, Mr Alastair Kent, asked if, as a paternity test usually arose in the context of a failing relationship and the information learned by a test was both significant and irreversible, the Code should recommend a 7-day cooling off period whereby a person could change their mind as to whether to go ahead with a test. This suggestion had some support from the Commission and, although we recognised that such a system was open to fakery as individuals could be dishonest when declaring dates on the test forms, it would at least encourage reflection from those thinking about undertaking a paternity test.

You had asked the Commission whether we agreed with the Code's position on peace of mind tests, namely that while the Department prefers the use of independent samplers in the paternity testing process, it recognises that they would not always be used in this setting and therefore recommends some additional safeguards, which could be introduced to protect people when carrying out peace of mind tests. There was a general discussion on this two-tier approach with one set of requirements for peace of mind testing and another much more stringent set of requirements for court admissible testing. However, there were no strong views expressed as to whether this approach was sensible and I think we would be keen to see how this idea would be developed in a later draft. One aspect of this approach that was applauded was the way that the Code explicitly warned people that some tests might not be admissible as evidence in the Courts as evidence should a paternity dispute end up there and that they should therefore choose their test carefully.

Some other suggestions from Members were that the Code should include a requirement on private testing companies that consumers would receive universal, standardised information when they purchased a test. As a voluntary guide, the Code itself could not ensure compliance with this but it might be possible to get the support of the Advertising Standards Agency on this issue or any other 'health warning' that could be suggested for packaging.

On the issue of access, one Member noted that, whilst the Code recommended that companies make customer information available in alternative formats, it said nothing about easy-read versions for people with learning difficulties. Alternative formats not relating to visual impairment are now available, which were not when the original Code was published in 2001 and it was important that the revised Code be updated to reflect that. Further, the annex of advice and help should reflect the range of advice available, especially for people in different ethnic communities. Finally, there should be clarification on what was meant by "*written consent*" (when some people were not able to write) and what was meant by "*those not competent*".

Several Members thought it would be helpful if the Code made some mention of DNA analysis after death for the purpose of establishing paternity. I am aware that the Human Tissue Authority (HTA) have recently set out guidance on this issue for consultation and the Code of Practice on Paternity could include a reference to the final HTA guidelines.

Finally, we agreed on a general drafting point, which was that the language used in the Code needed to be uniform and consistent. The Code begins with firm, authoritative language reflecting the fact that new and relevant legislation will soon be in force. However, later the language becomes rather nebulous, using terms like 'suggest' and 'recommend'. Again, we recognise that the Code is voluntary but we feel that the language must be clear and consistent so that providers know the absolute requirements they must operate under, if they are to abide by the Code.

I do hope this feedback is helpful. I look forward to reading the consultation draft in due course.

Yours sincerely

Dr Christine Patch
Human Genetics Commission

HGC response to the Equalities Review: Interim Report for Consultation

Trevor Phillips
Equalities Review
Room 3.32
22/26 Whitehall
London
SW1A 2WH

I am writing to you in my capacity as the Chair of the Human Genetics Commission (HGC), the Government's advisory body on human genetics. I would like to take this opportunity to thank you for the time you gave me to speak about genetic issues at the information gathering stage of the Equalities Review.

The *Equalities Review: Interim Report for Consultation* is an extremely interesting document. It contains thought provoking ideas and pulls together many fascinating statistics. As you are aware from our previous discussion, the HGC has a specific interest in the prevention of unfair discrimination arising from the misuse of personal genetic data. This limits the response that the HGC can provide to the interim report to Chapter 6 of the document.

The HGC was reassured that the report identified, in both the introduction and the main text, the potential for genetic discrimination and inequity to become a problem in the future. This is an area that the Commission has recognised needs careful monitoring and is covered in the HGC's report *Inside Information* (2002). There is a continuing concern that over time, Britain could see the emergence of a "genetic underclass" of people who are unable to get life insurance, or who may be rejected by employers after taking genetic tests for medical conditions.

Inside Information highlighted the possibility that as testing becomes cheaper and easier it may find its way into the workplace. Employers' use of personal genetic information in the future may affect the cost of their liability insurance and therefore lead to unfair genetic discrimination in employment. The direct use of genetic test results in an employment setting could be used to ban someone from a job or from career development. In September 2005, Lord Sainsbury asked the HGC to monitor the prevalence of genetic testing in the workplace. Although our initial research has not exposed testing of this kind, we are concerned about potential future developments. We were particularly concerned to find out that some employees have been required to reveal the results of genetic tests that have already been carried out, as part of the pre-employment questionnaire. Such issues have been debated in Parliament several times recently and the HGC will continue to monitor this area closely.

The HGC will also continue to monitor the situation with regards to genetic testing and insurance. Last year the Association of British Insurers extended its moratorium on the use of adverse test results until November 2011, with a review in 2008. The agreement means that nobody is required to disclose the result of a predictive genetic test, unless the Government's Genetics and Insurance Committee first approve it, and that no disclosure at all is required for insured sums below a certain threshold. The future after the review remains uncertain, with the result that many people are wary of taking genetic tests now in case they may have adverse consequences later.

The definition of what constitutes a 'genetic test' tends to be defined quite narrowly and only captures tests that analyse DNA, and this gives the Commission further cause for concern. For example, a cholesterol test may reveal something about the genetic make-up of an individual, but this bio-chemical test would not be defined as a 'genetic test'. The Commission is concerned that as

science advances, it would be possible to offer cheap bio-chemical tests that measure, for example, the protein produced, thus bypassing the need for a genetic test. These tests could offer the same end result/diagnosis but the bio-chemical test would have less associated safeguards; for example, it would not be covered by the insurance moratorium.

Another issue that you raise in the interim report is the National DNA Database. The use of this database is something that the Commission has commented on many times. Two HGC Commissioners now sit on the National DNA Database Strategy Board. The practice of genetic testing and storage of results is not in itself discriminatory. Discrimination arises from policies that lead to one group being tested more than another for reasons unrelated to genetics, and from discriminatory policies or inadequate safeguards in the use of the stored results. This can apply to arrest policies and to the testing of only certain individuals in the workplace, for example. HGC believe that the non-representative content of the National DNA Database is to do with such policies. I will forward your report onto the National DNA Database Strategy Board as they might want to comment further on this issue. The Commission is concerned about cases where incomplete samples found at a crime scene may lead to an incorrect 'match' for a sample already on the database, especially when the database sample belongs to a person who has not been charged or convicted of a crime. This situation disproportionally discriminates against people on the database and is a cause for concern.

The statistics provided in your report support the need to generate programmes and actions that will tackle the 11 areas identified as a priority. It would not be appropriate at this stage for genetic discrimination to be given this level of prominence, given that there is little evidence that it is occurring at present. However, it is important to avoid losing sight of potential areas of future inequity and we should seek to eradicate them before they become embedded in society. We should not only be reactive on this issue. You are therefore correct in the interim report that the issue of genetic inequity should be kept on the agenda.

The HGC does not want a situation to emerge where people are afraid to take a genetic test for clinical or research reasons because of how these results might be used in the future. People must not be inhibited from taking tests that will forewarn them of impending health problems, or enable them to implement preventative strategies. A cultural change towards a society that is less tolerant of all forms of discrimination and inequity will help to prevent a shift towards genetic discrimination in the future. The Commission will be responding to the planned consultation on the discrimination law review in the Summer and at this stage the Government will need to decide how forward looking it makes any legislation.

I would be happy to discuss any of these issues in more detail with you if required. I am also happy for you to reproduce this response and use quotes from it in your final report. To comply with the HGC's open working style, a copy of this response will be placed on the HGC's website.

Yours sincerely,

Baroness Helena Kennedy
Chair, Human Genetics Commission

Reply from Health Minister Andy Burnham MP to HGC letter of 31 March 2006 seeking support to follow up recommendations in *Genes Direct* on regulation of genetic tests supplied directly to the public

Baroness Helena Kennedy QC
Human Genetics Commission
605 Wellington House
133–135 Waterloo Road
London
SE1 8UG

10th July 2006

Dear Helena,

Human Genetics Commission: Oversight of genetic tests supplied directly to the public

Thank you for your letter to Jane Kennedy of 31 March 2006 about the Human Genetics Commission's report *Genes Direct* and the oversight of genetic tests that are supplied directly to the public. I am replying as the new health minister with responsibility for genetic issues. This letter contains a joint view from the Department of Health and Lord Sainsbury, the Science Minister.

At the time of *Genes Direct*'s publication, the Government welcomed the advice that the HGC gave in the report and recognised the need to find a balance between the right of individuals to have information about their own health and the need to protect vulnerable groups, particularly children. I would like to take this opportunity to set out some developments that have been taken forward since the publication of the report. *Genes Direct* recognised the need for a well-funded NHS genetics service and the genetics White Paper, published in May 2003, set out an additional investment of £50 million in genetics in England. I am also aware that the devolved administrations have been making similar investments in this area. This extra investment in funding and training has gone a long way towards meeting the HGC's main recommendation that the main route that people want to access predictive genetic testing is via their own GP or primary healthcare team and possibly referral to NHS specialists. This is the route where they can get the counselling that they need and appropriate consent can be obtained for proven and high quality genetic tests.

The Human Tissue Act, which comes into force later this year, helps place a responsibility on companies that provide private DNA testing to ensure that appropriate measures are in place to ensure that DNA testing is done with full and lawful consent. This will address another of your recommendations against the provision of services which may encourage non-consensual testing.

The Government agrees with the Commission that consumer education plays an important role in minimising the potential harms that may follow from direct genetic tests. We are committed to providing ready access to good quality information about genetic testing, for consumers, for patients and for health professionals and the White Paper provided investment aimed at developing information on all aspects of genetic testing and advances in genetic knowledge.

The Government remains grateful to the HGC for its helpful and constructive comments on possible regulatory mechanisms for this area. I am particularly grateful for your pragmatic suggestion of how to take this work forward now that it is clear that the MHRA is not able – under UK and EU law – to operate in the areas that you advocated. I warmly support your proposal that HGC should host a pan-European meeting on the regulation of direct-to-the-public genetic tests. HGC should fund this event out of its existing budget. Such an event could provide useful opportunities to consider work being undertaken by international partners, for example including the Council of Europe's Steering Committee on Bioethics.

While the commercial market for genetic testing in this area is still in its relative infancy this seems like an opportune moment to have this discussion about appropriate standards and controls. This forum will provide a valuable focus for the development of an effective policy on direct genetic testing services. Many of the issues that you raised in *Genes Direct* in 2003 are still current and the report continues to provide a useful framework for further discussion in this area.

I am copying this response to Health Ministers in Scotland, Wales and Northern Ireland.

I would like to take this opportunity to say that I look forward to working with you and the Human Genetics Commission as the new minister at the Department of Health.

Yours sincerely,

Andy Burnham

HGC response to the Consultation on the mid-term review of the European Commission Life Sciences and Biotechnology Strategy 2002–2010

1. The Human Genetics Commission (HGC) welcome the opportunity to comment on the assessment of the implementation and the way forward of the 2002 Life Sciences and Biotechnology Strategy Action Plan.
2. The HGC was established in 1999 following a comprehensive review of the regulatory and advisory framework for biotechnology in the UK. The HGC is a non-departmental public advisory body that gives the UK Government advice on the social, ethical and legal issues of human genetics and also seeks to promote debate among the public on these issues.
3. The HGC is chaired by Baroness Helena Kennedy QC and is made up of 24 members including experts in genetics, ethics, law and consumer affairs. The HGC also has a Consultative Panel of 100 people who have direct experience of living with genetic disorders and who act as a sounding board for their reports and recommendations.
4. The HGC has comments to make on part of the strategy relating to genetic testing and genetics and employment. The HGC document *Genes Direct: Ensuring the effective oversight of genetic tests supplied directly to the public* (2003) is referred to in the response. The document can be viewed at: http://www.hgc.gov.uk/Client/document.asp?DocId=34&CAtegoryId=8
The other HGC document mentioned in the response, *Inside Information*, can be viewed at: http://www.hgc.gov.uk/Client/document.asp?DocId=19&CAtegoryId=8
Alternatively please email gwen.nightingale@dh.gsi.gov.uk for a hard copy of these documents.

Annex II

Template to be used for the assessment of actions foreseen under the Life Sciences and Biotechnology (LS&B) Action Plan

Action (No/title)	Action 16 – Establish consensus on ethical guidelines/standards or best practice (including genetic testing).
Responsibility/Interest for this specific action	The Human Genetics Commission produced a report on the effective oversight of genetic tests supplied directly to the public in 2003 and continues to monitor this field.

Assessment of the level of achievement (fully; partly, not at all) for different actors	In *Our Inheritance, Our Future* (2003), the White Paper on genetics, the UK Government supported the view that *"...individuals who want to take a more direct responsibility for their own health should not face arbitrary barriers which restrict their access to services unnecessarily. It is arguable that genetic tests are not intrinsically different from other health tests that are available over the counter such as cholesterol, diabetes and pregnancy testing kits".* This was also the view of the UK Human Genetics Commission. In our report on direct to consumer testing, *Genes Direct* (2003), we concluded that there should not be a statutory ban on direct genetic tests. However we did highlight some controls that we would like to see enforced, for example we felt that most genetic tests that provide predictive health information should not be offered over the counter, but where they are they should be regulated. This regulation is not currently occurring in the UK and we are currently revisiting this issue. The HGC are aware of work within the Council of Europe to develop a protocol on Genetics and this attempts to address some issues in this field. This protocol needs to be sympathetic to the different way that healthcare is provided in member states and the different regulatory processes in place.
Re-evaluation of strategic importance (in case of partial or non-achievement)	The Human Genetics Commission feel that this is still a strategically important issue, which is why we are currently revisiting this issue.
Need to revise policies/actions	The Human Genetics Commission are currently revisiting this area as we feel that this is an area where some consumers remain unprotected. A solution to this issue may be achieved on a Pan-European level.
New and emerging challenges	

Action (No/title)	**Priorities for future actions** **Commission and Member States** • to enhance an EU-wide exchange of information on best practice and cooperation on the development and use of **genetic testing** through the open method of coordination. In particular, an evaluation of the clinical validity/utility of genetic tests and the establishment of a referral system at EU level for genetic testing of rare and complex diseases will be addressed in 2005–2006 • to take whatever action appropriate or required, as arising from the coordination. **The Commission will** • launch an initiative on the protection of workers' personal data in the employment context, taking account of the European Group on Ethics in Science and New Technologies Opinion No 18 "Ethical Aspects of Genetic Testing in the Workplace". The initiative will also address the processing of genetic data.
Responsibility/Interest for this specific action	The use of genetic information in an employment setting continues to be an issue that the Human Genetics Commission monitors.
Assessment of the level of achievement (fully; partly, not at all) for different actors	We published a report that covered this issue in 2002 (*Inside Information: Balancing interests in the use of personal genetic data*). Since the publication of this document, the UK Information Commissioner has issued further guidance on the use of genetic data in his Employment Code of Practice (can be viewed at http://www.ico.gov.uk/tools_and_resources/document_library/data_protection.aspx). This was a significant step forward, however we still feel that many people are unaware of their rights and that people remain unprotected in a pre-employment screen and we are currently considering how this could be addressed.
Re-evaluation of strategic importance (in case of partial or non-achievement)	As we become more aware of the particular significance of genetic information, the use of genetic data in employment will become more significant.
Need to revise policies/actions	The Human Genetics Commission supports the proposal to launch an initiative on the protection of workers' personal data in the employment context and would seek to be involved in this work.
New and emerging challenges	

HGC letter to Health Minister Andy Burnham MP about the review of the Government's genetics White Paper

Andy Burnham MP
Minister of State for Health
Richmond House
79 Whitehall
London
SW1A 2NS

I am writing to you as Chair of the Human Genetics Commission, the UK Government's advisory body on human genetics.

At the Commission's recent meeting in September in Swansea, the Commission had an interesting discussion on the review of the genetics White Paper and we are now in the process of compiling our formal response to the Department. However, as part of this discussion, several overarching issues were raised and the Commission would like to know the Government's views on these.

The first issue relates to patents and intellectual property. The Commission is currently about to carry out a small exercise looking at the current situation with regards to intellectual property rights and genetic developments. As part of this work it would be helpful to understand the central direction that Government is setting on this issue. At one point there was a drive for the NHS to maximise the potential of patenting and Trusts were encouraged to patent wherever possible to exploit inventiveness and possibly generate revenue. Is this still Departmental policy?

The second issue relates to the transfer of innovations from the laboratory into practice in the health service. The Commission recognises the importance of ensuring that novel developments in labs are transferred to the environments where they will be the most use. Are there any mechanisms that exist to rapidly transfer scientific developments that are discovered in the laboratory into the clinical front line? What routes are there for informing clinicians and medical practitioners of novel developments that may benefit patients? Are there any routes available to promote and advertise these novel developments such as meetings or networks? When we discussed this issue at our recent meeting the Commission concluded that this was an area that was not well developed and needed further work and I would welcome your views on this.

I would be happy to discuss these issues further if this would be of assistance and look forward to hearing your response.

A copy of this letter will be sent to Lord Sainsbury and the Health Ministers in the Devolved Administrations.

Baroness Helena Kennedy QC

HGC letter to heads of genetics services

To Heads of Service: Regional Genetics Centres and Services

27 October 2006

Dear Sir/Madam,

I am writing to you as Chair of the Human Genetics Commission (HGC), the UK Government's advisory body on human genetics.

The HGC is concerned about the potential impact that the current financial difficulties in the NHS may be having on the provision of genetic services. To get a better idea of the situation across the UK, I am writing to all heads of service to find out their local position.

I would be very grateful if you would be able to answer the following questions. The information that you provide does not need to be exact and can be brief. The intention is not for this to be a time-consuming task.

1. Which Region of the UK do you serve?
2. Are you having to make financial savings this year? If so, how much?
3. What do you anticipate will be the situation next year?
4. Are there 'demand management' processes operating in your area? E.g. restrictions on GP referrals etc – if so, please specify
5. Are there restrictions on the number of genetics tests you can request? If so, what are the limitations?
6. Have any of your genetics services been restricted? If so, please specify
7. Are you contemplating further cuts in the future e.g. a reduction in staff numbers?
8. Any other comments: we are particularly keen to find out the extent to which any financial restrictions within the NHS may be impacting on the provision of genetic services.

The HGC is due to meet at the beginning of December and will discuss this issue then. To enable the information to be compiled in advance of this meeting, I would be grateful if you could return the answer to these questions to me by **14 November 2006**.

Gwen Nightingale
Secretary to the Human Genetics Commission
604 Wellington House
133–155 Waterloo Road
London
SE1 8UG

gwen.nightingale@dh.gsi.gov.uk

As the HGC meets in public and the issue will be discussed in this forum, please indicate if you wish any information that you send to be anonymised.

Please contact me if you would like any further information.

Yours sincerely,

Baroness Helena Kennedy QC
Chair, Human Genetics Commission

HGC letter to National Screening Committee about information obtained from screening tests

J A Muir Gray, Kt, CBE, DSc, MD, FRCPSGlas, FCLIP
Programmes Director National Screening Committee
University of Oxford
Old Road Campus
Headington
Oxford
OX3 7LF

30 October 2006

Dear Sir Muir,

I am writing in response to your letter dated 19 October in which you asked whether Baroness Kennedy had responded to your initial letter dated 9 May 2006. Please accept my sincere apologies for the delay in you receiving a reply. After receiving your letter, the Commission also received a subsequent letter from Alison Streetly providing more information on haemoglobin screening.

The issue about whether all information obtained through screening should be disclosed has been discussed by the Commission at some length. The Commission stands by its *Making Babies* report in which it strongly supports sharing information about genetic status from screening and this includes the principle that carriers should be notified of their status (if it is known) and the implications of this. However, the Commission recognises that, as with many medical decisions, there may be situations where a medical judgement needs to be made about what genetic information is clinically significant – and should therefore be shared with the patient – and what is not. Such a decision may need to be made about non-sickle haemoglobin variants that are detected that have unknown clinical significance.

In your letter, you specifically mention the recommendation in the *Making Babies* report at paragraph 3.50, where the Commission recommended that efforts be made to develop accurate screening techniques that do not reveal carrier status (where this information is not clinically relevant). Through this recommendation, the Commission would like to see tests developed that reveal the disease phenotype only, as this would enable children to make decisions about whether they should be tested for carrier status when they were able to make this decision for themselves, perhaps before starting a family.

I hope this information clarifies the HGC's position on these issues.

I enclose a copy of the letter that has been sent to Alison Streetly for your information.

Yours sincerely,

Gwen Nightingale
Secretary to the Human Genetics Commission

Human Genetics Commission response to the 'Standard setting and quality regulation in forensic science' consultation document

14th November 2006

I would like to begin by saying that Members of the Human Genetics Commission (HGC) were grateful for the opportunity to comment on the Home Office's consultation on future standards and regulation of the Forensic Science Service. As Chair of the HGC's Identity Testing Monitoring Group, I have been asked to respond to the consultation on behalf of my fellow Commissioners. Before I go on to make specific points relating to your nine questions, I would like to make some general comments.

In our view, for the new Regulatory function to succeed, it is vital that it be given sufficient secretariat support and, in view of the current support arrangements in respect of the National DNA Strategy Board, we are not hopeful that sufficient support will be forthcoming. The current Custodian should have sufficient support to routinely monitor press and political comments on the Database so as to afford timely responses to controversial issues. This requires the facility to continually generate up-to-date data on uses of the Database and the demographics of people profiles held on it. Current resource arrangements do not allow for these functions to operate correctly.

It would be of great concern if the current Custodian role was to be expanded to include the other activities set out in the consultation document (or subsumed within a new Regulator role) without appropriate thought being given to secretariat provision.

I have tried to respond to the nine questions posed in the document as concisely as possible but please feel free to contact me, via the HGC's Secretariat, if you would like clarification on any of my points. Our response is as follows:

1. Is there a need for a forensic science quality Regulator?

Yes, we believe so.

2. Should this Regulator be a named individual?

Yes, in our view, appointing a named individual would serve to promote accountability.

3. Should the Regulator be appointed and with powers delegated by the Home Secretary?

Yes.

4. Should the Regulator be located within the Home Office and guided by a Forensic Science Advisory Council?

We take the view that the Regulator and guiding Council should be located within a Government Department and the Home Office would be the obvious and appropriate choice.

5. Who should be the members of the Forensic Science Advisory Council?

We would invite the Home Office to propose the scope and membership (including possible lay membership) of a new Forensic Science Advisory Council. The HGC would be happy to comment on any subsequent proposal.

6. **Do you agree that the Regulator should be funded initially by the Home Office but that other funding models should be evaluated once the Regulator has been established?**

In principal yes, we would agree with this approach. However, we would warn against the introduction of other funding models if they serve primarily to save money.

7. **Do you agree with the scope and accountability of the regulatory function as described in this document?**

Yes, we think the proposals reasonable.

8. **Do you agree that the Regulator should have oversight of existing and new regulatory arrangements to determine that appropriate standards are being set and enforced?**

We find it difficult to comment on whether the Regulator should have oversight of all regulatory arrangements at this early stage. The HGC has a particular interest in arrangements relating to the running of the National DNA Database as it currently has two of its Commissioners sitting as lay members on the National DNA Database Strategy Board. Existing arrangements dictate that the Database has a Custodian, a Strategy Board (with lay membership) and – we hope – it will shortly have an ethics review body. It is not clear from the consultation document how the new Regulator will interact with existing relationships within the National DNA Database structure. Would the Regulator operate above these bodies or would the post replace one or more of them? We would welcome more information about the proposed role of the Regulator before commenting on this point.

9. **Should the Regulator's role include regulatory oversight of forensic services undertaken by the police service?**

Yes, we think this a sensible approach.

I hope you find these comments helpful. I would be grateful if you could keep me informed of progress in this area.

Yours sincerely

Professor Stephen Bain
Chair, Identity Testing Monitoring Group
Human Genetics Commission

HGC response to the Nuffield Council of Bioethics consultation paper on the ethical aspects of the forensic use of bioinformation

Dr Carole McCartney
Nuffield Council on Bioethics
28 Bedford Square
London
WC1B 3JS

25th January 2007

Dear Dr McCartney

Thank you for sending the Human Genetics Commission Secretariat a copy of the Nuffield Council of Bioethics consultation paper on the ethical aspects of the forensic use of bioinformation. I am writing to you as lead member of the HGC Identity Testing Monitoring Group, the Group which oversees the social, ethical, legal and economic implications of the forensic use of genetic information on behalf of the HGC.

Rather than respond to the individual points set out in your questionnaire, I wanted to write to say that we welcome your involvement in this debate and strongly believe that public engagement on this issue is important and timely. As you will be aware, the HGC has been involved in this area since May 2002 when we published *Inside Information – Balancing interests in the use of personal genetic data*. Following publication of that report, the National DNA Database Board invited the Commission to put forward one HGC member to sit on the Board and this arrangement has continued to this day. Last year, they asked that we increase our input to two members and so, currently, Professor Sarah Cunningham-Burley and I represent the Commission on the Board.

We are often asked to contribute to public debates and policy discussions about various aspects of the database both here and in Scotland, where the law relating to the collection and retention of genetic samples differs from that in England, Wales and Northern Ireland. I am enclosing a copy of the Commission's 2006 Annual Report for your interest as it provides more detailed information about our work in this area over the past year or so.

You will also know of our plans to hold a public dialogue event on the use of genetic information for forensic purposes. It has proved difficult to secure full funding for the event. However, we have now secured £50k of funding from the Office of Science and Innovation (OSI) and a further £5k from the Genomics Forum based in Edinburgh. We have submitted an application to the Wellcome Trust for the remaining costs and we hope to hear if we have been successful in late February. In the meantime, we have set up a Working Group to oversee the event and we have agreed a project specification.

In my view, your Council's public consultation and our smaller, more contained examination of the issues is an excellent example of how the two organisations can work together to maximise public debate and understanding of the forensic use of genetic information. I would be grateful to you if you would send me a copy of the end-report when it is published in the autumn, as I am sure it would be a useful source document for our public dialogue.

Thank you again for giving us the opportunity to respond to the consultation. I will follow its progress closely and look forward to hearing from you later in the year.

Yours sincerely

Professor Stephen Bain
Chair, Identity Testing Monitoring Group
Human Genetics Commission

HGC letter to GeneWatch regarding supply of genetic tests to the public

Dr Helen Wallace
GeneWatch UK
The Mill House
Manchester Road
Tideswell
Buxton
Derbyshire
SK17 8LN

14 March 2007

Dear Dr Wallace,

I am writing to you as Chair of the Genetic Services Monitoring Group of the Human Genetics Commission. Thank you for your letter dated 5th February, in which you bring to the Commission's attention GeneWatch UK's concerns relating to genetic tests offered by the company 'Genetic Health'.

As you are aware, regulation of genetic tests is an issue of great interest to the Human Genetics Commission and in May 2003, we published *Genes Direct: Ensuring the effective oversight of genetic tests supplied directly to the public*. This followed a request from Health and Science Ministers to review the controls on genetic tests that are sold to the public.

In my letter to you of 20 November 2006, I mentioned our intention to hold a small meeting to follow up *Genes Direct* and discuss recent developments in this area. This meeting went ahead on the 29 January and focused on the following three areas in relation to the oversight of genetic tests supplied direct to the consumer.

Pre-Market Review – mainly but not exclusively dealing with analytical validity of genetic tests.

Quality Assurance – looking at the services offered by companies using the aforementioned tests as well as clinical utility and validity.

Advertising and Impartial Advice – looking at what oversight should be given to advertising of genetic services and what impartial advice is available.

The meeting was attended by representatives from key organisations with direct interests in this area, including the MHRA, the FDA, the Council of Europe and OECD. This gave us an excellent view into the issues surrounding the oversight of the tests offered by companies like 'Genetic Health'. At the meeting, the group stood by the recommendations contained in *Genes Direct* and felt there was a need to subject "direct genetic testing services" to appropriate oversight; however, it was clear that they felt that there should not be statutory prohibition of direct-to-the-public genetic tests.

During the meeting, several additional recommendations in the topic areas mentioned above were generated which, it was felt, would improve current regulatory mechanisms. The final report from the meeting has yet to be approved by the HGC and the recommendations should not be made public until they have received this approval. However, the draft recommendations are included below for your information:

Pre Market

- To revisit risk classification for tests, which are covered by IVDD directive but classified as low risk and are therefore exempt from independent pre-market review.
- For those tests that are going to fall outside the IVDD directive consider if an alternative regulatory mechanism should be set up to provide oversight e.g. lifestyle tests.
- To support original recommendation in *Genes Direct* that certain tests are only offered by a suitably qualified health professional.

Quality Assurance

- To develop a code of practice relating to genetic testing services that will consider the guidelines soon to be published by OECD and other relevant international standards e.g. EuroGentest.
- The development of this code of practice and its implementation should involve relevant stakeholders including governmental bodies, public bodies, charities and industry.
- To engage and participate with the Council of Europe on its work in this area.

Advice and Advertising

- Advertisements for tests, which are deemed only available via medical consultation, should be restricted to medical practitioners i.e. no direct to public advertising.
- To engage in discussion with Advertising Standards Authority (ASA) and Office of Fair Trading (OFT) about enhancing the codes of practice for tests that are permitted.
- To look at using existing web-based information sources to provide comprehensive, independent, information for consumers. Encourage test developers/providers to facilitate consumer access to this information.

In your letter, you mention that GeneWatch UK continues to believe that an independent pre-market assessment of the clinical validity and utility of genetic tests is essential. As you can see from the recommendations above, the group, which met on the 29th January, felt strongly that the In Vitro Diagnostic Devices directive (IVDD) should be re-visited to allow for the review of genetic tests, which currently fall outside its risk classification system. The group also felt that for lifestyle tests, which fall outside the IVDD, there should be an alternative regulatory mechanism.

Under the heading Quality Assurance, the panel agreed that a code of practice should be implemented (drawing upon the draft OECD guidelines and using stakeholder engagement), for companies offering genetic testing services. This would involve assessing analytical validity, but also review clinical validity and utility.

I hope that this reassures you that the Human Genetics Commission takes very seriously the issue of genetic tests supplied direct to the consumer and I look forward to supplying you shortly with a copy of the report of our recent meeting, which will be presented to Government when it is complete.

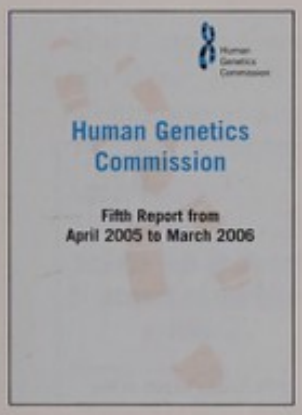
Kindest regards,

Dr Christine Patch
Chair, Genetic Services Monitoring Group

Appendix F: Publications

The following publications are downloadable from the HGC website (www.hgc.gov.uk) and in hard copy from the addresses stated.

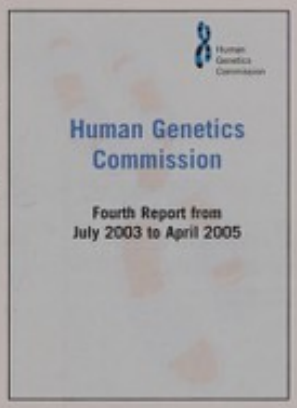
Reports and publications



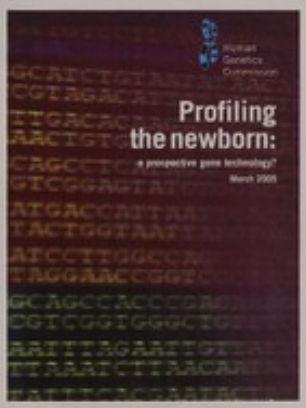
Human Genetics Commission
Fifth Annual Report, 2006
(ref 277332)

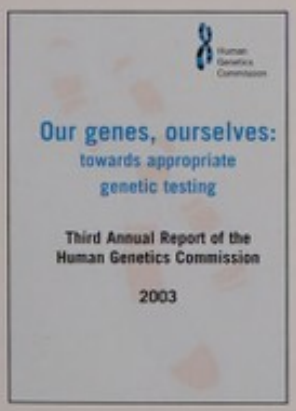
Making Babies: reproductive decisions and genetic technologies
Jan 2006 (ref 272321)*

Human Genetics Commission
Fourth Annual Report of the Human Genetics Commission, 2005
(ref 269491)

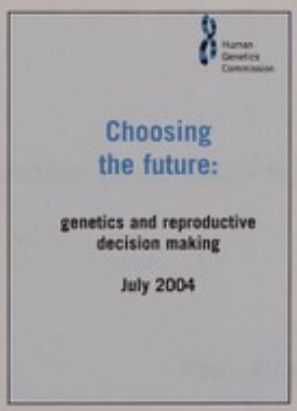


Profiling the newborn: a prospective gene technology?
March 2005
(ref 267377)

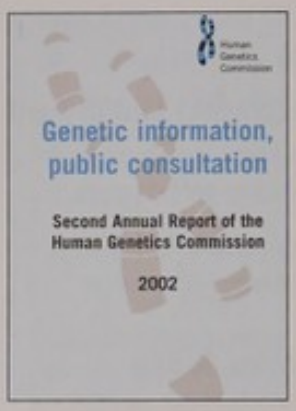




Our genes, ourselves: towards appropriate genetic testing
Third Annual Report of the Human Genetics Commission, 2003 (ref 34587)



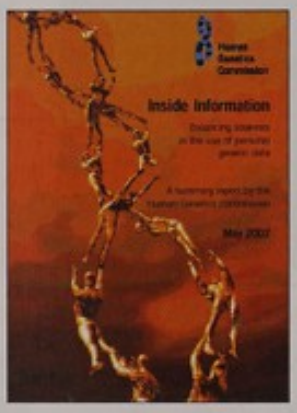
Choosing the future: genetics and reproductive decision making
July 2004 (ref 40293)



Genetic information, public consultation
Second Annual Report of the Human Genetics Commission 2002
(ref 30449)

Genes Direct: Ensuring the effective oversight of genetic tests supplied directly to the public
April 2003 (ref 31433)

Inside Information: Balancing interests in the use of personal genetic data
May 2002
(ref 27907)



Debating the ethical future of human genetics
First Annual Report of the Human Genetics Commission
2001 (ref 25256)

Whose hands on your genes?
November 2000
(ref 228048)

Public attitudes to human genetic information
March 2000 (ref 23992)

*Copies of this report can be obtained by writing to:
PO Box 777
London
SE1 6XH
Or by faxing: 01623 724524
Or by emailing: dh@prolog.uk.com

You can also download the reports from our website: www.hgc.gov.uk

Also available on the website:
HGC press notices
HGC plenary podcasts
HGC meeting papers

Keeping in touch

Tell us what you think

We are always keen to hear what you think and would welcome your comments about any aspect of our work.

The Secretariat for the HGC is provided by the Department of Health and the Office of Science and Technology officials and may be contacted at:

The Human Genetics Commission
6th Floor, North
Wellington House
133–155 Waterloo Road
London
SE1 8UG

If you would like to receive the HGC's news and publications, please register your details with us.

Press enquiries: 07990 550026 or 020 8675 1066

Public enquiries: 020 7972 4351

Fax: 020 7972 4300

Email: hgc@dh.gsi.gov.uk

If you contact the Secretariat by email, we would appreciate it if you could include your contact details. These will not be revealed to any third parties, but may be used to keep you informed of the work of the HGC, unless you state that you do not wish to receive any further information.

Human
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Commission

287420 1p 0.5k May 08 (FM)

This document is also on our website:
www.hgc.gov.uk