Human genetics : the science and its consequences : Government response to the Third Report of the House of Commons Select Committee on Science and Technology, 1994-95 session / [presented to Parliament by the President of the Board of Trade].

DEPARTMENT OF TRADE AND INDUSTRY

Human Genetics: the Science and its Consequences

Government Response to the Third Report of the House of Commons Select Committee on Science and Technology, 1994–95 Session

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HUMAN GENETICS: THE SCIENCE AND ITS CONSEQUENCES

GOVERNMENT RESPONSE TO THE REPORT BY THE HOUSE OF COMMONS SCIENCE AND TECHNOLOGY SELECT COMMITTEE

Introduction

1. The Government is grateful to the Select Committee for its extensive and detailed report. It recognises the growing importance of human genetics and the speed with which developments are taking place. It is helpful and timely, therefore, to be presented with a considered view of the complex issues which have arisen.

2. The UK is a world leader in genetic research. Some of the most important discoveries in the field have been made in the UK, from the structure of DNA to developments in the treatment of cystic fibrosis by gene therapy. The Medical Research Council (MRC) provides support for genetics research at all levels from the most basic molecular biology to studies of family genetic traits. The Government will continue to foster excellence in UK genetics research.

3. Genetics offers significant prospects for the diagnosis and prognosis of disease. Knowledge of the function of genes also has the potential for developing and improving the application of conventional treatments. The coherence of the NHS means it is well placed to take advantage of new advances in genetics.

4. Genetic studies also provide scope for enhancing UK competitiveness, offering major opportunities for partnership between industry, the science base and Government. The Government has demonstrated its awareness of these benefits by, for example, bringing the European Bioinformatics Institute to Cambridge, increasing funding for genome analysis in the Science Budget for 1995-96 and bringing forward two new MRC programmes under the LINK scheme which will encompass genetic research.

5. The recent Technology Foresight reports recognised the importance of genetic research. The Health and Life Sciences Panel recommended[1] with respect to genetics, that "the UK should develop the basic, disease-specific, knowledge that will underpin applications in medicine, health promotion, nutrition, pharmaceuticals, diagnostics and other health care businesses; and to explore sociological, ethical and practical issues in the use of this knowledge...". The Technology Foresight Steering Group recognised genetics and biomolecular engineering as a key priority area. The Government is now taking these recommendations forward in a variety of ways: the two new LINK programmes are part of the Government's overall response.

6. The Government fully recognises the sensitivities which apply to developments in the genetics field. There are a number of mechanisms which are designed to address ethical issues relating to medical - including genetic - research. A key example is the Gene Therapy Advisory Committee which was established by the Government in 1993 to consider all proposals for gene therapy research on humans. This Committee works closely with Local Research Ethics Committees which examine the ethical aspects of all health-related research carried out on patients in the NHS. Further details about these and other bodies referred to in this response are provided at Annex A.

7. The Committee particularly highlights the issue of genetic screening and testing. It recommends the establishment of a statutory Human Genetics Commission which, among other functions, would regulate genetic testing. The Government has considered this proposal carefully but believes that existing bodies, both within and outside government, already cover the majority of issues for which a Commission would have responsibility.

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[1] "Technology Foresight : Progress Through Partnership", Report Number 4 on Health and Life Sciences HMSO 1995

8. The Government recognises, however, that the Committee has identified a gap in the current arrangements. This will be covered by the new Advisory Committee on Genetic Testing, foreshadowed in a statement by the then Secretary of State for Health in June last year. The Committee will advise on the ethical, social and scientific aspects of genetic tests and establish standards to be met by the manufacturers and suppliers of these tests. Details are being announced separately by the Department of Health.

9. Further advice on ethical matters is provided by the Nuffield Council on Bioethics. This receives funding from the Nuffield Council, the Wellcome Trust and the MRC. One of its reports has specifically addressed the issue of genetic screening[2]. This report has been taken into account by the Government in developing its policies, as reflected in this response.

10. The Committee also raises a number of sensitive issues in relation to employment and insurance. The Government believes that employers and the insurance industry share responsibility for addressing these issues. In relation to employment, for example, the Health and Safety Commission's Occupational Health Advisory Committee has set up a working group on genetic screening. Meanwhile, the Government is actively encouraging dialogue between the Association of British Insurers and leading geneticists, who are working to identify and resolve the problems in using genetic information in insurance; it hopes to see substantial progress within a year.

11. The Committee draws attention to the important international dimension to human genetics, including the extensive collaboration on the Human Genome Mapping Project. The UK is a strong participant in such activities. The Government will continue to monitor developments in Europe and elsewhere.

12. The Government's detailed comments on the Committee's recommendations and conclusions are set out below. The response follows broadly the structure of the Committee's report.

The Science and Mapping of the Human Genome

13. The Government agrees with the Committee's comments (19, 24) on the science of human genetics. Genetic variation is a natural and entirely normal phenomenon - variation in blood types being one well-known example - and as understanding of our genetic make up increases so too does our appreciation of the complexities of the interactions between our genes and the environment. We are more than the sum of our genes.

14. The Government agrees with the Committee (34) about the value of the Human Genome Project (HGP) and the need to share the results of this work as widely as possible. The UK has played a leading role in the sequencing and analysis of the human genome. The project is stimulating important advances in genetics and in our understanding of disease. Through the HGP most of the important human disease genes are likely to be identified within the next five years. The task is enormous, but so are the potential gains. The HGP will provide new opportunities to improve treatment and prevention of many diseases and to offer more accurate diagnosis. The Government will continue to support this work in conjunction with other national and international sponsors.

15. In 1994, the Office of Science and Technology (OST) commissioned a report[3] to identify areas in human genome research with particular scientific and commercial promise for the UK. The report was produced by an independent group of experts chaired by Professor Kay Davies of Oxford University. The OST is now conducting a review of the report's impact and has sought the views of a cross-section of companies, charities and research organisations. The results of this review will be passed to the Technology Foresight Health and Life Sciences Panel.

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[2] "Genetic Screening: Ethical Issues" London 1993

[3] "The Human Genome Mapping Project In The UK : Priorities And Opportunities In Genome Research" HMSO 1994

16. By bridging science and the humanities, the Human Genome Diversity Project has the potential to contribute to our understanding of human genealogy and identity and to create a resource of data on the role of genetic factors in predisposition or resistance to disease. Concerns have been raised, however, about issues such as commercial exploitation of individuals or populations. It will be important to ensure that the project addresses such issues adequately. The Government notes the Committee's point (50) that samples supplied for the project should be used for the project alone. If it is proposed to use the samples for further research, it will be necessary for the research sponsor to obtain the advice of an appropriate research ethics committee.

Genetic Research in the UK

17. The Government notes the Committee's concerns (57) regarding the possible effect of NHS reforms on genetic research. In response to the need for robust mechanisms to support and fund all forms of medical research (including genetic research) within the NHS, the Government established a task force under the chairmanship of Professor Anthony Culyer of York University. The principles outlined in the task force's report[4] have gained general assent. New arrangements are now being put in place that will provide a sound basis for separately supporting research and patient care whilst promoting synergy between them. An implementation plan was published in April 1995. As a first stage, NHS Trusts have been asked to declare all R&D activity and to cost it by May 1996. Guidance on the declaration was published in September 1995. The declaration will provide the basis of future funding for R&D through a levy on all NHS purchasing authorities. This single stream of funding will allow R&D to be monitored and assessed more clearly, and directed to meeting identified priorities.

18. The Committee notes (60) that the medical charities, including the Wellcome Trust and the Imperial Cancer Research Fund, provide considerable funding for medical research in the United Kingdom. Such funding is complementary to that provided by the MRC and the higher education funding councils and helps to ensure that world-class research, including genetics research, is carried out in the United Kingdom.

19. Through its grant-in-aid to the MRC, the OST provides funds for research into human genetics, including work on the human genome. In 1994–95 the OST provided additional funding to the MRC for genome mapping research. A further £3.5m was given to the MRC for this financial year to fund high priority strategic research in genome analysis.

20. The Government agrees with the Committee (61) that investment in genetic research has produced positive results. The pharmaceutical and biotechnology industries in this country have been quick to respond to the opportunities that have arisen as a result of the power of genetics to explain the basic mechanisms of many common diseases. Genetics also offers new prospects of improving the targeting of many existing therapeutic agents. There is a small but growing number of UK based biotechnology companies which have been created to exploit new understanding derived from genetic research. These include Cambridge Antibody Technology Ltd, Therexsys Ltd, and Q-One Biotech.

21. By establishing more partnerships in this field, it will be possible to exploit the opportunities to a greater extent. Partnerships between the NHS, universities, research councils and industry already exist in some areas, for example pharmacology. To supplement existing partnerships, the Department of Health has now established the National Forum with representation from the aforementioned groups. The aim is to promote a better understanding among other funders of NHS R&D policies and priorities and a better understanding by the Department and the NHS of the plans and

[4] "Supporting Research and Development in the NHS" HMSO 1994

concerns of other research organisations. The National Forum will be considering how its members can in future work together in effective partnership to exploit new opportunities in research. The MRC's Gene Therapy Coordinating Committee also includes representatives from the different groups and, in addition, its Industrial Advisory Group has a specific remit to advise the Council on opportunities in genetics. In 1994, the MRC and the Association of British Pharmaceutical Industries ran a joint conference on genetics in Cambridge.

22. The Government's LINK scheme provides a well-established framework for collaborative R&D, with sharing of costs between the public and private sectors. LINK is one of the principal mechanisms through which industry and the Science Base can jointly take forward priority areas identified by the Technology Foresight Programme. The MRC has recently announced two new LINK programmes which address key recommendations arising from Foresight. The Genetic and Environmental Interactions in Health programme aims to identify key genetic and other risk factors that lead to major multifactorial diseases such as heart disease and will also study genetic factors affecting our susceptibility to drugs and environmental toxicants. The Integrated Approaches to Healthy Ageing programme aims to improve our understanding of molecular and other mechanisms contributing significantly to healthy ageing or to cognitive or physiological decline.

23. The Government agrees with the Committee (64) about the continuing need for investment in the Human Genome Project. This will be necessary to sustain current exploitation activity and to create new opportunities for wealth creation and novel treatment strategies for a variety of diseases.

24. The Committee draws attention (64) to subsequent uses of the maps and sequences of the human genome in research and development, and in therapies. Two reports have recently been published on the implications of the Human Genome Project and related progress in genetics for the NHS[5]. In line with the approach identified in the White Paper "Realising our Potential", and taken forward under the aegis of OST in the recent Technology Foresight Programme, these reports have explored the relevance of the opportunities offered by advances in genetics in relation to the quality of life - linking this to developments in NHS R&D and in clinical practice - and to wealth creation. The reports made a number of recommendations about further research. Some evaluative studies of screening procedures and counselling techniques have already been commissioned as a result.

Research on ethical, legal and social issues

25. The Committee calls (268) for more research into the ethical, legal and social implications of genetics. The MRC, through its Genetic Approach to Human Health initiative, has supported a number of research projects and training awards on the psychosocial aspects of the application of human genetics.

26. Some of the programmes funded by the Economic and Social Research Council (ESRC) cover related issues. For example, the Risk and Human Behaviour Programme investigates the perception and communication of risk in various areas, including genetically modified organisms and medical interventions. One of the projects in this programme is on the social and cultural impact of the new genetics. Looking to the future, the ESRC has developed nine priority themes which will guide its major allocation decisions. One of these themes covers the topic of social implications of technology, which includes new medical technologies.

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[5]"Report of the Genetics Research Advisory Group. A first report to the NHS Central Research and Development Committee on the new genetics" Department of Health London 1995
"The Genetics of Common Diseases. A second report to the NHS Central Research and Development Committee on the new genetics" Department of Health London 1995

27. The Government agrees with the Committee (268) about the importance of coordination between the MRC and the ESRC. These Councils already work closely to coordinate their research in health-related areas through formal annual meetings and regular meetings of officers.

28. The European Commission has established a committee of representatives from each member state to look at the ethical, legal and social issues of the three life sciences programmes in their Framework Programme for R&D. This committee will ensure that there is effective coordination between the programmes and that activities comply with regulations where necessary.

Medical Applications of Genetics

Genetic Diagnosis

29. The Government agrees with the Committee (79) that people who seek diagnosis of a genetic condition of late onset, ie in adult life, should be given adequate information about the medical and social implications of the findings and offered sufficient counselling, in advance of any testing, and subsequently if the result of a test is positive.

30. On the question of genetic diagnosis for late onset disorders in children (80), the Government believes that this is a matter for the clinician to decide upon in consultation with the child and the child's parents. In the case of children, unless there is the prospect of benefit to them, genetic diagnosis related to adult onset disorders is not generally offered or undertaken. This matter will be considered by the new Advisory Committee on Genetic Testing (see paragraphs 64–65).

Genetic Screening

31. The Committee has made a number of recommendations on genetic screening (83–98). The purpose of screening in health care is to detect those, who seemingly healthy, face sufficient risks of having or developing a significant disorder, or of bearing affected children, and could benefit from a subsequent intervention. The intervention might be a diagnostic procedure or preventive action; it might be the provision of information, supported by counselling, to guide important choices and decisions.

32. The Government is firmly of the view that any genetic testing should be subject to the following ethical principles:

— the decision whether or not to undergo testing is for the individual, or the parents/guardians in the case of a child, to make;

— that decision must be informed by knowledge of the possible significance of the results for that individual;

— confidentiality must be preserved.

33. The Government agrees with the Committee (83, 98) that such testing should not be offered or undertaken unless the possible and significant consequences of the investigation are known, there is the prospect of measurable benefit, and the individuals concerned are able to make a decision that is informed by this knowledge, and act upon it.

34. The findings of genetic testing are, like other personal health information, confidential. Therefore those who hold or have access to such information are subject to the common law duty of confidence, specific statutory provisions and professional codes of ethics.

35. Before any screening programme is introduced there must be sound knowledge of the natural history of the disease concerned, of the probability that it will occur, and of

the damage and burden that it can inflict. The interventions available to those who are identified by a positive test must have been assessed and as much information as possible obtained about their effectiveness and cost-effectiveness. In addition, depending on the incidence of the disease, the tests used in screening must achieve a balance between specificity (false negative rate) and sensitivity (false positive rate) to achieve a high predictive value. Tests must be subject to strict quality control and external quality assessment procedures. Screening can cause inadvertent harm. For example, findings that are falsely positive cause needless anxiety, and those that are falsely negative generate unwarranted reassurance. Lastly, the possible benefits and disbenefits to the individuals concerned of knowing the result must also be known. The Government believes that screening should not be introduced unless these requirements have been satisfied beforehand in rigorous evaluative studies.

36. As with any other health care intervention there is a need to evaluate the potential cost-effectiveness of population screening. The cost of screening and the actions that result from it should represent good value in relation to the health benefits offered.

37. The Government believes that the principles and requirements set out above apply to screening in the context of pregnancy and parenthood, neonatal life and childhood, and that screening for detection of the carrier state in genetic disorders should be subject to the same principles. The Government agrees with the Committee (94) that couples who undergo genetic carrier testing, in the context of pregnancy, should be informed that in any subsequent pregnancy with a new partner, the new partner should be offered the test. Widespread screening for carrier status for all genetically-linked diseases is unlikely to be achievable in the foreseeable future, even if it were desirable. The Government agrees with the Committee (95) that, where careful evaluation has demonstrated the cost benefits of screening for a specific trait, then serious consideration should be given to offering it.

38. Screening in the context of pregnancy raises particularly sensitive issues, including the question of termination of unborn children liable to suffer from late onset disorders (90). The Government believes that the purpose of prenatal screening and diagnosis, preceded and followed by information and counselling, is to inform parental decisions on influencing the outcome of pregnancy. Those decisions should be respected and the parents supported in their decision and given ready access to the healthcare interventions available, including termination of pregnancy within the terms of the Abortion Act 1967, as amended by the Human Fertilisation and Embryology Act 1990. Any decision to accept the offer of a screening test must rest on free and informed consent (88) in line with the principles set out in the Department of Health's 1993 report, "Changing Childbirth"[6].

39. On the issue of best practice (88), the Government expects NHS purchasing authorities to use the contracting process to ensure that providers of these services follow best practice. The booklet, "Population Needs and Genetics Services"[7], sets out the features of good practice. This was circulated to all Health Authorities in June 1993 under cover of a letter from the Chief Medical Officers and the Chief Nursing Officers of England and Wales.

40. Arrangements for monitoring the coverage and outcomes of the national screening programme for phenylketonuria, the only national programme for a genetic disorder, have been in place since the programme was introduced. The effectiveness of the arrangements is currently the subject of a national audit study.

41. The Government notes the Committee's point (89) on the desirability of providing screening programmes where there is a need to do so. The Government expects that where the evaluation of a proposed screening programme suggests that it is

[6] "Changing Childbirth: Part 1: Report of the Expert Maternity Group" Department of Health London 1993

[7] "Population Needs and Genetic Services - An Outline Guide" Department of Health London 1993

clearly desirable according to the criteria set out in paragraphs 31 to 36 and paragraph 42, then consideration will be given to providing it.

42. The Government agrees with the Committee (92) that there should be no mass screening for public health reasons unless a treatment for the disorder exists.

43. The Department of Health has set up mechanisms to ensure that any proposal for screening is subject to careful evaluation before introduction (97). Under the aegis of the NHS R&D Programme, the Health Technology Standing Group and its Population Screening Panel now provide a mechanism to evaluate new screening programmes before widespread introduction.

Commercial Screening

44. The Government recognises the Committee's concerns (104) on the need to ensure that commercial screening activity is properly conducted. Activity by anything less than fully responsible companies would do major harm and provide a serious obstacle to development and acceptability of the technology and the benefits it can offer. The Government intends, therefore, to charge the new Advisory Committee on Genetic Testing (see paragraphs 64-65) with regulating, on a non-statutory basis, commercial testing and screening.

45. The draft In Vitro Diagnostic Devices Directive to which the Committee refers (103) is concerned with the diagnostic device itself and not the use of the information resulting. It will regulate the safety and marketing of any test kit. The Medical Devices Agency will be leading for the UK in the negotiation of this Directive.

Screening for Research Purposes

46. The Committee comments (105) on screening for research purposes. Approval has to be sought from a Local Research Ethics Committee (LREC) for any research project involving patients, including genetic testing or screening. The purpose of the LREC is to consider the ethics of proposed research projects which involve patients and to offer independent advice to the local management team in the NHS or equivalent body. The LREC will always carefully consider the arrangements for obtaining consent. The MRC pays particular attention to ethical issues in evaluating proposals for funding.

Somatic Cell Gene Therapy

47. The Government agrees with the Committee (110) that public confidence in genetic medicine is an important issue. As the Committee acknowledges, holding meetings of the Gene Therapy Advisory Committee (GTAC) in public would cause difficulties. However, GTAC last year discussed ways by which greater dissemination of information about gene therapy could be achieved.

48. In addition to its annual report, GTAC has agreed the issue of press releases on the protocols it approves, the production of public consultation documents on developments in gene therapy as appropriate and the holding of workshops in which wide participation would be encouraged.

49. The Government believes that these measures will help maintain the confidence that already exists in the regulation that GTAC provides. It does not see that there would be any additional value in publishing in full the proposals submitted to GTAC. In any case, some of the information would be commercially confidential.

Germ Line Manipulation

50. The Government agrees with the Committee (124) that the existing prohibition on germ line gene therapy should remain in place. Developments in all areas of genetic therapy are kept under review by GTAC.

Genetic Modification of Animals

51. The use of animals in research is controlled in the UK by the Animal (Scientific Procedures) Act 1986, which is widely regarded as a highly effective legislative measure for ensuring that the interests of animal welfare are properly balanced against the general public interest in medical and scientific progress. The Government agrees wholly with the Committee's view (127) that the genetic modification of animals should remain subject to the controls contained in the Act. The Animal Procedures Committee considered that these controls were appropriate to this task when they examined the issues raised by transgenic work in 1990[8].

52. In February last year, a report was published by the committee that MAFF set up under the chairmanship of Professor Michael Banner to consider the ethical implications of emerging technologies in the breeding of farm animals. One of the principal recommendations of this report accepted by the Government, was that present and future uses of animals should be assessed within the framework of the following principles:

i. harms of a certain degree and kind ought under no circumstances to be inflicted on an animal;

ii. any harm to an animal, even if not absolutely impermissible, nonetheless requires justification and must be outweighed by the good which is realistically sought in so treating it;

iii. any harm which is justified by the second principle ought, however, to be minimised as far as is reasonably possible.

Professional Training

53. The Government welcomes the interest shown by a wide range of professional bodies including the British Medical Association, Clinical Genetics Society, the Royal College of General Practitioners, the Royal College of Obstetricians and Gynaecologists, and the Royal College of Physicians in educational initiatives related to genetic medicine (130). This has been supported by increasing numbers of relevant articles in the professional journals.

54. The standard and content of medical training is the responsibility of the Royal Colleges or Faculties which will be fully aware of the importance of genetics within training programmes. It is part of the professional responsibility of individual general practitioners to ensure they keep up to date with new procedures and developments - further training and experience are provided as part of their continuing education (131).

55. The Specialist Workforce Advisory Group meets regularly with specialty representatives and discusses developments in the specialties. Any staffing implications are fed into the manpower model and reflected in a change in training numbers.

Provision of Genetic Services

56. The Government agrees with the Committee (133) that the distinctive features of services for genetic disorders have implications for almost all the clinical specialties, not solely primary care and not for any specialty in isolation. It also agrees that there will be a continuing need for specialised laboratory facilities and clinical services for those with rare genetic disorders (see paragraph 58). There is no intention to devolve funding for all the functions and elements, or the collaborative and coordinating roles, of the genetic services to GP fundholders.

[8] "Report of the Animal Procedures Committee for 1990" Cm 1646

57. The Government's recognition of the importance of genetics and its potential impact upon services has been set out above. The Government believes that the emphasis and direction that have been given to the provision of genetic services by these and related initiatives, building on the strength of the established network of specialised genetic services that has been developed nationally, are sufficient to ensure their orderly development without additional central oversight (133).

58. The Government agrees with the Committee (135) that patient participation in genetic research generates a commitment to continued support and care. The arrangements now being put in place following the recommendations of the report of the Task Force set up under the chairmanship of Professor Anthony Culyer will provide a sound basis for fulfilling such a commitment. It is recognised that some highly specialised services or units treating very rare conditions may experience difficulties in establishing themselves in the internal market arrangements. The NHS Executive is currently exploring the most appropriate contracting arrangements for the provision of these services.

59. Existing arrangements for the provision of specialist services, such as genetics services, may vary locally. Purchasing authorities, including GP fundholders, are encouraged to consider, in collaboration with NHS provider units, how they can most effectively ensure the maintenance and orderly development of these services.

60. It is already current practice to ensure that the quality of any new national screening programme should be monitored against nationally agreed standards, and that adequate arrangements for monitoring should be an integral part of the programme (138).

61. The Government agrees that the development of measures of outcome for genetic services requires sensitivity and caution (139). Whether in the context of pregnancy and parenthood, or life planning, the effectiveness and quality of genetic services are to be judged by the degree to which individuals and couples at risk are identified and given timely information that is sufficiently precise to enable them to make informed decisions on the interventions available.

62. The Select Committee heard from the Chief Medical Officer of the Department of Health of the 1993 initiative entitled "Population needs and Genetic services - an outline guide" which was prepared for those in the NHS who are not specialists in this field to assist in the review of genetic services.

Regulation

63. The Government supports the view of the Select Committee that the existing systems which control genetic research have worked well (142). It believes that the systems and bodies in place will continue to provide an appropriate level of coverage and control and does not agree, therefore, that a Human Genetics Commission is necessary (144).

64. However, the Government does agree with the Select Committee that a further initiative is required to deal specifically with genetic tests, particularly those made available directly to the public (144-146). In a speech to the Royal Society of Medicine in June 1995, the then Secretary of State for Health announced the Government's intention to establish a UK Advisory Committee on Genetic Testing.

65. This new body, reporting to Health Ministers, will advise on the ethical, social and scientific aspects of genetic tests and establish agreed standards for efficacy and product information to be met by manufacturers and suppliers of genetic tests. The Advisory Committee will consider the use and potential use of tests, both in clinical practice and sales to the public (144). The Advisory Committee will be asked to produce an annual report of its activities which will be made available to Parliament and to the public (146).

66. The Government believes that in such a rapidly developing field of medical science, a mixture of statutory and non-statutory arrangements will produce the flexibility that will be needed. Experience with GTAC shows how efficient a non-statutory approach can be in the area of genetics. However, Health Ministers will monitor the workings of the Advisory Committee on Genetic Testing (ACGT) and will keep the option of statutory control open (145).

67. It is agreed that the Government needs to respond positively to other new developments in this field. However, in our view, the guidance and regulatory mechanisms that are already in place will deal with the other functions identified (144) by the Committee. Many of these are also referred to elsewhere in the response.

68. Genetic material for therapeutic use and medicines produced by recombinant DNA technology are covered by the definition of a medicinal product in the Medicines Act and by EC Directives. Therefore the regulation of safety, quality and efficacy are either the responsibility of Health Ministers as the Licensing Authority served by the Medicines Control Agency (MCA) or of the European Medicines Evaluation Agency (EMEA). For medicines based on genetic technology, applications for marketing authorisation are handled by the EMEA via the centralised procedure. Applications for clinical trials are assessed by the MCA in accordance with the Medicines Act and its secondary legislation. The responsibility for surveillance in use of such medicinal products after licensing by the EMEA is a national responsibility and falls to the MCA. The Government notes the Committee's recommendation (176) that the MCA should continue to ensure it has the expertise to regulate medicines which use genetic technology. Present expertise and future requirements will continue to be monitored by the Licensing Authority and its independent expert advisory bodies.

69. The Committee suggests (280) that a Commission might cover other related issues. The Government's position on insurance (100-104), employment (97-99), patenting (78-87), ethical, legal and social research (25-28), and public understanding (105-110) is set out elsewhere in this response. It does not believe that the Commission would provide a more effective mechanism than the current arrangements for dealing with these issues.

70. In view of the widely held view supported by the Committee that GTAC functions excellently (147), no change is proposed to its status and present mode of working with the exception of the changes outlined in paragraph 48.

International Regulation

71. The Government continues to participate actively in the development of the draft Bioethics Convention (278). The Department of Health will provide the Committee with papers as they are published by the Council of Europe.

Genetic Science and Industry

72. The Committee comments (162) on the shortage of qualified professionals. The UK has an enviable record of attracting high calibre professionals into related areas such as the pharmaceutical industry. The Government is confident that, as UK biotechnology grows, the sector will be able to satisfy its management requirements in full. Equally, as the sector establishes itself over time there is every reason to suppose that it will prove attractive to internationally mobile talent looking to take advantage of the excellent opportunities offered by the UK's many emerging biotechnology companies. However, a poor level of business awareness among bioscience graduates has been identified as one of the factors which limit the potential of the UK Science Base in developing biotechnology start-ups. To address this, the DTI and the Biotechnology and Biological Sciences Research Council (BBSRC) are supporting a universities "biotechnology and business" competition for undergraduates, led by the University of

Nottingham, with co-sponsorship from industry. The BBSRC is piloting a similar scheme for postgraduates and post-doctorates. In addition, the DTI is working with the MRC to identify and implement appropriate activities to improve the situation.

73. The Government welcomes the Committee's recognition (163) of the MRC's support for biotechnology companies. The MRC continues to explore new mechanisms of working intended to further enhance that support. The Government agrees with the Committee that there is the potential for more growth than is currently supported by the venture capital sector. The Government is encouraging venture capital investments in smaller companies through two schemes, Venture Capital Trusts and the Enterprise Investment Scheme (EIS). The first three Venture Capital Trusts have raised over £40 million since August last year; over 200 companies have invested a total of £19 million through the EIS.

74. As to the Committee's recommendation on "industrial sabbaticals" (169), the Government is keen to encourage collaboration between higher education and industry. Universities and colleges are increasingly aware of the benefits of sharing expertise with industry and many have developed close links with local and regional firms. It is a matter for the institutions themselves whether they wish to provide "industrial sabbaticals" for their academic staff. However, initiatives such as the Teaching Company Scheme, which supports partnerships between industry and academia, help to build enduring links which can be beneficial to both groups. The MRC encourages movement between industry and academia, both in its own research units and in universities, through MRC fellowships and other career awards, many of which now include the possibility of secondment to industry.

75. The Committee comments (173) on the recommendations of the Technology Foresight Panel on Health and Life Sciences. Technology Foresight recommendations are addressed to the public and the industrial sectors and the charities, as they concern the process of interaction and networking as much as they do the specific subjects highlighted in the recommendations. Industry is well represented on the current membership of all the Panels and is responding favourably to the concept of Foresight as well as to implementing the specific recommendations.

76. For the Health and Life Sciences Panel, the Association of British Pharmaceutical Industries has indicated that it is able to hold a workshop on implementation and the Chairman of the Panel is talking directly with several major pharmaceutical companies about the response to Foresight. This collaboration is reinforced in the terms of the Foresight Challenge, which was launched last year.

77. As part of its response to the Technology Foresight recommendations, the MRC has announced two new LINK programmes which will encompass genetic research (see paragraph 22). These programmes will significantly increase work in this area already supported under LINK. In order to encourage and optimise broad industrial participation, MRC will appoint a senior coordinator who will be given an active role in the management of the programmes.

Patenting

78. The Government fully agrees with the Committee's view (177) that there is a role for patenting in the application of the results of genetic research so as to continue to provide a helpful structure for encouraging industrial exploitation of those results.

79. The Government accepts the Committee's conclusion (195) that the exclusion on the grounds of morality should continue to apply, so long as it continues to be narrowly construed and only applied in very clear cases. There is no directly applicable UK case law in this area. Accordingly, in considering the legal requirement that a patent shall not be granted for an invention whose publication or exploitation would be expected to encourage immoral behaviour, the UK Patent Office follows the guidance laid down by

the European Patent Office's (EPO) Technical Board of Appeal in the "oncomouse" case (T19–90 OJEPO 12–90). The Board indicated that the desire to remedy disease should be balanced against the need to protect the environment from the spread of harmful genes and to consider the welfare of animals. The oncomouse patent is currently being challenged in opposition proceedings before the EPO; the outcome of those proceedings is awaited.

80. The Committee addressed (199, 202, 212) the question of whether patents on genetic research inhibit subsequent research and its exploitation. The Government shares the Committee's view that it is primarily a matter for the parties to resolve by, for example, cross-licensing. Provision already exists for the grant of a compulsory licence where a licence needed to exploit a later invention which makes a substantial contribution to the art, is refused. It is for the later patent holder to invoke the compulsory licence provisions and none has yet done so in respect of a biotechnological invention.

81. However, the very existence of the compulsory licence provisions are an incentive to voluntary licensing and there is no evidence that they are ineffective. Some changes to the compulsory licence regime will need to be made in order for them to be clearly consistent with the UK's obligations under the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the auspices of the World Trade Organisation. In particular, TRIPS requires the criterion, "a substantial contribution to the art," to be replaced by, "an important technical advance of considerable economic significance". If the compulsory licence provisions were shown to need improvement, the Government would consider further amendments to the Patents Act 1977 but any changes would have to be consistent with TRIPS.

82. The Government notes the Committee's view (200) on clarification of the extent to which the research exemption applies. The wording of this exemption in the Patents Act follows closely the wording of the Community Patent Convention, with which the UK has an obligation to align. In the light of the little judicial consideration there has so far been of this provision, it is difficult to give firm guidance on its scope, but the Patent Office will give prominence to it in its publicity about the patent system.

83. The Government notes the Committee's conclusion (205, 206) that genes and fragments of genes should be patentable only in a context of a particular utility but does not accept that there should be a specific provision to that effect. The Government believes in the current state of the art that application of the normal criteria of patentability - novelty, inventive step and industrial applicability - will normally preclude the grant of a patent for genes of unknown function. The Committee's view that there have been problems in the practice of patenting (207) and in particular (208) that some examiners have applied the criteria of patentability too liberally is noted. However, it must be remembered that what might seem obvious at the time of grant of the patent would not have been so at the time the patent was applied for. It is in the light of knowledge at that time that the patentability of an invention must be judged. Nevertheless, if third parties consider that the criteria have been applied too liberally, they may apply for revocation of the patent.

84. The Government notes the Committee's comments (209) that the European Patent Convention should be amended to allow patents to be challenged on the grounds that their claims go too wide. Breadth of claim is no objection of itself, provided the claim is commensurate with the contribution to the art disclosed in the patent. Any amendment of the Convention to make lack of support of the claims a ground for revocation would go beyond biotechnology and affect all inventions. The Government has therefore sought the views of its Standing Advisory Committee on Industrial Property (SACIP) on whether such an amendment would be desirable. It is already possible to seek revocation of a patent on the grounds that the specification does not sufficiently disclose the method by which it is to be performed. This objection will often, if not always, apply where the breadth of the claim is not supported by the description.

85. The Government notes the Committee's comments (214) regarding invocation of the Crown Use provisions of the Patent Act 1977 by the Department of Health. The need to apply these provisions will be reviewed as appropriate. It believes, however, that every effort should be made to arrive at a voluntary commercial agreement before the provisions are invoked. The compatibility of the Crown Use provisions with TRIPS is being studied and amendments will probably be required.

86. The Committee comments (215) on the need to consider the effects of patenting practice on various groups. The Government is always prepared to consider views on the way the patent system operates and its effects on industry, public sector researchers and the Health Service. The Patent Office has established channels for this in SACIP and, in relation to other government departments, the Interdepartmental Committee on Intellectual Property.

87. The Government agrees with the Committee (218) that in the present circumstances an EC Directive harmonising patent law in relation to biotechnological inventions could be more harmful than having no harmonising measure. The Government has made clear to the European Commission its view that they should reflect on the need for a new proposal and proceed only if they are confident they can secure agreement on a text which enhances the legal framework for investment in the European Union.

Privacy and Other Issues

88. The Committee raises difficult and important issues concerning the potential for misuse of genetic information (220-226). The Government agrees with the Committee (224) that the fundamental question relates to personal privacy, rather than genetic information.

89. The Government has reflected carefully on the question of a general provision to protect personal privacy. It has decided against developing the law (225, 226) in that way and does not believe that there is a strong enough case for making an exception in this area.

90. The Government is satisfied that the privacy of medical records, including genetic information about an individual, is properly covered by the existing law, either the Data Protection Act or the common law duty of confidence.

91. The Government agrees that genetic information may raise the issue of disclosure to others who have a potential interest. Information gathered from one patient leads to inferences about other family members (222), raising the potential problem of unsolicited disclosure. Information must be used in a way that is ethically acceptable.

92. The Committee also draws attention (226) to the recent report of the National Heritage Committee calling for a Privacy Bill involving both criminal and civil sanctions. The Committee will now be aware of the Government's response[9] to these proposals. The Secretary of State for the National Heritage has indicated[10] that the difficulty of formulating a criminal intrusion offence that was both clear and enforceable, but which did not at the same time inhibit legitimate journalistic investigation (and the absence, after consultation, of any clear consensus in favour of a new civil remedy for invasion of privacy) had persuaded the Government that it was preferable, for the moment, to rely upon the new forms of self-regulation on which the press had agreed, rather than fresh legislation.

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[9]"Privacy and Media Intrusion: The Government's Response" Cm 2918 July 1995
[10]Hansard, 17 July, Col 1323 *et seq*

Medical Confidentiality

93. The right of the individual to confidentiality in regard to their personal health information, obtained from whatever source, should be protected apart from very exceptional circumstances. The Government therefore agrees (231) that, as a general principle, the individual's right to privacy should prevail. The issues that surround the sharing of confidential information with other family members (228) are familiar to clinical geneticists[11]. Each case must be considered on its own merits; generally, the release of information in the interests of another person can only take place where this outweighs the duty of confidence to the individual.

94. The Government understands the Committee's point (230) on the review of the Office of the Data Protection Registrar but would like to clarify the nature of the review. This review, which is planned to be completed by the end of this financial year, is one of the regular series of quinquennial reviews to which Non-Departmental Public Bodies are subject. It will be conducted in two parts. The first, the so called "prior options review" is, in accordance with established practice, looking at the continued justification for the performance of the functions vested in the Registrar. It will thus take into account the extent to which personal data remain under threat (whether because of developments in new technologies, or for other reasons) and are thus in need of the protection afforded by a data protection authority.

95. The Government is satisfied, however, that the Registrar's current powers are cast in sufficiently broad terms to enable her to respond as necessary to any new threats posed by new technologies. The opportunity will be taken to review the investigation and enforcement powers of the Registrar, when considering the implementation of the recently approved EU Directive on Data Protection.

96. The second stage of the review will be concerned with matters relating to the efficiency of the organisation, its financial management and the value for money it provides.

Employment

97. The Committee makes a number of recommendations relating to the possible use of genetic testing for employment purposes (232, 233). It is clear that genetic testing has potentially important implications for the employer-employee relationship, particularly by its use in recruitment and subsequently during employment. However, there is currently very little evidence, as the Nuffield Council found in their report on genetic screening, of the systematic use (let alone abuse) of genetic testing programmes by UK employers. Given this, the Government does not agree with the Committee (232) that legislation is required to regulate the circumstances in which genetic testing may be carried out but it will, nevertheless, keep the situation under review. The Health and Safety Commission's Occupational Health Advisory Committee has set up a working group on genetic screening.

98. It is the Government's view that, while we would encourage employers to follow good practice and procedure, company policy and practice at the recruitment stage and subsequently during employment is essentially a matter for employers themselves, consulting employees (or their representatives) as appropriate in formulating the policy, depending upon their own circumstances, needs and priorities. Such policy may include medical, including genetic, testing which should be in the interests of both employers and employees.

99. The Government agrees with the Committee (233) that employers will need to seek the agreement of job applicants and existing employees to genetic testing and permission should always be sought if the testing is to be extended to other conditions

[11] "Changing Childbirth: Part 1: Report of the Expert Maternity Group" Department of Health London 1993

not covered by the initial agreement. Where employers seek to impose unilaterally such a term, any employee who is dismissed for refusing will generally have the right to make a complaint of unfair dismissal to an Industrial Tribunal.

Insurance

100. Although testing technology is developing quickly, there seems to be little early prospect of a major increase in the number of tests which would be of potential use to the underwriter. There have been isolated cases where insurers have treated genetic information inappropriately, but there is no evidence that this has been widespread. Indeed, the Committee found the industry's attitude to be responsible. In light of the above, the Government does not believe that legislation would be appropriate now or in the foreseeable future.

101. The Government does not agree with the Committee (248) that a deadline should be imposed on the insurance industry for the development of an acceptable solution on the use of genetic information for insurance purposes. It believes that more work needs to be done to define the problems in this area before the search for a solution begins. To that end, the Government very much welcomes and encourages the dialogue taking place between the Association of British Insurers (ABI) and leading geneticists with a view to correctly identifying problems and exploring common ground on solutions. The current discussions might lead to the development of an industry-wide code of practice. Such a code might, for example, state that the taking of a genetic test would not, of itself, be taken into account for the purposes of accepting risks or setting premium rates, although the positive results of such a test might be taken into account for such purposes. Although this is the industry's current practice, there is plenty of scope for public misconception at present, which may deter some from taking tests which are indicated on health grounds.

102. The Committee refers (246) to a proposal for the establishment of a pool for the reinsurance of genetic risks. This is an interesting idea which is, in the first instance, a matter for the industry itself to consider. The Government is pleased that the ABI have started a careful examination of the proposal. However, the practical difficulties should not be underestimated. For example, it would be important that relevant diseases were properly defined, appropriate limits were set, and also that other policyholders were not materially disadvantaged.

103. The Government will keep in touch with the above developments and, in the light of them, will review whether it needs to take action. It hopes to see substantial progress within 12 months.

104. The Government notes the Committee's view (250) that genetic information may limit the scope of medical insurance in the medium to long term. It has yet to be persuaded by any evidence that such problems may occur in the foreseeable future.

Public Understanding

105. The Government agrees with the Committee (256, 261, 263) about the importance of public understanding. It announced its policy in this area in the 1993 White Paper, "Realising our Potential". Since then the OST has promoted a campaign to increase the general public's awareness and understanding of the contribution that science, engineering and technology make to the nation's wealth and well-being.

106. A major new initiative has been the introduction of an annual National Week of Science, Engineering and Technology. The second of these took place in March last year and involved, through events arranged in all parts of the UK and programmes on BBC television and radio, millions of people of all ages.

107. The Research Councils also play a major role in promoting public understanding in the areas of science for which they have responsibility. New Royal Charters introduced on 1 April 1994 include public understanding as one of their objectives. For example, as part of their contribution to National Science and Engineering Week, the MRC and the Wellcome Trust jointly ran an exhibition on the concourse of Euston Station entitled "Genes are Us". They also ran a genetics course for members of the Women's Institute at their residential college in October 1995. Through its funding for a Consensus Conference, BBSRC also raised public awareness of genetics and initiated a debate. Separating this work from the Research Councils in a Human Genetics Commission would hinder rather than help.

108. The MRC have been involved in producing information for schools and two of the "research updates" in school resource materials are on genetics. They are also currently developing "Geneweb", with teachers and others, which will enable secondary schools on World Wide Web to have access to information on developments in genetics.

109. The Government notes the Committee's comments (259) on the revisions that should be made to the teaching about human genetics within the science curriculum when the National Curriculum is reconsidered. Schools may already provide additional teaching about human genetics within their programmes of sex education and personal, social and health education. Within the statutory framework for such provision it remains, however, for individual schools to determine how best to organise and deliver the curriculum to meet their pupils' needs and to consider whether, and if so how, they might wish to extend provision for education about human genetics beyond this.

110. The five year moratorium on further change to the National Curriculum offers an opportunity to undertake a systematic evaluation of its content and structure. The School Curriculum and Assessment Authority is responsible for advising the Government upon the school curriculum. It will take the Committee's views into account when it advises the Government on what changes might be required in five years time.

CONCLUSION

111. It is clear that a balance needs to be struck between, on the one hand a desire to harness the benefits of human genetics and maintain at least the same level of development as other leading countries, and on the other hand a careful consideration of ethical issues.

112. The Government believes this can best be achieved by a mixture of statutory and non-statutory arrangements, and by taking advice from governmental advisory bodies and independent organisations. By establishing the Advisory Committee on Genetic Testing, the Government has filled a gap rightly identified by the Committee and now has, it believes, mechanisms in place for effectively addressing all the issues which the Committee's proposed Human Genetics Commission would have been asked to consider.

113. The Government is not complacent, however, and will continue, as has been said in various sections of this response, monitoring developments to ensure that its policies remain effective.

Annex A MAIN BODIES COVERED IN THE GOVERNMENT RESPONSE ON HUMAN GENETICS

Body	Status	Role
Gene Therapy Advisory Committee (GTAC)	Non-statutory committee reporting to Health Ministers	Considers all proposals for gene therapy research on human subjects in the UK and provides advice on their acceptability on ethical grounds, taking account of the scientific merits and the potential benefits and risks. Also provides advice on general developments in the field of gene therapy.
Local Research Ethics Committees	Non-statutory committees which provide advice to health authorities	Examine the ethical aspects of all health-related research carried out on patients in the NHS. Their approval must be obtained before the research can be conducted.
Nuffield Council on Bioethics	Independent body set up in 1991 and chaired by Rt Hon Sir Patrick Nairne	Provides advice on ethical issues arising from current biomedical and biological scientific developments. Has produced two reports so far on genetic screening, and the uses of human tissue.
Advisory Committee on Genetic Testing (to be established)	Non-statutory committee reporting to Health Ministers	Will advise on the ethical, social and scientific aspects of genetic tests and establish standards to be met by the manufacturers and suppliers of these tests.
Occupational Health Advisory Committee	An advisory committee of the Health and Safety Commission.	This Committee has recently set up a working group on genetic screening.
Medicines Control Agency	An agency of the Department of Health	Regulates the handling and preparation of medicinal products, and applications for their use in clinical trials.
Medical Devices Agency	An agency of the Department of Health	Ensures that medical devices and equipment for sale or use in the UK meet acceptable standards of safety, quality and effectiveness, and that these standards comply with relevant EC directives.

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