Government response to the report by the House of Lords Select Committee on Science and Technology inquiry on human genetic databases : challenges and opportunities / presented to Parliament by the Secretary of State for Health by Command of Her Majesty, July 2001.

DEPARTMENT OF HEALTH

GOVERNMENT RESPONSE TO THE REPORT FROM THE HOUSE OF LORDS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY INQUIRY ON HUMAN GENETIC DATABASES : CHALLENGES AND OPPORTUNITIES

Presented to Parliament by the Secretary of State for Health
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FOREWORD

In July 2000, the Science and Technology Committee of the House of Lords established an Inquiry into the present use of human genetic databases and plans for their development. It published its findings on 29th March 2001.

This Inquiry had been prompted by recent and projected advances in the techniques for genetic sequencing and by the many potential benefits that the accumulation and interpretation of human genetic information might bring. In time it should be possible to assess the risk an individual has of developing disease and to better predict the likelihood of an individual having an adverse reaction to a particular medicine. Achieving some of these benefits will require longitudinal studies on large population cohorts during which genetic, physiological and environmental (life style) data are linked to defined clinical end points. Large databases containing genetic and health information will be generated as a consequence.

The storage and processing of the information held in these databases will make enormous demands on existing computing capacity and will require access to increasing numbers of suitably qualified staff trained in data analysis and bioinformatics. In addition, as access to health and medical information about individuals raises many issues over confidentiality and privacy, there is a need to ensure that adequate guidance, or regulation, is available on how data held in genetic databases are collected, protected and subsequently used. The possible benefits of creating these databases will need to be balanced against public concerns over the wider access to, and subsequent use of, the data they contain. It is the Government's job to achieve this balance and to secure public approval to move forward. The challenge is to ensure that the rights of individuals are not neglected in the search for benefits for society as a whole.

The Inquiry concluded that the Data Protection Act 1998 offers significant protection in this area but recognised that the new genetic advances could generate unforeseen challenges. Of particular concern was the ownership of the data, the consent needed to obtain this data and possible linkage back to individuals. The Inquiry also raised concerns over the intellectual property rights and patenting implications for the commercial development of any discoveries resulting from the use of information held in genetic databases.

The Inquiry was informed of the prospective genetic study involving a cohort of half a million volunteers that is currently being considered by the Medical Research Council and the Wellcome Trust, in association with the Department of Health. It also discussed how NHS health records represented a unique, but as yet largely untapped, source of information on the health of the nation. The Inquiry felt that it was important for the NHS to adopt and implement uniform standards and protocols for the collection, storage and subsequent use of all medical information both for the proposed genetic studies and for broader considerations relating to health.

The Inquiry also considered forensic databases. The use of DNA evidence is becoming an increasingly important tool in the fight against crime. The way in which DNA profiling is used contrasts with that of medical databases. It brings different challenges in terms of ensuring that the police can make full and effective use of DNA profiling whilst ensuring data and samples are properly used and protected.

The United Kingdom is in a unique position to capitalise on, and derive benefit

from, advances in human genetics. The Inquiry advised that the Government should ensure that a regulatory regime is in place that is sympathetic to the work and that offers individuals the privacy they have a right to expect. The Inquiry indicated that appropriate financial and human resources should be made available to achieve this. In any consideration of this area it is important to bear in mind that whilst human genetics is a reserved issue under the devolution settlement, many of the recommendations made in the report refer to devolved issues. Policy areas that are not reserved include:

- Health records, including electronic patient records
- Unique patient identifiers
- Information systems
- Patient confidentiality

The devolved administrations may therefore wish to individually consider the Committee's report and comment accordingly.

The Government welcomes this thoughtful and constructive report from the House of Lords Select Committee on Science and Technology. It considers it a helpful overview and assessment of the many issues that follow on from the recent advances in our knowledge of human genetics and the creation of databases of human genetic information. The Government is aware of the importance of creating an appropriate regulatory, and where necessary legislative, environment in which research involving human genetic information can be used to eventually improve the health of the general public.

The Government has a duty to provide positive safeguards to address legitimate public concerns over human genetics. It was for this reason that the Human Genetics Commission was established to provide independent advice in this difficult and sensitive area. The Commission is currently reviewing the storage, protection and use of personal genetic information and will be advising Government on a framework for future regulation. The Human Genetics Commission and the House of Lords Select Committee have worked together to co-ordinate the content and timing of their respective inquiries to ensure that all the issues are properly addressed. It is anticipated that the Human Genetics Commission will publish its report and recommendations in December 2001.

In several instances the Science and Technology Committee makes recommendations to both the Human Genetics Commission and to Government. The Commission has considered these recommendations and has commented on the Government's position based on their work to date. The Government's response given below takes note of these comments.

The Government has considered carefully all the recommendations made by the Select Committee. Its response to each of the recommendations is set out in this document using the chapter headings, paragraph numbering and order given in the Select Committee's report.

CHAPTER 3: SETTING THE SCENE

Paragraph 3.1 : We recommend that the HGC and Government should conclude that the primary means of regulating human genetic databases should continue to be the *Data Protection Act 1998* and that, except as recommended in paragraph 7.58, no additional protection is required for personal genetic data.

The Government agrees that the Data Protection Act 1998 is, and should remain, the primary means of regulating human genetic databases. While policies and codes of practice may need more work, the primary legislation in place is adequate. Those that process genetic data must also comply with Human Rights and common law obligations; if necessary, clarification of these obligations can be obtained through the interpretation of legislation in the courts. The Human Genetics Commission has indicated that it is still considering its advice on this point, particularly as the Information Commissioner has indicated that personal genetic information might be regarded as different and may therefore require special treatment or even regulation by a separate body. The Government will consider advice on the need for further legislation when it is received. Comments on the recommendation (paragraph 7.58) to establish a Medical Data Panel are given later.

CHAPTER 4 : CURRENT AND FUTURE BENEFITS

Paragraph 4.33 : We recommend that the Government should provide sufficient earmarked resources to the MRC and the Department of Health to ensure that the support and infrastructure required for this important initiative are in place.

The Government accepts that the United Kingdom is ideally placed to establish the proposed large-scale prospective study to further the understanding of the interactions between genetic and life style factors in determining susceptibility to disease. The Government views the proposed study as being one of the most important strategic initiatives in medical genetics at this time. It recognised the significance of the project in the NHS Plan and gave it a corresponding priority in the recent Spending Review, which allocated resources for genetics research to both the MRC and the Department of Health. In addition, the NHS R&D budget will provide for NHS support and infrastructure required by this research.

Until the scope of this prospective study and the methodology for data collection and analysis has been finalised, it is impossible to be precise about the lifetime costs of the initiative. Nevertheless, the MRC, the Wellcome Trust and the Department of Health will continue to work together to ensure that a suitable management infrastructure is developed to support this important programme.

CHAPTER 5 : INFORMATION TECHNOLOGY AND DATA LINKAGE

Paragraph 5.25 : Recognising that the UK Population Biomedical Collection project will stand or fall on its ability to manage the data, we recommend that the MRC and the Wellcome Trust should give high priority to ensuring that all aspects of the data handling and computing requirements for this important project have been fully addressed, and make appropriate plans to meet its needs.

The Government agrees with this recommendation and understands that the MRC and the Wellcome Trust will address these issues in their response.

Paragraph 5.27 : We recommend that the Government (and the various education funding councils), the Medical and other relevant Research Councils, the Wellcome Trust and other research charities, and the pharmaceutical companies should give high priority to funding training and supporting research in the areas of bioinformatics, statistical genetics and the computing science underlying database management.

The Government acknowledges that skills shortages exist in bioinformatics, statistical genetics and computing science and accepts this recommendation. In the recent White Paper 'Opportunity for All in a World of Change', a new £25 million, 5 year programme on 'Harnessing Genomics' was announced. A significant proportion of the money available will be targeted at support for bioinformatics. The Research Councils will also be using some of the additional £200 million made available for genomics and e-science in November 2000 to build on current initiatives aimed at strengthening bioinformatics and related disciplines. These initiatives have already led to the development of a very active bioinformatics community in the UK. It is worth noting that funding for the European Bioinformatics Institute (EBI) outside Cambridge is also expected to increase substantially over the next few years.

The Science and Technology Committee may wish to note that the Government has asked Sir Gareth Roberts to undertake a review of the supply of skilled scientists and engineers in the UK, reporting in spring 2002. The aim of this review is to ensure that businesses can recruit and retain the scientists and engineers necessary to lead and underpin their research and development activities. The review will focus on high level scientific and technical skills possessed by postgraduates and well qualified graduates.

Paragraph 5.28 : GP databases need to be made compatible with one another and held in a way that allows the computer retrieval of the wealth of clinical information they contain. Accordingly, we recommend that the Government should ensure that the necessary financial and other resources are made available for this purpose. The aim must be to have such systems operational nationally within five years. Achieving this will require an NHS-wide standard protocol for data capture and retrieval, and that will need to be in place much sooner.

The Department of Health has established an initiative known as Project Connect. This aims to ensure that:

- People working in GP practices in England can access NHSnet at their desktops, as appropriate.
- GP connections to NHSnet are implemented effectively and work properly.
- The benefits of networks and connections to NHSnet are identified and delivered.
- People working in GP practices and NHS trusts are capable of communicating effectively over the NHSnet and accessing information on both the NHSnet and Internet, as appropriate.
- The NHS provides secure national standard messaging systems for pathology over NHSnet.

The NHS Requirements for Accreditation (RFA) specifies a core set of requirements, which all GP systems should be capable of performing. These are supported by a testing and accreditation programme run by the NHS Information Authority which, as a consequence, also provides a way of influencing the development of capacity in GP computing.

Information for Health recommended that Primary Care needed to develop the means to access, aggregate and analyse data held within practice systems to support the delivery of care and (as a by-product) the planning, commissioning, monitoring and evaluation of health and healthcare services. A suite of work programmes is addressing this requirement. These include :

- The production of a nationally agreed set of definitions and terms in key clinical priority areas to produce harmonised datasets for patient records.
- The development of standardised methodologies to interrogate and extract data from different types of practice systems. Existing methodologies are able to provide information on issues such as the prevalence of morbidity and changes over time, progress towards health gain targets for specified groups (for example, in support of Health Improvement Programmes), outcomes for patients with specified illness, and monitoring at risk groups. Work continues to refine these processes.
- The creation of collation, analysis and feedback services to provide benchmarked data to primary care teams.

These programmes are being taken forward as part of the implementation of the NHS information strategy. The aim is to complete the work by 2005, but many aspects of these programmes will become available within the next year. In the meantime, the General Practice Research Database (GPRD) will continue to be used as a resource which can provide aggregated population data derived from a sub-set of general practices (with the caveat that the GPRD may not provide entirely typical data as the contributing GPs are self-selected).

CHAPTER 6 : ROLE OF THE NHS

Paragraph 6.23 : We recommend that the Government should review the strategy for instituting electronic patient records throughout the NHS, to include clinical information contained in GP, hospital and other health records. Delivering a fully functioning national system by 2005 will require firmness of purpose to drive forward the development of robust and standardised systems. This must be supported by appropriate funding, including proper investment in the NHS skills base.

The NHS Plan requires the development of electronic patient records to support many aspects of its vision. They are crucial to the full development of a patient-centred service. The programme to deliver electronic records is based on five key goals.

- Lifelong electronic health records for every person in the country.
- Round-the-clock on-line access to patient records and information about best clinical practice, for all NHS clinicians.

- Genuinely seamless care for patients through GPs, hospitals and community services sharing information across the NHS information highway.

- Fast and convenient public access to information and care through on-line information services and telemedicine.

- The effective use of NHS resources by providing health planners and managers with the information they need.

The NHS Plan and ***Information for Health*** lay out a number of objectives for implementing the Electronic Records initiative. Ministers regard achieving these objectives as having a high priority. Local Health Communities are currently addressing how they will achieve the required targets through their local implementation strategies. The NHS Information Authority and the Regional Offices keep progress against these targets under continuous review. The Department of Health will shortly be receiving the local implementation strategies that will provide a firm indication of progress being made against the targets set.

During the last two years, an additional £214 million has been made available to support modernisation of NHS information systems. This includes £79 million announced in 1999 as a recurring sum and a further £53 million made recurrently available to Health Authorities from 2000. Additional sums are now being made available as part of the allocations for the next three years. An extra £113 million will be provided to the NHS in 2001/02 for investment in Information, Management and Technology initiatives. This will increase to £210 million in 2002/03 with a further £210 million in 2003/04. The Government therefore considers that appropriate funding has been made available as an investment in this area.

Investment in the NHS skills base is being made through the NHS Information Authority's "Ways of Working with Information" programme. This will introduce programmes to develop the right skills to the right time scales for local communities and should, in the longer-term, help to change the culture so that information, management and technology becomes a natural tool for healthcare professionals to use. It will also establish networks of information champions in each region and ensure that appropriate products and services will be used to support every national programme.

Paragraph 6.24 : We fully endorse the intention in *Saving Lives: Our Healthier Nation* to extend and strengthen disease registers, and recommend that the Government should give this high priority.

The Government accepts this recommendation. The Department of Health has already commissioned a study to help draw up the criteria to create high quality disease registers and robust clinical audit databases.

Paragraph 6.25 : To facilitate proper communication and data linkage throughout the NHS, we recommend that the Government should urgently develop and implement a unified information system specifying and requiring adherence to completely compatible common standards. This will need to be backed with sufficient resources. Without such standards and the necessary resources, projects relying on large-scale use of NHS data will not succeed.

The Government recognises that strong national leadership will be needed and agrees that a set of national standards covering both the clinical and technical requirements of information communication technology backed by appropriately targeted resources and performance managed outcomes is also required. However a unified information system is not seen as feasible or desirable. ***Building the Information Core***, updates the Information Management and Technology strategy and describes how a more corporate approach will be adopted to implement this recommendation.

The strategic aim is to ensure that information can be transferred seamlessly, where authorised, across all care sectors in the NHS. The following principles apply to the work now underway to put a coherent standards framework in place.

- Where possible, existing standards will be adopted.
- New standards will be developed only where none are already available and where there is a defined business need.
- Standards must be capable of being implemented, and therefore need to be tested in use before adoption.
- Standards can only be agreed where there are measures that can be used to test for conformance.
- The standards set out in the Government Interoperability Framework and the various e-government guidelines will be adopted in preference to any health specific standards.
- Where there is a need for health specific standards, then established international standards will be adopted rather than developing new NHS-specific ones.

Four national Standards Boards have been established:

- The Information Standards Board will oversee the whole standards process, setting priority areas for standardisation and approving proposals.
- The Clinical Data Standards Board will be responsible for agreeing standards for clinical terms and clinical messages used in the care of individual patients.
- The Technical Standards Board will work closely with the Government Interoperability Framework and will be responsible for agreeing technical standards.
- The Management Information Standards Board will be responsible for agreeing standards associated with management, organisation and performance assessment.

Paragraph 6.26 : Accordingly, we recommend that the Government should urgently make use of the NHS number mandatory as a common identifier. It should appear on all health records in the health service, including death certification. The NHS number must be assigned at birth (or on arrival in the United Kingdom for those born elsewhere). Furthermore, we recommend that the Government should give appropriate publicity to this change in practice, ensuring that patients not only know their NHS numbers

but also understand why it is important to use them in their interactions with the health service.

Use of the NHS number is a requirement of NHS Information Technology Standards and options for increasing its presence in key information flows are being introduced. For example, Trusts were informed in the 1997/98 financial year that they should incorporate the NHS number into the minimum data set obtained from admitted patients and this is now in place. In parallel they were also instructed to ensure that the NHS number is quoted in correspondence and other documents supplied to the patient, and in discharge letters and similar correspondence to GP practices and others. Usage of the NHS number is estimated to be around 80% and this is monitored to encourage and promote full uptake.

To support increased reliance upon the NHS number, the National NHS Number Strategic Tracing Service (NSTS), with agreed access security protocols, has been established. Phase one of this initiative was launched in March 2000. Batch and on-line tracing services for Trusts are now available. The NSTS will be the prime source for identifying NHS numbers. All Health Authorities are therefore expected to submit data to the NSTS, and all Trusts are expected to make use of the service in order to obtain or verify patients' NHS numbers.

Publicity about the new NHS number has been available since 1997 and the NHS Information Authority continues to promote its use and the Tracing Service at conferences, NHS events and through specialist journals etc. Procedures are therefore in place to ensure that greater use is made of the NHS number and that more people are aware of its existence.

CHAPTER 7 : ETHICS, PRIVACY AND CONSENT

Paragraph 7.55 : As a matter of urgency, we recommend that the GMC should make it clear that, as their representative told us in evidence, doctors are not required to obtain signed consent before data are passed to disease registries. Instead, patients need simply to know that data about them may be used in this way. Such clarification may require a rewording of the GMC guidelines to put their position beyond doubt.

This welcome recommendation is for the GMC to consider how to take forward. However, the Government wishes to stress the importance of access to, and use of, patient information for both the operation of the NHS and for research. Several examples where access and use of patient information, most notably that held within cancer registries, have led to the better understanding of the epidemiology of disease and to improved patient care, were described in the evidence presented to the Inquiry. The Government's continued commitment to using patient information held by GPs and others in the NHS is demonstrated by the current and planned investment in the maintenance of existing databases and the creation of new ones. The proposed partnership with the Wellcome Trust and the MRC to create the population database for studies on genetic susceptibility to the acquisition of common diseases of adult life represents one example of this commitment. Effective present and future patient care, is founded on learning from, and sharing past experience in, managing patients subject, of course, to appropriate confidentiality safeguards. The Government would not want to see the acquisition of patient information or its subsequent use for improving patient care unnecessarily compromised.

Paragraph 7.56 : We recommend that the HGC and the Government should promulgate guidance for all those who collect or hold genetic data about identifiable individuals, reminding them of their obligations under the *Data Protection Act 1998* and stressing the need to record, alongside the data or in an appropriately accessible form, whether or not the individuals concerned had been informed of the use to which their data might be put and whether they had expressed any reservations.

The Government accepts this recommendation but questions the need to mount a separate exercise to implement it. Audits of existing collections of human biological material (tissue/organs and DNA samples) are ongoing both in the NHS and by the MRC. The MRC has recently issued new guidelines, in consultation with the Department of Health, NHS Ethics Committees and other funding bodies on "Human tissue and biological samples for use in research" and on "Personal information in medical research". These guidelines cover the consent requirements for the use of medical data and biological samples from which human genetic data can be obtained. MRC research staff and grant holders are required to comply with these guidelines. All collections will now be expected to be able to give information on donors' knowledge of, and consent to, specific research studies or future uses. It is unlikely that similar records from previous studies will be found in which people have given consent to general use subject to particular restrictions, as the nature of existing past procedures encouraged an all or nothing response.

The Department of Health is currently in the process of developing a national confidentiality strategy for the NHS. The existence of systems and processes to record and respect patient preferences including objections to disclosures is a key element of the strategy. In addition, the Human Genetics Commission will carefully consider the recommendation for additional guidance in the light of the consultation responses on genetic research. However, the terms of reference for the Human Genetics Commission may not extend to producing guidance material on matters that it considers. Its primary purpose is to advise Ministers and to involve and include the public in the debate on the wider ethical, legal and social implications of developments in human genetics.

Paragraph 7.58 : We recommend that the Government establish a Medical Data Panel to provide a single, clear process for approving projects involving the secondary use of NHS and medical research data (including data derived from retained biological specimens). Its functions would be three-fold:

(a) to consider for approval projects involving national or supra-regional secondary use of health and related data;

(b) to set policy for approval of projects involving secondary use of such data at regional and local levels; and

(c) to advise the Government and the Data Protection Commissioner on the interpretation of the *Data Protection Act* in its application to medical data - and, if necessary in the light of medical advances, changing public attitudes or other changing circumstances, to advise on possible amendments to the legislative framework.

This independent body should have wide representation, including both lay and professional members.

The Government recognises the need to gain public confidence in the mechanisms used to obtain proper consent for the secondary use of NHS and medical research data, and that the recommendation to establish a Medical Data Panel is intended to achieve that aim. However, the recommendation itself appears to give the Panel wide-ranging powers to make decisions about the use of confidential patient information, without providing any legal basis for doing so. The need for a body to assess and approve the use of confidential patient information for NHS purposes such as medical research and public health work has been met in Section 60 of the newly enacted Health and Social Care Act 2001. In view of this, the Government does not accept that the proposed Medical Data Panel, whose remit appears to be far wider than the use of genetic databases, is necessary.

Section 60 of the Health and Social Care Act 2001 provides powers to require patient identifiable data to be used for specified medical purposes. However, this is restricted to where there is a benefit to patient care or public health and where there is no practicable reasonable alternative to the use of the information without consent.

Within the Act there is a requirement for the Secretary of State for Health to establish a statutory body, the "Patient Information Advisory Group". This group will have a broad-based membership and will reflect the interests of patients, NHS professionals and the research community. The role of the group will be to scrutinize applications for use of the powers provided in Section 60, provide advice on the confidentiality and security standards that should apply and advise the Secretary of State for Health about any proposed regulations. Following this process, the Secretary of State for Health is required to consult with bodies representing the interests of those likely to be affected. Prospective regulations must then be introduced under the affirmative procedure of both Houses of Parliament; this applies only to England and Wales. Regulations to establish the Patient Information Advisory Group are in the process of being devised.

It should also be noted that the proposed responsibilities of the Medical Data Panel clash directly with the role of Multi-Centre Research Ethics Committees (MRECs). These Committees were established in 1997 following the issuance of guidance to the health service (HSG(97)23), and similar documents for Scotland and Wales). The key principle was that the favourable opinion of any one MREC should cover the whole of the UK.

The process establishing MRECs was more rigorous than had occurred previously for the Local Ethics Research Committees. It included public advertisement in the national press, formal trawling of professional networks and consultation through Community Health Councils. Interested prospective members were asked to complete an application form and provide character references. An appointment procedure was established, including interviews where appropriate. MRECs include both expert and lay members as specified in the original guidance.

From 1 April 2001, management of MRECs in England was transferred to the Central Office for Research Ethics Committees (COREC). The MREC Chairmen meet regularly with COREC (at least four times per year) during which common approaches to ethical issues are debated. The MREC Administrators also meet with COREC six times a year to revise administrative procedures in line with any new legal or regulatory requirements. Between these meetings there is considerable communication on key issues. There is close

collaboration with Scotland and Wales and there are regular regional and national training meetings.

MRECs operate in a coordinated way and in line with Department of Health policy. However, their ethical decisions must clearly remain independent, operating within an established governance framework, accountable through COREC to the Department of Health.

MRECs are well placed to reflect current public views on ethical issues and have the experience and training to reach UK-wide defensible positions on the ethical standards of research protocols. They are therefore also well placed to provide ethical approval for the secondary use of health and related data. In addition, LRECs and MRECs have a possible role to play in the independent scrutiny of research applications that require regulations under Section 60 of the Health and Social Care Act 2001. Many of these roles are identical to those being proposed for the Medical Data Panel.

Paragraph 7.59 : We recommend that endorsement by this body, or by others within its policies, of a proposed use of data should constitute a sufficient protection under the terms of the *Data Protection Act.* The process should also afford additional protection for people's data (and any genetic implications for their relatives) after their death.

Important safeguards, approved by the Information Commissioner (formerly the Data Protection Commissioner) are included within Section 60 of the Health and Social Care Act 2001, to protect the interests of patients. The Patient Information Advisory Group will have an important role in ensuring that use of the powers provided by Section 60 are in accordance with the Data Protection Act 1998 and Human Rights legislation. The Secretary of State for Health may also seek the views of the Advisory Group on such other matters connected with the processing of patient information or of any information obtained or generated in the course of the provision of the health service as he considers appropriate. This could potentially include genetic data.

It should be noted that it would be for the *courts* to decide whether the Data Protection Act 1998 has been breached in a specific instance, irrespective of any "guidance". While such guidance may influence a court's decision, it could not replace it.

Paragraph 7.60 : We recommend that the Government amend the remit of the Research Ethics Committees to require them, as far as projects involving secondary use of health and related data at regional or sub-regional level are concerned, to operate within the policies set by the new Medical Data Panel.

Research Ethics Committees are already bound to follow Department of Health guidance available in the 'Red Book'. A revised 'Red Book' has been the subject of consultation and will be published shortly. Further, the Government notes the international expectation set out in the 5th revision of the Declaration of Helsinki (2000) that an independent research ethics committee should consider research on identifiable data. It is therefore not considered appropriate to amend the remit of Research Ethics Committees at the present time to implement this recommendation from the Select Committee.

Paragraph 7.61 : We recommend that the Government should, in the light of our recommendation for a Medical Data Panel, consult the MRC and the

Wellcome Trust about the committee which the latter have proposed for the UK Biomedical Population Collection.

The Department of Health is part of the funding consortium that is involved in establishing the proposed UK Biomedical Population Collection. The structure and remit of the oversight committee to be established to represent the public interest in this important study is still under consideration. However, it is likely that this committee would have, for example, an interest in overseeing communications with potential volunteers including the provision of information about endpoints of the research being done, consent procedures, handling queries or complaints, and quality control and audit of the programme. It is important to stress that this body would not be empowered to give ethical approval as this is the responsibility of the Research Ethics Committees involved.

Paragraph 7.65 : We recommend that the procedure to be followed by all those involved in seeking consent for participation in research involving the collection and retention of biological samples that could be used for genetic analysis should include the following elements:

(a) pointing out that

(i) the medical treatment that all receive is based on studies carried out on very many earlier patients and that the request is for them to provide similar help for future generations;

(ii) because medical science is changing very rapidly, some of the valuable uses to which the data could sooner or later be put are not foreseeable;

(b) seeking the individuals' agreement

(i) to participate in the study;

(ii) to entrust oversight of secondary use of their data to the arrangements in place under the proposed Medical Data Panel;

(c) asking whether participants would wish to be informed of any element in their genetic make-up that might be a cause for concern based on current knowledge - or to be alerted in the future in the light of new discoveries;

(d) explaining the arrangements for withdrawing the consent; and

(e) thanking participants for their help.

In January 2001, the Chief Medical Officer issued advice on *The Removal, Retention and Use of Human Organs and Tissue from Post-Mortem Examination*. He recommended that as soon as possible, there should be a more fundamental and broader revision of the law encompassing the taking, storage and use of human tissue from the living and the dead and introducing an independent system of regulatory control. He further recommended that procedures should be established (after public consultation) to provide for obtaining appropriate consent for research using stored human tissue. The prospect for research involving new genetics techniques was highlighted in this context. The Government therefore welcomes these helpful suggestions from the Select Committee which will be taken into account as the Chief Medical Officer's recommendations are taken forward.

Paragraph 7.66 : We recommend that the Government should establish an independent body, including lay membership, to oversee the workings of the National DNA Database, to put beyond doubt that individuals' data are being properly used and protected.

The National DNA Database is managed by a Home Office Agency - the Forensic Science Service (FSS) - which acts as "custodian" on behalf the Association of Chief Police Officers (ACPO). There is a Memorandum of Understanding (MoU) which sets out the role of the "custodian". The FSS, as well as acting as custodian, has a separate discrete function as the major "supplier" of DNA profiles to the National DNA Database. There are other commercial companies that provide a DNA profiling service for the police and submit profiles to the FSS custodian for entry onto the National DNA Database.

The National DNA Database enables matches to be made between profiles from DNA recovered from crime scenes and DNA profiles obtained from suspects. When a match is established this is reported to the police. Samples may be taken from anyone suspected of, cautioned for, or convicted of a recordable offence (these are generally those offences that are punishable by a term of imprisonment). The Criminal Justice and Police Act 2001 now allows all samples and profiles taken on suspicion of involvement in a crime to be retained and used.

Fingerprints and samples given voluntarily for the purposes of elimination play an important part in many police investigations. An example of this is DNA intelligence screens. Volunteers participating in intelligence screens have questioned why their samples can not be retained and used in other investigations. The Criminal Justice and Police Act now enables fingerprints and samples given voluntarily for the purposes of elimination, where the volunteer gives their written consent, to be retained and used for other investigations. If a volunteer does not consent to the retention of their fingerprints and samples they will be destroyed once they have fulfilled the purpose for which they were taken.

There are now in excess of one million DNA profiles from individuals on the database. The Government has committed a £143 million to ensure that more than three million active criminals will be on the database by April 2004. It has also committed a further £59 million to support police scenes of crime work and to encourage the most effective use to be made of DNA evidence.

It is important to ensure that public confidence is maintained. There are already safeguards in place relating to both the operation of the National DNA Database and the storage of samples. The National DNA Database is registered under the Data Protection Act 1998. This not only deals with disclosure of data but also covers the physical security arrangements in terms of those that have access to the data. Additional safeguards are afforded by amendments to the Police and Criminal Evidence Act (PACE), made by the Criminal Justice and Police Act 2001. This makes it clear that samples and the information derived from them can only be used for the prevention and detection of crime, the investigation of an offence and the conduct of a prosecution.

The Government has already given an undertaking to give consideration to the idea of an independent body to oversee the samples held by the FSS and recognises the importance of having a system which people have confidence in. It has a continuing commitment to ensure that samples are securely stored and cannot be used inappropriately. The National DNA Database is an operational police database and the Government would not wish to do anything that would

compromise its effective and efficient operation.

The Human Genetics Commission has also carefully considered the recommendation for independent oversight of forensic DNA databases and samples and has discussed this with the Home Office and the Forensic Science Service. Its public consultation has revealed a very high level of support for the National DNA Database, especially in relation to the investigation of serious crime. The Commission considers it important to take into account the potential benefits independent oversight has in ensuring that public confidence in the National DNA Database and developments in the forensic use of DNA is maintained.

CHAPTER 8 : COMMERCIAL APPLICATIONS

Paragraph 8.30 : We recommend that the Government should press, both within Europe and more widely, for patent rights over genes to continue to be granted only where a significant gene function has been established, and to ensure that the patent should cover only that function and direct extensions of it. Possible but not yet envisaged and speculative uses of a gene should not be patentable.

Patenting in the field of genetics is dealt with by EC Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, adopted in July 1998. The Directive provides a clearly laid out and pragmatic system for protecting biotechnological inventions, creating not only a predictable system for all working in biotechnology, but also a level playing field throughout Europe. It did not change the fundamental aspects of UK national law, which have been in place since 1977 and which have provided the basis for the development of the biotechnology and genetics industries in the UK. Patents and genes were considered in depth in the run-up to the adoption of the Directive.

The Government agrees with the recommendation that patent rights over genes should continue to be granted only where a significant gene function has been established, and that possible but not yet envisaged and speculative use of a gene should not be patentable. Article 5(3) of the Directive makes it clear that the industrial application of a sequence or a partial sequence of a gene must be disclosed in a patent application. If no use is envisaged, or if any such use is purely speculative, then a valid patent cannot be obtained.

When an inventor is the first to isolate a gene and determine an industrial application for that gene, s/he has opened the door for others to take that gene and experiment further to determine other uses. Thus, at present, patents may cover genetic sequences themselves where for the first time the gene has been isolated and a significant industrial application is described.

By protecting the gene itself, a patentee will be entitled to recover a licensing fee from anyone who develops a new treatment or process that uses the gene s/he has isolated.

However, a patent on a gene does not preclude further research based on that gene; this does not require payment of a licensing fee. In addition further patents may be obtained for new applications of the gene developed through such research. This has been common practice in the pharmaceutical industry for some considerable time. Thus, for example, the Government has long argued that 'second medical use' patents within Europe provide a further spur to both academic and commercial medical research.

Where there are individual cases in which patents are being used in an anti-competitive manner to prevent commercial development of ideas or research, then steps can be taken using existing safeguards built into the patent system or through the use of competition law. For example, if a holder of a second patented invention is unable to market it without infringing an earlier patent, the holder of the second patent can seek a compulsory license of the earlier patent.

In contrast, if patent claims were restricted to only the application disclosed in the patent of a newly isolated gene sequence as the Select Committee recommends, anyone could market a further application for the gene without having to pay any fee to the patentee. The patentee, whose investment opened the door to such work by the original isolation of the gene and identification of its significance in use, would receive nothing. This could have a negative effect on the future isolation of further gene sequences, and thus on healthcare advances. The Government is not persuaded, therefore, that it should press for patents to cover only a specific function and direct extensions of it.

Article 16 of the Directive provides specifically for regular review of the Directive's impact. For example, the Commission is obliged to report to the European Parliament and the Council annually on the development and implications of patent law in biotechnology and genetic engineering, although these reports may be delayed pending full implementation by all member states. In preparation for this eventual review process, the Government proposes to conduct its own investigations into the effects of the current practice of granting patents for genetic sequences themselves on the economics and growth of the biotechnology industry and on the implications for research and access to medical treatments.

Paragraph 8.31 : For the future, we recommend that the Government should monitor closely patenting practices in the field of genetics and take steps as necessary to ensure that the proper balance is maintained between protecting inventors' interests, facilitating commercial development of ideas and allowing research to flourish.

The Government accepts this recommendation and will continue to monitor developments in this area. Where there are cases in which patents are being used in an anti-competitive manner to prevent commercial development of ideas, or research, then steps can be taken using existing safeguards built into the patent system or through the use of competition law. In addition, and as noted in the response to paragraph 8.30, the Government proposes to conduct its own investigations into the effects of the current practice of granting patents for genetic sequences themselves on the economics and growth of the biotechnology industry.

The Government recognises that further work may be necessary to address this issue and, indeed, to address the more general public concern over patenting practices in the field of genetics. The Department of Health is currently commissioning a scoping study to identify the implications of current patenting practices on the future delivery of genetic services in the NHS. This is an issue that is likely to feature in both the forthcoming Green Paper on genetics and the further deliberations of the Human Genetics Commission. The Green Paper and the Human Genetics Commission will both take into account public concern over the patenting of gene sequences during general consultation and the subsequent development of advice to Government.

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