



Human  
Genetics  
Commission

# Debating the ethical future of human genetics

**First Annual Report of the  
Human Genetics Commission**

**2001**

## Chair's introduction

### Who are we?

The Human Genetics Commission began its work during one of the most dramatic years in the history of genetics. With the publication of the map of the human genome, our understanding of our genetic heritage took a major step forward. But the potency of this new knowledge underlined the need for the careful consideration of the many ethical, social and legal issues which follow major advances in science. It is for this task that the HGC was created.



The work plan of the HGC was agreed with Ministers in May 2000. It was drawn up following a consultation exercise and public meeting asking people what they felt our priorities should be. Since then, we have been working on a number of issues of acute public interest, which are set out in this report. The report covers the first year of our work plan to May 2001. It also covers the period from December 1999, which was when we were first established, and looks forward to what we plan to do over the coming year.

One aspect of our work which is of the greatest importance is openness. At the very beginning of our existence we made the decision to conduct our business in public. This involves inviting the public to all main meetings and publishing on our website all agendas, minutes and key background material. It seems that this is working well, as the HGC has received very positive comments on this policy. Openness, however, is only the beginning: public involvement, to which we are equally committed, is another goal of the HGC. Any major decisions which we reach are taken after full consultation with the public. This is a lengthy and sometimes fairly expensive process, but it is one which I think must be an essential element in any modern policy-making process.

### What have we done?

We are very much aware of the range of issues which are posed by modern genetics. Many of these issues are of a profound philosophical nature, taking us to the heart of our idea of ourselves as humans. Others are more practical, being concerned with questions which require answers in the very near future. We have to make choices about what we address first and strike a balance between matters which need attention today, and developments or trends which need to be watched over the longer term. In this first year of our working, we have, in general, to deal with those issues over which most urgent public or governmental concern has been expressed. This does not mean that the "big questions" are being ignored; they are present in much of the work which we have been doing and are under constant review.

At the very outset, we had to organise ourselves. Our first meeting was an encounter of over twenty people who generally did not know one another and who had many differing ideas as to how we might proceed. After setting up Sub-groups to deal with specific areas, we identified what we thought were the most important matters confronting us. Prominent on this list was the question of personal genetic information and what we, as a society,

did with it. It seemed to us that this was the source of very grave public concern and that much of the public debate ultimately came back to this issue. For this reason, we decided to undertake an immediate examination of the issue, including an extensive public consultation. The full details of this exercise, which is now in its final stages, are set out later in this report.

Although our year entailed a great deal of background work, there were certain highlights which brought the HGC to public attention. These included:

- Commissioning and publication of our People's Panel survey of attitudes to personal genetic information carried out by MORI.
- Launching our consultation document, "*Whose hands on your genes?*". This took place at a meeting at the International Centre for Life in Newcastle in which the entire Commission engaged in face-to-face discussion with several hundred members of the public. This event appears to have been extremely successful.
- Our subsequent wide-ranging and comprehensive consultation on personal genetic information. This met with a good response, both from individuals and organisations.
- Our recommendations to Government on the use of genetic test results in insurance.

In addition to work on these matters, we addressed a range of specific issues that arose in the course of the period under review, or which we had inherited from earlier advisory bodies in this area. Some of these concerned other public bodies, such as the Human Fertilisation and Embryology Authority (HFEA), with whom we have worked on the production of a statement on preimplantation genetic diagnosis (genetic testing of IVF embryos). Other issues involved following, and commenting upon, developments in legislation, as in the case of changes in the statutory provisions affecting the forensic use of DNA, or the new regulations relating to the research use of confidential medical information.

Steering a course between conflicting views on these matters is a delicate task for a public commission that wishes to take an independent and balanced view. However, we have not avoided an issue simply because it is politically sensitive. We regard it as our responsibility to look very carefully at any ethical issue associated with the use of human DNA, as we know that the public, and the Government, wishes us to be frank in our advice. We regard this as being very important in maintaining the trust of the public.

The HGC is very much aware of its duty to participate in the public debate on genetics. This is a healthy and often controversial debate, which takes place at both a national and international level. The international dimension is crucial. Modern science is not parochial, and the ethical development of human genetics is now clearly an international question. To this end we have set out to talk to people doing similar work to ourselves in other countries. I spent several days in Washington, together with the Vice-Chair, Sandy McCall Smith, and the Secretary, Mark Bale, meeting our counterparts there and talking to a very wide range of experts. We have also participated in numerous conferences and meetings, in the United Kingdom and abroad, explaining the work of the Commission and listening to the views of others. These exchanges continue and we hope that these efforts will ensure

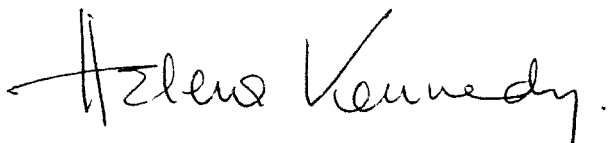
that the HGC continues to have a high profile in the international forum in which the ethical future of human genetics will be determined. In view of the major role which the United Kingdom plays in genetics, it is important that it has a strong voice in the debate on the broader issues of the subject.

At a national level, we have been particularly keen to talk to groups, both Government and non-government, who have an interest in human genetics. The HGC has therefore been represented at numerous events up and down the United Kingdom, including meetings organised by – amongst many others – the HFEA, the Disability Rights Commission, the Genetic Interest Group, and the UK Forum for Genetics and Insurance.

In my personal capacity as a member of the House of Lords I have also been able to participate in the discussion of some of these issues.

All of this has entailed a great deal of hard work by the members of the HGC and by the Secretariat. I should like to thank both these groups for their efforts, and for their continuing commitment to our task.

I should also like to thank all those who have taken the trouble to talk to us. Many people have put up with our questions and our probing, and have thus enabled us to form an idea of what people think about these often troublesome issues. Your help is much appreciated, and I hope that many of you will recognise in our reports and recommendations the influence of the views which you have expressed. Of course, you may disagree with some of our conclusions, but that is what a constructive moral conversation is all about.

A handwritten signature in black ink that reads "Helena Kennedy." The signature is written in a cursive, flowing style.

**Helena Kennedy**  
**Chair, Human Genetics Commission**



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## What people think about genetics

We need to know what people think about genetics, both about the ‘big’ issues in general and about specific issues in more detail. This year we set out to discover what people feel about the use of genetic information. These findings underpinned our subsequent work in this area.

### Survey of the People’s Panel

In July 2000 we commissioned MORI to carry out a detailed survey of people’s attitudes to human genetic information using the People’s Panel. This is a randomly recruited, nationally representative, group of 5,000 people selected from across the UK. For our survey, over 1,000 people were questioned in detailed face to face interviews. We also included two ethnic minority boosters, involving an additional 100 people interviewed in both of the groups Asian (or Asian British) and Black (or Black British). MORI and HGC members worked together in drawing up the survey questions, which were very broad in their scope.

The results of this study have given us valuable background information on what people think and have provided important pointers for where we go next. In general, people expressed an appreciation of the potential benefits of the use of human genetic information, even if many had significant reservations.

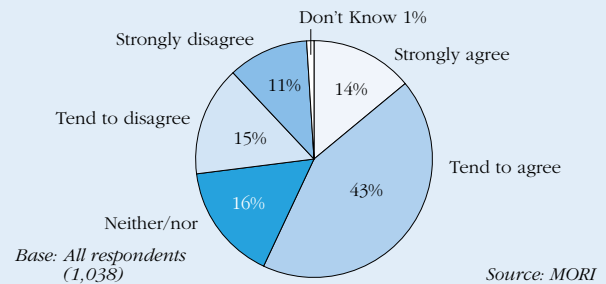
In particular, some are worried that developments in genetics might lead to discrimination or exploitation, and, in addition, they feel they are not as well informed as they would like to be. We feel this confirms the importance of establishing a set of basic principles in this area. These principles should cover matters such as the obtaining of consent to genetic testing, the maintenance of

## Results of the survey

These graphs are taken from the report of the People’s Panel survey “Public attitudes to human genetic information”:

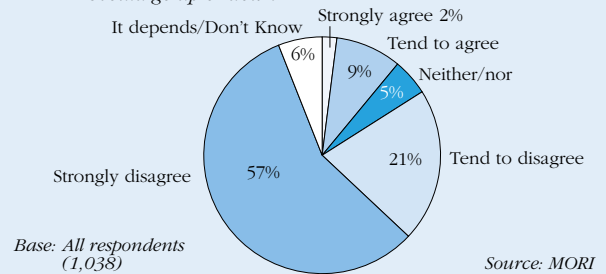
### Use of genetic testing

Q33 Please tell me to what extent you agree or disagree... Genetic information may be used by parents to decide if children with certain disabling conditions are born?



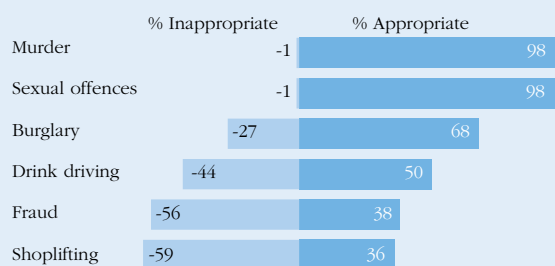
### Insurance premiums

Q46 To what extent do you agree or disagree with the following statement: ‘Insurance companies should be able to ask to see the results of genetic tests to assess whether premiums should go up or down’



### Access to genetic information by the Police

Q54-59 The Police can currently take DNA samples of anyone charged with any crime that may carry a prison sentence. Please tell me whether you think it is appropriate or inappropriate for the Police to take DNA samples for people charged with ...?



Copies of this report are available by writing to:  
Public attitudes to human genetic information  
PO Box 777  
London  
SE1 6XH  
Or by faxing: 01623 724524  
Or by emailing: doh@prolog.uk.com  
It is also on the HGC website: www.hgc.gov.uk/  
business\_publications.htm.

confidentiality, and the identification of appropriate uses of genetic information.

## Diversity of views

There is no such thing as a single public attitude to genetics. Views are influenced by many factors: age, gender, ethnicity, how much you know about genetics, strong religious beliefs and personal experience of genetic conditions. For instance:

- Nine out of ten agree developments in genetics should be used to cure diseases.
- One third feel that genetics research is tampering with nature/unethical.
- Most have little or no confidence that rules and regulations are keeping pace with new scientific developments.
- Women are more likely to think genetics research is tampering with nature, as are Asian people and those with strong religious beliefs.
- Black and Asian people are significantly less likely to trust police use of DNA databases.
- Older people (over 65) and Asian and Black people are more likely to think insurers and employers should see the results of genetic tests.

## What next?

The survey shows that people are very interested in genetic issues and we need to make sure they are properly engaged in any debate. Our aim is to hear from as wide a range of views as possible – those with specific concerns, those with personal experience and those with general views on the wider issues. We also recognise that those affected by genetic disorders are a priority group. So as well as continuing to hold public consultation events we are going to set up a Consultative Panel of those affected by genetic disorders (including carers, family members, etc) which we can consult regularly. This is a key piece of work for the immediate future.

## Public Involvement Sub-group

Setting up this Sub-group reflects how seriously HGC takes its commitment to proper public involvement.

We see this area as a priority. We are looking beyond traditional approaches and are exploring new ways to involve the public in our work. We have agreed we will hold meetings in the different parts of the UK and will hold events that will engage the public in different ways.

### Public Involvement Sub-group

**Chair:** Ruth Evans

**Members:**

Elizabeth Anionwu  
 Jackie Axelby  
 Harry Cayton  
 John Durant (until Oct 2000)  
 Keith Palmer  
 John Polkinghorne  
 Martin Richards  
 Gill Samuels  
 Geoff 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.

All of our work is based on principles of openness, accessibility and inclusiveness.

We do not believe that it is enough to engage in public education: we are interested in public engagement, which involves a dialogue between the HGC and those who wish to express views on the issues of genetics. This is not a simple process, and it will take a good deal of time and energy to work out a good system. We also want to look at the best ways of reaching a wider

section of the community.

We held public discussion events in April 2000, when we discussed the HGC work plan, and in November when we discussed genetic information (see page 4). We plan to hold large-scale meetings like this at least once a year.

Details of its membership and remit are given in Annex C and minutes of its meetings can be found on the HGC website: [www.hgc.gov.uk/business\\_groups.htm](http://www.hgc.gov.uk/business_groups.htm).

## Personal genetic information

### Starting the debate

We identified the storage, protection and use of personal genetic information as a key work area at our first meeting. This is a crucial subject which goes to the heart of some of the major ethical issues surrounding genetics. For this reason it seemed important to us to devote much of our time and effort at this stage to a careful laying of the groundwork in this area.

In November 2000 we launched our major consultation paper “*Whose hands on your genes?*” (WHOYG?). This was drawn up by a Working Group of HGC Members, chaired by Sandy McCall Smith (see Annex C). After a discussion of basic issues – such as the definition of genetic information – it went on to deal with issues such as consent and confidentiality in medicine and research, genetic databases (both for research and forensic purposes), and the use of genetic information in insurance and employment.

WHOYG? set out to do more than ask a series of questions about personal genetic information. It was our intention to start a public debate on these matters and so we attempted to set out the issues of principle. Some of these involve important individual rights, and the balancing of these rights against social and public health values.

This task is not always easy. For example, we raised the issue of the use of DNA in identifying those who have committed criminal offences. This is a controversial issue because while there are arguments in favour of comprehensive forensic DNA databases, doubts have been expressed to us about the civil liberties aspects of retaining the genetic profiles and samples of those who have been acquitted of criminal offences (or not charged).

### Issues raised in WHOYG?



The document included a ‘tick-box’ section for ease of reply and a Freepost address for responses. Electronic versions of the both parts were available on the HGC website. Key questions included:

- How different and special is genetic information compared to other types?
- Does it need special protection?
- Should there be controls on insurers’ access to your genetic information, and should there be controls on what they can do with it?
- Should your employer have a right to know if you are likely to get an inherited disease or disability? What if tests reveal that you may become a risk to colleagues or others in your place of work?
- Should the police take DNA samples from people suspected of murder? But what about drunken driving or fraud?
- Can the principle of confidentiality co exist with the making available of genetic information for long term research?

## Newcastle

In November 2000 the HGC went to Newcastle to launch the WHOYG? consultation and to talk to people directly about their views on genetic information.

The event was held at the International Centre for Life and had two discussion elements to it. During the afternoon we toured the Life Interactive World exhibition with groups of pupils from local schools and colleges. During the tour the students filled in a questionnaire, the results of which are summarised on the following page. We then watched a video presentation of *The Gift* (a programme from the Y Touring Theatre Company, which was funded by the Wellcome Trust), a thought-provoking film about genetic testing and the impact which genetic information may have within a family, and broke into smaller discussion groups to discuss the film and broader issues. We were particularly keen to hear from younger people and they responded in a very encouraging way. Over two hundred students and teachers from local schools and colleges took part and we are grateful to them.



We are also grateful to the numerous local people who gave up their Monday evening to come and talk to us. In this part of the event, John Burn, a member of HGC engaged in an entertaining and stimulating debate with Dr Tom Shakespeare of the Policy, Ethics and Life Sciences Research Institute. After this discussion we again split

into groups to discuss these issues with members of the public. We list below some of the views expressed in these discussions.

### Summary of group discussions

- Several groups expressed concerns about the development of a new form of underclass, with distinctions being made between the affected and the 'clear' population. This could develop further such that a refusal to provide genetic information is taken to imply you have something to hide. Some groups felt that people wanted to stick together and to not isolate individuals (which genetic screening would do). Some stressed that people were more than just their genes.
- A number of groups mentioned the importance of trust in general and some said they distrusted certain groups – the scientific community, insurers, doctors, Government, employers, police. One group felt it didn't have sufficient influence over, or knowledge of, the issues and another felt the public needed a wider knowledge of genetics to make an informed decision.

A fuller report of the discussion is given in Annex D.

This event seems to have been well received, with 98% who filled in the evaluation form saying it was excellent or good and 100% saying we should do it again. We also had some positive and useful feedback, and were pleased to hear, for example *“if other major societal issues had been given such a forum in the past far fewer ‘mistakes’ would have been made! Good luck to the Human Genetics Commission”* and *“round table format much more conducive to discussion than the lecture theatre in London.”*



### Results of Choices questionnaire

The Choices exhibit of the Life Interactive World included a questionnaire covering some of the same issues as the HGC’s consultation on human genetic information. Many of the students and teachers who visited the exhibits completed the questionnaire (175 responses). Annex D gives the total responses and a breakdown by age and gender. Most respondents (78%) were aged 18 and under, and of these

65% (103) were female. The sub-groups identified in the Annex do not include large enough numbers of people to allow any statistically significant comparisons between them. They do provide interesting information nonetheless. The results are summarised here:

- There is general support for a police DNA database – over half (54%) agree that the police should hold information on everyone’s DNA to reduce crime, although only 21% of the over-18 age group agree.
- There is a less-clear picture when it comes to whether or not people think genetic screening discriminates against disabled people – 39% are not sure and 38% agree that it does. Views are also fairly evenly split on whether or not genetic screening is the start of a slippery slope towards creating a super-race – 38% agree and 35% disagree.
- In total 41% disagree that doctors should decide what tests should be available (and 27% agree) – 34% of the female 18 and under age group agree but only 17% of the males in this group agree. 47% think that genetic screening is good because it reduces suffering, rising to 68% in the over 18 group.

### What we found

The consultation period ended on 23 March 2001 and we received over 250 responses. Of these, 181 were tick-box responses to the 'fold out' section (32 of these included some additional text comments); and 87 were detailed comments on the main document and questions (64 from organisations and 23 from individuals).

Many organisations and individuals provided detailed and considered responses to some or all of the issues raised in *"Whose hands on your genes?"* The challenge facing the Commission has been how to do justice to these responses and the additional information that many have drawn to our attention. In some cases we have been able to consider some topics – genetics and insurance, for instance – in some depth. We have now turned our attention to the bulk of the discussion document and the responses on medical practice, research and the uses of genetic information in the wider context. The intention is to publish a report and recommendations for Ministers by the end of 2001.

The majority of the work will be done by the Working Group, but it will be important to discuss the initial analysis of the responses and draft reports at the main HGC meetings in June and September. The tick-box responses were analysed and full details will be included in the final report.

Of the 36 people who filled in the evaluation form about the consultation document, 90% said they felt we presented the consultation in an unbiased way and 85% agreed that they had had sufficient time and background information to allow them to respond.

### What people said about our consultation process

#### *"Whose hands on your genes?"*

*"The content of this document raised some very important issues, which initiated a thought-provoking debate amongst members."*

*"Could have been more discussion of the relevant professional and organisational controls."*

*"...commends the Human Genetics Commission (HGC) on the clarity and thoughtfulness of its Consultative document ... we believe the measured and balanced approach of the HGC will be of great assistance."*

*"The questions in this [genetic testing] section focus too narrowly on detail rather than stepping back to examine basic principles."*

*"...it acts as a substantive overview of the genetic issues of the day."*

*"Thank you for encouraging the public to comment on this document."*

#### **Newcastle meeting**

*"I was profoundly impressed by the HGC turnout and the desire of members to listen to what was being said. It was an exercise in education and consultation, the like of which I have never before attended."*

*"I think that the event could have been longer – many issues were raised however there was little time to talk in depth."*

## Genetic testing and insurance

The use by insurance companies of genetic test results was the subject of considerable public debate during the first year of the HGC's existence. Tests currently exist for a small number of rare genetic disorders. We gave this priority in our work plan following a request from the Government that we address the issue. We held a public information gathering day in February. We subsequently wrote to a range of insurers and industry experts seeking additional information. Some HGC members also attended a workshop on genetics and insurance organised by the Genetic Interest Group (GIG) to advise the Association of British Insurers on research needs. A report of the workshop is available from GIG.

At the same time, the House of Commons Science and Technology Select Committee carried out an investigation into the matter and issued a report on the subject in April 2001. Shortly thereafter, at a special meeting of the whole Commission, the HGC decided to recommend to Government that there be a moratorium on the use of adverse genetic test result information by insurance companies. This was to apply to policies up to the figure of £500,000.

Our recommendations are given in full in Annex E.

The decision to recommend a moratorium was made against a background of considerable public disquiet over the role of genetic test results in insurance decisions. The survey of attitudes to personal genetic information – discussed at greater length at page 1 of this report – made it clear that there was widespread opposition to the use of genetic test result information by insurers.

### Information gathering day on genetics and insurance

**Royal Commonwealth Club,  
London, February 2001**

An audience of around 100 people, including the Commission and officials, experts and interested parties and the wider public, attended this event.

The day consisted of a morning of presentations and questions covering the various sides of the issue, followed by an afternoon discussion session involving all those present.

#### Summary of discussion

Presentations and discussion highlighted the different perspectives of those on all sides of the debate. There were strongly held objections to the use of genetic information in insurance – including moral concerns about unfair genetic discrimination and the disproportionate impact on a few affected individuals and families.

There were also concerns about the impact on health care and research should people decline genetic testing because of fears about insurance.

In a clinical context there were concerns about the impact on relationships between patients and GPs, the nature of the primary care record and the willingness of affected families and others to participate in research (including carers, family members etc).

The insurance industry was sympathetic to these concerns and emphasised a willingness to control the use of such information, preferably by the continuation and improvement in their system of voluntary self-regulation.

A full report of the day is available on the HGC website: [www.hgc.gov.uk/business\\_meetings\\_09february.htm](http://www.hgc.gov.uk/business_meetings_09february.htm).

The majority of responses to our consultation have revealed similar concerns.

The HGC did not take the decision to recommend a moratorium simply on the basis of public hostility to insurance practice in this area. It investigated the many different aspects of this question, and went to some lengths to ascertain the arguments on either side. At the end of the day, the view was taken that the doubts expressed by the House of Commons Committee accorded with the doubts that were emerging in the Commission itself and that there appeared to be enough evidence to conclude that the present practice of the insurance industry did not provide a sufficiently robust system of protection against arbitrary or inconsistent decisions. For this reason we thought it best to allow for a period of further investigation of alternatives in a climate in which the public would not feel threatened by the possibility of the inappropriate use of genetic test results.

We recognise that this issue gives rise to major social, economic and legal questions. All of these will require to be addressed with great care. It is particularly important that we maintain public confidence in genetic testing for clinical and medical research purposes. The public must be confident that they will not be disadvantaged in some way by agreeing to have a DNA test. This was a major factor in our decision to recommend a moratorium.

## **The move towards a moratorium**

*“The best way forward ... would be a voluntary moratorium on the use of all positive genetic test results by insurers for at least the next two years.”*

(House of Commons report on Genetics and Insurance 26/01/01)

*“...the Government will look sympathetically at any proposals to prevent the inappropriate use of genetic information for insurance purposes, including legislation if necessary. If the Human Genetics Commission recommends a temporary moratorium on the use of genetic tests by the insurance industry then we will pursue it.”*

(Secretary of State for Health, Alan Milburn, 19/04/01)

*“Insurers confirm decision to extend moratorium on use of genetic test results ... The industry recognises the depth of public concern about society’s use of genetic information and is keen to ensure that discussion about the fundamental principles should take place calmly and on a consensual basis.”*

(Association of British Insurers 01/05/01)

*“Alzheimer’s Society welcomes no nonsense assurance from Human Genetics Commission.”*

(Alzheimer’s Society 01/05/01)

*“Breakthrough welcomes genetics and insurance recommendations.”*

(Breakthrough Breast Cancer 01/05/01)

## Preimplantation Genetic Diagnosis

Preimplantation genetic diagnosis (PGD), the genetic testing of IVF embryos, was another issue that we discussed in detail this year. In November 1999 the HFEA and the Advisory Committee on Genetic Testing published a joint consultation on this issue and what controls and guidance should be put in place.

A Joint Working Party of HFEA and HGC members was set up in December 2000 to look at preimplantation genetic diagnosis (see Annex C). Its remit was to make recommendations on: the HFEA's licensing of such diagnosis; guidance on when it should be offered; and a joint public response on the outcome of the consultation. Our Genetic Testing Sub-group spent two of its four meetings in 2000/01 discussing aspects of this issue and the outcome of the consultation. This resulted in an agreed HGC statement on its benefits and limitations (see Annex F).

In summary, we felt that the consultation suggested that there was support in the community for using this technique, but many respondents also expressed reservations about its use. It has been necessary to adopt a position between an outright ban on the use of PGD and total freedom to use it for any and all reasons. Accordingly, we strongly recommended that the use of PGD should be limited to **specific and serious conditions**, with careful consideration given to the information given to parents.

The Joint Working Party is now in the process of finalising its recommendations which will be put to the HFEA and HGC later this year. A formal response to the consultation exercise will also be published shortly.

### Genetic Testing Sub-group

The Genetic Testing Sub-group inherited a number of ongoing commitments from a predecessor body the Advisory Committee on Genetic Testing and these have set the agenda for much of its work during the period of this report. Preimplantation genetic diagnosis has dominated its discussions this year.

The Advisory Committee on Genetic Testing had previously prepared a report on prenatal genetic testing, testing offered to pregnant women, with the aim of raising standards and offering practical guidance. This had been

issued for consultation before HGC was established and the Sub-group discussed the outcome of the consultation. We felt we needed to look at the wider social and ethical issues, but interim guidance should be issued to the NHS, possibly through the Department of Health.

HGC visited the regional genetics services laboratories in Newcastle in November. In February the Sub-group welcomed Dr Allison Streetly, who spoke on the National Haemoglobinopathy

#### Genetic Testing Sub-group

**Chair:** Philip Webb

**Members:**

Bill Albert  
Bob Bestow  
John Burn  
Heather Draper  
Frances Flinter  
Hilary Harris

**Remit:** To advise on genetic testing issues, including services provided direct to the public and new and evolving genetic tests; to provide guidance to Research Ethics Committees; to recommend HGC laboratory visits in relation to genetic testing.

Screening Programme.

Details of its membership and remit are given in Annex C and minutes of its meetings can be found on the HGC website:  
[www.hgc.gov.uk/business\\_groups.htm](http://www.hgc.gov.uk/business_groups.htm).

## What the future holds

A number of forward-looking UK reports covering human genetics emerged over the period of this report (referenced in Annex H). The Horizon-Scanning Sub-group took note of these when considering the issues on which HGC and the Sub-group might wish to focus in future. The following are some of the issues, with varying ethical and technological content:

### **New testing and sequencing technologies:**

for example gene chips, will radically alter the capacity and scope of genetic testing, but which raise ethical, legal and social concerns.

### **Susceptibility to common disorders:**

appropriate use of large population databases to look at the interaction between genetic, environmental and lifestyle risk factors.

**Genetic screening:** growing opportunities for preventive screening, but requiring broad social and economic analysis of impacts.

**Pharmacogenetics:** screening to decide the best drug for treatment is almost ready for initial testing.

**Reproductive choice:** will be affected by developments in the ease and range of genetic testing and the social and ethical implications.

**Stem cell research:** some aspects involve the use of embryonic materials and are controlled by HFEA. But HGC is also concerned about non-embryonic aspects of stem cell work.

**The regulatory framework:** need to keep UK, EU and global regulations under review, including i.p.r, patenting and commercial exploitation.

**Research in behavioural genetics:** its scientific validity and the ethical, social, legal and practical implications.

## Horizon-Scanning Sub-group

It was recognised when HGC was established that it would need a mechanism to help it to keep abreast of developments of broad significance to its work. We set up the Horizon-Scanning Sub-group to fulfil this role (see Annex C), whilst conscious that there were already a number of existing bodies considering future developments in human genetics from a UK perspective. The Sub-group was therefore asked to consider important new developments, taking account of existing work, and to identify the key issues for HGC.

### **Horizon-Scanning Sub-group**

**Chair:** Veronica van Heyningen

**Members:**  
Lesley Greene  
John Harris  
John James  
Hilary Newiss  
Bruce Ponder  
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.

This Sub-group got off to a later start than the other Sub-groups and in the period up to May 2001 it met twice.

At these meetings Members discussed:

- the scope of the Sub-group's remit (interpreted broadly);
- whether its primary focus should be on the nearer or longer term future (or a bit of both);
- the horizon-scanning activities of other bodies in the UK and

internationally and how best to take account of them; and

- the key issues that would eventually be included in a report to HGC at the time it considered its future work plan in September 2001.

Details of its membership and remit are given in Annex C and minutes of meetings can be found on the HGC website:

[www.hgc.gov.uk/business\\_groups.htm](http://www.hgc.gov.uk/business_groups.htm).

## Work plan 2002

Our first work plan was based on the outcome of a consultation exercise held in March and April 2000. The consultation took two different forms – a public consultative meeting involving presentations and a consultation document (paper and web-based). Both of these asked people about the priority issues we had identified for our work. This useful exercise identified genetic testing, the storage and use of genetic information and the provision of NHS genetic services as particularly important areas of public interest and concern. A summary of the final agreed work plan is given in Annex B.

The work plan consultation also helped us identify the key areas of work that determined the Sub-groups we established: encouraging public debate; horizon-scanning; and reviewing the use of genetic testing. It also highlighted what people thought about the ways in which we should work, especially the importance of genuine public involvement in our decision-making process, of openness and of having a balanced focus between horizon-scanning and current issues.

We feel that we have made good progress, and have covered a lot in our first year, but recognise that there is much still to do. The pressing nature of some of our work, on insurance for example, has meant we have not had time to look at other important areas. But we have not lost sight of these issues. Many people have suggested that we should consider gene patents. While we are conscious of the importance of this issue, we are aware of the fact that the patent debate is one that crosses many conceptual frontiers and is principally a matter of policy within intellectual property law and international trade law. The HGC, with its relatively limited resources, has had to make choices as to priorities and we have decided to concentrate in the first instance on those areas where our guidance is most urgently required. We shall continue to keep the patent issue under review at those points at which it is relevant to our work.

We are considering our next work plan and will be discussing this later on in the year, but we are keen to know what people see as priority issues for our future work. Several issues have emerged as possible areas for inclusion, including:

- Continuing work on aspects of the use of personal genetic information (eg genetic testing and insurance, consent following on from the *'Whose hands on your genes?'* consultation and HGC's future report).
- Genetics and reproductive choice (eg following on from work on PND).
- Predictive genetic screening of individuals.
- Research involving stem cells.
- Ownership, intellectual property rights and patenting.
- Large population databases and susceptibility to common disorders.
- Pharmacogenetics.

These are suggestions only and are not intended to be a comprehensive or prioritised list. We are interested in views on the relative importance of these and other issues, and of HGC's possible role in taking forward work in these areas.

## Out and about

One of our roles is to build links with key organisations and we have had many useful meetings with a range of organisations and individuals. There are too many to cover in detail in this report, but details of some are given here.

Members of HGC and the Secretariat met the **Information Commissioner** and members of her Office in February 2001. During a useful meeting we learned about the role and scope of the Information Commission (IC) and the relevant legislation. Genetic information may or may not fall into the category of sensitive data, depending on how it was obtained, eg in a medical research rather than a clinical context, and whether it refers to physical or mental health condition. The IC highlighted the need to obtain consent, tell people how data was processed and to be clear and transparent at all times.

Members had an interesting discussion with **MRC/Wellcome Trust** in March 2001 about the Population Biomedical Collection. We agreed the need for further exploration of certain key issues, including: the need to respond to public perception and communication issues; recruitment issues such as GP's time, consent, and counselling skills; the extent of any feedback to participants; and commercial access and involvement and intellectual property rights.

Helena Kennedy, Sandy McCall Smith and Mark Bale visited **Washington DC**, in April 2001 to make contact with our equivalents in the US and to explore the approach to genetics and insurance and to forensic uses of DNA. We met with some of the main bodies that cover ethical and legal aspects of human genetics and medicine, such as the Secretary's Advisory Group on Genetic Testing, the National Bioethics Advisory Commission, and the National Human Genome Research Institute at the National Institutes of Health. We also held useful meetings with the American Association for the Advancement of Science (AAAS), industry (Celera Genomics, the Pharmaceutical Research & Manufacturers Association) and patient support groups (the Alliance of Genetic Support Groups). Specific discussions on genetics and insurance were held with the American Council of Life Insurers as well as representatives of Congress promoting a Genetic Non-discrimination Bill. Discussions on forensic uses of DNA were held with the FBI, the National Institute of Justice and the American Civil Liberties Union.

Helena Kennedy held a meeting with Professor Malcolm Grant and Ms Julie Hill, the Chair and Vice-Chair, respectively, of the **Agriculture and Environmental Biotechnology Commission** (AEBC, HGC's sister Commission) to discuss respective priorities and the approach taken to openness and transparency. The Secretariats of the two Commissions hold liaison meetings.

Members have also spoken at and attended many interesting events, and held useful meetings with many other organisations, for example with the Dutch Platform for Biotechnology, the HFEA, the National Screening Committee, the Nuffield Council on Bioethics, the UK Council on Deafness and the Patients Forum to name a few.

## Keeping in touch

We are always interested to hear from people, so why not tell us what you think about:

- what we have done so far;
- what we should do next; or
- any of the issues in this report.

### How?

HGC Secretariat:

e-mail: [hgc@doh.gsi.gov.uk](mailto:hgc@doh.gsi.gov.uk)

address: Human Genetics Commission  
652C Skipton House  
80, London Road  
London SE1 6LH

phone: 020 7972 1518

fax: 020 7972 1717

HGC Press Office:

phone: 020 7838 4897

e-mail: [hgc@westminster.com](mailto:hgc@westminster.com)

### Find out more

To find out more about the HGC please visit our **website**:  
[www.hgc.gov.uk](http://www.hgc.gov.uk)



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:  
[www.hgc.gov.uk/about\\_contactus1.htm](http://www.hgc.gov.uk/about_contactus1.htm)

Full details of HGC publications are given in Annex H.



## 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

##### **Professor John Burn**

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

##### **Professor John Durant (until October 2000)**

Head of Science and Communication at the Science Museum, London and Professor of  
Public Understanding, University of London

##### **Ms Ruth Evans**

Formerly Director of the National Consumer Council

##### **Professor Peter Goodfellow**

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**

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**

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

**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**

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)**

Chief Executive, Northumberland Health Authority

**Professor Peter Harper (Wales) (from September 2000)**

Professor and consultant in medical genetics, University of Wales

**Professor Norman Nevin (Northern Ireland) (until December 2000)**

Professor of Clinical Genetics at Belfast City Hospital

**Dr Patrick Morrison (Northern Ireland) (from December 2000)**

Consultant clinical geneticist, Belfast City Hospital

**Dr Rosalind Skinner (Scotland)**

Principal Medical Officer of Public Health Medical Division, SEHD

### ***Co-opted Members of Sub-groups***

**Mr Bob Bestow** (Co-opted Member, Genetic Testing 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 Testing Sub-group)  
Senior Lecturer, Centre for Biomedical Ethics, University of Birmingham

**Dr Frances Flinter** (Co-opted Member, Genetic Testing 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

**Professor 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)  
Director, NHS Health Technology Assessment Programme

### ***Secretariat***

Dr Mark Bale, Secretary (from September 2000)

Dr Manny Chandra (from March 2000)

Dr David Coles, Secretary (until September 2000)

Mr Richard Pitts

Mrs Margaret Straughan

Ms Emma Wilbraham (from June 2000)

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

HGC Secretariat:

e-mail: [hgc@doh.gsi.gov.uk](mailto:hgc@doh.gsi.gov.uk)

address: Human Genetics Commission  
652C Skipton House  
80, London Road  
London SE1 6LH

phone: 020 7972 1518

fax: 020 7972 1717

HGC Press Office:

phone: 020 7838 4897

e-mail: [hgc@westminster.com](mailto:hgc@westminster.com)

### ***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

#### **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

#### **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  
Rolls Royce supports engineering at St Anne's College

**Professor John Durant (until October 2000)****Remunerated employment, office, profession, etc**

Head of Science and Communication at the Science Museum, London and Professor of Public Understanding of Science, University of London

The Science Museum receives grants and sponsorships from a number of companies which include:

Aventis  
Glaxo Wellcome  
Pfizer  
SmithKline Beecham

In addition, the following non-commercial bodies provide funding:

Action Research  
British Diabetic Association  
British Heart Foundation  
Engineering and Physical Sciences Research Council  
Medical Research Council  
Multiple Sclerosis Society  
Wellcome Trust

**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

**Professor Peter Goodfellow**

**Remunerated employment, office, profession, etc**

Senior Vice-President, Discovery Research, GlaxoSmithKline  
Pharmaceuticals

**Registrable shareholdings**

Celera Pharmaceuticals  
GlaxoSmithKline

**Miscellaneous and unremunerated interests**

Trustee, Imperial Cancer Research Fund

**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**

**Miscellaneous and unremunerated interests**

President, Civil Liberties Trust

**Professor Alexander McCall Smith**

**Registrable shareholdings**

GlaxoSmithKline (family)

**Ms Hilary Newiss**

None

**Reverend Dr John Polkinghorne**

None

**Professor Bruce Ponder**

**Remunerated employment, office, profession, etc**

Professor and Head of Department of Oncology, Cambridge University  
Grants, Cancer Research Campaign, Medical Research Council, European Community  
Member, KuDos Scientific Advisory Board  
Member, Scientific Committee, Cancer Research Campaign  
Member, DNA Sciences Scientific Advisory Board  
Consultant, Onyx Pharmaceuticals  
Non-executive Director, 3i Biosciences Investment Trust

**Registrable shareholdings**

Share options, Onyx Pharmaceuticals

**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 of Science Policy and 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 IPR Commission

### **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

### **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  
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 Bob Bestow** (Genetic Testing)

None

**Mr Harry Cayton** (Public Involvement)**Remunerated employment, office, profession, etc**

Chief Executive, Alzheimer's Society  
Member, Board of Governors, Synergence plc

**Miscellaneous & unremunerated interests**

Trustee, Hearing Research Trust (Defeating Deafness)  
Member, Board, Alzheimer Europe  
Member, Central Research & Development Committee for the NHS  
Member, Department of Health CJD Experts Group  
Member, NHS Modernisation Board  
Patron, Heritage Medical Centre, Hyderabad, India

**Dr Heather Draper** (Genetic Testing)**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 Anaesthetists

**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 for the UK Human Tissue Bank  
Member, Local Ethical Review Process Medical School Committee, University of Birmingham

**Dr Frances Flinter** (Genetic Testing)

**Remunerated employment, officed, 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**

Chief Executive, Kensington & Chelsea and Westminster Health Authority

**Dr Keith Palmer** (Public Involvement)

**Registrable shareholdings**

Portfolio of shares including:  
GlaxoSmithKline

**Dr Nigel Spurr** (Horizon-Scanning)

**Remunerated employment, office, profession, etc**

Director, US Discovery Genetics, GlaxoSmithKline

**Registrable shareholdings**

GlaxoSmithKline

**Professor Kent Woods** (Horizon-Scanning)

**Remunerated employment, office, profession, etc**

Consultant physician, University of Leicester Hospitals NHS Trust  
Professor of Therapeutics, University of Leicester  
Director, NHS Health Technology Assessment Programme

**Registrable shareholdings**

Nycomed Amersham  
GlaxoSmithKline  
Legal & General

## ANNEX B: About HGC

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.

### Origin

HGC was established following a comprehensive review in May 1999 by the UK Government of the regulatory and advisory framework for biotechnology. This concluded that the system for regulating individual products and processes operated satisfactorily but the advisory framework needed to:

- be more transparent, in order to gain public and professional confidence;
- be more streamlined, in order to avoid gaps, overlaps and fragmentation;
- ensure capacity to deal with rapid developments, and to take broad social and ethical issues fully into account.

HGC was set up to take forward these issues in the field of human genetics. The Foods Standards Agency (FSA) has similar responsibilities for GM foods, and the Agriculture and Environment Biotechnology Commission (AEBC) has responsibility for all other areas of biotechnology. The UK Government's Genetic Modification Issues website provides key policy messages and links to other Government GM-related sites.

As part of streamlining the framework, three advisory human genetics committees were wound up and their responsibilities passed to HGC. These are: the Advisory Committee on Genetic Testing, the Advisory Group on Scientific Advances in Genetics and the Human Genetics Advisory Commission. As a result, HGC has taken forward the work initiated by these bodies and built this into its initial work plan.

HGC's role should also be seen in the context of other advisory and regulatory bodies in the regulatory and advisory 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. Finally, HGC needs to work 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.

### **HGC's relationship to Government**

Advances in human genetics are being made at a rapid rate. This rate may increase considerably following publication of the first sequence of the human genome in 2000.

In response to this, the Government needs to:

- ensure an effective strategic advisory and regulatory structure that identifies and maximises benefits from potential advances in human genetics;
- address broad ethical, legal and social implications arising from advances; and
- manage the process of change as practical applications of advances are introduced, especially in the NHS.

To achieve this, the Government will need advice from a variety of sources. HGC will have a strategic role as one independent source of advice.

### **2000/2001 Work Plan**

The work plan was agreed by HGC members at their meeting on 18 May 2000, and was approved by Ministers. It was drawn up following discussions within HGC and was based on the outcome of a consultation exercise held in March and April 2000. The consultation exercise identified genetic testing, the storage and use of genetic information and the provision of NHS genetic services as particularly important areas of public interest and concern. Our work programme focuses on co-ordination and exchange of information with relevant bodies while developing the underlying strategic principles and providing advice to Ministers. The plan outlines areas for HGC's consideration and identifies the main issues, current work in progress and the HGC's intended work in these areas. The full work plan is on the HGC website [www.hgc.gov.uk/business\\_work.htm](http://www.hgc.gov.uk/business_work.htm) and, in summary, covered the following:

- **Genetic information**

This was agreed as a broad and important area underpinning much of HGC's work and was therefore a priority for its first year. HGC would maintain links with the existing Genetics and Insurance Committee (GAIC) and set up a Working Group to consider this area in detail. HGC would report its findings to Ministers.

- **NHS genetic services**

HGC did not plan to initiate additional work in this area but would monitor and review developments in the Department of Health and the NHS.

- **Genetic testing**

HGC would set up a Genetics Testing Sub-group to monitor developments in genetic testing, including over the counter tests, reviewing guidance and advising on the need for future work.

- **Patents**

HGC would seek to clarify and inform the public on the legal position on patents encompassing human gene sequences and will monitor the application of ethical and social responsibility clauses in the European Patent directive.

- **Reproductive issues**

HGC would maintain links with the Human Fertilisation and Embryology Authority and monitor developments to identify and address any issues that fall outside the HFEA's statutory remit. HGC would encourage public debate on issues related to reproductive choice.

## ANNEX C: How HGC works

### 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 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: [www.hgc.gov.uk/about\\_approach.htm](http://www.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.

### The Sub-groups

**The Genetic Testing Sub-group** (established May 2000)

#### *Terms of reference*

1. To keep under review and advise the Commission of new issues and developments in the following areas:
  - Human genetic testing services supplied direct to the public;
  - Significant new and evolving genetic tests; and
  - Guidance and advice to Research Ethics Committees (LRECs and MRECs) on the issues to consider in the ethical review of medical research involving genetic testing.
2. To receive and consider the approval of applications for ‘direct to the public’ genetic tests.
3. To make recommendations for visits of the Commission to laboratories or events in relation to genetic testing.
4. To prepare draft documents and reports to the Commission as required and contribute to the drafting and analysis of consultation documents and responses in relation to genetic testing.

## ***Members***

**Mr Philip Webb** (Chair, HGC Member)

Member of Board of Trustees of Genetics Interest Group (GIG)

**Dr Bill Albert** (HGC Member)

Chair of the Norfolk Coalition of Disabled People

**Mr Bob Bestow** (Co-opted Member)

Director, NF (Neurofibromatosis) Association

**Professor John Burn** (HGC Member)

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

**Dr Heather Draper** (Co-opted Member)

Senior Lecturer, Centre for Biomedical Ethics, University of Birmingham

**Dr Frances Flinter** (Co-opted Member)

Clinical Director and Consultant Clinical Geneticist, Genetics Centre. Guy's and St Thomas' Hospital Trust

**Dr Hilary Harris** (HGC Member)

General Practitioner, Manchester

The Sub-group met on the following dates:

13 June 2000

27 July 2000

12 January 2001

16 February 2001

**The Public Involvement Sub-group** (established May 2000)

## ***Terms of Reference***

1. To advise the Commission on strategies for promoting debate and achieving effective, representative and ongoing public and stakeholder consultation on their views of social, legal and ethical issues in relation to developments in human genetics.
2. To propose HGC consultation exercises and identify mechanisms for evaluating their outcomes.
3. To survey and comment on existing initiatives that provide information and educational material on genetic technologies, including educational programmes and Internet and other resources.

4. To advise whether current initiatives meet existing and future requirements and to recommend to the Commission ways in which other bodies can improve the availability and accessibility of such resources for a broad range of publics.

**Members**

**Ms Ruth Evans** (Chair, HGC Member)

Formerly Director of the National Consumer Council

**Professor Elizabeth Anionwu** (HGC Member)

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

**Mrs Jackie Axelby** (HGC CMO Representative)

Chief Executive, Northern England Workforce Development Confederation

**Mr Harry Cayton** (Co-opted Member)

Chief Executive, Alzheimer's Society

**Professor John Durant** (HGC Member) (until October 2000)

Head of Science and Communication at the Science Museum, London and Professor of Public Understanding, University of London

**Professor Keith Palmer** (Co-opted Member)

Vice Chairman, Investment Banking, N.M. Rothschild & Sons Ltd

**Reverend John Polkinghorne** (HGC Member)

Canon Theologian of Liverpool; formerly President of Queen's College Cambridge

**Professor Martin Richards** (HGC Member)

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

**Dr Gill Samuels** (HGC Member)

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

**Mr Geoff Watts** (HGC Member)

Journalist and presenter of BBC Radio 4's 'Leading Edge'

The Sub-group met on the following dates:

7 July 2000 (including joint session with the Working Group on Storage, Protection and Use of Genetic Information)

11 December 2000

8 May 2001

## **The Horizon-Scanning Sub-group** (established May 2000)

### ***Terms of Reference***

To take account of the work of existing bodies with a horizon-scanning role that includes a human genetics component. From this body of work, and the expertise of Members in identifying important new developments, to:

- identify what the key issues appear to be for the Commission in fulfilling its terms of reference; and
- produce a report on these issues for general dissemination and for the plenary session of the Commission to consider

### ***Members***

**Professor Veronica van Heyningen** (Chair, HGC Member)

Head of Cell Genetics Section, MRC Human Genetics Unit, Edinburgh

**Mrs Lesley Greene** (Co-opted Member)

Support Services Director, CLIMB (formerly the Research Trust for Metabolic Diseases in Children)

**Professor John Harris** (HGC Member)

Sir David Alliance Professor of Bioethics, University of Manchester

**Mr John James** (Co-opted Member)

Chief Executive, Kensington, Chelsea & Westminster (KCW) Health Authority

**Ms Hilary Newiss** (HGC Member)

Solicitor

**Professor Bruce Ponder** (HGC Member)

Professor and Head of Department of Oncology, Cambridge University

**Dr Nigel Spurr** (Co-opted Member)

Director, US Discovery Genetics, GlaxoSmithKline

**Professor Kent Woods** (Co-opted Member)

Director, NHS Health Technology Assessment Programme

**Dr Peter Greenaway** (Observer)

Assistant Director of R&D, Department of Health

The Sub-group met on the following dates:

13 October 2000

22 March 2001

## **The Working Group on the Storage, Protection and Use of Genetic Information** (established in May 2000)

### ***Terms of Reference***

1. To develop a set of general principles relating to the storage, protection and use of genetic information for approval by HGC.
2. To collate information on the existing protections for the storage and use of personal genetic information across the range of areas in which such information is likely to arise.
3. To review the range of purposes/uses for which personal genetic data may be used including research (including databases), clinical, insurance, employment, forensic, public/commercial partnerships *etc*, taking account of the work of HGC's Horizon-Scanning Sub-group.
4. To identify and summarise the relevant protections, review their adequacy in the light of potential uses and highlight any inconsistencies or gaps in those protections, taking account of relevant European initiatives, international agreements and the experience of other countries in these areas.
5. To work with the Sub-group on Involving the Public to develop a proposed strategy for public and professional involvement in these issues for consideration by HGC.
6. To provide regular progress reports to HGC.

### ***Members***

**Professor Alexander McCall Smith** (Chair, HGC Member)  
Professor of Medical Law, University of Edinburgh

**Dr Elaine Gadd** (Co-opted Member)  
Senior Medical Officer, Medical Ethics, Department of Health

**Professor John Harris** (HGC Member)  
Sir David Alliance Professor of Bioethics, University of Manchester

**Dr Patrick Morrison** (HGC CMO Representative) (from December 2000)  
Consultant clinical geneticist, Belfast City Hospital

**Professor Norman Nevin** (HGC CMO Representative) (until December 2000)  
Professor of Clinical Genetics at Belfast City Hospital

**Ms Hilary Newiss** (HGC Member)  
Solicitor

**Reverend John Polkinghorne** (HGC Member)  
Canon Theologian of Liverpool; formerly President of Queens' College Cambridge

**Professor Martin Richards** (HGC Member)

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

The Group met on the following dates:

7 July 2000 (including joint session with Public Involvement Sub-group)

27 September 2000

17 April 2001

**The Business Committee** (established November 2000)

In November 2000 Members decided to set up a Business Committee to make easier for HGC to carry out its day-to-day business. It provides HGC with a more responsive executive structure and its role is distinct from that of the HGC Sub-groups. It meets once a month on average and membership is on a rotating basis, with Members serving for four to six months.

**Purpose**

- To provide a more responsive executive structure so that HGC can react to developments quickly and involve the Membership as fully as possible.
- The Committee will have a rotating membership, and the Chair will report directly to the HGC Chair.

**Members**

**Professor Alexander McCall Smith** (Chair, HGC Member)

Professor of Medical Law, University of Edinburgh

**Dr Patrick Morrison** (HGC CMO Representative)

Consultant clinical geneticist, Belfast City Hospital

**Ms Hilary Newiss** (HGC Member) (from May 2001)

Solicitor

**Professor Martin Richards** (HGC Member)

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

**Dr Gill Samuels** (HGC Member)

Director of Science Policy (Europe), Pfizer

**Mr Geoff Watts** (HGC Member) (from May 2001)

Journalist and presenter of BBC Radio 4's Leading Edge

**Mr Philip Webb** (HGC Member)

Member of the Board of Trustees of Genetic Interest Group

The Committee met on the following dates:

19 December 2000

8 February 2001

8 March 2001

11 April 2001

10 May 2001

**The Joint Working Party of the Human Fertilisation & Embryology Authority and the Human Genetics Commission** (established December 2000)

***Terms of Reference***

1. To make recommendations concerning the HFEA's licensing of PGD.
2. To make recommendations concerning the nature of guidance as to when PGD should be offered in clinical treatment in the light of ethical issues raised by the technique; these recommendations to include recommendations relating to preimplantation genetic screening (PGS), for example, aneuploidy screening.
3. To report the Working Party's discussions to the Human Fertilisation and Embryology Authority and the Human Genetics Commission respectively.
4. To make recommendations concerning a joint public response based on the results of the PGD consultation exercise.

***Members***

**Mr Allan Templeton** (Chair)

Professor of Obstetrics and Gynaecology, University of Aberdeen

**Dr Bill Albert** (HGC Member)

Chair of the Norfolk Coalition of Disabled People

**Dr Frances Flinter** (HGC Member)

Clinical Director and Consultant Clinical Geneticist, Genetics Centre. Guy's and St Thomas' Hospital Trust

**Professor Christine Gosden** (HFEA)

Professor of Medical Genetics, University of Liverpool, Liverpool Women's Hospital

**Dr Hilary Harris** (HGC Member)

General Practitioner, Manchester

**Professor Henry Leese** (HFEA)

Professor of Biology, University of York

**Professor Stuart Lewis** (HFEA)

Consultant Psychologist, Ulster Hospital and Community Trust; formerly Professor of Psychology Applied to Medicine, The Queen's University, Belfast

**Mr Philip Webb** (HGC Member)

Member of Board of Trustees of Genetic Interest Group

The Working Party met on the following dates:

20 December 2000

25 January 2001

30 March 2001

11 May 2001

## Annex D: Report from Newcastle

In November 2000 the HGC went to Newcastle to launch its public consultation “*Whose hands on your genes?*” (see page 4). The consultation sought views on the wide range of issues around the storage, protection and use of human genetic information and started with two public meetings at the Centre for Life. People were invited to talk to us about their views on the way that genetic information should be used now and in the future. Notes were taken during both the afternoon and evening sessions and the comments we heard are summarised below, including quotes that give a flavour of the discussion.

### In general

*“Testing should not be mandatory and people should be protected from discrimination by insurers, society, and employers.”*

*“Most important that the ethical questions should be aired and vigorously debated now as in 5 years time it will be too late.”*

- Several groups expressed concerns about the development of a new form of underclass with distinctions being made between the affected and the ‘clear’ population. This could develop further with a refusal to provide genetic information being taken to imply you have something to hide. Some groups felt that people wanted to stick together and not isolate individuals, which genetic screening would do, and some stressed that people were more than just their genes.
- A number of groups mentioned the importance of trust in general and some said they distrusted various groups – the scientific community, insurers, doctors, Government, employers, police. And one table felt they didn’t have sufficient influence over, or knowledge of, the issues and another felt the public needed a wider knowledge of genetics to make an informed decision.

### Genetic information – consent/confidentiality/ownership

*“Only you have the ‘right’ to know what’s in your genes and should be able to keep it to yourself.”*

- General agreement that genetic information is not neutral information, it is different from other sorts of information and is seen as more personal and in need of special consideration. There was strong support for the importance of obtaining consent before genetic tests are carried out and a rejection of the idea of anyone being forced to undergo genetic tests.
- Genetic test results should be treated as confidential to the patient and only passed on to others with their consent. Several groups had worries about how well genetic information would be protected with computer failure, human error and deliberate attempts to find test results mentioned. Several groups mentioned the importance of trusting an organisation that has access to the information.
- Several groups expressed disagreement with the idea of patenting genes.

## Medical testing

*“There are too many plus sides to genetics to stop it completely, but no one should be God.”*

### Having genetic tests yourself

- It was generally agreed that this is always the individual’s decision. A lot of groups felt they would want to be tested for a genetic disorder and many would want to know if they were a carrier. However, many also felt that this wasn’t a straightforward decision, and was one that it was much easier to make in theory than in practice. Some people would rather not know. There was more support for having a test if there was a treatment available for the condition. One table noted that lifestyle was important, but wondered how willing we were to change lifestyle?
- There was much less support for the idea of knowing your genetic profile or for having a standard range of tests at birth, with many saying the results would lead to anxiety. Some felt that it would be unacceptable if their parents knew the results of genetic tests but they themselves didn’t. Children shouldn’t be tested until they can make the decision themselves.

### Prenatal testing

- A large number of groups expressed strong concerns about the use of genetic testing in ways they felt were inappropriate – to screen out certain characteristics, to make ‘perfect’ people, to discriminate against disabled people. Some mentioned the importance of variety between people and the possibility that if fewer disabled people were born then those who are would be increasingly stigmatised.
- Groups felt that there were clear areas which were inappropriate for testing – sex, physical characteristics such as eye colour or ‘looks’, skills, and non-health related attributes in general. (Although one table felt it would be all right to choose the sex if for example parents wanted a girl and had all boys.) There was greater support for testing for severe conditions but many felt it was difficult to decide what counts as severe and how good a person’s quality of life is and that it was important there were some sort of rules in this area.

### Insurance

*“With this information you could insure the healthy and not those with genetic predisposition. Insurance needs to be global.”*

- There was general agreement that insurers shouldn’t be allowed to ask people to have tests, nor should they see the results if people have already had tests. However, some felt that in some situations insurers could see test results and some pointed out the benefits for families who have been tested and found to be negative. All were clear that test results should not be used in a discriminatory way, either by insurers or by any other organisations, and many were worried that this may happen in the future.

- Some were concerned that genetic information could be misunderstood with a predisposition being seen as a definite outcome. It was important to remember that environmental factors were significant. One table said that you don't have to disclose alcohol consumption or dangerous driving. And another expressed concerns that a low-risk population could "opt out" of social and health care provision.

### Employment

*"I don't think that any employer has the right to use your genetic information to choose whether they want to employ you or not"*

- Again, many were concerned that test results could be used in a discriminatory way and there was a strong rejection of such a development. Some could see benefits for employees if they were tested for eg allergies and chemical sensitivities or to protect other employees or the public, but in the main there was general agreement that employers should not have access to employees test results.
- Several groups suggested there needed to be limits on how much information employers should have and legal protection for employees against discrimination. Some felt that employers would not understand genetic information if they did see it and may misinterpret it.

### Police databases

*"A police DNA database is fairly widely supported. Need to assess how bad you have to be to get on the database and also some way to get off it."*

- There was general support for the police DNA database and an appreciation that it was a useful way to help the police solve crimes and identify offenders. Some tables felt that samples should be destroyed if a person was not charged or was acquitted and some felt samples should only be taken for people charged with serious criminal offences. Others felt samples should be taken from as wide a group as possible
- Several groups mentioned the need to have safeguards in place and expressed concerns about the security of DNA information held in this way.

### Medical databases and research

*"Consent is extremely important as it will eradicate the mistrust."*

- It was felt that research could help develop treatments for many disorders. Many felt that people's concerns centred on the policing of the system and the issue of consent. The importance of trust was mentioned by several groups, as was the need to maintain anonymity or the need for genetic information to be stored in an encoded way.
- One group said that people's views varied depending on whether the research was seen as being for the good of mankind or for commercial gain. Another commented that genetic research should not be seen as a black and white issue as things are grey, "ie we, who complain, will possibly benefit from this research"



## Choices Questionnaire

As part of their tour of the Interactive Life World the students who attended the event were asked to fill in a questionnaire. We had a total of 175 responses, which are summarised in the following table, including a breakdown by age and gender. Most respondents (78%) were aged 18 and under, and of these 65% were female. The sub-groups identified in the table do not include a large enough number of people to allow any statistically significant comparisons between them (for example there were only 35 responses from 'over 18s'). They do provide interesting information nonetheless. In summary,

- There is general support for a police DNA database – over half (54%) agree that the police should hold information on everyone's DNA to reduce crime, although only 21% of the over-18 age group agree.
- 62% of people support the idea that their medical record should contain their DNA profile, this falls to 44% for males in the 18 and under age group. 69% of people would volunteer a DNA sample for medical research. Only 30% agree with the statement “no-one has the right to the information in my DNA”, which rises to 44% of males in the 18 and under age group.
- There is a less clear picture when it comes to whether or not people think genetic screening discriminates against disabled people – 39% are not sure and 38% agree that it does. Views are also fairly evenly split on whether or not genetic screening is the start of a slippery slope towards creating a super-race – 38% agree and 35% disagree.
- In total 27% agree that doctors should decide what tests should be available (and 41% disagree) – 34% of the female 18 and under age group agree but only 17% of the males in this group agree. 47% think that genetic screening is good because it reduces suffering, rising to 68% in the over 18 group.
- 50% agree that we should follow our instincts as to what scientific research we want, rising to 58% of the female 18 and under age group, but falling to 26% of the over 18 age group.
- Again views are less clear cut in response to the statement “if the creator had not wanted us to carry out genetic modification it would not be possible” – 25% agreed and 30% were not sure. 39% disagreed that it was better to apply resources to organic agriculture than biotechnology and 36% were unsure.
- 33% felt that science should not be used to change nature, although there was stronger agreement among females in the 18 and under age group (41%) than among males (24%).



**Summary of all responses**

A = agree + agree strongly  
 N = neither agree nor disagree  
 D = disagree + disagree strongly

number of responses: 175  
 male: 49; female: 114; not stated: 12  
 aged 18 and under: 140; over 18: 35

Question	Total Group			All 18s & Under			Females 18 & Under			Males 18 & Under			Over 18s		
	A	N	D	A	N	D	A	N	D	A	N	D	A	N	D
<b>Genes in the news</b>															
If the creator had not wanted us to carry out genetic modification it would not be possible	25%	30%	42%	26%	35%	37%	24%	38%	36%	33%	27%	38%	21%	5%	69%
We would be better to apply resources to organic agriculture than biotechnology	23%	36%	39%	26%	39%	34%	28%	37%	34%	19%	46%	35%	11%	11%	74%
Science should not be used to change nature	33%	27%	38%	36%	31%	31%	41%	29%	28%	24%	35%	41%	5%	0%	84%
We should follow our instincts as to what scientific research we want	50%	29%	21%	54%	31%	14%	58%	28%	12%	43%	38%	19%	26%	16%	53%
<b>Genes and your rights</b>															
The police should hold information on everyone's DNA to reduce crime	54%	15%	31%	61%	14%	25%	66%	13%	22%	49%	16%	35%	21%	16%	58%
I'd be happy for my medical record to contain my DNA profile	62%	17%	21%	64%	16%	20%	71%	13%	17%	44%	24%	30%	47%	16%	32%
No-one has the right to the information in my DNA	30%	22%	46%	28%	25%	46%	23%	25%	53%	44%	24%	31%	26%	16%	42%
I'd volunteer a sample of my DNA for medical research	69%	17%	13%	66%	19%	14%	65%	22%	12%	68%	11%	21%	84%	5%	5%
<b>Genes and health</b>															
Genetic screening discriminates against disabled people	38%	39%	23%	41%	41%	19%	43%	36%	21%	35%	54%	11%	16%	21%	58%
Doctors should decide what tests should be available	27%	31%	41%	29%	34%	36%	34%	33%	33%	17%	38%	46%	5%	21%	68%
Genetic screening is the start of a slippery slope towards creating a super-race	38%	30%	35%	42%	33%	24%	44%	33%	22%	38%	32%	30%	5%	21%	68%
Genetic screening is good because it reduces suffering	47%	38%	14%	44%	41%	14%	48%	40%	12%	35%	43%	22%	68%	11%	11%

## Annex E: Interim recommendations on the use of genetic information in insurance

### The use of genetic information in insurance: Interim recommendations of the Human Genetics Commission

1. At the request of Ministers, the Human Genetics Commission (HGC) has been reviewing the wider social and ethical implications of the use of genetic information in insurance. As part of the ongoing review, the HGC met on 1 May to consider consultation responses, additional information from the insurance industry and the report of the House of Commons Science and Technology Committee.

2. The HGC concluded that it was important to establish a clear and defensible regulatory system which not only balances the interests of insurers, insured persons, and the broader community but also enjoys the confidence of the public. In order to achieve this aim, the HGC has therefore decided to recommend to Government an immediate moratorium on the use by insurance companies of the results of genetic tests. We note that the industry has accepted that genetic tests of any real predictive value are only relevant in relation to a very few rare diseases and agree that to exclude their use would have no serious economic impact on the insurance industry.

3. In the HGC's view the moratorium should embrace the following features:

**No insurance company should require disclosure of adverse results of any genetic tests, or use such results in determining the availability or terms of all classes of insurance.**

**The moratorium should last for a period of not less than three years. This will allow time for a full review of regulatory options and afford the opportunity to collect data which is not currently available. The moratorium should continue if the issues have not been resolved satisfactorily within this period.**

**The moratorium will not affect the current ability of insurance companies to take into account favourable results of any genetic test result which the applicant has chosen to disclose.**

**The issue of family history information presents particular difficulties. The Commission is concerned that the insurance industry's principle of open disclosure and utmost good faith by the parties seems to fall most heavily on the consumer. Few people are provided with information as to how their premiums are loaded. HGC understands that family history information can amount to genetic information and is not always interpreted appropriately in underwriting. During the moratorium period HGC will address the issue as to how family history information is used by insurers.**

**An exception should be made for policies greater than £500,000. This will address concerns about adverse selection, the process by which persons having a known risk set out to acquire substantial insurance cover. (The HGC, however, has yet to see evidence of the extent to which adverse selection takes place in this context.) We recommend this upper financial limit on the basis of the industry’s own tables and information as a protection from significant financial loss.**

**Only genetic tests approved by the Genetics and Insurance Committee (GAIC) should be taken into account for these high-value policies. The HGC believes that there remains a need for an expert body of this kind, but that the criticisms of the GAIC voiced by the House of Commons Science and Technology Select Committee must be addressed.**

**In view of the failings of the current system of self-regulation of the insurance industry a method of independent enforcement of this moratorium will be needed. The HGC believes that legislation will be necessary to achieve this.**

**During the moratorium period, the HGC will continue with its consideration of the wider issues and should work with other bodies to identify a system which enjoys public confidence and the confidence of the insurance industry. An appropriate recommendation could then be made to the Government which could replace the moratorium with new arrangements.**

### **Background to the decision**

The current public debate in the United Kingdom on the use of genetic information in insurance may be traced back to reports of the House of Commons Science and Technology Committee in 1995 and the Human Genetics Advisory Committee in 1997. This latter committee, which was a predecessor body of the Human Genetics Commission, suggested that there should be a two year moratorium in the insurance industry’s practice of taking genetic test results into account in deciding whether or not to provide insurance cover to a particular applicant, or deciding the terms of such cover. This recommendation was not accepted, and agreement was reached on a system of voluntary regulation based largely on proposals put forward by the Association of British Insurers. As part of this system, the Government set up the Genetics and Insurance Committee (GAIC) and the Association of British Insurers published a Code of Conduct, which was intended to be observed by all members of the Association.

The aim of this system is twofold. Firstly, it is designed to prevent insurers from requiring applicants to take genetic tests. Secondly, it sets out to ensure that insurance companies do not give to any particular genetic test a weight which it does not deserve. If an applicant has already undergone such a test, then he or she is bound to make that fact known to the insurance company before insurance cover is agreed. This is in accordance with the well-established principle of “utmost good faith” that an applicant for insurance should make known to the insurance company all those facts which are relevant to the underwriting decision. However, insurance companies should pay attention only to those tests which

have been considered by the GAIC and are scientifically reliable and are capable of yielding relevant information.

In theory, this policy should provide both reassurance for the public and protection from arbitrary and unjustifiable decisions. In practice, there is reason to believe that the system is not achieving these objectives.

The House of Commons Committee on Science and Technology has recently published a report entitled "Genetics and Insurance". The Committee took both oral and written evidence from a range of persons and bodies, including representatives of the Association of British Insurers, individual insurance companies, and clinical geneticists. The House of Commons report admirably sets out a number of concerns, the overall conclusion was that the current system was not working well.

The HGC is also aware of these and other concerns from its preliminary analysis of the response to its public consultation. In November 2000 the Human Genetics Commission launched its consultation document on personal genetic information, *Whose hand on your genes?* One of the issues which was raised in this document was that of genetics and insurance, and the public was invited to respond to a number of questions on this matter.

This attracted responses relating to insurance from about 50 organizations. These included those bodies which have a close interest in the subject – such as the Faculty and Institute of Actuaries and the Association of British Insurers – in addition to a wide range of charities, unions, and medical royal colleges. A number of individuals also made submissions. As might be expected, many contrasting views were expressed, but it is nonetheless possible to identify certain concerns which are repeatedly expressed in the responses.

The HGC is not yet in a position to make detailed comment on public attitudes to this question, but it now has a body of evidence which suggests that there is a fairly strong public opposition to the use of genetic test results by insurance companies. This is revealed in the major MORI public opinion survey undertaken by the HGC and published in March 2001. It is also revealed in the majority of the responses received from individuals and organisations. The HGC has therefore concluded that the level of public concern over this issue requires a response. It is not suggested, of course, that strongly expressed press or public demands should dictate the precise form of any recommendation which we might make; all that is suggested at this stage is that we cannot ignore the widely-held view that the current system is unsatisfactory.

The HGC has now decided to recommend a selective moratorium on the use by insurance companies of the results of genetic tests. This decision is reached for the following reasons:

### **Regulation**

The current system is not achieving the objectives which were envisaged when it was created. The most cogent recent criticism of it is that expressed by the House of Commons Committee on Science and Technology, which concluded that individual insurance

companies were not equally observing the ABI Code of Practice, that they were using genetic tests that had not been approved by GAIC, and that currently there seemed to be no satisfactory means of monitoring and enforcing the Code. The HGC agrees with this assessment of the situation.

### **Genetic Tests**

There remains a great deal of uncertainty about the interpretation of many genetic tests. The significance to be attributed to many tests is still a matter of debate, and this issue needs to be further clarified. It is likely that a clearer understanding of the possibilities and limitations of genetic testing will evolve, but at present it seems undesirable to apply a technology which is disputed.

### **Social Exclusion**

There are strong reasons for some effective form of regulation in this area, whether regulation is achieved by the insurance industry itself, or by more formal means. These reasons include the need to ensure that those who are affected by genetic conditions should not feel excluded from the normal benefits of society (employment, participation in public life, and, it might be argued, access to insurance). Over recent decades, the position of those with a disability has been steadily improved by legislation designed to enhance their opportunities in society. It would run counter to this commitment were society to allow new classes of persons to grow up which would be subjected to improper discrimination.

### **Individual and public health**

Closely related to this consideration is the factor of public trust in genetic testing. If people feel that the taking of a genetic test may at some future stage seriously disadvantage them in some respect, then they may be reluctant to undergo genetic tests in a clinical context. There is evidence that this is already so. If this were to become widespread, then extremely important genetic screening programmes – such as those for some forms of cancer – would be adversely affected. This has implications for the health of appreciable numbers of people, and it is also relevant to public health issues.

### **Research**

Concern that genetic analysis may adversely affect one's chance of obtaining insurance also threatens public participation in genetic research. The proposal to establish a major DNA research database in the United Kingdom, a proposal which would have far-reaching implications for progress in the treatment of disease, could be adversely affected by public reluctance to give samples for analysis. We welcome, however, the statement on genetic test results and research which was recently issued by the Association of British Insurers, the British Society of Human Genetics, and the United Kingdom Forum on Genetics and Insurance.

In view of these concerns, the HGC believes that it is vital that there should be a clear and defensible system of regulation which is capable of enjoying the confidence of the public. The setting up of such a system will involve the careful balancing of interests including those of insurers, insured persons, and the broader community. A variety of options is available, ranging from an almost complete ban on the use of genetic test results (as is found in some

European systems), to a properly enforceable system in which limited use of certain results may be allowed. It seems to the HGC that at this stage the options of complete non-regulation and the option of continuing with the current system are not viable.

The task of identifying what is the best system is a major one. There is a case for this being performed by the HGC, as part of its overall enquiry into the use of personal genetic information. This would ensure consistency of approach in relation to a number of questions relating to genetic testing. The HGC has already given substantial consideration to this issue, and could continue to do so during the moratorium period with a view to making recommendations to Government. This would obviously involve further discussion with the insurance industry, as well as continued exploration of the economic and legal issues which the HGC has already started to address.

HGC believes that the priorities for further consideration should be:

- To review the use of family history information as part of the wider review of personal genetic information following our recent public consultation;
- To identify means of ensuring access to affordable insurance for those affected by a genetic condition;
- To promote openness about underwriting decisions involving genetic factors and the information given to consumers;
- To consider wider regulatory and arbitration systems for genetic information and insurance;
- To consider the role of insurance and the use of genetic information in a reformed welfare state, and;
- To initiate a debate on the wider role of private insurance in providing access to social goods.

**The Human Genetics Commission**  
**May 2001**

## Annex F: Statement on PGD

### Response to the Human Fertilisation and Embryology Authority on the Consultation on Preimplantation Genetic Diagnosis

1. The Human Fertilisation and Embryology Authority (HFEA) and the then Advisory Committee on Genetic Testing (ACGT) published a joint consultation document in November 1999 in response to concerns raised by potential uses of the technique of preimplantation genetic diagnosis (PGD). The HFEA analysed the responses in the summer of 2000 and subsequently wrote to the Chair of the Human Genetics Commission (HGC), which has succeeded ACGT, with their findings and conclusions.
2. In December 2000 the HFEA and HGC set-up a Joint Working Party on PGD to make recommendations on HFEA's licensing of PGD and the nature of guidance as to when it should be offered. It will also advise later this year on a joint public response to the consultation exercise. Meanwhile, this statement represents HGC's response to the HFEA on the outcome of the consultation. It is largely based on extensive discussions in early 2001 within HGC's Genetic Testing Sub-group.
3. PGD is a technique helpful to some potential or actual parents who know that they are likely to have a child with a serious genetic condition. At present, the majority of couples seeking PGD will have either had a previously affected child or pregnancy, or a close relative affected by the condition for which it is requested.
4. PGD offers such couples the opportunity of having a child unaffected by this serious condition without repeated antenatal diagnosis and possible termination of pregnancy. Despite this advantage, it is unlikely to be a widely used technique because of its complexity (it incorporates all the physical, emotional and financial problems of IVF) and the very small number of viable offspring which result. In England there have so far been around 200-250 cycles completed to egg collection since PGD was introduced about 10 years ago, and around 1300 cycles worldwide. The numbers are growing each year. PGD pregnancy rates can range from 17-40% per cycle depending on the genetic condition. By comparison over 18,000 amniocenteses are performed each year in the UK, mostly to help with the diagnosis of chromosomal disorders such as Down's syndrome.
5. The outcome of the HFEA/ACGT consultation suggested that there is support in the community for using this technique, but many respondents, even those in favour of PGD, also expressed reservations about its use. These reservations were varied, but fell broadly into two categories: concerns that PGD should not be used to deliberately choose 'desirable' characteristics and also that the use of the technology should not further disadvantage disabled people now and in the future. In response to these concerns, and those expressed by members both of the HFEA and HGC, it has been necessary to tread a fine line between an outright ban on the use of PGD and total freedom to use it for any and all reasons. Accordingly, HGC strongly recommends that the use of PGD should be limited to **specific and serious conditions**.

6. It has proved impossible to define what ‘serious’ should mean in this context. We have listed some factors that should be taken into account when considering seriousness, but perhaps the most important is that this technique should not be used for the purposes of trait selection or in a manner which could give rise to eugenic outcomes.

7. At present it is only possible to test embryos for one or two specific conditions at a time, though some limited screening for chromosomal abnormalities is also possible. This screening aims to inform clinicians and potential parents about which embryos are most viable. In the future, as the technology develops, clinicians may be able to increase the number of simultaneous tests. If this situation arises, these guidelines will have to be re-visited as a matter of urgency. For now, the limitations of the technique itself seems to be the best protection against its misuse.

8. HGC needs more time to fully consider the issues involved in the implanting of affected embryos before it can advise on this aspect.

9. Below are a few points that should be made clear in guidelines on the use of PGD:

- Licences to carry out PGD should continue to be applied for, and considered, on a centre by centre and a condition by condition basis.
- Tests should only be performed to diagnose or exclude the genetic condition for which PGD is indicated.
- As the technology develops, guidance in this area should be reviewed as a matter of urgency.
- There should be consistency between conditions considered as appropriate for PGD and PND.

### **Seriousness of inherited conditions**

- Decisions about the seriousness of a condition should be made by the parents in collaboration with clinicians. In this process:
  - Disabled people and parents of disabled children should be involved in putting together information for prospective parents about the reality of living with a disability. Information should be clear and accessible. Relevant patient organisations, many coming under the Genetic Interest Group (GIG) umbrella, provide a source of written information and practical support for couples making reproductive decisions.
  - Decisions on the use of PGD should depend on many things, including:
    1. the clinical burden which is a composite of:
      - the parents’ view of the condition,
      - the likely degree of suffering associated with the condition,
      - the availability of effective therapy or treatment,
      - the speed of degeneration in progressive disorders,
      - the extent of any intellectual impairment;
    2. the sensitivity and specificity of the tests in general and in the hands of the local team;
    3. the individual circumstances of the family or woman, including other siblings.

### **Late-onset disorders**

- The criteria detailed above for deciding on the seriousness of an inherited condition should be applied to late-onset disorders as for all conditions considered for PGD.

### **Aneuploidy screening**

- Aneuploidy screening may be offered to enable clinicians to choose the embryo(s) most likely to result in a viable pregnancy. This has yet to be shown to be an effective approach and should only be undertaken in the context of a formal evaluation, which may require randomisation. Older couples in particular are concerned about the risk of Down's syndrome and all are offered prenatal testing as a routine part of pregnancy care. In many centres maternal serum screening is offered to all pregnant women to identify couples at increased risk to whom an offer of amniocentesis can be made. Given the risk of miscarriage associated with this later diagnostic process, it would be reasonable to exclude trisomy 21 before implantation if requested. This is not yet feasible in practice without compromising the pregnancy success rate but would be reasonable in future if technical limitations could be overcome.

### **Replacing carrier embryos**

- In the case of chromosomal re-arrangements or autosomal recessive conditions, if it is possible to exclude affected embryos without discovering the carrier status of others and without compromising the accuracy of the test, then this is to be preferred. This will result in an increased chance of the couple achieving an unaffected pregnancy. It will also protect the unborn child's subsequent right to decide for themselves whether or not to be tested for their carrier status.

### **Predisposition testing and multiplex testing for a range of genetic disorders**

- Neither of these types of testing is feasible at present and is therefore not suitable for licensing. Developments should be kept under review.

### **Continuing support**

- Couples choosing PGD may require ongoing psychological support from obstetric and primary care services.

### **The Human Genetics Commission**

**March 2001**

## ANNEX G: Finance

The Human Genetics Commission is funded by the Department of Health, supported by contributions from the Office of Science and Technology, Welsh Assembly and Northern Ireland Assembly. The Scottish Executive has recently transferred their contribution for HGC to the Department of Health.

Aside from the staff costs of the HGC Secretariat, the total budget for 2000/1 was approximately £250,000.

In 2000/1 the Commission's work also benefited from £100,000 from the Department of Health's Public Health Development Fund and from the R&D budget (£2,500). This contributed towards the cost of the MORI survey of the People's Panel, the Newcastle open meeting and a review of international legislation and regulations concerning the use of personal genetic information.

Almost half of the overall budget was spent on running the main Commission and Sub-group meetings (fees and travel, catering), including the open public meetings.

The remainder was split evenly between our external communications work such as:

- The external Press Office and PR function, and;
- Printing and publication of reports and discussion documents.

In this first year of the new Commission there were a number of one-off costs associated with establishing the Commission in the public eye (logo and website design) and determining its roles and priorities (consultation on the work plan, communications audit etc.).

## ANNEX H: Publications and references

### HGC reports and publications

‘Public attitudes to human genetic information’ (March 2001)\*

‘Whose hands on your genes?’ (November 2000)

‘Protection of Genetic Information: An International Comparison’ (September 2000)  
[A review of international law and regulations concerning the use of genetic information]

‘Report to the Human Genetics Commission on Public Attitudes to the Uses of Human Genetic Information’ [A literature review of public attitudes to use of human genetic information]

Downloadable copies of these reports can be found on the HGC website:  
[www.hgc.gov.uk/business\\_publications.htm](http://www.hgc.gov.uk/business_publications.htm)

HGC press notices: copies of HGC’s press notices can be found on the website:  
[www.hgc.gov.uk/business\\_press.htm](http://www.hgc.gov.uk/business_press.htm)

### References

What the future holds – (see page 10)

**Genetics and Health: Policy issues for genetic science and their implications for health and health services**, Dr Ron Zimmern & Mr Christopher Cook, (The Nuffield Trust & The Public Health Genetics Trust), The Stationary Office (May 2000)

**Laboratory Services for Genetics: Report of an Expert Working Group to the NHS Executive and the Human Genetics Commission**, Working Group chaired by Professor Martin Bobrow, Department of Health, (August 2000)

**Foresight: Healthcare 2020**, Report of the Foresight Healthcare Panel chaired by Sir Michael Peckham, Department of Trade and Industry, (December 2000)

**Harnessing the Potential of Gene Science**, Unpublished Department of Health strategy & planning report

(\*page 1 gives more details of how to get a copy of this report)

## Glossary of terms

DNA	Deoxyribonucleic acid, the chemical substance in chromosomes and genes in which genetic information is coded.
Genetic disorders	Disorders which are due to defects in the genetic constitution of an individual. They may be the direct consequences of defects in single genes; or in whole chromosomes, parts of which may be lost, duplicated or misplaced; or due to the interaction of multiple genes.
HFEA	Human Fertilisation and Embryology Authority.
i.p.r.	Intellectual property rights.
IVF	In vitro fertilisation.
PGD	Preimplantation genetic diagnosis, the genetic testing of IVF embryos.
Pharmacogenetics	Screening to decide the best drug for treatment.
PND	Prenatal genetic testing, the genetic testing offered to pregnant women.
WHOYG?	<i>“Whose hands on your genes?”</i> , the HGC consultation on personal genetic information.



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