ADVISORY COMMITTEE ON GENETIC TESTING

First Annual Report

July 1996-December 1997

Health Departments of the United Kingdom
March 1998

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FOREWORD

The Committee came into being in July 1996. Its members are drawn from a wide range of relevant backgrounds, bringing with them expertise derived from science, medicine, ethical philosophy, and participation in the work of patient groups. Its first year and a half of life has been an active one.

The first major topic to engage our attention arose from the availability, for the first time in the United Kingdom, of a genetic test (for Cystsic Fibrosis (CF) carrier status) offered direct to the public, outside the context of professional medical practice. The Committee sought to formulate a Code of Practice for such "over the counter tests", believing that this non-statutory approach is appropriate to a rapidly developing field like genetic testing in which revisions of recommended procedures may from time to time need to be considered in the light of further experience. After extensive consultation, the Code was published in September 1997. It sets requirements for maintaining high professional standards and it emphasises the necessity of providing information and opportunities for appropriate genetic consultation, in order to ensure that clients make informed decisions before and after testing. The Committee expects that the provision of direct access facilities of this kind will centre on testing for carrier status for recessive disorders. Firms are requested to submit proposals to ACGT prior to introducing their service, so that arrangements can be checked for compliance with the Code of Practice.

The Report and its Code were well received and there has also been much international interest in the proposals. ACGT intend to keep the matter under review and to monitor compliance.

The second major area considered by the Committee has been testing for late onset disorders, such as Huntington's Disease. A draft Report has been the subject of an extensive consultation exercise and ACGT expects shortly to publish its definitive version. Our work benefits very much from the willingness of many interested parties to make their opinions, experience and recommendations known to us and we are very grateful for the help that we receive in this way.

Further matters of current concern to the Committee include issues relating to prenatal testing, and the formulation of advice to Research Ethics Committees about questions whose answers may help them in adjudicating proposals for projects involving genetic testing. In the longer term, ACGT expects it may need to look at questions relating to testing for genetic susceptibilities for common diseases, including possible population screening initiatives.

This is our first Annual Report. It indicates something of the range of significant issues that can arise in this rapidly developing area of scientific and medical advance. The Committee itself will be reviewed after three years of its existence. It hopes that towards the end of that initial period it will have accumulated enough particular experience to allow it to distil some general principles that apply across the field of genetic testing.

I would like to pay tribute to the unstinting hard work and extensive expertise of my colleagues on the Committee, and to the similar qualities of its Secretariat, which alone enable it to discharge its public duty.

ACGT will continue to make information about its work, including consultation documents and reports, available on the Department of Health Homepage at http://www.open.gov.uk/doh/genetics/htm.

Reverend Dr John Polkinghorne KBE FRS
March 1998

CONTENTS

SECTION 1. INTRODUCTION*

1.1 ACGT was established in June 1996 under the chairmanship of Rev Dr John Polkinghorne KBE FRS to advise on the ethical, social and scientific aspects of genetic testing. Its establishment was in part a response to a Report of the Select Committee on Science and Technology[1] but also recognised the continuing growth in professional and public interest in genetics and the potential of future developments in genetic testing. The terms of reference are at Annex A and the membership is at Annex B."

1.2 ACGT was established to aid the Government with its public health and consumer protection role; in particular the committee aims to ensure:

- that full consideration is given to the ethical and social aspects of genetic testing, and

- that if genetic tests are marketed for public use they conform to appropriate criteria.

At the same time Government wishes to ensure that science is encouraged, and further developed to the benefit of the UK population and that UK industry, academia and voluntary agencies, continue to make developments in this field.

1.3 ACGT is just one of the means for ensuring that advice is available to Ministers on the ethical and social aspects of developments in human genetics.

1.4 ACGT shares a Department of Health based secretariat with another advisory committee reporting to UK Health Ministers, the Gene Therapy Advisory Committee (GTAC). GTAC, established in 1993, considers and advises on the acceptability of proposals for gene therapy research on human subjects, on ethical grounds, taking account of the scientific merits of the proposals and the potential benefits and risks.

1.5 Non-healthcare areas of human genetics, such as insurance, patents, privacy and employment issues are considered by the interdepartmental advisory body the Human Genetics Advisory Commission (HGAC). HGAC, whose secretariat is based at the Office of Science and Technology within the Department of Trade and Industry, reports to UK Industry and Health Ministers.

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* Because it has been necessary to use some technical terms in this report a glossary is included.

ACGT's Current Work Plan

1.6 ACGT considers the use, or potential use, of tests both in the field of clinical practice and for those testing services which are supplied direct to the public. Amongst other issues ACGT considers: the accuracy and predictive power of any test; the value of results to the individual; the implications for relatives and future children; what preventive action/treatment may be available; the contents of information leaflets for individuals and "data sheets" for professionals; the provision of counselling aspects of the consent process; and the arrangements for the protection of personal genetic data.

1.7 ACGT does not consider systematic, profession-led population screening programmes, as opposed to requests from individuals or families for testing. Use of such screening programmes carries a heavy obligation to ensure that potential benefits outweigh potential risks. Arrangements already exist to obtain systematic information from research about the effectiveness of such programmes. This work is the responsibility of the Department of Health's Standing Group on Health Technology and its Population Screening Panel, and the National Screening Committee chaired by the Chief Medical Officer (England).

1.8 One particular issue, raised in the 1995 Select Committee report, was that of tests made available directly to the public without involvement, before testing, of either a GP or genetics clinic. ACGT response to this concern is detailed in section 2 of this report.

1.9 At ACGT's first meeting held on 19 July 1996 the following areas were identified and agreed as work priorities:

a. Over the counter genetic testing - see Section 2.

b. Genetic testing for late onset disorders - see Section 3.

c. Carrier testing with particular reference to children.

Subsequently additional work areas have been identified on prenatal genetic testing, and the production of advice to Research Ethics Committees.

CURRENT DEVELOPMENTS IN GENETIC TESTING

1.10 Genetic tests fall into two main groups:-

- Biochemical analysis to detect a change in the level of a specific gene product (protein) or a characteristic disturbance of biochemistry, indicative of the presence of a heritable mutation in a single gene. Whilst important in the diagnosis of symptomatic patients, with rare exceptions, for example sickle cell and thalassaemia, biochemical tests have limitations in detecting healthy carriers of disorders.

- Analysis of the heritable genetic material itself - the DNA or the chromosomes into which it is packaged. DNA analysis can be used to confirm or establish the diagnosis in the patients, or detect the gene mutation in healthy carriers or in pre-symptomatic individuals who will later develop the disorder. Whilst detecting the causal change in the relevant gene (mutation detection) is the definitive genetic test, when the gene is not known, but its location on the chromosome is, DNA markers close by can be used to track it through affected families. Any tissue can be used for DNA analysis, not just that affected by the disease. Rapid advances in genetic research means that in the next 5 years we can expect many more specific genetic tests for inherited disorders, based on knowledge of the DNA mutations, to become available.

1.11 Genetic testing activity takes place in various settings:

a. Use of tests by clinical geneticists and/or other clinicians.

At present, genetic tests in NHS clinical practice are largely confined to simply inherited (monogenic) disorders and are performed in association with regional genetic centres. Much development of this genetic testing is based in university research laboratories and is gradually moving to NHS funded clinical molecular genetics laboratories within the genetic centres. One of the most important goals of clinical genetics is to help families with genetic disorders to live and have children as normally as possible. The offer of an opportunity for family members to discover their genetic status through genetic testing is one important component of the help provided. The interests of patients are safeguarded by the professional standards of clinicians and relevant guidance. Among the implications of such tests, other than for the actual affected patient, are:

i. that an abnormal result may require consideration to be given to approaching relatives, through the patient and with the patient's agreement, to forewarn them of their genetic risk;

ii. that there may be a requirement to discuss the chance of occurrence of the disorder in future children and the possibility of offering prenatal diagnosis.

b. Clinical research.

This is usually carried out in association with the NHS in university departments, teaching hospitals and medical research centres. Whenever patients are involved personally, projects and protocols are subject to approval by Research Ethics Committees. By this means the interests of individual patients are safeguarded. By the very nature of being research, the significance of genetic test results to the individual patient will be unclear, particularly where the disorder under study is not inherited in a straightforward manner, and will not be disclosed. In simply inherited monogenic disorders, there is often the potential to rapidly translate research findings into clinical services for families, whilst in the area of common diseases of complex causation establishing the clinical value of testing for genetic susceptibility may take a long time. Part of the research strategy for discovering how genetic variation interacts with the physical and social environment to determine health, development and wellbeing involves incorporating undisclosed, confidential genetic analysis into epidemiological studies of whole population samples. Again the interests of the research subjects are safeguarded by the requirement for Research Ethics Committee approval.

c. Commercial development of genetic tests

Some tests may have commercial potential either through contracts with the NHS services or supplied direct to the public (see below). Collaboration between researchers, clinicians and manufacturers may lead to the prospect of marketable products. It is likely to be tests for common single gene disorders such as cystic fibrosis and for genes indicating a susceptibility to common diseases which will attract the attention of manufacturers. Initially, any widespread application of genetic testing in health care is likely to be focused on symptomatic patients, being used to subclassify their clinical disorder or determine the way they handle specific drugs in order to optimise treatment. It may be a long time before the clinical value is established of using genetic tests to establish a healthy person's "susceptibility profile" to guide lifestyle, nutritional or other preventive interventions. For people with a significant family history of a common disorder such as cardiovascular disease or a common cancer, ongoing research may well establish the clinical value of offering genetic tests to identify the few percent of the population where there is a strong genetic component and referral to a genetic service is appropriate.

d. Marketed Tests

These are tests which have passed through the development stage described above and are available for supply direct to the public through advertised testing services. Such services have been the subject of ACGT's first publication - see section 2.

SECTION 2. CODE OF PRACTICE AND GUIDANCE ON HUMAN GENETIC TESTING SERVICES SUPPLIED DIRECT TO THE PUBLIC[2]

2.1 In their 1995 report on human genetics, the House of Commons Select Committee on Science and Technology highlighted concerns over genetic testing services offered direct to the public. ACGT decided to give this issue early attention.

2.2 ACGT consulted in November and December 1996 on a draft voluntary Code of Practice. A meeting was held in June 1997 to present a revised document to organisations representing the key interests, including manufacturers, clinicians and patient interest groups. The final report was published on 23 September 1997.

2.3 The seven key issues covered in the Code of Practice are:

i. Testing Laboratories, Equipment and Reagents - All equipment and reagents for testing should be manufactured and maintained to an appropriate level and provide assured levels of accuracy and reliability that reflects current best practice. All laboratories offering genetic testing services should be appropriately staffed and equipped, and should:

a. participate in an appropriate accreditation scheme;
b. join an appropriate external quality assurance scheme; and
c. perform adequate internal quality control.

All such systems should reflect current best practice.

ii. Confidentiality and Storage of Samples and Records - Suppliers should keep the customer's data confidential, excepting information provided to GPs under section vii below. Suppliers should inform the customer of their procedures for ensuring confidentiality of data. Suppliers should inform the customer of their procedures for storage and disposal of samples and records before obtaining samples and information from the customer. Suppliers should test samples and use identifiable customer data only as contracted with the customer.

iii. Testing services that may be supplied - Those proposing to offer any human genetic testing service direct to the public are expected to comply with this Code of Practice and Guidance and present their proposals to ACGT for comment. Suppliers should advise all customers with a known family history of a genetic disorder, to consult a medical practitioner.

iv. Who may be supplied a testing service - Genetic testing services supplied direct to the public should not be supplied to those under the age of 16, or to those who are not competent to make a decision regarding testing.

v. Customer Information - Suppliers should provide appropriate information to the customer giving details of the tested condition, to ensure that the customer understands the nature of the testing, its scope and limitations, and the accuracy, significance and use of a result. Such information should be supplied before the test is performed.

vi. Genetic Consultation - Suppliers should provide opportunities for appropriate pre- and post-test genetic consultation, for which there should be no additional charge.

vii. Involvement of General Medical Practitioners - Suppliers should supply a copy of test results, with the customer's written consent, to general medical practitioners for inclusion in the customer's health record.

2.4 Copies of the Code of Practice and Guidance may be obtained from the ACGT Secretariat.

2.5 ACGT has undertaken to reconsider and if necessary update this work after a couple of years of operation and experience. If there are significant areas of non-compliance ACGT may consider recommending additional regulatory action to Health Ministers. In addition ACGT will in its Annual Report publish details of those suppliers who have submitted their proposals for a testing service to the committee and which comply with the Code of Practice. ACGT will also publish details of any service brought to its attention which does not comply with the Code of Practice.

SECTION 3. GENETIC TESTING FOR LATE ONSET DISORDERS

3.1 Genetic testing for late onset disorders such as Huntington's Disease is a key service offered by NHS Genetics Centres and other providers of genetic testing services. The level of provision and proficiency of such services is high, though there are increasing demands on existing services as the number of disorders that can be tested for grows.

3.2 The House of Commons Select Committee on Science and Technology highlighted late onset disorders in their 1995 report on Human Genetics, and ACGT have accorded this issue high priority. A draft report was published for public consultation on 29 October 1997 for comments by 16 January 1998[3]. Subject to Ministerial approval the report will be published later this year.

3.3 The draft report outlines ACGT's thinking on the special features of genetic tests for late onset genetic disorders, current service provision, and the validity of such tests. In addition it sets out the Committee's views on issues that all service providers need to consider when providing testing services for late onset disorders. These include, the known error and failure rates of tests, requirements for laboratories performing tests, information and support needs of those tested, requirements for consent to testing, statements on prenatal testing and testing of children and adolescents, and the use of test results in research studies. The report also includes for completeness brief statements on population screening, diagnostic genetic testing and genetic susceptibility; ACGT expects to return to some of these subjects in a fuller manner in future reports.

3.4 ACGT hopes that the report will provide a useful reference for all those currently providing genetic testing for late onset disorders and those considering developing such services.

SECTION 4. OTHER ACGT ACTIVITIES

Research Ethics Committees (RECs)

4.1 ACGT has received correspondence from RECs raising genetic testing issues. The Committee has identified these issues for future work and hopes in 1998 to produce information for RECs setting out a series of "points to consider"/"questions to ask" when they are presented with research proposals which involve genetic testing.

ACGT Visits

4.2 ACGT agreed at an early stage that it would be important for the committee to visit centres undertaking genetic testing.

4.3 Groups of ACGT members and secretariat have visited:

a: The Department of Human Genetics and Northern Genetics Service in Newcastle upon Tyne in December 1996.

b: The Cambridge Regional Genetics Centre in January 1997.

c: The Gene Shop at Manchester Airport, the Clinical Genetics Department and the Willink Biochemical Genetics Unit at Manchester Childrens Hospital in July 1997.

4.4 ACGT plans to visit University Diagnostics Ltd. in January 1998 and The Royal Devon and Exeter Hospital Genetics Centre in February 1998, and expect to continue a programme of further visits during the next year.

4.5 ACGT wishes to record thanks to all those in the centres above who kindly gave up time to make the visits successful.

SECTION 5. GENETIC TESTING: OTHER DEVELOPMENTS

Technology has often led to the globalisation of certain values. It seems appropriate therefore that in the field of human genetics, countries should work together towards the recognition of common ethical frameworks. It is within this context that in addition to initiating original work ACGT has received updates for information on other issues which include:

5.1 European Draft Directive on In Vitro Diagnostic (IVD) Medical Devices[4].

The IVD Directive was first published by the Commission in July 1995. It is the third of three Directives on medical devices designed to harmonise essential safety and marketing requirements, to complete the single market for this product group. Two earlier Directives covering active implants and other medical devices have already been implemented. Genetic tests will be covered by the IVD Directive along with all other classes of diagnostic tests.
Negotiations at Working Group level on the IVD Directive have been lengthy and complex, due largely to a proposal contained within it to extend the scope of the Medical Devices Directive to include devices containing substances derived from human tissue. Some 18 months later, as agreement on this proposal had still not been reached, the wording was removed in October 1997 to allow the rest of the text, on which there was broad agreement, to progress.

As a result Political Agreement on a Common Position, supported by all Member States, was reached at the Internal Market Council meeting held on 27 November 1997. Formal agreement is expected in March 1998, after which the Directive will be submitted to the European Parliament for a second reading.

5.2 European Proposal for a Directive on the Protection of Biotechnological Inventions ('The Patents Directive')[5].

A fair and robust patent system is seen as a means to encourage investment in research and development of products. The current system in Europe for patenting of biotechnological products is subject to delay and backlog due to uncertainty over interpretation of the European Patent Convention, for example, in the area of patenting inventions relating to human genetic material, and is subject to national laws.

The proposed Directive is a 'Single Market' measure to establish a clear legal framework for the protection of biotechnological inventions without prejudice to other legislation. It aims to harmonize European patent laws and clarify interpretation, thus underpinning the confidence of industry. The Directive should lead to little change to existing UK regulation and practice. The three conditions which currently apply to invention patentability (including inventions relating to human genetic material) - that it is new, inventive, and capable of industrial applicability - will continue to do so.

The previous proposal was rejected by the Conciliation of the Council and Parliament in 1995, mainly on ethical grounds. The current draft reached

'Common Position' at the Internal Market Council on 27 November 1997 following a series of EC Working Party meetings over the previous months. The proposal is expected to go to the European Parliament in early 1998, and following that Council and Parliament are expected to adopt the Directive. The Directive should be implemented within two years of adoption ie. no earlier than 2000.

The Directive will be relevant to those academic, charitable and commercial ventures developing genetic tests and genetic testing services for Europe. ACGT has held detailed discussions with the Patent Office during the development of the Draft Directive.

5.3 UNESCO

In November 1997, the General Conference of UNESCO adopted the Declaration on the Human Genome and Human Rights[6], noting that research on the human genome and the resulting applications offer vast prospects for progress in improving the health of individuals and mankind, but emphasising that such work needs to fully respect human dignity, freedom and human rights. The Declaration contains principles prohibiting unjustified discrimination, emphasising principles of consent and confidentiality and encourages the development of educational activities to improve awareness of the implications of developments in genetics.

5.4 International Bar Association

The International Bar Association[7] is preparing a convention on genetics which it hopes to have approved by the United Nations General Assembly.

5.5 Council of Europe

The Council of Europe Convention on Human Rights and Biomedicine[8], which sets out common general standards for the protection of the human being in the context of developments in biology and medicine, was opened for signature in April 1997. The Convention prohibits unjustified discrimination on grounds of genetic heritage and includes a moratorium, for a minimum of five years, on germ line gene therapy in humans. A protocol to the Convention prohibiting the cloning of human beings will be opened for signature in January 1998 and further protocols on genetics, medical research, organ transplantation and the protection of the embryo and fetus are being developed.

5.6 Human Genetics Advisory Commission

In December 1997 HGAC, a non-statutory body reporting to both UK Industry and Health Ministers, published a report on "The Implications of Genetic Testing for Insurance"[9]. Copies of the report can be obtained from the HGAC Secretariat, Office of Science and Technology, Albany House, 94-98 Petty France, LONDON SW1H 9ST.

GLOSSARY

ACGT

Advisory Committee on Genetic Testing

Autosomal Dominant Disorders

Disorders where inheritance of a mutation from one parent only (or arising anew during egg or sperm formation) can be sufficient for the person to be affected. Dominant disorders include familial hypercholesterolaemia, Huntington's Disease, adult polycystic kidney disease and neurofibromatosis.

Autosomal Recessive Disorders

Disorders, where for a person to be affected, a mutation has to be inherited from both parents. Such parents are usually unaffected carriers because they only have a single copy of the affected gene. Common recessive disorders in the UK are cystic fibrosis, sickle cell disease and thalassaemia.

Cell

The smallest unit of living organisms which, given the right conditions, can survive independently and reproduce itself. It has been estimated that the body of a human adult comprises 50 million million cells.

Chromosomes

Microscopically dark staining bodies which carry the nuclear DNA , and are the vehicles which carry the DNA during reproduction. Each chromosome contains a very long double strand of DNA, bearing thousands of genes in a linear array. Chromosomes are present in pairs, in body cells, but only one of each pair is present in germ line cells. In humans there are normally 46 chromosomes; 44 are arranged, and numbered in order of decreasing size, as 22 matching pairs (autosomes). The two remaining chromosomes are sex chromosomes, in females XX and in males XY.

DNA (deoxyribonucleic acid)

The chemical substance in chromosomes and genes in which genetic information is coded.

Enzyme

A protein which acts as a catalyst in the body's many chemical reactions. A deficit in the production of an enzyme or its function may result in an inherited disorder of metabolism.

Gene

A part of the DNA molecule of a chromosome which directs the synthesis of a protein.

Gene therapy

Used without qualification means the genetic modification of body cells of an individual patient, directed to alleviating disease in that patient.

Genetic Consultation

The purpose of genetic consultation is to deal with issues that relate to the suitability of the test for addressing the individual's concern. Including the interpretation of the result, and to arrange a clinical referral, should that prove necessary, providing appropriate professional support in the interim. The necessary range and extent of genetic consultation will vary for each genetic test. It should include taking a family history and those elements of genetic counselling which embody the imparting of accurate information. Also discussion of reproductive options where relevant and management plans for the patient and the family in a sensitive, objective and "non directive" way.

Genetic disorders or diseases

Afflictions which are due to defects in the genetic endowment 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 and external factors in fetal development. Later in life such interactions appear to be the basis of many of the common serious disorders, such as heart disease, diabetes and cancer.

Genetic test

A test to detect the presence or absence of, or change in, a particular gene or chromosome.

Genetic Testing Supplied Direct to the Public

Genetic Testing service supplied by a supplier to the public, outside the context of conventional medical referral systems.

GTAC

Gene Therapy Advisory Committee

HGAC

Human Genetics Advisory Commission

Mutation

The change in a gene or chromosome that causes a disorder or the inherited susceptibility to a disorder.

Protein

Proteins are essential constituents of the body. They form the structural materials of muscles, tissues, organs and are regulators of function, as enzymes and some hormones. Proteins are coded for by DNA.

X-Linked Recessive Disorders

Those disorders due to a mutation on the X chromosome. X-linked recessive disorders usually only affect males, but the disorders can be transmitted through healthy female carriers. Examples are haemophilia, Duchenne muscular dystrophy, and the Fragile X syndrome which is associated with learning disability.

TERMS OF REFERENCE OF THE ADVISORY COMMITTEE ON GENETIC TESTING (ACGT)

The terms of reference of ACGT are:

- to provide advice to Ministers on developments in genetic testing;
- to advise on genetic tests taking account of ethical, social and scientific aspects;
- to establish requirements, especially in respect of efficacy and product information, to be met by manufacturers and suppliers of genetic tests.

ANNEX B

MEMBERS OF ACGT

Chairman

Rev. Dr John Polkinghorne KBE FRS

Members

Professor Kay Davies†	Dr Lee's Professor of Anatomy and Head of Department, Department of Human Anatomy, University of Oxford.
Professor Robin Downie	*Until September 1997.*
Professor John Durant*	Assistant Director, The Science Museum, South Kensington.
Professor Peter Harper†	Professor & Consultant, Institute of Medical Genetics, Cardiff.
Dr Hilary Harris*	General Practitioner, Manchester.
Professor John Harris†	Sir David Alliance Professor of Bioethics, University of Manchester.
Miss Wendy Johnston†	Specialist Health Visitor in Genetics, Belfast City Hospital
Mrs Christine Lavery†	Director of the Society for Mucopolysaccharide Diseases & founding trustee of the Genetic Interest Group.
Professor Sally Macintyre	Director, MRC Medical Sociology Unit, University of Glasgow.
Mr Matthew Parris	The Times.
Professor Marcus Pembrey*	Mothercare Professor of Paediatric Genetics, Institute of Child Health, London.
Dr Sultana Saeed	Formerly Lecturer in Law, University College London.
Mr Philip Webb*	General Manager, Zeneca Diagnostics, Abingdon, Oxfordshire.

***** Members of the Code of Practice & Guidance Subgroup.
† Members of the Late Onset Disorder Subgroup.

Observers

Dr Elaine Gadd
Department of Health
London

Mrs Jill Dhell
Medical Devices Agency
London

Dr Amanda Goldin
Human Genetics Advisory Commission
Office of Science and Technology

Secretariat

Mr Anthony J Taylor
Mr Mark Noterman
Mrs Margaret Straughan
Dr Veronica Lecomte

REGISTER OF MEMBERS' INTERESTS.

ACGT members have declared the following personal share holdings or funding from the biotechnology/pharmaceutical industry.

Rev. Dr John Polkinghorne	None
Professor Kay Davies	Personal Shareholder, SmithKline Beecham
Professor John Durant	The Science Museum receives grants and sponsorships from a number of companies. These include: Glaxo Wellcome SmithKline Beecham Draeger In addition, the following non-commercial bodies provide funding: BBSRC Wellcome Trust MRC Action Research British Diabetic Association British Heart Foundation Multiple Sclerosis Society
Professor Peter Harper	None
Dr Hilary Harris	None
Professor John Harris	Member of "Ethics and Public Policy Board", SmithKline Beecham
Miss Wendy Johnston	None
Mrs Christine Lavery	None
Professor Sally Macintyre	None
Mr Matthew Parris	None
Professor Marcus Pembrey	None
Dr Sultana Saeed	None
Mr Philip Webb	Personal Shareholder, Zeneca Limited

ANNEX D

DATES OF ACGT MEETINGS 1996/1998

1st	19 July 1996
2nd	16 September 1996
3rd	14 January 1997
4th	13 May 1997
5th	4 September 1997
6th	6 January 1998
7th	9 March 1998

REFERENCES

[1] Select Committee on Science and Technology: Third Report of the House of Commons Select Committee on Science and Technology 1995-1996 Session. London. HC231 HMSO 1996.

[2] Advisory Committee on Genetic Testing: Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public. Health Departments of the United Kingdom. London. Department of Health. September 1997.

[3] Advisory Committee on Genetic Testing: Consultation Report on Genetic Testing for Late Onset Disorders. Health Departments of the United Kingdom. London. Department of Health. October 1997.

[4] Proposed Directive on 'In Vitro Diagnostic Medical Devices' COM(95)130 final.

[5] Directive on the legal protection of biotechnological inventions. COM(97)446 final.

[6] UNESCO. (1997) Universal Declaration on the Human Genome and Human Rights. UNESCO: Paris.

[7] International bar Association Bioethics Subcommittee of the Law and Medicine Committee: Draft International Convention on Human Genome. October 1996.

[8] Council of Europe. (2997) Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine. Convention on Human Rights and Biomedicine. ETS 164 Council of Europe: Strasbourg.

[9] Human Genetics Advisory Commission; The Implications of Genetic Testing for Insurance. Office of Science and Technology. London. Department of Trade and Industry. December 1997.

1. Select Committee on Science and Technology: Third Report of the House of Commons Select Committee on Science and Technology 1995-1996 Session. London. HC231 HMSO 1996.