Annual report of the Human Genetics Commission : 2002

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Human
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Genetic information, public consultation

Second Annual Report of the Human Genetics Commission

2002

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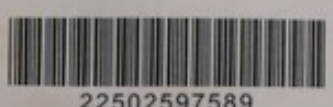
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Chair's introduction

The setting up of the Human Genetics Commission three years ago was a very concrete indication by the Government that it hoped to encourage a debate on human genetics. Establishing a public commission was a courageous move, but I think that it has paid off for all of us. For my part, and I suspect this is true of all members of the Commission, I have learned a great deal from my involvement. But what has been more important is the knowledge that we have been part of a very general debate that has reached out to so many people. Over the past three years the Commission and public have engaged in a fascinating discussion of how we as a society should deal with important aspects of human genetics. During the last twelve months this discussion has been particularly lively – just as it should be – and I take great pleasure in submitting our Annual Report to Ministers. I hope that they will conclude that the faith which they showed in starting this debate has been justified by the outcome. I believe that it has and that there are a number of respects in which our work has made a real difference.

In May we published *Inside Information*, our report on personal genetic information. We had put a lot of time into this report, but I think that devoting that amount of effort was entirely justified. When we were first set up we had identified this topic as being the most immediate issue facing us, and we were determined to ensure that we covered all aspects of it. This led us into fundamental issues of privacy, human dignity, and scientific progress – matters that call for a great deal of very careful thinking.

As I stressed in the preface which I wrote to *Inside Information*, we were very much concerned with achieving a balance between the general interest in scientific progress, and the legitimate interest which people have in preserving their privacy. We made a number of recommendations which we have now forwarded to Ministers and to which we are awaiting a response. These recommendations range from the general to the specific on which we think the Government should consider action. On a number of points we have confined ourselves to observations about good practice and about how those providing genetic services or handling genetic information might improve the security and confidentiality of information.

It was gratifying to see *Inside Information* attracting intense media attention when it was published. I welcome this because I think that it is important that as wide a group of people as possible hear about our findings. By and large people welcomed our report. However, it would have been extraordinary had there not been some adverse comment. Some commented that we had been too ready to endorse the objectives of the research community. I would argue that we have consistently emphasised how important it is that research in human genetics should proceed, and we have done this because we understand what benefits it can bring. But at the same time, we have called for a widening of the controls protecting volunteers to ensure that genetic research is ethical.

Another recommendation that drew a robust response was our suggestion that the Government should consider whether the wrongful obtaining of genetic information about an individual should, in certain circumstances, be a criminal offence. This attracted strong comment from those who thought that such a measure would prevent men from being able to check the paternity of their child. We do not want to stop this sort of test provided that there is proper consent on behalf of the child.

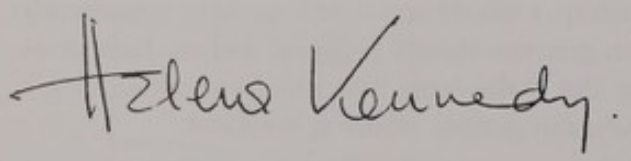
Chair's introduction

Inside Information followed upon a very extensive consultation with a wide range of people – not only those who have a specialist interest in the topic, but with others who contacted us with their views. Our thanks go out to those who took the time and trouble to respond. Openness is an aspect of our work which we take very seriously and which we keep under constant review through our Public Involvement Sub-group. This year we have set out a strategy to involve the public. Central to this is the establishment of our Consultative Panel. This consists of just over one hundred people with experience of genetic conditions, either personally, or as family members or carers of those with a genetic disease. We have been delighted with the level of interest in the Panel and with the valuable comments that Panel members gave us as we finalised our report.

During the course of the year we made a commitment to deal with a number of other issues. We have been aware of the interest people have in the use of genetic information in making choices in reproduction. Advances in prenatal genetic diagnosis mean that it will be increasingly possible to find out more about our children before they are born. Such knowledge should not be used lightly. We decided earlier this year to start to examine this issue in more detail and to discuss it with other public bodies. I have already appeared before the House of Commons Science and Technology Committee to talk about this. We have also been asked by the Government to deal with the provision of genetic tests direct to the public (so-called over-the-counter tests). Such tests have already been offered in this country, and we believe that they raise many issues, including that of the right to obtain information about oneself as well as the duty of the Government to protect vulnerable people.

Alongside these projects, there are various issues which we keep under scrutiny. The whole question of genes and patenting is a matter we are monitoring, and last year we devoted a full session at a plenary meeting to an informative series of talks on patent law as applied to genetics. Such sessions are a valuable part of our meetings, as they provide an opportunity for members of the Commission to discuss issues with invited experts. But it is not just experts to whom we wish to speak. We are keen to continue to hear from everybody who has a view on any of these topics. Our door is always open.

I would like to thank those members of the Commission who stood down this year due to other commitments: Bruce Ponder, Peter Goodfellow, Jackie Axelby and Ruth Deech. I am also grateful to the Secretariat who have put so much effort into our heavy programme of work and who have done this so efficiently and helpfully. Finally, my thanks are due to the Commissioners, who have given their time so generously to ensure that all the issues which we tackle are examined with the degree of attention they unquestionably deserve.



Helena Kennedy
Chair, Human Genetics Commission

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Our meetings this year

Our main meetings are held in public around the country and we are pleased that people have been interested enough to come and see us in action. We have settled into a pattern of meeting over two days – usually holding an information-gathering session, when we invite a number of people to talk to us about a particular issue, on the first day and the plenary meeting on the second. The papers and minutes of our meetings and reports of the information-gathering sessions are published on our website (hgc.gov.uk/business_meetings.htm). Details of the sessions are included at Annex D.

'At the very beginning of our existence we made the decision to conduct our business in public.' Helena Kennedy

June 2001 – Cambridge

We met in Cambridge on 25 June, where our discussions focused on the outcome of the consultation on the use of personal genetic information (PGI) and we identified the key areas that would shape our report. We also discussed setting up the Consultative Panel (see page 6) and our first annual report. We were invited to visit the Wellcome Trust Genome Campus at Hinxton and to tour the Sanger Institute the following day and would like to thank all those involved for an interesting day.

While there we held an information-gathering session on genetic testing and screening techniques and were joined by experts and interested parties. We heard about 'FISH and Chips' – Fluorescent In Situ Hybridisation and DNA chips – and our discussions flagged up important areas for further consideration. This is a quickly developing field bringing with it new ethical and social concerns which we felt needs further public scrutiny. Our thanks are due to Martin Richards for arranging our time in Cambridge. Also in June, Bruce Ponder resigned to work on a new cancer genetics centre and we were delighted to welcome John Sulston to the Commission.

September 2001 – Edinburgh

In September we went to Edinburgh, meeting on the 24th at the Scottish Executive Conference Centre and would like to thank Ros Skinner and her colleagues at the Scottish Executive Health Department for hosting our meeting. We continued discussions on PGI and, in particular, the overarching ethical principles that should govern the use of such information. We discussed the recommendations from the HFEA/HGC Joint Working Party, set up to consider the use of preimplantation genetic diagnosis (PGD). The earlier consultation on this showed public support for the use of PGD to help couples with serious genetic disorders in their families have healthy children. But at the same time the responses showed that the wider implications of the technique are of concern to many people.

Our work plan is submitted to Ministers each year and we discussed priorities for updating it at the meeting. We felt that looking at the wider social and ethical issues around developments in genetics and reproductive choice should be a priority and identified stem cell research and pharmacogenetics as important for discussion in the near future. Over dinner we heard from Professor David Porteous about plans in Scotland to set up a large research cohort. September also saw the publication of our first annual report *Debating the ethical future of human genetics*.

Our meetings this year

February 2002 – London

We met in London on 13 February, where we finalised our report on PGI *Inside Information* (see page 3), agreeing that separate legislation would be the best way of preventing genetic discrimination and that the deceitful obtaining or analysis of genetic information should be made a criminal offence. We also agreed our Public Involvement Strategy (see page 5 and Annex B) which emphasises our commitment to openness and public consultation – it is important that people know what we are doing and why. And we agreed our updated work plan (see page 9 and Annex F) identifying areas to focus on in the future. An increasingly diverse range of genetic tests are being offered directly to the public so we decided to look at what tests might be offered, what issues are raised and the need for regulation. The wider aspects of developments in genetics in relation to reproductive issues was also confirmed as an important piece of work and one requiring future consultation.

'Has been an interesting and informative session for me, being a first time attender. Hope to be invited to future meetings.' Plenary attendee

At the information-gathering session prior to the plenary meeting we discussed gene patenting. We learnt about patent law and its interpretation and heard from an industry and academic perspective and that the subject was a complex one and that views were often polarised. We felt there to be a need to engage with people and their views and for a reassurance that patents do not threaten academic research. We were very pleased that Stephen Bain joined the Commission in January.

May 2002 – Manchester

May saw us travelling to Manchester and we and would like to thank Manchester University for the warm welcome we received and for hosting our meeting on 14 May. Our thanks also go to John Harris and Hilary Harris for all their work to make this a successful and enjoyable two days. A lot of our discussion focused on genetic tests supplied direct to the public and HGC's role in considering such tests, this is covered in more detail on page 7. We also discussed other future work, such as follow-up to our report on PGI and genetics and insurance in particular, concluding that information as well as meetings would be needed to enable the debate to move forward during the moratorium.

'Important that not all meetings are in London. … I think there are issues about the extent to which the public are aware that there are open meetings and where this fact is advertised.' Plenary attendee

On 13 May we met with Eurostem (the Ethics of Human Stem Cell Research and Therapy in Europe) and discussed stem cell research and therapy. From what we heard it is clear that little is known at this stage of how successful particular therapies or interventions are likely to be. There is also a wide diversity of views in Europe with respect to the ethics of stem cell research and therapy. We also considered HGC's role in this debate – the HFEA is responsible for licensing the extraction of embryonic stem cells, but the Commission agreed to consider any wider implications at its next meeting. There were several other changes in membership, with Suzi Leather joining HGC as an ex-officio member as Chair of the Human Fertilisation and Embryology Authority, succeeding Ruth Deech in March. We were also pleased to welcome Stephen Singleton as the representative of the English Chief Medical Officer on HGC in May and Jackie Axelby and Peter Goodfellow resigned from HGC due to the pressure of other commitments.

Inside Information

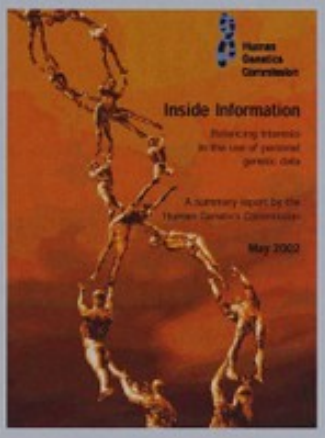
This year saw the publication of our first major report, *Inside Information Balancing interests in the use of personal genetic data*, on personal genetic information and how it is obtained, used and stored.

We concluded that:

- in the main, people see genetic information as special and as a private matter. We agree that there are sometimes good reasons for this. However, not all genetic information has the same level of sensitivity; some information is especially sensitive and we feel this type of information needs additional protection.
- people must feel confident that proper safeguards are in place to protect genetic information and that these safeguards are rigorously monitored. But we must not miss out on the major benefits that medical research using genetic information can bring. This means that we should not hinder research by imposing unworkable restrictions. We recognise therefore the need for a balance between an individual's interest in privacy and the interests of others in the use of personal genetic information for medicine or research.

With a view to achieving this balance, our recommendations suggest a number of new ways to protect people. These include:

- A new criminal offence to prevent the wrongful obtaining or non-consensual analysis of a person's genetic information for non-medical purposes. This offence is intended to prevent what we consider to be a serious invasion of privacy. The offence would not cover clinical testing or forensic use.
- The introduction of measures to protect individuals from unfair genetic discrimination. To this end we suggested that the Government should consider in detail the possible need for separate UK legislation to deal with this issue.



There were several key elements to our consultation on PGI. The evidence gathered is published on our website (details of how to get copies of the report and the evidence are given in Annex J).

- **Survey of public attitudes**

We commissioned a large-scale survey of people's attitudes to PGI with over 1,000 people interviewed about their views on how this information is used now and on the ways it should be used in the future.

- **Public meetings**

The consultation was launched at a public meeting in Newcastle. We met students from local schools and colleges to hear views from young people and a wide range of local people interested in this issue.

- **Consultation document**

Our consultation paper ***Whose hands on your genes?***, which included a 'tick-box' section for ease of reply, resulted in over 250 responses.

- **The Consultative Panel (see page 6 and Annex C)**

Before finalising our report we sent a summary of our conclusions and recommendations to Panel Members and received 64 responses, giving a comprehensive range of comments and suggestions.

- **Discussions with other organisations**

We met several key national organisations to discuss relevant areas of work while drawing up our recommendations and also international counterpart organisations, most notably in the US. We also benefited from the useful work of the Science and Technology Committee of the House of Lords on genetic databases and of the House of Commons on genetics and insurance.

Inside information

- We considered the question of genetic information and employment. We advised that employers should not require an individual to take a genetic test as a condition of employment or for employment benefits. We will continue to monitor any proposals for the voluntary use of genetic information in the workplace.

- Participants in medical research should be assured that their personal genetic information is kept confidential. We recommended that clear policies for ethical research in genetics should be followed and monitored. In particular, we welcomed the setting-up of large-scale genetic research databases, but urged that these be subject to independent oversight and that considerations of access and security be carefully addressed.

- We noted the importance of the use of DNA evidence in the detection of crime. An independent body should be created to oversee the operation of the national forensic database.

- We welcomed the announcement by the Government and the insurance industry of a moratorium on the use of genetic tests results for most insurance policies. We are keen to make the best use of this moratorium period to engage in further research and discussion of possible approaches to the issue of genetics and insurance.

Inside Information was published in May 2002 and attracted a good deal of interest and comment with different groups picking up on different aspects of the report.

'We would like to congratulate you on completing such an important and comprehensive report... the Government shares your concerns about the need to put in place protections to ensure privacy and prevent inappropriate uses of genetic material.'
Lord Hunt, Parliamentary Under Secretary of State for Health

'GeneWatch UK warned that the need to control commercial exploitation of personal genetic information had been neglected in today's "Inside Information" report ... However, GeneWatch welcomed several of the recommendations and the HGC's commitment to openness and public consultation.' ['This report could be a charter for abuse by private companies']
GeneWatch UK press release 21/05/02

'Gaps that must be plugged to safeguard human rights'
The Guardian 22/05/02

'Advisory group targets 'genetic discrimination' in the workplace'
Financial Times 22/05/02

Report urges ban on secret DNA tests'
Daily Telegraph 22/05/02

'Ban the Bing Bin Burglars Call to outlaw theft of DNA clues'
The Sun 22/05/02

'Baroness Kennedy should know better – I don't know why she is picking on journalists'
National Union of Journalists quoted in The Herald (Glasgow) 22/05/02

'[insurance] Industry backs HGC over use of genetic data laws'
Cover 01/06/02

'The safeguards suggested by the HGC should ensure that such knowledge benefits everyone's health without compromising the privacy of those involved'
BioNews Commentary 27/05/02

'Keep your hands off other people's DNA'
New Scientist 25/05/02

Professor's bid to ban bosses' 'abuse' of DNA'
Cambridge Evening News 29/05/02

Public involvement

We have continued to put our commitment to public involvement into practice this year and see our Consultative Panel (see page 6 and Annex C) as a concrete example of this. In March we published our Public Involvement Strategy (Annex B) which aims to promote debate and achieve effective representative dialogue with a wide cross-section of people. It is based on some core principles to ensure that we will:

- set new standards of openness, accessibility and inclusiveness for our meetings;
- make our findings and the evidence and reasons for our advice public;
- work with other groups, including the media, to ensure that the public is aware of the issues and the various points of view;
- seek the views of stakeholders before submitting our advice to Government and will take account of the views expressed;
- work to achieve public trust that social and ethical considerations are being taken seriously;
- encourage people to give us their views and listen to others;
- make effective use of the Internet to promote our work, provide an information resource and an avenue for dialogue.

As part of this we publish a regular newsletter and hold our main meetings in public, meeting in various places around the UK. We make good use of our web-site and we are always interested to hear about new and better ways to involve people in our work.

Public Involvement Sub-group

The Public Involvement Sub-group concentrated its efforts on setting up the Consultative Panel. Members thought long and hard about how best to set up the Panel and agreed that it was important to avoid bureaucratic and cumbersome arrangements. Members were also keen to try something new and were interested in involving more people than a traditional committee sub-group approach would allow. We sent out a general invitation encouraging people to register their interest in joining the Consultative Panel and are grateful to the organisations and regional genetics centres who helped us with this.

Public Involvement Sub-group

Chair: Ruth Evans

Members:
Elizabeth Anionwu
Jackie Axelby
Harry Cayton
Alastair Kent
Keith Palmer
John Polkinghorne
Martin Richards
Gillian Samuels
Geoffrey Watts

Remit: To advise on strategies for promoting debate and effective public and stakeholder consultation; to oversee HGC consultation exercises; to advise on education/information initiatives.

There was a positive response to this, with over 180 people interested in the Panel. The Sub-group sifted these, drawing up a list of over 100 Members and a reserve list of 50 people, making sure there was as wide a range of members as possible. Members have been appointed to the Panel for three years. The Sub-group will manage HGC's relationship with Panel, consider the information sent to Panel Members and review membership on a regular basis.

The Sub-group also drew up the Public Involvement Strategy, which pulled together HGC's various activities in this area. Members also looked at ways of improving the openness of HGC's meetings and of encouraging people to come to meetings. They felt that the newsletter, was a good way to do this and to keep people up to date with HGC's work. They also oversaw the work of the HGC Press Office, who provided regular activity reports.

The Consultative Panel

'With the wide range of social, ethical and moral issues facing many of us in our daily living the panel will provide us with a way to channel our views and opinions in a representative way' Panel Member

'I am very concerned that it will be very easy for the individual members of the public's views to be lost in views of especially interested parties in the debate.' Panel Member

'I believe that most groups offering their suggestions/thoughts have not had the first hand experience of dealing with a child/adult suffering from genetic disorders' Panel Member

What is the Panel? – We invited around 100 people to join our panel and act 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 and multifactorial disorders, and of childhood and adult onset disorders. Some are affected themselves or are carriers. They may also have experience as a parent of a child affected by a genetic disorder or of caring for someone in their family who is affected. The Panel membership has a wide age range and includes people who live in England, Scotland, Wales and Northern Ireland.

'I am interested in being part of an effort that ensures the views of those directly affected are included in the debate on modern genetics.' Panel Member

'I congratulate the Human Genetics Commission for taking this proactive and positive step forward' Genetic Support Network, Victoria, Australia

Why was it set up? – We believe that in reaching our decisions we must listen to people directly affected by a genetic disorder. We need to learn from those who know about the reality of living with a genetic disorder. We can benefit from their experience in many areas – such as deciding whether to take a genetic test. We also wish to hear about other concerns they may have, for example about insurance and employment. The panel works primarily by correspondence. We hope that this will allow people who cannot easily travel to meetings to participate in a way which suits them best and which fits in with their other commitments. More information on the Panel is given in Annex C and on the website hgc.gov.uk/cpanel/.

'I am delighted to announce the establishment of this panel … We had a very positive response to our request for people to join and I would like to thank all those who wrote in.' Helena Kennedy

'Plans for how this panel will operate are very fluid, reflecting the Commission's view that the best way of working will emerge from the ideas and input of the Panel's members.' PHGU Newsletter

'I believe strongly that people like myself should have a voice and be prepared to investigate further the many issues … genetics disorders present' Panel Member

Genetic testing services

The Genetic Services Sub-group identified direct testing as a major issue of concern. The HGC had inherited from a previous committee, the Advisory Committee on Genetic Testing, responsibility for considering applications made under the current voluntary Code of Practice governing the provision of genetic tests direct to the public. We received an application from Sciona for a genetic testing service offering nutritional and life-style advice. Concerns about aspects of the tests offered led to discussion with the company in question. The Sub-group visited the Sciona laboratories to see the facilities and discuss the issues in more detail. In the course of this work the HGC decided that it would be appropriate for further consideration to be given to all aspects of this code, including mechanisms for approval and its scope.

At our Manchester meeting in May we decided that the HGC's primary role was to provide independent strategic advice and that making decisions about individual tests conflicts with this. A subsequent invitation was received from Ministers to review and advise on the best approach to 'over-the-counter' tests as a priority, and we have now embarked on this task.

We understand that Sciona has withdrawn its product from direct marketing, and is awaiting the outcome of the review. Until a new system is in place, we will continue to receive and consider any applications made under the existing Code, and we shall offer informal advice on these.

Genetic Services Sub-group

The HGC reviewed the Sub-group's terms of reference in 2001 and agreed that the remit should be broadened to encompass wider aspects of service delivery as well as laboratory-based testing, which had been its main focus previously. It was agreed that the Sub-group should be known as the Genetic Services Sub-group.

Genetic Services Sub-group

Chair: Philip Webb

Members:
William Albert
Elizabeth Anionwu
Robert Bestow
John Burn
Heather Draper
Frances Flinter
Hilary Harris
Peter Harper
Patrick Morrison
Ros Skinner

Remit: To advise on genetic testing issues, including routine exchange of information with other relevant bodies, such as: services provided direct to the public; strategic issues in the delivery of genetic services; new and evolving genetic testing and screening technologies; to provide guidance to Research Ethics Committees; to recommend HGC laboratory visits in relation to genetic testing.

In addition to the oversight of direct genetic testing services (see opposite) the Sub-group considered other work emanating from the former Advisory Committee on Genetic Testing, such as the survey of testing in childhood. It has also received updates and commented on the work of the National Screening Committee.

The Sub-group considered the wider developments in NHS genetic services, such as the establishment of the Genetics Commissioning Advisory Group (GenCAG). This arose from the report of the Department of Health Laboratory Services Working Group and the commitments made by the Secretary of State for Health in April 2001.

The Sub-group has also considered and commented on some of the issues being considered by the Green Paper Advisory Panel which was formed to advise the Department of Health on the drafting of the Genetics Green Paper. In April the Sub-group visited the Institute of Medical Genetics in Cardiff and had an opportunity to meet with National Assembly of Wales officials and with those involved with commissioning and providing genetic services in Wales.

On the horizon

One of the important functions of HGC is to provide the Government with advice on developments in human genetics and their implications for healthcare and the wider ethical and social implications. The Horizon-Scanning Sub-group continued to consider some of the likely developments in technology, legislation and public attitudes that might have wider implications for HGC's work. This was particularly relevant to the consideration of future HGC work.

Some of the issues that the Sub-group considered were:

- **Reproductive choice** – where it was noted that testing technology would have implications for prenatal genetic diagnosis, preimplantation genetic diagnosis and screening. This is likely to be a major topic for future HGC work.
- **Pharmacogenetics** – where people were tested for their likely response to a particular drug before being given that drug either as part of a research study or to help with prescribing decisions. This was felt to be an important and urgent topic for consideration.
- **Stem cell research** – the Sub-group noted the legislative changes affecting embryonic stem cells but that it was also important not to ignore work with adult or fetal stem cells and cultured stem cell lines. It was possible that no other group was taking an overview of the whole subject and the possible safety issues.
- **Patenting, ownership and intellectual property rights** – this was the subject of a number of reviews and HGC should keep a watching brief as part of the oversight of regulatory frameworks
- **Consent and use of personal genetic information** – in the light of the proposed large research database – Biobank UK – and also of changing attitudes to consent following the Alder Hey and Bristol Inquiries. Large research databases raised once more the issues of ownership, management and information security that should be considered in depth in future.

Horizon-Scanning Sub-group

The Horizon-Scanning Sub-group is responsible for providing HGC with such advice. This year it has considered its role and the most effective way of producing relevant information in a short time. It was agreed that rather than placing the emphasis on producing a single all-embracing report, the Sub-group should monitor developments and assist the main Commission in reaching a view on new developments. The new terms of reference were agreed in May 2002.

Horizon-Scanning Sub-group

Chair: Veronica van Heyningen

Members:
Lesley Greene
John Harris
John James
Hilary Newiss
John Sulston
Nigel Spurr
Kent Woods

Remit: To take account of the work of existing bodies with a horizon-scanning role to identify and report back on the key issues for HGC to consider.

One method of achieving this, which the Commission has found useful, has been to organise information-gathering sessions preceding the main HGC plenary meetings. The aim is to provide HGC members with an understanding of a range of views on a particular issue by inviting expert speakers and allowing time for questions and discussion. More information about these sessions is given on pages 1 and 2 and at Annex D. The Horizon-Scanning Sub-group has contributed to the organisation of meetings on new genetic testing, gene patenting and stem cell technologies.

The Sub-group also felt there to be a number of general areas such as the use of animals, behavioural genetics and the provision of genetic services that are are being dealt with by other bodies, and they agreed to monitor these as well.

Work plan 2002

During the year we drew up a plan of work for 2002. We took stock of what we had achieved against the objectives in our first work plan and identified priorities for the future. We wanted to hear what others with an interest saw as priorities for our work in 2002 and wrote to some 60 key organisations and the Department of Health and other Government departments seeking views on our proposals. Our final work plan took account of their comments. Most were largely content with what we proposed although Health and Science Ministers did make one significant request emphasising the need to address the review of genetic testing services sold direct to the public as a priority, whilst still recognising the importance of genetics and reproductive issues.

This meant that, in the second half of 2002 after publishing our report on personal genetic information, we gave first priority to a review of the provision of genetic testing services direct to the public. As a consequence we will not be able to give as much early consideration as originally intended to preparation for a possible review of developments in genetics in relation to reproductive issues.

We identified the following as our priorities for work in 2002:

- To publish our report on personal genetic information and to provide further advice on some of the issues in the report.
- To review arrangements for the provision of genetic testing services direct to the public and to make recommendations to Ministers by December 2002, including the need for any changes to the relevant advisory and regulatory framework.
- To feed our strategic perspective into discussions on the development of genetic testing and services, in particular to ensure that social and ethical aspects are properly addressed in the context of emerging technical advances.
- To monitor the broad ethical, social and human rights aspects of developments in genetics in relation to reproductive issues and discuss these with the relevant bodies with a view to possible future in-depth consideration.
- To consider developments in pharmacogenetics, stem cell research and therapy, and gene patents.
- To build on existing links with bodies in the regulatory and advisory framework for human genetics and to continue to pursue a policy of openness and public involvement.

Out and about

We have continued our work building links with key organisations, having had many useful meetings with organisations and individuals. We shall not cover them all in detail but information about some of them is given here.

A number of meetings were associated with our work on personal genetic information. Members visited the Forensic Science Services (FSS) in June 2001 to discuss issues around the oversight and security in the handling of DNA samples and profiles. Members were impressed with the high professional standards of the FSS but formed the view that there was a strong case for the establishment of an independent oversight body, both for controlling access to samples and for considering ethical issues in research. Liaison with the Medical Research Council and Wellcome Trust continued this year. Although the detailed operation of Biobank UK was not to be decided until the announcement of funding, the HGC was able to discuss these operational matters with the sponsors at several consultation meetings.

In June Helena Kennedy met Bert Massie and Agnes Fletcher of the Disability Rights Commission (DRC) and discussed the future work of the DRC and areas of mutual interest around public attitudes to genetics. She also had a useful meeting with the Institute of Actuaries and the UK Forum for Genetics and Insurance (UKFGI). Sandy McCall Smith and Philip Webb both spoke at UKFGI meetings in 2001 to update them on the report on PGI. Sandy McCall Smith spoke to the Department of Health's Green Paper Advisory Panel to advise them of progress on the report. His other meetings included discussions with a delegation from Japan's National Bioethics Committee and an address to the Enquiry Commission of the German Bundestag. He also spoke at a conference organised by Disability North in Newcastle, a parliamentary meeting of the Danish National Ethics Committee and a number of meetings organised by the Council of Europe as part of its bioethics initiative for Eastern Europe.

The Business Committee met a number of organisations. David Johns, the new chair of the Genetics and Insurance Committee (GAIC) was invited to the Business Committee's April meeting, where he told Members about the Government decision to reconstitute GAIC and strengthen its membership. Jade Donovanik of the Thai Working Group on Bioethics and Medical Research came to the Committee's November meeting. This Working Group was looking at the views and experiences of other countries in deciding how to take these issues forward in Thailand. Particular issues had arisen around foreign national-led research projects involving the collection of DNA samples as these had bypassed the usual route through an ethics committee. Members also met Prof James Childress and a delegation from the US National Bioethics Commission in August 2001.

The Secretariat and Members were also involved in the Wellcome/BBC gene stories project, which included a number of related television programmes and an interactive website (bbc.co.uk/genes). There have also been Parliamentary discussions: Helena Kennedy took part in the House of Lords debate on the Science and Technology Committee's report *Human Genetic Databases: Challenges and Opportunities* in January 2002 and appeared before the House of Commons Science and Technology Committee in April.

Keeping in touch

Tell us what you think

We are always keen to hear what you think and comments are welcomed about

- the report we published on personal genetic information
- the issues we have identified in our work plan, in particular on genetic tests supplied direct to the public and genetics and reproduction
- how we can involve people in our work
- or any of the issues in this report

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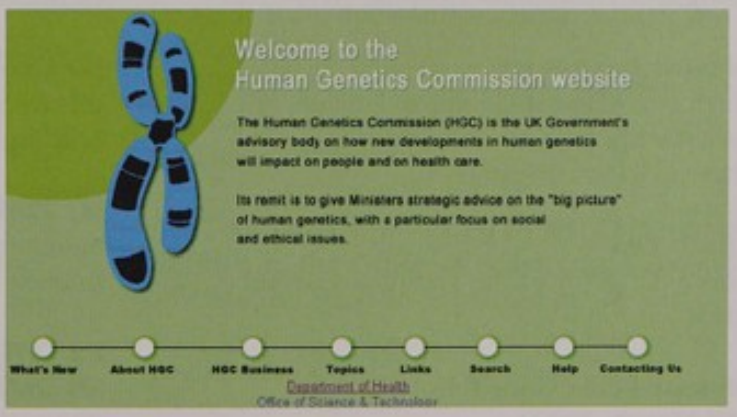
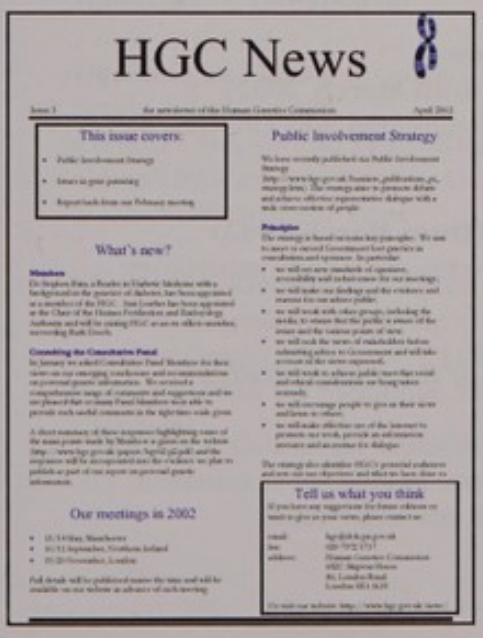
Find out more

To find out more about the HGC please visit our website: hgc.gov.uk




HGC News

This issue covers:

What's new?

Public involvement Strategy

Our meetings in 2002

Tell us what you think

Or sign up for copies of our newsletter HGC News, by writing to us at the above address giving your full contact detail or by registering online hgc.gov.uk/news/

Details of HGC publications are given in Annex J

ANNEX A: Membership

The Human Genetics Commission

Chair
Baroness Helena Kennedy
Barrister and broadcaster

Vice-Chair
Professor Alexander McCall Smith
Professor of Medical Law, University of Edinburgh

Members
Dr Bill Albert
Chair of the Norfolk Coalition of Disabled People

Professor Elizabeth Anionwu
Professor of Nursing, Head of Mary Seacole Centre for Nursing Practice, Thames Valley University

Dr Stephen Bain (from January 2002)
Reader in Diabetic Medicine at Birmingham University and Consultant Physician at Birmingham Heartlands Hospital NHS Trust

Professor John Burn
Professor of Clinical Genetics, University of Newcastle upon Tyne and Director, Northern Genetics Service

Ms Ruth Evans
Formerly Director of the National Consumer Council

Professor Peter Goodfellow (until March 2002)
Senior Vice-President, Discovery Worldwide, SmithKline Beecham Pharmaceuticals

Dr Hilary Harris
General Practitioner, Manchester

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

Ms Hilary Newiss
Solicitor

Reverend John Polkinghorne
Canon Theologian of Liverpool and formerly President of Queens' College Cambridge

Professor Bruce Ponder (until June 2001)
Professor and Head of Department of Oncology, Cambridge University

Professor Martin Richards
Professor of Family Research, Centre for Family Research, University of Cambridge

Dr Gill Samuels
Director of Science Policy (Europe), Pfizer

Sir John Sulston (from July 2001)
Former Director of the Sanger Center, part of the Wellcome Trust Genome Campus, Cambridge

Professor Veronica van Heyningen
Head of Cell Genetics Section, MRC Human Genetics Unit, Edinburgh

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

Mr Philip Webb
Member of the Board of Trustees of Genetic Interest Group

Ex Officio Member
Ms Ruth Deech (until March 2002)
Chair of Human Fertilisation and Embryology Authority

Ms Suzi Leather (from March 2002)
Chair of Human Fertilisation and Embryology Authority

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

Mrs Jackie Axelby (England) (until May 2002)
Chief Executive, Northumberland Health Authority

Dr Stephen Singleton (England) (from May 2002)
Medical Director, Northumberland and Tyne & Wear Health Authority

Professor Peter Harper (Wales)
Professor and consultant in medical genetics, University of Wales

Professor Patrick Morrison (Northern Ireland)
Consultant clinical geneticist, Belfast City Hospital

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

Co-opted Members

Mr Robert Bestow (Co-opted Member, Genetic Services Sub-group)
Director, NF (Neurofibromatosis) Association

Mr Harry Cayton (Co-opted Member, Public Involvement Sub-group)
Chief Executive, Alzheimer's Society

Dr Heather Draper (Co-opted Member, Genetic Services Sub-group)
Senior Lecturer, Centre for Biomedical Ethics, University of Birmingham

Dr Frances Flinter (Co-opted Member, Genetic Services Sub-group)
Clinical Director and Consultant Clinical Geneticist, Genetics Centre. Guy's and St Thomas' Hospital Trust

Mrs Lesley Greene (Co-opted Member, Horizon-Scanning Sub-group)
Support Services Director, CLIMB (formerly the Research Trust for Metabolic Diseases in Children)

Mr John James (Co-opted Member, Horizon-Scanning Sub-group)
Chief Executive, Kensington, Chelsea & Westminster (KCW) Health Authority

Mr Alastair Kent (Public Involvement in Genetics Sub-group) **(from September 2001)**
Director, Genetic Interest Group

Dr Keith Palmer (Co-opted Member, Public Involvement Sub-group)
Vice Chairman, Investment Banking, N.M. Rothschild & Sons Ltd
Confederation

Dr Nigel Spurr (Co-opted Member, Horizon-Scanning Sub-group)
Director, Genetic Technologies, SmithKline Beecham Pharmaceuticals

Professor Kent Woods
(Co-opted Member, Horizon-Scanning Sub-group) **(until January 2002)**
Director, NHS Health Technology Assessment Programme

Secretariat

Dr Mark Bale, Secretary
Dr Manny Chandra
Mr Richard Pitts
Mrs Margaret Straughan
Ms Emma Wilbraham

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Annex B: HGC's Public Involvement Strategy

Aim

So that we can properly advise Government on developments in human genetics and the social and ethical implications, we will promote debate and achieve effective representative dialogue with a wide cross-section of people.

Principles

We aim to meet or exceed Government best practice in consultation and openness. In particular:

- we will set new standards of openness, accessibility and inclusiveness for our meetings;
- we will make our findings and the evidence and reasons for our advice public;
- we will work with other groups, including the media, to ensure that the public is aware of the issues and the various points of view;
- we will seek the views of stakeholders before submitting advice to Government and will take account of the views expressed;
- we will work to achieve public trust that social and ethical considerations are being taken seriously;
- we will encourage people to give us their views and listen to others;
- we will make effective use of the Internet to promote our work, provide an information resource and an avenue for dialogue.

Our audience

There is no such thing as the general public, but we feel it useful to identify the potential audiences on the basis of their level of interest in and knowledge of the issues:

Stakeholders	Those with a professional interest in our work, such as informed professionals, scientists, industry, patient groups, charities, and people with personal experience of genetic conditions.
Involved	Those aware of the issues in our work with views based on personal circumstances, through friends, relatives or work or those with strong ethical viewpoints.
Everyone else	Those without a particular interest in the issues we cover, but who may welcome assurances that there are effective mechanisms in place to consider the issues.

These distinctions are not rigid and people will fit into different categories depending on issue under discussion or changes in personal circumstances.

We aim to involve as many as possible in the stakeholder and involved groups, but we recognise that we cannot reach everyone and must look to intermediaries to reach a wider audience.

Objectives for 2002 and beyond

Public involvement is a dynamic process, it will need to be adapted to the issue under discussion. It will need to change and develop over time depending on what we finds works best. It will depend on resources and time available and the Public Involvement Subgroup will co-ordinate all of our activities in this area. We envisage that the following will be important elements of our strategy.

Basic mechanisms and routine activities

- all main HGC meetings are held in public and the papers are published on the website;
- fully attributable minutes of sub-group meetings are published on the HGC website;
- we publish a regular newsletter and an annual report;
- we engage in public dialogue when drawing up advice and recommendations.

We will evaluate and further develop the HGC website, particularly the information, external links and interactive elements.

Major initiatives and campaigns

Our approach to public involvement will depend on the issue under discussion. We can envisage a need for both large-scale consultations and timely and realistic information-gathering exercises and stakeholder conferences.

The Consultative Panel (see below) will be an integral part of all major discussions and consultations.

In all cases, we will draw up implementation programme for individual pieces of work on the advice of the Public Involvement Subgroup, and seek the views Consultative Panel and other stakeholders.

In all cases, we will evaluate public involvement and liaison work and learn from experience. We will look to move away from only using the tried and tested methods and towards new ways engaging people in the future debate and the decision making process.

We support the development of a dialogue between science and society, and intend to pursue our public involvement work within that context.

What we have done so far

We have carried out a number of public involvement events so far, including:

Consultations

- April 2000 – 'theatre style' public meeting to help formulate our work programme. The meeting involved a number of presentations from invited speakers from stakeholder groups and the audience (including stakeholders and the public) discussed priority issues for inclusion in the work plan. The work plan was also issued as a consultation document on paper and on our website.
- From November 2000 – comprehensive consultation on the storage protection and use of human genetic information. This consultation had several strands:
  - a survey of over 1000 people by detailed face to face interviews, who were asked about a wide range of ways genetic information is used now and how it should be used in the future.
  - a consultation document, which was designed in 2 parts – with a shorter, 'tick-box' part to allow people to reply quickly and easily and a longer part raising the issues and prompting detailed responses. We met several key national organisations to discuss relevant areas of work while drawing up document and also international counterpart organisations, most notably in the US.

– a large-scale discussion meeting in Newcastle where we talked to people in small groups with around 200 students in the afternoon and a similar number of members of the public in the evening. Presentations designed to raise relevant issues preceded both discussions.

Information gathering events

- February 2001 – Genetics and insurance information gathering day. An invited audience of key stakeholders and the public attended a meeting of presentations from experts and an afternoon discussion covering all sides of the 'genetics and insurance' debate. June 2001 – a similar style information gathering day was held to look at genetic testing and screening techniques.
- We will continue to hold these style of events on a regular basis as we have found them useful and they have been well supported.

The Consultative Panel

We need to hear from people directly affected by genetic disorders and have set up a Panel of 106 people who are affected themselves or who have family members who are affected. The Panel will act as a sounding board for our reports and recommendations and will give us their views on the reality of living with a genetic disorder. Much of the Panel's work will be by correspondence, with Panel Members being sent short summaries of reports we are writing or issues we are discussing for comment. They will also be invited to meetings to discuss specific issues in more detail.

Annex C: The Consultative Panel

What is the Consultative Panel?

- The HGC has set up a Consultative Panel of people affected by a genetic disorder. The panel, made up of over 100 people with direct experience of living with genetic disorders, acts as a sounding board for our reports and recommendations, as well as giving us insight into their concerns about genetic issues.
- Much of the Panel's work is by correspondence, with Panel Members being sent short summaries of reports we are writing or issues we are discussing for comment. Annual meetings are also held to allow Panel and Commission Members to meet and discuss issues in depth.
- The Panel includes people who have experience of single gene, chromosomal or multifactorial disorders, and/or of childhood or adult onset disorders. Some people are affected themselves or are carriers and/or have experience as a parent of a child affected by a genetic disorder and/or caring for someone in their family who is affected. The Panel membership has a wide age range and includes people who live in England, Scotland, Wales and Northern Ireland.

Why was the Panel set up?

- We wanted to hear from people directly affected by a genetic disorder so that they can help inform us when we make our decisions. We need to learn from people who know about the reality of living with a genetic disorder, their experience in deciding whether to take a genetic test and whether for example they have concerns about insurance and employment issues. Our hope is that the Panel will let us do this in a way that is very useful for the HGC while also being rewarding for those who participate.
- We see the Panel as an important element of our public involvement strategy. We hope that the fact that the panel works primarily by correspondence allows people who cannot easily travel to meetings to join the Panel and means people can take part at times that suit them best and fit in with other commitments. We use the Panel to supplement our more traditional consultation via national organisations and patient groups.

How was the Panel set up?

- In October 2001 we sent out a letter inviting people to join the Consultative Panel and set up a form on the HGC website that people could fill in. We are grateful to the organisations and regional genetics centres who helped in distributing the forms and publicising the Panel.
- We had a very positive response to this initiative, with over 180 people interested in joining the Panel. These were divided into three main groups based on genetic disorder: single gene/Mendelian inheritance disorders, chromosomal disorders and multifactorial disorders; and were then grouped by type of personal experience: those affected, family member affected, carer or a combination of these. These groupings are fairly general but helped to identify people with similar experience and who we looked at in more detail. We used the other details such as age, geographic location, ethnic origin and the comments on the form to get as wide a range of members as possible.

- Members have been appointed to the Panel for three years and we will be reviewing membership on a regular basis.

What has the Panel done?

- Summaries and details of the Panel's responses to the issues we put to them are on the HGC website: www.hgc.gov.uk/cpanel/.
- We consulted the Panel when drawing up our report on personal genetic information *Inside Information*. We asked Panel Members for views on our then draft conclusions and recommendations in February 2002 and some of the main points made are on the website along with the anonymised version of Member's comments (www.hgc.gov.uk/insideinformation/iievidence_cpanel_view.htm).

Annex D: Reports from information gathering sessions

We have found it useful to build a regular information-gathering session into our meeting structure (see page 1). This gives us a chance to discuss a particular issue in more detail, inviting a number of people to talk to us about varying aspects and to consider the implications for our own work. Summaries of these sessions are given below, with full reports of the meetings available on the website www.hgc.gov.uk/business_meetings.htm

'FISH and Chips'

On 26 June 2001 we held an information-gathering meeting on the genetic testing and screening techniques at the Wellcome Trust Genome Campus in Cambridge. We heard about to the techniques of Fluorescent In Situ Hybridisation (FISH) and microarrays or DNA chips, giving us a clear picture of the current techniques used in high throughput genetic screening and what might be achieved in the future. The discussion covered topics such as what might be the desirable aims of cytogenetic testing, the need for more extensive genetic counselling and for greater public education, and the extent to which the technology drove the demand for genetic services.

Developments in cytogenetic testing
FISH – (Fluorescent In Situ Hybridisation) is a technique in which one or more specific sections of DNA are labelled with fluorescent coloured dyes and the position where that labelled DNA finds its exact pairing partner can be identified. Most FISH tests are used to help in cancer diagnosis. They are also used to identify or confirm abnormal chromosomal banding patterns, eg for couples with reproductive problems.

FISH is also used in preimplantation genetic diagnosis (PGD). HGC, together with the Human Fertilisation and Embryology Authority (HFEA), finalised its response to a consultation exercise on the subject that was held jointly by the HFEA and HGC's predecessor body, the Advisory Committee on Genetic Testing (ACGT), in November 1999.

Developments in molecular techniques for genetic testing
DNA Chips – or microarrays, are glass slides containing different DNA sequences, representing many different genes in the cell, laid out in an array of spots. Microarrays are being used in research into tumour progression and to help in deciding on the best form of treatment. This technology is also used to detect SNPs (single nucleotide polymorphism), changes in the gene code which have no direct adverse effect but might have a subtle effect on a genetic trait such as susceptibility or resistance to a disease.

The discussion covered a range of issues and flagged up important areas for further consideration, including:

- This is a quickly developing area and will mean significant changes to the capacity and scope of genetic testing, which will bring new ethical, legal and social concerns and it is important that we look at these now.
- There will be a need to regulate genetic testing, especially with the growth on the Internet of companies offering different kinds of tests.
- The whole area of genetic screening needs further public scrutiny.

Issues in gene patenting

We held an information-gathering meeting on gene patenting on 12 February 2002. We heard presentations on the facts about gene patenting and discussed issues of potential concern and the best role for HGC. There is not enough space in this newsletter to allow more than a very brief summary of the meeting, more information is given on the website: www.hgc.gov.uk/business_meetings_12february.htm

We heard about patent law and its interpretation:

- There are 2 routes to obtaining patent protection: via the UK or European Patent Offices. Whilst there is no fundamental bar to patenting biological material, some categories are excluded, eg therapeutic/surgical/diagnostic treatments. An invention must be novel, inventive and have a real industrial application for it to be patentable, and it must be fully disclosed. Patents are challengable.

And also heard an industry perspective:

- Industry feels existing patent law should apply to genetic as to other inventions, with each application judged on its own merits and does not want a blanket ban on gene patents. Says that less research would be done without patents, as it is easier to imitate than to innovate and there would be more secrecy. And that only industry can afford the full investment for research and development of new drugs.

And an academic perspective:

- Heard that the patent system can and does have great value – it enables inventions to translate into tradable commodities - but need to see public not just industry benefit. Bear in mind that some companies are not carrying out research if patents are already held in that area and legal challenges to patents are very expensive and can be daunting to smaller companies. Need to consider societal and industry interests.

Discussion

- Gene patenting has given rise to a great deal of debate, the subject is a complex one and views are often polarised. We discussed whether it was inherently wrong to patent genes, and if so why was this different from other areas of healthcare; whether the system provided a balance between encouraging innovation and adequate reward; and if some form of ombudsman would be useful.

- We see a need to engage with people and their views and for a reassurance that patents do not threaten academic research. HGC could facilitate public debate on this issue and keep a watching brief on how the system operates. The various parties' interests need to be taken into account and a fair balance drawn between public interest and commercial protection.

Stem cell research and therapy

On 13 May 2002 there was a joint meeting between HGC and Eurostem (the Ethics of Human Stem Cell Research and Therapy in Europe), whose role is to provide an ethical framework for, and monitor public reaction to stem cell research. We heard from Eurostem members about:

Tissue Storage and Retention

- There are numerous uses to which human tissue can be put, which makes it difficult to effectively regulate the retention and use of tissue. However, transparency of the process, and the public trust so engendered, are important in allowing research to progress.

- A common perception is that public opinion is misinformed and emotional, and the media does not always facilitate understanding. There can be a basic failure of communication between doctors/nurses and patients/relatives.

HFEA licensing

- Under the HFE Act 1990 research concerning human embryos can only be carried out once licensed by the HFEA. This now includes research concerned with increasing knowledge of development of embryos and of serious disease (not defined), and to enable such knowledge to be developed into therapy.

- Information important to the HFEA in a licence application includes: the source and disposal of the embryos; how audit and consent procedures are managed; whether the centre is adhering to the scope of the project originally granted.

Scientific Fact and Fantasy

- It has been only 3 years since the human first embryonic stem cells were created. The public perception of the area is much influenced by its presentation in the media, which can be misinforming. Future major tasks include: making cell lines without use of mouse cells or of human fetuses if possible; integration of different tissues; avoidance of immune rejection of stem cells.

- Should stem cell therapy be regulated as a surgical procedure, or as drug therapy? If regulation were too strict, this might result in no treatment becoming available to clinical practice. The technology brings challenges to ethicists, clinicians and regulators. It was a challenge that was being responded to enthusiastically by scientists but which also required support by the public.

Discussion

- From what we heard it is clear that little is known at this stage of how successful particular therapies or interventions are likely to be. It will be difficult to judge the pace of developments in the short- and medium-term future.

- An element of flexibility is required in any regulatory framework governing the use of human tissue. A 'tickbox' approach would do nothing to engender trust; instead broad principles must be developed, adherence to which would induce public confidence.

- The subject of commercial applications, which had been raised in the House of Lords report, was very pertinent to future development, and means of regulation would need to be considered.

- A ban on embryonic stem cell research might induce researchers to explore other areas, but researchers required consistency of regulation.

- We heard about the position in other European countries. There is a wide diversity of views in Europe with respect to the ethics of stem cell research and therapy. We noted how the political situation can affect scientific policy and advice – for example in Italy, the newly elected Government completely changed the composition of the National Bioethics Committee.

Annex E: Comments to inform Government responses

HGC's comments to inform the Government response to the House of Lords report on Genetic Databases.

HGC welcomes this important report* and is grateful to the House of Lords Select Committee on Science and Technology for agreeing to time its work to assist our review of the storage, protection and use of personal genetic information.

This review is now going to take somewhat longer than anticipated because of urgent work on insurance and forensic DNA databases. We now aim to publish our report and recommendations before the end of the year, but recognises that some of our work will continue into next year. In the meantime, HGC offers the following commentary on the House of Lords' conclusions and recommendations which stem from our work to date and which may help to inform the Government response.

We take note of the Committee's **recommendation (3.17)** that the Data Protection Act 1998 (DPA) should be the primary means of regulating human genetic databases. However, in their evidence to the Lords, the Office of the Data Protection Commissioner indicated that there was a question about whether personal genetic information was different and might require special treatment or even regulation by a separate body. Similar comments have been repeatedly made in response to our consultation set out in "Whose hands on your genes?". The now renamed Information Commissioner has responded to HGC with some concerns about how the DPA may fail to protect against inappropriate disclosure from a genetic database. We would therefore ask you to note that we are still considering our advice on this point.

We will also consider carefully **recommendation 7.56** for guidance to those who hold genetic information reminding them of their duties under the DPA in the light of our considerations above. There is a further element to this recommendation that proposes a record of whether patients had been informed of the use to which the genetic information might be put and any reservations that they may have. On this point we note the clear response from the MORI People's Panel survey (published in March) that new research should require fresh consent and also the general opposition to the idea of an "opt-out" from particular types of research.

We note too the Lord's recommendation for a Medical Data Panel **(paragraphs 7.58 –7.60)** to consider the secondary use of NHS data. Clearly this is considerably broader than the focus of our work on personal genetic information. We are uncertain at present how this might relate to the new Patient Information Advisory Group arising from the Health and Social Care Act 2001 or from reviews following the Alder Hey inquiry. It is also difficult to see at present how such a body would be able to adequately cover the range of roles presently done by research ethics committees and comply with existing legal duties such as the DPA.

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* "Human Genetic Databases: Challenges and Opportunities". Session 2000-01, 4 th report. HL Paper 57. Ordered to be printed 20 March 2001.

With regard to **recommendation 7.66**, we also are inclined support the calls for greater independent oversight of forensic DNA databases and samples. We note that the results of our public consultation reveal a very high level of support for the national forensic DNA database, especially in relation to the investigation of serious crime. We feel, however, that it is important to take into account the potential which independent oversight has to ensure that this public confidence be maintained. The Commission has discussed this matter in connection with the recent passage of the Criminal Justice and Police Bill. The Government appears to accept the need for a review of the arrangements for independent oversight of forensic DNA samples. In the debate in the Lords on the Criminal Justice and Police Bill, the Government gave an undertaking to consider the need for an independent body to hold the DNA samples. HGC have recently met Home Office and the Forensic Science Service experts to gather more evidence on forensic uses of DNA and will be discussing this again at its meeting on 25 June. The Commission feels that it should play an active role in the review of the oversight of forensic DNA samples; it would also wish to consider whether this oversight should extend to the use of genetic data stored on the database itself, as an incomplete oversight arrangement might not allay the strong misgivings which have been communicated to the Commission in the course of its consultation. We aim to consider this further in developing our report and recommendations on personal genetic information due by the end of the year.

The recommendations on patent rights and genes **(paragraphs 8.30 and 8.31)** are largely in accordance with the HGC's workplan (agreed by Ministers in May 2000) in which we propose taking evidence and holding a watching brief on patents. Patents and ownership arising from research are touched upon in our consultation on personal genetic information. We also recently met with members of the Nuffield Council on Bioethics and heard about their work on patenting in genomics and proteomics. It is our intention to consider the subject in more depth in the light of the Nuffield Council's report.

Our survey of the People's Panel, published in March, appears to show that people, especially younger people, were strongly against the ownership (presumably patenting) of genetic information. We can therefore see a role for the HGC in seeking a wider public understanding of the role of patents. In particular we see a need to look beyond the difficult debate about the "patenting of life" towards more practical aspects of gene patents and licensing.

Human Genetics Commission
13 June 2001

HGC's comments to inform the Government response to the House of Commons report on Genetics and Insurance

HGC welcomes the House of Commons Science and Technology Committee's report "Genetics and Insurance"* which has proved extremely valuable to us in our own review of the matter. Stemming from our considerations to date, HGC offers the following commentary on the wider issues covered in the House of Commons report which may help to inform the Government response.

The Commission published its advice on the use of genetic information in insurance on 1 May 2001. Our recommendations on a temporary moratorium broadly agree with the Science and Technology Committee's **recommendation 29**. Like them, we feel that this is a necessary step to restore confidence, to gather information and to look at some wider issues of the use of personal genetic information in insurance.

HGC agree with the Science and Technology Committee that legislation to deny insurers access to all genetic test results is not appropriate **(recommendation 28)**. But we differ from them in concluding that legislation will be necessary to enforce the moratorium. This will need to be new legislation if existing statutory provisions (such as financial service or consumer protection legislation) are deemed to be inappropriate.

We have also noted the Association of British Insurer's (ABI) amended voluntary moratorium announced on 1 May. There are clearly some differences of emphasis and detail in the various positions, but we hope that this will not distract the Government from the underlying principle in support of a wide-ranging moratorium.

HGC has also made recommendations about what should be done during the moratorium period. We therefore strongly agree with **recommendation 11** about the need to examine the use of family history information in setting insurance premiums. HGC will be considering this further and seeking additional expert advice in preparing our final report and recommendations on the use of personal genetic information.

HGC has joined the House of Commons **(recommendations 6 and 11)** in recommending that insurers give more information about how premiums are calculated, especially where family history information is being considered. It is our impression that the main principle underpinning private insurance contracts – "utmost good faith" bears more heavily on the applicant than on the insurer. There is also an increasing presumption across society in favour of greater openness and transparency and this area should not escape this shift of emphasis.

We would also agree with the Science and Technology Committee's call for more research **(recommendation 12)**. We would be interested to see whether such research needs will be considered as part of the recently announced Genetics Knowledge Parks or under the Economic and Social Research Council's programme for social research on genomics. We also believe that the insurance industry should continue to fund independent research on genetics. They should also encourage their member companies to consider publishing the results of their own research and analysis in peer-reviewed journals. This would add immeasurably to the knowledge of the real world

* "Genetics and Insurance". Session 2000-01, Fifth report. HC 174. Ordered to be printed 26 March 2001.

insurance market and would supplement the existing mathematical modelling techniques. The Commission has also funded a small survey by the Genetics Interest Group looking at experiences of obtaining insurance and we hope to have the completed report by the end of June.

The Commission has also proposed that it will consider mechanisms to provide access to affordable insurance **(recommendation 15)**. This point has been made to us repeatedly in our consultation. HGC wishes to work with experts in the insurance and actuarial profession and to consider further recommendations in this area in our final report

The Report makes a strong case for a review of the membership of the Genetics and Insurance Committee (GAIC; **recommendations 16 – 22**). HGC has previously commented on its relationship with GAIC and we would wish to be consulted on any review of GAIC as part of our remit to advise on the effectiveness of the regulatory and advisory framework. We believe that there is now an even greater need for such a committee as a means of drawing together expertise from among geneticists, patient/consumer groups and insurers. In our view, HGC has shown the benefits that can be obtained from a committee with a broad skills mix in a complex area such as this. In particular, we are convinced of the benefits of adopting a high degree of openness and transparency in order to involve and reassure the wider public.

HGC shares the House of Commons' concerns about the lack of evidence on compliance with the industry Code of Practice **(recommendation 24 & 25)**. We understand that compliance data will be available from the ABI in June and we may wish to comment further at that stage. There is some published evidence suggesting that those with a genetic predisposition to ill health can experience difficulties in obtaining insurance. Whilst we agree that GAIC can play a role here, we feel that the Government should also make use of new or existing statutory enforcement agencies in order to help to reassure the public that genetic test results are not being improperly used during the moratorium period.

We agree with **recommendation 31** on the need to monitor the developments in genetic testing and the wider implications. In June we will be holding a public meeting at the Sanger Centre in Cambridge to learn about technical developments in high volume genetic testing and the possible impact on a range of areas, especially insurance.

We do not know to what extent Ministers will expect HGC to conduct some of these wider reviews, and therefore precisely what additional resources we might need **(recommendation 32)**. Given the complexities of the subject and the need to inform and engage the public, we can already foresee a need to fund external expert advice, surveys and modelling as well as further public consultative meetings.

Human Genetics Commission
13 June 2001

Annex F: About HGC (role, terms of reference and work plan)

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 health care. Its remit is to give Ministers strategic advice on the "big picture" of human genetics, with a particular focus on social and ethical issues.

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. HGC does not direct these bodies or interfere with their lines of accountability, but works with them and help form links between them. 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 National Health Service (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;
  - 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;
  - 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.

2002 Work Plan

During the year we drew up a plan of work for 2002. This updated work plan, and a report summarising HGC's achievements against the objectives in its first work plan are on the website (hgc.gov.uk/business_work.htm). In updating the work plan HGC consulted a number of organisations and Government departments and the plan takes account of the comments received. Most who commented largely agreed with the priorities HGC had identified and Health and Science Ministers did make one significant request to reprioritise two items, resulting in HGC giving first priority to a review of the provision of genetic testing services direct to the public in the second half of 2002.

Achievements Against the 2000/2001 Work Plan

HGC assessed its achievements against the aims set out in the 2000/2001 work plan for its general approach and communication and public involvement aspects as well as against its proposals in the following five areas: NHS genetic services, genetic information, genetic testing, patents, and reproductive issues. The work plan also focused on co-ordination and exchange of information with relevant bodies while developing underlying strategic principles and providing advice to Ministers.

Work in 2002

Members discussed HGC's future work at several stages during the year, agreeing that it was important to allow adequate time to complete the report on personal genetic information and to take forward various associated actions. It was also felt to be important to continue to provide input to Government thinking on genetic services and the genetics Green Paper in the coming months. The most important 'new' issue for 2002 that HGC Members identified was to consider the broad social and ethical aspects of developments in reproductive choice and genetic screening. Members agreed that a review was needed of the Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public. It was also felt that future developments in pharmacogenetics and stem cell research and therapy could initially be considered by the Horizon-Scanning Sub-group. HGC agreed its work plan at its plenary meeting on 13 February 2002 and it was approved by Ministers later the same month.

In summary, HGC is proposing to focus on the following main activities in 2002:

- To publish a report on personal genetic information in spring 2002 and to provide further advice on some of the issues in the report, in particular: genetic testing and insurance (in 2002 and beyond); large genetic databases such as BioBank(UK); and the forensic use of DNA.
- To review arrangements for the provision of genetic testing services direct to the public and to make recommendations to Ministers by December 2002, including the need for any changes to the relevant advisory and regulatory framework.
- To feed its own strategic perspective into discussions on the development of genetic testing and services, in particular to ensure that social and ethical aspects are properly addressed in the context of emerging technical advances.
- To monitor the broad ethical, social and human rights aspects of developments in genetics in relation to reproductive issues and discuss these with the relevant bodies with a view to possible future in-depth consideration.
- To consider developments in pharmacogenetics, stem cell research and therapy, and gene patents.

In addition HGC will: build on its existing links with bodies in the regulatory and advisory framework for human genetics; continue to pursue a policy of openness and public involvement; and further develop its website.

ANNEX G: how HGC works (methods of working, code of practice, sub-groups)

Methods of working

A constant theme and priority within our work is to actively seek input from the public and other stakeholders and this will involve a variety of consultation exercises and open meetings.

We work in accordance with best practice principles on openness and transparency.

We are introducing a systematic approach to exchanging information with other bodies in the advisory and regulatory framework, including meetings at secretariat level and between chairs.

We have established sub-groups or panels which involve both Members and external participants, and which may co-opt input from individuals. These approaches could be used for carrying out specific projects, for overseeing areas of work, or to act as a standing technical resource. We may also adopt innovative approaches such as "virtual working groups".

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

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: hgc.gov.uk/about_approach.htm. The Chair, Vice-Chair, Members and Representatives of the Chief Medical Officers (CMOs) (collectively referred to as "Members") are expected to follow it in carrying out duties associated with HGC. Co-opted members are also expected to follow the Code as it applies to the work they do on behalf of HGC.

Sub-groups

HGC has a number of sub-groups, working-groups and a Business Committee, which focus on specific aspects of HGC's work, reporting back to the Commission at plenary meetings. Full details of these groups, their terms of reference and attributable minutes of meetings are on the website hgc.gov.uk/business_groups.htm.

Genetic Services Sub-group

Chair: Philip Webb
Members:
William Albert
Elizabeth Anionwu (from Dec 2001)
Robert Bestow
John Burn
Heather Draper
Frances Flinter
Hilary Harris
Peter Harper (from Dec 2001)
Patrick Morrison (from Dec 2001)
Ros Skinner (from Dec 2001)

Remit: To advise on genetic testing issues, including routine exchange of information with other relevant bodies, such as services provided direct to the public; strategic issues in the delivery of genetic services; new and evolving genetic testing and screening techniques; to provide guidance to Research Ethics Committees; to recommend HGC laboratory visits in relation to genetic testing.

The Subgroup **met** on the following dates:
3 December 2001
19 April 2002

Public Involvement Sub-group

Chair: Ruth Evans
Members:
Elizabeth Anionwu (until Dec 2001)
Jackie Axelby (until May 2002)
Harry Cayton
Alastair Kent (from Sept 2001)
Keith Palmer
John Polkinghorne
Martin Richards
Gillian Samuels
Geoffrey Watts

Remit: To advise on strategies for promoting debate and effective public and stakeholder consultation; to oversee HGC consultation exercises; to advise on education/information initiatives.

The Sub-group **met** on the following dates:
11 September 2001
10 December 2001
1 March 2002

Horizon-Scanning Sub-group

Chair: Veronica van Heyningen
Members:
Lesley Greene
John Harris
John James
Hilary Newiss
Bruce Ponder (until June 2001)
John Sulston (from July 2001)
Nigel Spurr
Kent Woods (until Jan 2002)

Remit: To take account of the work of existing bodies with a horizon-scanning role to identify and report back on the key issues for HGC to consider.

The Sub-group **met** on the following dates:
28 August 2001
30 April 2002

Working Group on the Storage, Protection and Use of Genetic Information

Chair: Sandy McCall Smith
Members:
Elaine Gadd
John Harris
Patrick Morrison
Hilary Newiss
John Polkinghorne
Martin Richards

Remit: To consult widely on the issues relating to the storage, protection and use of genetic information and draft a report making recommendations to Government on these issues.

The Group **met** on the following dates:
18 July 2001
4 September 2001
26 November 2001
15 January 2002
4 March 2002
14 March 2002
15 April 2002

Business Committee

Chair: Sandy McCall Smith
The committee has a rolling **membership**, currently:
Hilary Harris
Peter Harper
Hilary Newiss
Gill Samuels
Geoff Watts
Mr Philip Webb

Remit: To provide a responsive executive structure to allow HGC to react to developments quickly and involve the Membership as fully as possible.

The Committee **met** on the following dates:
14 June 2001
12 July 2001
11 October 2001
8 November 2001
13 December 2001
10 January 2002
11 April 2002

Annex H: Register of HGC Members' Interests

Members are asked to make a statement of any personal or business interest which, they consider members of the public might reasonably think, could influence the judgements they have to make as part of the activities of the HGC. This includes personal direct and indirect pecuniary interests and such interests of close family members and others living in the same household. Interests have been categorised under the following five headings: Remunerated employment, office, profession, etc; Remunerated directorships; Registrable shareholdings; Miscellaneous and unremunerated interests; Political activity. Headings have only been included for each person where there is an interest to declare.

Dr Bill Albert

Remunerated employment, office, profession, *etc*

Chair, Norfolk Coalition of Disabled People
Director, Nordat Limited, a disability awareness training organisation

Professor Elizabeth Anionwu

Remunerated employment, office, profession, *etc*

Professor of Nursing, Head of Mary Seacole Centre for Nursing Practice, Thames Valley University

Mrs Jackie Axelby

Remunerated employment, office, profession, *etc*

Chief Executive, Northern England Workforce Development Confederation

Dr Stephen Bain

Remunerated employment, office, profession, *etc*

Reader in Diabetic Medicine, University of Birmingham & Honorary
Consultant Physician, Birmingham Heartlands Hospital, Birmingham, UK

Miscellaneous and unremunerated interests

Member, 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.

Professor John Burn

Remunerated employment, office, profession, *etc*

Professor of Clinical Genetics, University of Newcastle (tenured chair, part funded by National Health Service)

Remunerated Directorships

Honorary Director, Imperial Cancer Research Fund, Clinical Cancer Genetics Network
Executive Chairman of Northgene (Identity testing) Limited, a small not-for-profit company providing a commercial paternity testing service

Miscellaneous and unremunerated interests

Director Northern Genetics Service, Newcastle NHS Hospitals Trust
Chair, Cancer Genetics Group of British Society of Human Genetics (formerly Cancer Family Study Group)
Member, Medical Advisory Board of Genetics Interest Group
Member, Ethics in Medicine Committee of Royal College of Physicians
Member, Scientific Committee of Royal College of Obstetricians & Gynaecologists

Ms Ruth Deech

Remunerated employment, office, profession, etc

Principal, St Anne's College, Oxford
Chairman, Human Fertilisation & Embryology Authority
Linnells solicitors (family)
Rhodes Trustee (family)

Registrable shareholdings
GlaxoSmithKline
Oxford Glycobiology
St Anne's College has shares in (amongst other companies):
London International
GP Glaxo
SmithKline Beecham
Zeneca GP
Nycomed Amersham

Miscellaneous and unremunerated interests
Member, United Oxford and Cambridge Club
Member, Royal Society of Art
Roll's Royce supports engineering at St Anne's College

Ms Ruth Evans
Miscellaneous and unremunerated interests
Lay member, General Medical Council
Non-executive Board Member, Financial Ombudsman
Non-executive Board Member, Liverpool Victoria Friendly Society

Dr Peter Harper
Remunerated employment, office, profession, *etc*
Professor of Medical Genetics, University of Wales College of Medicine, Cardiff

Dr Hilary Harris
Remunerated employment, office, profession, *etc*
General practitioner, Manchester

Professor John Harris
Remunerated employment, office, profession, *etc*
Sir David Alliance Professor of Bioethics, University of Manchester
Member, Data Safety Monitoring Board, Chiron Corporation

Baroness Helena Kennedy QC
Remunerated employment, office, profession, *etc*
Board Member, Independent Newspapers

Miscellaneous and unremunerated interests
Advisory Council Member of the Foreign Policy Centre
Member of the External Advisory Council, World Bank Institute
Patron, Charter 88
Patron, Liberty
President, Civil Liberties Trust
Trustee, KPMG Charitable Trust

Political activity
Labour Peer

Ms Suzi Leather
Remunerated employment, office, profession, etc
Chair, Human Embryology and Fertilisation Authority

Miscellaneous and unremunerated interests
Member, Christian Socialist Movement
Individual and executive Member, National Heart Forum
Member, Child Poverty Action Group
Trustee, Food Foundation
Member, Organophosphate Information Network
Advisor to the Maternity Alliance
Honorary Senior Lectureship, Department of Epidemiology & Population Health, London School of Hygiene & Tropical Medicine
Honorary Research Fellow, Department of Biological Sciences, University of Exeter

Political activity
Labour Party Member

Professor Alexander McCall Smith
Regististrable shareholdings
GlaxoSmithKline (family)

Miscellaneous and unremunerated interests
Chair, Independent Ethics Committee, The Roslin Institute
Occasional lectures at meetings supported by pharmaceutical and other companies.

Professor Patrick Morrison

Remunerated employment, office, profession, *etc*

Consultant in Clinical Genetics, Belfast City Hospital Trust (fully funded by National Health Service)
Postgraduate Tutor and Director of the Belfast Postgraduate Centre (funded by Northern Ireland Council for Postgraduate Medical and Dental Education)

Miscellaneous and unremunerated interests

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

Ms Hilary Newiss

None

Reverend Dr John Polkinghorne

None

Professor Martin Richards

Remunerated employment, office, profession, *etc*

Professor of Family Research, Centre for Family Research, University of Cambridge
Grants, Wellcome Foundation
Previous grants, Medical Research Council and Cancer Research Campaign
Member, Wellcome Trust Medicine in Society Panel

Registrable shareholdings

CGNU Ordinary CBPO. 25 shares (formerly Norwich Union)

Miscellaneous and unremunerated interests

Member, Friends of the Earth
Member, North Cumbria Community Genetics Project Ethics Committee
Adviser to Genetics Interest Group

Dr Gill Samuels

Remunerated employment, office, profession, *etc*

Senior Director Science Policy & Scientific Affairs, Europe, Pfizer Global Research and Development

Registrable shareholdings

Pfizer Inc

Miscellaneous and unremunerated interests

Member, Association of the British Pharmaceutical Industry R&D Committee
Member, Chemical Industries Association Science, Education and Technology Committee
Co-Chair, WHO/IFPMA Working Group on New Drugs for Neglected Infectious Diseases
Director, Babraham Institute (BBSRC)
Member, MS Society Science Policy Development Group
Member, UK Government Commission on Intellectual Property Rights
Member, European Research Advisory Board (EURAB) of DG III
Member, Science and Technology Advisory Group (STAC) of WHO's Tropical Diseases Research (TDR)

Dr Stephen Singleton

Remunerated employment, office, profession, *etc*

Medical Director, Northumberland and Tyne & Wear Health Authority

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*

Short term contract with the Wellcome Trust

Professor Veronica van Heyningen

Remunerated employment, office, profession, *etc*

Head of Cell Genetics Section, Medical Research Council, Human Genetics Unit, Edinburgh

Registrable shareholdings
GlaxoSmithKline
Unilever
Bernard Matthews (family)
Boots (family)
Diageo (family)
Elan Corp. (family)
ICI (family)
J Sainsbury (family)
Nycomed Amersham (family)
PPL Pharmaceuticals (family)
Zeneca (family)

Mr Geoff Watts

Remunerated employment, office, profession, *etc*
Journalism (writing and broadcasting), often requiring the collection of information on, the description of and the expression of opinions about topics in biology and medicine lying within the Commission's remit.
Sometimes chairs meetings and conferences, takes part in recorded discussion or acts as an occasional paid consultant to organisations which may have a commercial interest in some of the topics considered by the Commission. (No regular or continuing commitments of this kind.)

Mr Philip Webb

Remunerated employment, office, profession, *etc*
Self-employed Independent Business Advisor
Director, Hydroponic Herbs Ltd
Retired General Manager, AstraZeneca Diagnostics

Registrable shareholdings
AstraZeneca Group
Oxford Biomedica
Syngenta

Miscellaneous and unremunerated interests
Member of the Board of Trustees of the Genetic Interest Group
Chairman, Witney United Football Club

Register of Co-opted Members' Interests

Mr Robert Bestow (Genetic Services)

Remunerated employment, office, profession, *etc*
Director, Neurofibromatosis Association

Registrable shareholdings
Member of a club which holds shares in Astra-Zeneca and Aortech
(Purchase or disposal of shares is group decision)

Mr Harry Cayton (Public Involvement

Remunerated employment, office, profession, *etc*
Chief Executive, Alzheimer's Society
Director for Patient Experience and Public Involvement, Department of Health
Member, Ethics Board, Synigence PLC

Miscellaneous & unremunerated interests
Trustee, Hearing Research Trust (Defeating Deafness)
Member, Board, Alzheimer Europe
Member, Central Research & Development Committee for the NHS
Member, NHS Modernisation Board
Patron, Heritage Medical Centre, Hyderabad, India

Dr Heather Draper (Genetic Services)

Remunerated employment, office, profession, *etc*
Senior Lecturer, Centre for Biomedical Ethics, University of Birmingham
Occasionally paid for lectures on different aspects of medical ethics by eg hospitals, institutes of higher education and professional bodies such as the Association of Anaethetists

Miscellaneous and unremunerated interests
Member, Unrelated Live Transplantation Regulatory Authority (ULTRA)
Member, Advisory Committee on Ethics for the Assisted Conception Unit, Birmingham Women's Hospital
Member, Ethics Advisory Board of the UK Human Tissue Bank
Member, Local Ethical Review Process, Medical School Committee, University of Birmingham

Dr Frances Flinter (Genetic Services)

Remunerated employment, office, profession, *etc*

Senior Lecturer/Honorary Consultant in Clinical Genetics, King's College London (NHS funded)

Mrs Lesley Greene (Horizon-Scanning)

None

Mr John James (Horizon-Scanning)

Remunerated employment, office, profession, *etc*

Project Director for Health and Education Strategic Partnerships
Ex-Chief Executive, Kensington & Chelsea and Westminster Health Authority)

Miscellaneous & unremunerated interests

Carried out project to advise Chair and Chief Executive of the HFEA on the implications, if any, of the House of Lords Committee report on Stem Cells for the governance of the HFEA (2002)

Mr Alastair Kent (Public Involvement)

Remunerated employment, office, profession, *etc*

Director, Genetic Interest Group

Miscellaneous & unremunerated interests

Member, the Joint Committee on Medical Genetics
Member, the Public Engagement Committee of the West London Database (NHS)
Member, the Genetics Committee of the Association of British Insurers (ABI)
Member, the Genetic Commissioning Advisory Group (DH)
Member, 3 Regions Commissioning Group (NHS)
Member, Genetics Commissioning Group (London NHS)
Member, Orphan Medicinal Products Committee (EMEA)
Member, European Health Forum (EC)
Member, Progress Educational Trust Advisory Committee

Dr Keith Palmer (Public Involvement)

Registrable shareholdings

Portifolio of shares including:
GlaxoSmithKline

Dr Nigel Spurr (Horizon-Scanning)

Remunerated employment, office, profession, *etc*

Director, Discovery Genetics-US, GlaxoSmithKline Pharmaceuticals

Registrable shareholdings

GlaxoSmithKline

Professor Kent Woods (Horizon-Scanning)

Remunerated employment, office, profession, *etc*

Professor of Therapeutics, University of Leicester
Director, NHS Health Technology Assessment Programme

Registrable shareholdings

Glaxo Wellcome
SmithKline Beecham

Annex I: Finance

The Human Genetics Commission is funded by the Department of Health, supported by contributions from the Office of Science and Technology, Scottish Executive, Welsh Assembly Government and Northern Ireland Assembly.

Aside from the staff costs of the HGC Secretariat, the total budget for 2001/2 was £248,000. As was the case last year, a significan proportion of the budget was spent on working in an open way, with roughly:

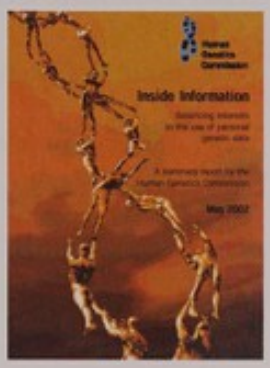
- £75,000 spent on plenary meetings and information gathering sessions, and
- £70,000 spent on external communications, including the Press Office and PR function and printing and publishing.

The rest of the costs were associated with running the Commission and its various activities, Sub-group and other meetings and maintaining the website. Fees are payable to Members at a rate of £138.66 per meeting, £172.56 per meeting for the Chair, and Members are reimbursed for all reasonable travelling expenses.

Annex J: Publications

The following publications are downlaodable from the HGC website (hgc.gov.uk/business_publications.htm) and in hard copy from the addresses stated.

Reports and Documents



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

We drew on a wide range of evidence during our review of personal genetic information, which is available on our website: hgc.gov.uk/insideinformation/

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

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

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

*Copies of these reports can be obtained by writing to:
PO Box 777
London
SE1 6XH

Or by faxing: 01623 724524
Or by emailing: doh@prolog.uk.com

'Outcome of the Public Consultation on Preimplantation Genetic Diagnosis' (November 2001) †

HGC Public Involvement Strategy (March 2002) †

Policy Statements

HGC comments to inform the Government response to the House of Lords report on Genetic Databases. June 2001†

HGC comments to inform Government response to the House of Commons report on Genetics and Insurance. June 2001†

HGC's interim recommendations on genetic testing and insurance. May 2001†

HGC's response to HFEA on the consultation on PGD. March 2001†

† these documents are downloadable from the website hgc.gov.uk/business_publications.htm

Newsletter

Copies of HGC News are downloadable from the website hgc.gov.uk/news/
you can resgister online to receive future editions or write to us to to receive copies by post


HGC News

This issue covers:

Public Involvement Strategy

What's new?

Our meetings in 2002

Tell us what you think

Also available on the website

HGC press noticeshgc.gov.uk/business_press.htm

HGC meeting papers hgc.gov.uk/papers/business_papers_list.htm

Human
Genetics
Commission

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It is also on our website on http://www.hgc.gov.uk/