



Bioscience for Life?

Appendix A

The history of UK Biobank, electronic medical records in the NHS, and the proposal for data-sharing without consent

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1. Introduction

UK Biobank is currently recruiting volunteers willing to allow researchers to access information about their illnesses and lifestyles, linked with samples of their blood and urine, stored in a 'biobank'. Although data is being collected for the biobank with the consent of the people involved, it is a pilot project for a much larger NHS-wide biobank for which data in electronic medical records would be linked with genetic data. The legislation that would allow this to happen was published as part of the Coroners and Justice Bill in January 2009. The Bill is the first step in a two step process which could allow this data to be shared with third parties – including private companies and the police – without consent. Once the Bill is adopted ministers in the Department of Health and/or the Home Office will be able to issue an 'information-sharing order' to allow a national DNA database of everyone registered in the NHS to be built without parliamentary scrutiny.

2. Summary

This case study is part of a forthcoming report by GeneWatch UK on the role of the Knowledge-Based Economy and how research funding decisions are made in biosciences, funded by the Joseph Rowntree Charitable Trust. The case study is an investigation of how the decision was made to fund UK Biobank and to make the investment needed in NHS information technology (IT), in order to begin to build a national genetic database in the NHS.

The main findings are:

- In 1999, a small group of influential people with close links to the biotechnology, venture capital and pharmaceutical industries (Sir George Poste, Sir Richard Sykes, Sir John Bell, and Sir David Cooksey) began lobbying for a national database of NHS electronic medical records linked to individuals' DNA.
- The proposal was intended to allow Britain to take the lead in commercialising the human genome and to transform the NHS into a service based on the genetic 'prediction and prevention' of disease, in which large numbers of people could be given 'pre-symptomatic' treatment, massively expanding the drug market.
- Following lobbying via the House of Lords Science and Technology Committee, this proposal strongly influenced the Government's decision to upload electronic medical records to a central database (the 'Spine'), at an additional cost of more than £11 billion compared to a localised system.
- Despite widespread scientific criticism of this strategy for health, government ministers have repeatedly claimed that genetics will transform healthcare and allow common diseases such as heart disease, cancer and diabetes to be predicted from a person's genes. A Ministerial Medical Technology Strategy Group has been set up to drive forward this agenda, co-chaired by US company GE Healthcare.
- Risk assessment of every individual in the UK population means turning healthy people into patients and could lead to massive over-treatment and huge financial burdens on the NHS, as well as causing major privacy concerns. No Government analysis of the cost-effectiveness, impact on health, or impact on the NHS has ever been undertaken to support this plan. Industry lobbying has also led to Government opposition to any regulation of the health claims made for genetic tests, most of which are known to be misleading.
- The genetic research project UK Biobank, funded jointly by the Government and the Wellcome Trust, was developed as a pilot project for the planned national genetic database. Although it continues to recruit volunteers to give their DNA,

the project shifted its emphasis away from genetics in the face of strong scientific criticism. However, as more data confirms criticisms that genes will be poor predictors of common diseases in most people, the Wellcome Trust is leading plans to link DNA databases across Europe in an attempt to make a study big enough to identify very small genetic effects.

- The current Director of the Wellcome Trust (Sir Mark Walport) and other enthusiasts for genetic 'prediction and 'prevention' of disease have lobbied for researchers – including those from industry – to be able to access information in people's electronic medical records without their consent, via the Secondary Uses Service (SUS). This would allow UK Biobank to expand without consent to include the entire NHS, for example by using DNA contained in the blood spots collected from every baby at birth, linked to their electronic medical records.
- Proposals which would allow this to happen were made in the Data-Sharing Review, led by Walport and the Information Commissioner Richard Thomas in 2008, and have been included in the Coroners and Justice Bill published in January 2009. Current legislation would not prevent the police from being given access to DNA stored by the NHS, but the data-sharing proposals in the Bill mean that this could happen as a matter of routine. DNA collected for health purposes could also be used to reveal paternity. There is widespread expert agreement that privacy cannot be protected if individuals' genome sequences are widely accessible.
- A series of public engagement exercises conducted by the Royal Society, the Medical Research Council (MRC), the Wellcome Trust and the Office of Science and Technology (OST) have highlighted public opposition to research without consent; concern about the role of commercial companies and the lack of regulation of genetic tests, and about protection of personal data; and a "*striking trust deficit*" regarding whether research is being conducted in the public interest.
- The same small group of people that backed the original plans for UK Biobank is now lobbying for further public money to include more detailed levels of medical surveillance, as well as genetic make-up, in an attempt to improve predictions of each individual's risk. GE Healthcare and other companies have also backed this plan via the Ministerial Medical Technology Strategy Group. However, individual health predictions will always be limited by the complexity of biology, the role of chance, and the multiple environmental and social factors which are involved.
- The proposals imply that GPs will be replaced with computer systems and Smart cards containing genetic and other screening data. However, most screening programmes need careful evaluation to avoid doing more harm than good, and most laboratory and genetic tests require expert interpretation. The implications of a major shift in the role of the NHS away from treatment to 'prediction and prevention' have never been debated.

3. What is UK Biobank?

UK Biobank is currently being established as a resource that links many different sources of information on individuals for research.¹ It aims to enable studies to be carried out on the relationships between genes, lifestyle and health through the collection of DNA samples and information from half a million people across the UK.

The biobank is funded by the Wellcome Trust and the UK Government (via the Medical Research Council, Department of Health and Scottish Executive) and has been set up as a charity. £61.5 million has been allocated to establishing the biobank.² No funding has yet been allocated to research using the data – academic researchers and companies are expected to bid to use the biobank, with commercial companies paying larger fees.

UK Biobank is dependent for its success on the implementation of 'Connecting for Health' - the national database of electronic medical records now being implemented in Britain's National Health Service (NHS), at a forecast cost of £12.4 billion.³ Genetic data, and results of other tests, will be linked with lifestyle information from an initial questionnaire and follow-up data from electronic medical records. Recruitment of people to take part in the study began in 2007 and is expected to take around 5 years. It is intended that information will be added to over time (the time scale is anticipated to be 30 years) and that this resource will be open to many researchers for many different kinds of studies that are currently unforeseen. The biobank has therefore adopted a new system of 'broad' consent that does not involve telling people before the project starts exactly how their data will be used or who will gain access to it.

UK Biobank is now collecting sufficient blood and urine to measure not just genes, but also other biological factors such as proteins. Biological measurements that might be used to predict a person's risk of illness are known as 'biomarkers'.

4. Concerns about UK Biobank and genetic 'prediction and prevention' of disease

Since it was first proposed, GeneWatch UK has raised serious concerns about UK Biobank, including that its aims are controversial because prediction of future common illnesses by testing people's genetic make-up is unlikely to be a successful or cost-effective means of disease prevention.⁴ Even if other biological factors ('biomarkers') are also considered, individual risks will be inevitably highly uncertain and hard to predict. However, in the future, people who are told they are 'genetically susceptible' to future illness may become a good market for expensive new 'personalised' products, including medicines, foods, supplements and skin creams.

Although rare genetic mutations sometimes predispose people to diseases such as rare familial forms of cancer (including about 5% of cases of breast cancer), no common genetic variant has yet been identified that has a sufficiently high predictive value to be useful for medical screening in the general population. Genes are now thought to be poor predictors of common diseases like cancer in most people, and some scientists have warned that undertaking ever larger studies is a waste of money and that misleading promises about the predictive power of genes are being made in order to secure research funding.^{5,6,7,8} Despite this, many gene tests are now being marketed by commercial companies without any regulation of the claims they make, which are often false and usually misleading.⁹

Although recent large studies undertaken by the Wellcome Trust Case Control Consortium (WTCC) have identified some new genes linked with common diseases, the researchers have also highlighted the "*limited potential of the [genetic] variants thus far identified (singly or in combination) to provide clinically useful prediction of disease*".¹⁰ This type of study can still be useful because it helps scientists to understand the mechanisms of these diseases: but the results do not support the idea that widespread genetic screening will be useful or that it will allow the genetic 'prediction and prevention' of common diseases in most people.

Similarly, although many common genetic variants (polymorphisms) have been identified which influence drug metabolism, genetic testing to predict drug efficacy or safety (pharmacogenetics) has rarely proved to be medically justified, except prior to prescribing a few specific drugs.^{11,12,13,14} Although enthusiasts have often claimed that

drug response is largely determined by genetic factors, this assumption has never been properly tested, even though this could be done.¹⁵

'Individualised' prevention, based on genetic screening, has long been advocated by the tobacco, chemical, nuclear and food industries, which want people to focus on internal, biological risk factors for diseases such as cancer and heart disease, rather than on their products or pollution. The pharmaceutical industry, and more recently the food industry^{16,17}, also favour individualised prevention, whether based on genes or other 'biomarkers', because this will allow them to market 'preventive' drugs and new 'functional' foods (such as cholesterol-lowering margarine, or new genetically modified (GM) crops) to the (rich, healthy) individuals claimed to be at high genetic risk. A relatively small number of 'genetic susceptibility' tests could classify the entire population as 'at risk' for life, making everyone a patient who can be sold 'personalised' products.^{18,19} With the whole population potentially 'at risk' and eligible for preventive medication, the cost implications of 'genetic susceptibility' testing have been described as "*staggering*"²⁰. Unless tests are strictly regulated, large numbers of people will be either falsely worried (and over-treated) or falsely reassured that they do not need changes to be made in their lifestyle or environment.

There are also serious concerns about privacy, surveillance and discrimination, particularly by insurers and employers, should a system of health screening based on individual genetic make-up be implemented in the future. Under current legislation, the police will be able to access genetic profiles and DNA samples held by UK Biobank, provided they can get an access order granted by a court.²¹ The new data-sharing powers proposed under the Coroners and Justice Bill could make such access a matter of routine. If genetic profiles are held in a searchable form in future, linked to each person's unique NHS number (allocated at birth), they could also be used by governments to track individuals and their relatives.

5. Timeline

1995

The Foresight report

Foresight panels were set up in 1994 to involve academics and industry in advising the Department of Trade and Industry (DTI) on research priorities. The 1995 Foresight Report on health and life sciences includes "*genetics in risk evaluation and management*" for common multi-factorial diseases, such as heart disease, as a key area for greater investment.²² The report states (Section 4.2) that: "*It is too early to predict how difficult it might be to dissect out the complex interplay of factors at different stages in life that lead to disease, or how effective individualised risk might be as a public health measure*". Annex 2 also notes: "*It might become possible to use individuals' genetic makeup, lifestyle and environment to individualise risk and target interventions, but it is questionable how widespread and useful this would be at a population level. The effectiveness of public health interventions is strongly influenced by education, culture, affluence and other variables. Identifying risk without changes on other areas might have little impact*". Nevertheless, the report concludes (Section 4.2): "*Despite the uncertainty, the genetic element in common disease is potentially so important that the UK should begin building a leading-edge position in research in the area. Consumer demand will certainly be strong, and the export potential is high*".

The remit for the Foresight report was to consider factors important in future markets, and it also recommends investments in infrastructure, particularly information technology, and close links between industry and the NHS. The steering group's overall report²³ closes with a quote from Dr George Poste (Box G), then Chairman of Research & Development at SmithKline Beecham Pharmaceuticals: "*It is time to applaud the tremendous achievement of the Office of Science & Technology in generating the enthusiastic commitment of so many researchers in industry and academia to the programme*".

1997

The biotech economy

In the run up to the 1997 election, political parties in Britain were competing to show how they would revitalise the economy. Prior to 'Biotechnology Day' in March, the consultants Arthur Andersen published a report "*UK biotech '97 - making the right moves*". Stuart Henderson, head of Arthur Andersen's UK biotechnology group, claimed that the UK biotech sector would be one of Britain's fastest growing industries and "*UK biotechnology company revenues could double to as much as £1.5 billion over the next two years*"²⁴. Support from the "biotech barons" (Box A) helped win New Labour its first election victory in May 1997 and, in June, shortly after the election, Chancellor Gordon Brown began his first "Comprehensive Spending Review", promising more public-private partnerships to revitalise Britain's economy.²⁵

Box A: The "Biotech Barons" and New Labour

Prior to the 2001 and 2005 elections, the biotech investors Sir Christopher Evans, Baron Drayson and Sir Ronald Cohen wrote joint letters to the Financial Times, endorsing New Labour's commitment to investing in science and biotechnology companies.^{26,27} They have strongly influenced New Labour's commitment to the 'knowledge-based bio-economy', particularly the party's policies towards venture capital and start-up companies.

Professor **Sir Christopher Evans** OBE is Chairman and founder of Merlin Biosciences, a venture capital firm investing in life sciences companies. He also founded the biotech firms Chiroscience (now merged with Celltech), Celsis, and Enzymatix.²⁸ Evans first met Tony Blair at a breakfast at The Savoy in 1995. In the lead-up to the 1997 election he "...gave a string of supportive media interviews and strongly endorsed their [Blair and Brown's] commitment to science enterprise and business".²⁹ Subsequently, he sat on a variety of government task forces in the UK and Europe. In 2002, Evans was professor of biotechnology at three British universities, including his alma mater, London's Imperial College, and Business Week claimed: "*If Europe's biotech industry has a center, it's Chris Evans*".³⁰ Evans, a New Labour donor and a former member of Blair's Council for Science and Technology, was awarded the OBE in 1995 and knighted in 2001.³¹ He was arrested in 2006 during the police investigation of the "cash for honours" allegations made against the Labour Party, but charges were not pursued.³²

Paul Drayson (now Baron Drayson) co-founded the vaccines company Powderject in 1993, with the help of John Bell (Box C) and was Chief Executive until 2003, when the company was acquired by Chiron Corporation (now part of Novartis).³³ He was Chairman of the BioIndustry Association (BIA) from 2001-2002, launching its 'Manifesto for Biotechnology' in 2001³⁴. Labour faced allegations of sleaze when Drayson gave the party £100,000 while successfully bidding for a lucrative government vaccine contract, and again when he gave it another £500,000 within six weeks of being made a life peer.^{35,36} The BBC also reported allegations that his company Powderject had supplied faulty TB vaccines for children.³⁷ In May 2005,

Drayson became minister for defence procurement and in 2007 was also made a minister in the newly created Department for Business, Enterprise and Regulatory Reform (BERR). He resigned in November 2007 to pursue his ambition as a racing driver but returned to government as Minister of State for Science and Innovation in the Department of Innovation Universities and Skills (DIUS) in October 2008.³⁸

Sir Ronald Cohen is considered the founder of Britain's venture capital industry.³⁹ Apax Partners is a global private equity group which he co-founded, and which has ploughed billions into small start-up companies, including PPL Therapeutics, which produced Dolly the cloned sheep. In 2000, the then Chancellor, Gordon Brown, appointed Cohen chairman of a Treasury fund set up to encourage investment in deprived areas of the country. He was knighted the following year and became Brown's fundraiser during his bid to win the leadership from Tony Blair. He stepped down from management responsibilities at Apax in 2006.⁴⁰

The European directive and gene patenting

In November, despite protests against the patenting of life, including human gene sequences, the Government signed up to the European Directive on the Legal Protection of Biological Inventions (Box B), honouring its pre-election pledge to do so.^{41,42} The Directive allows human gene sequences to be patented, provided the 'inventor' has identified the function of the gene (for example, by claiming that it is useful to predict a person's risk of cancer). The approach taken in the Directive is supported by organisations such as the Wellcome Trust (Box E), which opposed the patenting of 'raw' gene sequences (information on genes published without knowledge of their function, such as the information produced by the Human Genome Project).⁴³

Box B: The European Patenting Directive

In July 1997, the European Parliament voted in favour of a proposed European Directive on the 'Legal Protection of Biotechnological Inventions', reversing its earlier opposition to gene patenting and clearing the way for the Directive's adoption as EC Directive 98/44/EC. Lobbying for the Directive was led by Dr Nick-Scott Ram, who chaired committees on Intellectual Property and Regulatory Affairs for the BioIndustry Association (BIA), Association of British Pharmaceutical Industry (ABPI) and EuropaBio, and who was awarded the MBE for services to biotechnology in 2001.^{44,45,46} The pharmaceutical company SmithKline Beecham is also credited with paying a key role in securing adoption of the Directive, especially via its lobbying and funding of patient groups such as the Genetic Interest Group (GIG), and the role of David Earnshaw, the company's Director of European Government Affairs and Public Policy in Brussels.^{47,48,49} George Poste (Box G), then chair of research and development at SmithKline Beecham, was also involved in the negotiations.⁵⁰

A new NHS

On 8th December, the Department of Health published its White Paper 'The new NHS, modern, dependable'.⁵¹ The policy sets out how the internal market will be replaced by a system called 'integrated care', "*based on partnership and driven by performance*". It forms the basis for a ten year programme for the NHS.

1998

Claims that genetics will transform medicine

In February 1998, Oxford Professor John Bell (Box C) published a paper in the British Medical Journal, which claimed that “*Genetic information is likely to transform the practice of clinical medicine*” within the next decade and “*Genetic variation will be another form of "risk factor" and will permit early treatment and directed screening*”.⁵² In his article Bell claimed that the adverse effects of drugs would be avoided by genetic screening and “*"Risk factor" analysis will facilitate environmental modification, screening, and therapeutic management of people before they develop symptoms*”. The article acknowledges funding from “The Wellcome Fund” and declares that Bell is a non-executive member on the board of Oxagen (see Box C), but holds no equity.

Box C: Professor Sir John Bell^{53,54,55,56}

John Bell is a Canadian who became the Nuffield Professor of Clinical Medicine at Oxford University in 1992, where he founded the Wellcome Trust Centre for Human Genetics in 1993. Bell co-founded the biotech company Oxagen in April 1997 as a ‘spin-out’ company from the Centre. By 2002 Oxagen had filed for over 30 patents on disease-related genes.⁵⁷ The Wellcome Trust is one of the investors in the company. Bell also helped the biotech entrepreneur and Labour donor Paul Drayson establish the vaccine company Powderject (later involved in the “cash for vaccines” controversy).^{58,59}

Bell was “*closely involved in the establishment of UK Biobank*”⁶⁰ and is a member of its Board of Directors.⁶¹ His appointment as Chair of its Scientific Committee was criticised in an Editorial in the Lancet in 2004 because of his links with the pharmaceutical industry.⁶²

In 2002, Professor Bell became the Regius Professor of Medicine at Oxford. He is a strong advocate of public-private partnerships and is Chair of the ‘Partnership Board’ of the Oxford Centre for Diabetes, Endocrinology and Metabolism (which involves the NHS and pharmaceutical companies). Bell is also a Non-Executive Director of Roche, and a member of the Science Advisory Board of AstraZeneca. In November 2006, he became President of the influential Academy of Medical Sciences and in 2007, he was appointed as the first Chair of Office for Strategic Coordination of Health Research (OSCHR). He was also a member of the 2004 Research for Patient Benefit Working Party. Bell was knighted in the 2007 New Year Honours list.

The Government partners with the Wellcome Trust

In March, the then Chancellor Gordon Brown announced that £20 million of public money, matched by funding from charities including the Wellcome Trust, would be put into a fund set up to provide seed-corn finance to turn bright ideas from university labs into commercial products.⁶³

The McKinsey Report

In his speech to the CBI in April, the Chancellor stated that he would be holding a series of seminars with business leaders, to be informed by a report by management consultants McKinsey.⁶⁴ On 14 May 1998, Brown and the President of the Board of Trade, Margaret Beckett, launched a joint programme of work designed to address the “productivity gap” between Britain and the US, identified in the McKinsey report.⁶⁵^{66,67,68} The process, intended to inform the forthcoming Competitiveness White Paper and the next Budget, began with a seminar held at No 11 Downing Street, which included a presentation from McKinsey to which Sir Richard Sykes (Box D), the Chairman of pharmaceutical company Glaxo Wellcome, and Adair Turner, the Director-General of the CBI responded.⁶⁹

Box D: Sir Richard Sykes^{70,71}

Sykes had a 30-year career in the pharmaceutical industry, becoming Deputy Chairman and Chief Executive of Glaxo, then Chairman and Chief Executive of what became Glaxo Wellcome (after the merger of the two companies in 1995) and then GlaxoSmithKline (when Glaxo Wellcome and SmithKline Beecham merged in 2000).

Amongst many other roles he was Chairman of Task Force – Inward Investment in UK Pharmaceutical Industry 1994-1997; Member of President's Committee, CBI 1995-1998; Member of Advisory Group on Competitiveness to the President of the Board of Trade 1997-1999; Member of Council for Science and Technology 1993-2000; President of the British Association for the Advancement of Science, 1998-99⁷².

Sykes became Rector of Imperial College London in January 2001 and stood down as Chairman of GlaxoSmithKline in 2002. He controversially tried to introduce top-up fees for students at Imperial in October 2002 and later convinced Tony Blair to back the idea in a Government Bill, leading to a major rebellion by Labour MPs.^{73,74}

Sir Richard is also chairman of the UK Stem Cell Foundation and chairs CATALYST, London's Council for the Advancement of Science and Industry. He is Senior Director of Rio Tinto plc and Rio Tinto Ltd, Deputy Chairman of Lonza Group Ltd (a chemicals and biotechnology company), Chairman of the Healthcare Advisory Group of Apax (see Box A) and Chairman of MerLion Pharmaceuticals Pte Ltd.

Sykes was also chair of the Bioscience Leadership Council, established in response to the BIGT report in 2003 (Box N) and is a member of the advisory panel of the Science Media Centre⁷⁷ and Chairman of the Advisory Board of the think tank Reform.

An increasing role for the Wellcome Trust

In July 1998, the results of the Comprehensive Spending Review were published. Chancellor Gordon Brown announced that he would be providing £1.1 billion for the science base through a public-private partnership, to support innovative research programmes.⁷⁸ This would be "*the biggest ever Government-led public/private partnership for science*", with the help of £400 million in support from the Wellcome Trust. He claimed: "*This innovative step-change in our approach to science will lay the foundations for putting Britain at the forefront of the next generation of scientific and industrial research*".⁷⁹ The announcement was welcomed by the pharmaceutical firm SmithKline Beecham, which said⁸⁰: "*This new spending will make the UK a more attractive place for investment by SB and other pharmaceutical companies.*"

Originally committed to sequencing one-sixth of the human genome, the Wellcome Trust increased its investment in 1998 to allow its Sanger Institute to decode one-third of the human genome.⁸¹

Box E: The Wellcome Trust

The Wellcome Trust is Britain's largest charity and it has invested heavily in human genetic research⁸², including the Human Genome Project, the UK part of which was undertaken at its Sanger Centre. The trust is the world's second richest medical charity after the Bill and Melinda Gates Foundation, with net assets at 30 September 2006 of over £13.4 billion (\$26.8 billion).⁸³

Until 1986, the Wellcome Trust was the sole owner of the Wellcome pharmaceutical company, confusingly known as The Wellcome Foundation Ltd in

the UK, which generated all of the charity's income. In 1986, the first of two share sales created a public limited company, Wellcome PLC, which owned the Wellcome pharmaceutical company. The second sale took place in 1992, reducing the Wellcome Trust's shareholding to around 25 per cent of Wellcome PLC. Further asset diversification resulted from the 1995 merger of Wellcome PLC with Glaxo PLC, creating Glaxo Wellcome PLC. The Wellcome Trust, then the company's largest shareholder, supported the merger by backing a hostile bid from Sir Richard Sykes (Box D) without consulting the company's board.⁸⁴ Glaxo Wellcome subsequently merged with SmithKline Beecham PLC to create GlaxoSmithKline PLC. The Wellcome Trust now maintains only a small stake in GlaxoSmithKline.⁸⁵ Since 1998, the Government has aligned its bioscience objectives with the Wellcome Trust's, involving over £2 billion in Wellcome Trust funding and a joint commitment to "*create a regulatory environment that fosters and promotes biomedical sciences in the UK*".⁸⁶ The Trust is also a part-owner of Diamond Light Source Ltd, the company that runs the Diamond synchrotron⁸⁷, a new X-ray source being constructed in Oxfordshire which is causing controversial science cuts due to its massive overspending.⁸⁸

Dr Mike Dexter was Director of the Wellcome Trust from 1998-2003. **Dr Mark Walport** succeeded him on 30th January 2003.⁸⁹ He had been Head of the Division of Medicine at Imperial College London since 1997, with a research interest in the genetics of rheumatic diseases. Walport is a member of the Council for Science and Technology⁹⁰, a founder Fellow of the Academy of Medical Sciences and a member of the Government's Funders Forum, which advises it on non-commercial research priorities⁹¹. He previously served as a member of the Research and Development Advisory Board of SmithKline Beecham. He was also a member of the 2004 Research for Patient Benefit Working Party. He was awarded a knighthood in the 2009 New Year's Honours list.

Localised electronic medical records in the NHS

In September, the Department of Health published 'Information for Health'⁹² its £1 billion information strategy for the NHS from 1998-2005, which it described as "*A national Strategy for local implementation*". The Strategy commits to lifelong electronic health records for every person in the country as part of the Government's "modernisation" programme. It states that the creation and maintenance of electronic healthcare records (EHRs) is best undertaken in primary care, moving with the patient when they change doctors. "*Analysing anonymised and aggregated subsets of EHR data for epidemiological research*" is listed as a potential future use that would need further consultation (para 2.21). The Strategy states that requests for privacy must be respected, if patients do not wish for certain aspects of the medical history to be included or communicated to other parts of the NHS (para 2.26).

High Technology Businesses and the Competitiveness White Paper

In November 1998, the Working Group on the Financing of High Technology Businesses, reported to the Treasury.⁹³ The Working Group was chaired by Dr Keith McCullagh of British Biotech PLC (who had already suspended its Head of Clinical Research, the beginning of a series of events which ultimately led to the downfall of Britain's flagship biotech company⁹⁴). The panel also included Sir David Cooksey of Advent Ltd (Box F). The report cited the 1997 Andersen report to support its view that "*the UK has the opportunity to become a world leader in biotechnology and bioindustry*" (para 19). It claimed that "*The new science of genomics, understanding the genetic basis of our idiosyncrasies, has the capacity to open doors to rapid diagnosis and prevention and to make health care delivery more effective. New food*

crops with better productivity, nutritional value and taste are already beginning to come into our supermarkets...". The report (para 85) welcomed the joint science funding of £1.1 billion already announced by the Wellcome Trust and the Government, part of which would be allocated to human genome research, and made a serious of recommendations to remove "barriers to growth", including further reforms to Capital Gains Tax and tax incentives for Venture Capital Trusts.

Box F: Sir David Cooksey^{95,96}

Sir David Cooksey chaired the Bioscience Innovation and Growth Team in 2003 (Box N) and led the Cooksey Review of NHS research in 2006. He was also a panel member for the 2002 National Audit Office (NAO) Report: 'Delivering the commercialisation of Public Sector Science'.⁹⁷ He was Chairman of the Audit Commission from 1986 to 1995, and a Governor of the Wellcome Trust from 1995 to 1999. From 2000 to 2004 he chaired the Small Business Investment Task Force which oversees the UK Government's interventions in small business investment. In 1998, the Government launched its University Challenge Fund to provide venture capital to universities, described by Lord Sainsbury as the "*brainchild*" of Cooksey.^{98,99} He is Chairman of the UK Clinical Research Collaboration Industry Reference Group (Box P), Chairman of the Joint Health Research Delivery Group and a member of the Health Innovation Council (Box S).

Cooksey is also Chairman of London & Continental Railways Ltd, Chairman of the Board of Diamond Light Source Ltd (see Box E)¹⁰⁰ and a Director of Resolution PLC. In 2006, he retired as Chairman of Advent Venture Partners, which he founded in 1981. He was also the first Chairman of the British Venture Capital Association in 1983/84 and was Chairman of the European Private Equity & Venture Capital Association for 2005/6. He retired in 2005 as Chairman of the Directors of the Bank of England.

In December 1998, Trade Secretary Peter Mandelson launched the UK Competitiveness White Paper 'Our Competitive Future: Building the Knowledge Driven Economy', stressing the need to bridge the gulf between scientific advance and business application.¹⁰¹ He announced that the Wellcome Trust had now promised to support research in the UK with £1.4bn, that the DTI's innovation budget would be increased by 20% to £220m and a new £20m fund would promote the commercialisation of university research.

1999

A national genetic database for Britain? George Poste's proposal

In January 1999, a special edition of the British Medical Bulletin "*Impact of Genomics on Healthcare*" was published. Dr (now Sir) George Poste (see Box G) then Chief Science and Technology Officer of the pharmaceutical company, SmithKline Beecham, and Professor John Bell were two of the publication's scientific editors.¹⁰² It included an article¹⁰³ by Poste, his colleague Robin Fears (Box G) and David Weatherall from the University of Oxford, which argued that there was an "*urgent imperative for medicine to harness the accelerating pace of progress in genomics*"; that doctors needed more education in genetics and "*What is also needed is to prepare doctors for the changing culture of the clinical transaction arising, for example, in the use of disease predisposition data by hitherto healthy individuals*". The Overview was written by Dr Peter Goodfellow (Box I), Senior Vice President, Discovery, at SmithKline Beecham, who stated: "*The advances that will allow identification of individuals at risk for disease can be portrayed as being responsible for social stigmatisation of the same individuals. The dangers*

are real but I believe the benefits are greater - we must argue the case for genetics and genomics, the new biology and the new medicine".¹⁰⁴

In April 1999, Fears and Poste published a further article in the journal Science, which highlighted the potential use of "cradle to grave" electronic medical records, as outlined in the 'Information for Health' strategy, for medical research.¹⁰⁵ They argued that "*the NHS is probably the largest single source of medical information and well-characterized biological samples in Europe*" and that a national DNA database – consisting of electronic medical records linked with DNA samples - should be made available for research into the links between genes and diseases. Recognising that access to this information by commercial companies might be controversial – particularly in view of the problems experienced by DeCode in Iceland (see Box H) - they proposed a "*public-private partnership*" (PPP).

Box G: Sir George Poste^{106,107}

Poste joined SmithKline in 1980 and was Chief Science and Technology Officer and President of Research & Development for SmithKline Beecham from 1992 to 1999, when he left and became a Board Member and Chairman of a number of biotechnology companies. In 1993, in an article in which he advocated gene patenting, he told Der Spiegel magazine, "*Genes are the currency of the future*".¹⁰⁸ He is now Director of the BioDesign Institute in Arizona and CEO of Health Technology Networks.

In the UK, he is a Fellow of the Royal Society, and the Academy of Medicine. In the wake of the 9-11 terrorist attacks, Poste became chairman of the task force on bioterrorism for the U.S. Department of Defense, and a member of the Threat Reduction Advisory Committee for the Defense Threat Reduction Agency. He became a Board Member of Monsanto in 2003, where he chairs the Science and Technology Committee and is a member of the Public Policy and Corporate Responsibility Committee.¹⁰⁹ He is also Non-Executive Chairman of Orchid Biosciences (one of the companies which analyses DNA for the police in England and Wales).

Dr Robin Fears¹¹⁰

Poste's former colleague Robin Fears is now a freelance consultant in Research & Development policy and strategy with expertise in life sciences and biotechnology. He has recently undertaken work for the UK Academy of Medical Sciences, the Royal Society, the European Academies Science Advisory Council, and the Food and Agriculture Organisation (FAO) of the United Nations, in fields such as plant genomics and infectious diseases.

Box H: DeCode Genetics

The Icelandic proposal was the first plan for a population biobank at the beginning of the era of genome sequencing. This proposal to link DNA samples and medical records in Iceland was highly controversial because it gave the biotech company DeCode Genetics a licence to carry out the linkage on the basis of an opt-out consent.^{111,112}

In July 2001, Roche signed a five-year alliance with DeCode Genetics to develop and market genetic tests for major diseases. However, although DeCode has identified some genes linked with common diseases, such as type 2 diabetes, its attempts to market these have been criticised by other scientists because the tests have very low predictive value.^{113,114,115,116}

In 2003, the law which created the Icelandic Health Sector Database was rejected by the courts as unconstitutional.¹¹⁷

Despite the poor predictive value of its tests, DeCode launched an online DNA testing service in November 2007¹¹⁸, in an attempt to stem heavy financial losses.¹¹⁹
.120

Many Icelanders have lost their savings as a result of investing in the company.¹²¹ Its shares plummeted from a reported 'grey market' price of US\$65 in Iceland before flotation to a record low of US\$0.42 in September 2008 and the company was de-listed from the NASDAQ stock exchange in November 2008.^{122,123,124}

The development of a biobank proposal by the Wellcome Trust

In May 1999, the leader of the Human Genome project at the US National Institutes of Health, Francis Collins, gave an oft-cited lecture to the Massachusetts Medical Society.¹²⁵ He described a hypothetical future in which, by 2010, a healthy 23-year-old college graduate gives a cheek-swab of DNA to his doctor and receives a battery of genetic tests, to assess his genetic risk of colon, lung and prostate cancer, heart disease and Alzheimer's disease, leading to a regime of new prophylactic drugs, annual colonoscopy and the motivation to quit smoking.¹²⁶

In the same month, the Wellcome Trust held a workshop to discuss plans for a "UK Population Biomedical Collection" (later to become UK Biobank)¹²⁷ and by June 1999, the Wellcome Trust and the Medical Research Council (MRC) had committed funds "*in principle*" to the project. Between August 1999 and January 2000, a small group developed proposals, chaired by Professor Tom Meade, Director of the MRC's Epidemiology and Medical Care Unit.¹²⁸

A new advisory body

In May 1999 the Government published a report resulting from its review of the advisory and regulatory framework for biotechnology.¹²⁹ Concerned about public opposition to GM crops, the report stated "*We must use and not deny the potential benefits of this technology to the British people*" and proposed two new 'strategic' advisory bodies, the Agriculture and Environment Biotechnology Commission (AEBC) and the Human Genetics Commission (HGC).

Biotechnology clusters

Reinforcing its commitment to biotechnology as a key driver for the economy, the Government published Lord Sainsbury's report on "biotechnology clusters" in August 1999.¹³⁰

Poste's proposal is adopted by the House of Lords Science and Technology Committee

Poste's idea for a population biobank, using NHS medical records, was proposed to members of the House of Lords Science and Technology Committee when they visited the SmithKline Beecham's laboratories in May 1999¹³¹. Poste presented written evidence to the Committee in November 1999.¹³² In it, he stated that:

"—The NHS is an under-utilised research resource in population genetics which could yield large benefits for public health (through enhancing our understanding of disease) and industrial research.

— A public-private sector strategy should be developed to identify and mobilise the appropriate scientific and clinical skills, to build large-scale computational infrastructure and to debate, and address, the ethical, legal and social

dimensions relating to the use of clinical information, particularly in the context of privacy and consent issues”.

Poste claimed that: *“Creation of the health research database transcends both what the NHS is currently doing in information technology (relating mainly to clinical care and governance) and what researchers are building with genomic databases. A consortial approach would generate a new lead for the UK in the biosciences and their application in the delivery of rational medicine”.*

In its written response to the Committee¹³³ the Department of Health welcomed *“the opportunity to contribute to the Select Committee’s consideration of an NHS-wide database of patient-specific genetic and clinical information, for use by doctors, clinical researchers and epidemiologists”.* However, it also questioned the feasibility of the project and raised a number of questions, including:

- “— is the use of personal health information in large scale database justified by the potential research and treatment benefits?*
- should data be anonymised?*
- should explicit consent from an individual be required before entering information on a database, even if the data are anonymised?*
- what safeguards or legal controls should be required to protect confidentiality, consent and use?”.*

In relation to costs, the Department of Health’s evidence stated: *“Resource consequences would depend on the model chosen but are potentially enormous. Technical and security issues combined with the need for long-term maintenance suggest that any national database would be an expensive undertaking”.* It also stated that *“Broader issues such as the implications of gene patenting, commercial ownership of personal health information and questions about intellectual property would also need to be investigated further”.*

Health and Science ministers gave oral evidence to the Committee in December 1999.¹³⁴ Science minister, Lord Sainsbury, stated that the Medical Research Council (MRC) had already been allocated £12 million *“to develop a database of genetic and clinical information designed to look at the interaction between genetic and environmental factors in disease”* and that discussions were already taking place between the MRC and other funders about establishing a major clinical and genetic database of 500,000 individuals (the study which later became known as UK Biobank). Sainsbury stated: *“For that database, electronic access to national health records would be needed to assure efficient and cost-effective follow-up. Then we are considering George Poste’s proposal. I do not think he is, in fact, basing his memorandum on suggesting that we immediately go to a nationwide database, although at some stage we would need to consider that after we have gained the sort of experience we are gaining on limited databases. That would raise very significantly greater issues in terms of both the ethical and the social questions. Of course, it would also raise huge cost implications. If you base it on the Iceland situation, you would be talking about huge costs. It would be a very real question as to whether the additional benefits you got from that made those costs applicable to the sorts of databases we are talking about at the moment”.*

In their cross-examination of ministers, the Lords were critical of the Department of Health’s lack of enthusiasm for Poste’s idea and expressed concerns that the then plans for IT in the NHS – the £1billion ‘Information for Health’ strategy that had been published in 1998 - were *“essentially a series of islands in terms of the GPs and the hospitals”*, rather than the far greater integrated systems that would be needed.

The Source Informatics case

In May 1999, the High Court made a decision that personal information collected for the purposes of healthcare and treatment cannot be given to a third party for research purposes without the consent of the patients who are the subject of the data.¹³⁵ The case involved a company called Source Informatics which had requested access to anonymised data from patients' prescription forms. The company wanted to create a database to market this information to pharmaceutical companies, but the Department of Health had refused it access on the grounds that it would breach patients' confidentiality. However, the Court of Appeal overturned the original High Court judgment in the Source Informatics case. The Court ruled that the use of such information does not involve a breach of confidentiality and therefore it is not necessary to consider whether implied consent has been given. The successful challenge was mounted by Source Informatics (now IMS Health), the Association of the British Pharmaceutical Industry (ABPI), the General Medical Council (GMC), the Medical Research Council (MRC) and the National Pharmaceutical Association against the Department of Health.¹³⁶

The Government's Genome Valley report: a commitment to making NHS data available to industry for research

On 8th December 1999, the Department of Trade and Industry (DTI) published its report "*Genome Valley: the economic potential and strategic importance of biotechnology in the UK*"¹³⁷, following a series of discussion groups involving representatives of the biotech, food and pharmaceutical industries (listed on page 56 of the report), including Dr Robin Fears of SmithKline Beecham.

Paragraph 2.9 states: "*The collection of DNA samples, with associated health records, would facilitate studies to detect susceptibility to genetic disease, and to understand the impact of genes on diseases. Iceland passed a Bill in December 1998 to make its national patient database of tissue samples available to researchers without compromising patient confidentiality. The National Health Service (NHS) in the UK is the largest source of clinical data and would be invaluable for comparative studies...*". Paragraph 2.27 describes how "*Biotechnology, and in particular applied genomics, is expected to revolutionise health care*", including claims that "*it [will be] possible to tailor treatments for each individual on the basis of knowledge from each person's genetic code (i.e. his/her predispositions for diseases, allergies and an understanding of which drugs will work most effectively for that individual)*".

In the section "*What does industry want from government?*" (para 5.1), the list includes: "*Availability of NHS information for research purposes within an appropriate ethical framework*".

2000

The Human Genetics Commission (HGC)

The Human Genetics Advisory Commission was succeeded by the Human Genetics Commission (HGC) on 1 January 2000. The pharmaceutical industry was represented on the HGC by Dr Gill Samuels of Pfizer (also head of the Bioscience Futures Forum, see Box N) and Dr Peter Goodfellow of GlaxoSmithKline (Box I).¹³⁸

Box I: Peter Goodfellow ¹³⁹

Peter Goodfellow worked at the Imperial Cancer Research Fund (ICRF) in the 1980s, moved to the University of Cambridge to head the genetics department in 1992, and after four years there founded a biotech company called Hexagen. He joined SmithKlineBeecham in 1996. After GlaxoSmithKline (GSK) was formed in 2000 from SmithKline Beecham's merger with Glaxo Wellcome, Goodfellow was appointed Senior Vice President for Discovery Research and given the task of unblocking the drug pipeline by reducing the average "cycle time" from the identification of a drug target to the discovery of a promising compound. He argued this could be done by combining genomics, genetics and automation¹⁴⁰, requiring GSK to have "access to large scale publicly or partly publicly funded genetic epidemiological databases".¹⁴¹ He was a member of the Human Genetics Commission from 2000 to August 2002. He left GSK and joined the Board of Directors of DeCode Genetics (Box H) in September 2006¹⁴². He is also a Scientific Advisor to Abingworth Life Science Investments, a venture capital firm that invests in both private and public life science companies.¹⁴³ He is married to Professor Julia Goodfellow, Chief Executive of the BBSRC (the Biotechnology and Biological Sciences Research Council) from 2002-2007.¹⁴⁴

Development of UK Biobank

A 'call for proposals' for large DNA collections was issued by the Medical Research Council (MRC) in January 2000.¹⁴⁵ From March to April 2000, the Wellcome Trust and MRC funded a study on public attitudes to the collection of blood samples for UK Biobank.¹⁴⁶ The focus group of GPs wanted assurances that the involvement of commercial organisations would be strictly controlled, and religious and community leaders also raised concerns about profiteering by companies.

On 13th February, the Observer published an article announcing the proposal for a "gene map of Britain", claiming "*Cancer and heart attacks could become rarities. Millions of lives could be saved*" and that ethical issues are "huge" but must be met.¹⁴⁷ On 18th February, the journal Science reported that the study's "*main goal is to tease apart the genetic and environmental components of conditions such as cardiovascular disease and cancer and, eventually, to come up with new drugs to treat--or even prevent--these conditions*".¹⁴⁸

Blair and the completion of the first draft of the Human Genome

In March 2000, Chris Sander of US biotech company Millennium Pharmaceuticals and Millennium Predictive Medicine elaborated Francis Collins' vision further in a paper in the journal Science. Sander's hypothetical patient has her whole genotype recorded at birth, rather than taking selected genetic tests by choice as an adult. Subsequently: "*The genotyping information is complemented throughout her life by a screening program based on biomolecular profiling*". At any point, screening may lead to recommendations about lifestyle, nutrition, or personalised therapy.

Also in March, the Prime Minister announced increased investment for the NHS and specialist teams began preparing a plan "*with the vision of a health service designed around the patient*".¹⁴⁹

On 14th March, a statement by Tony Blair and President Bill Clinton that the human genome "*should be made freely available to scientists everywhere*," upset investors and wiped tens of billions of dollars in market value from the biotech industry.¹⁵⁰ However their statement had only argued that the raw sequence data should be

made public and had explicitly endorsed the patenting of genes with known function. The BBC reported: *"In fact, Clinton and Blair do not question either the appropriateness or right of universities, governments or private companies to patent a gene, provided they have sufficient data on what it does and what its medical uses are"*. The statement was consistent with the European Patenting Directive (Box B) and with the Wellcome Trust's position, which states¹⁵¹:

"... the Trust is supportive of [gene patents] if there is sufficient information to indicate that the DNA sequences in question can be used to develop healthcare benefits. The Trust does not support the patenting of raw DNA sequences in the absence of such information. This is in line with EU law, which states that a gene sequence, whether partial or complete, is only patentable when it has been isolated and its function described".

On 1st April, Fears, Poste and a co-author published a paper in the British Medical Journal, again arguing that *"a strategic public-private partnership is essential"* to realise *"the promise of genetics for improved clinical practice"*.¹⁵²

On 26th June, 2000, Tony Blair and President Bill Clinton announced the completed draft of the human genome, together with Dr. Francis Collins, Director of the US National Human Genome Research Institute, and Dr. Craig Venter, President and Chief Scientific Officer of Celera Genomics Corporation.¹⁵³ The timing of the announcement was political (sequencing of the genome had not been completed).¹⁵⁴ A packed press conference was held at the Wellcome Trust (which was thanked by Blair in his speech).¹⁵⁵ Most British papers highlighted the race between the public sequencing project led by Dr John Sulston at the Wellcome Trust's Sanger Centre and the private project led by Dr Craig Venter in the US. Many stories wrongly implied that genes would not be patented as a result of the Wellcome Trust's role in the project. Headlines were overwhelmingly positive, although most papers also referred to possible misuses of personal genetic information. The role of genes in predicting future health and determining the "causes" of cancer were emphasised in many articles, although the project had produced only a DNA sequence and no information regarding human health.

The NHS Plan

The NHS Plan¹⁵⁶, published on 1st July, made a strong Government commitment to UK Biobank (paragraph 11.14): *"We now have the first provisional map of the human genome and innovation will occur at an ever faster rate. It is vital that the NHS plays an active and collaborative role in realising the benefits in genetics. We will contribute with other government departments and medical charities to a long-term study of the interactions of genetics and the environment in common diseases of adults such as cancer, heart disease and diabetes"*. New genetics research partnerships between the NHS and industry were also proposed. The Plan promised an extra £250 million for information technology in 2003/04 (paragraph 4.21) and went further than 'Information for Health' in promising patient access to electronic medical records by 2004. It also stated: *"When the necessary infrastructure has been put in place, and we have fully evaluated technical feasibility on effectiveness, smart cards for patients allowing easier access to health records will be introduced"*.

Exploiting the genome

Later in July, genomics and e-science were identified as priority areas for science funding in the DTI's 'Excellence and Opportunity' White Paper¹⁵⁷ and given a £250 million funding boost. The report states (para 26): *"Competitor countries are increasing their expenditure in genomics to accelerate identification of genome*

function – a key step in understanding the genetic basis of susceptibility to illnesses, including cancer and heart disease, which should then lead to improvements in diagnosis of disease, its prevention and treatment. By knowing the genetic make-up of each individual person, we will have greater ability to target therapies on individuals; at present nearly one-third of drugs do not have the desired effect on the patients who are prescribed them. Exploiting the genome is a unique opportunity and the UK has the right mix of strong companies, scientific expertise and available risk capital to capitalise on that mix. This will depend crucially on accelerating momentum in the science base.”

However, critics continued to argue that, except in a small percentage of cases, genes are poor predictors of people’s future health¹⁵⁸.

The House of Lords Science and Technology Committee pursue Poste’s proposal

During 2000, the House of Lords Science and Technology Committee set up a sub-committee in human genetic databases and, on 20th July, issued a call for evidence. Members included Lord Turnberg (Box J), who was co-opted onto the sub-committee on 19th July, and Lord Patel, Chairman of the MRC’s Genetics Advisory Committee and a Founder and Council Member of the Academy of Medical Sciences. The sub-committee’s advisor Professor Paul Elliott, Professor of Epidemiology at Imperial College London, now leads the London Regional Collaborating Centre for UK Biobank.¹⁵⁹

Box J: Lord Turnberg¹⁶⁰

Lord (Leslie) Turnberg was Professor of Medicine University of Manchester from 1973 to 1997 and President of the Royal College of Physicians from 1992 to 1997. He was Vice President of the Academy of Medical Sciences from 1998-2004 and is President of the Medical Protection Society, scientific adviser to the Association of Medical Research Charities (AMRC) and a Non-Executive Director of the biotech company Renovo (a spin-out company from the University of Manchester¹⁶¹). He chaired the advisory group for the Genetics White Paper, published in 2003, and was also a member of the Academy of Medical Sciences working group which developed its 2003 report ‘Strengthening clinical research’.

Sir Richard Sykes’ vision for the NHS

Sir Richard Sykes, Chairman of GlaxoWellcome (Box D), published a book in November 2000⁸⁸, written during the process of the merger between Glaxo Wellcome and Smith Kline Beecham, and funded by a Rock Carling Fellowship from the Nuffield Trust. The book sets out “*a strategic vision of how innovation in the development of medicines will impact on the practice of medicine and the delivery of healthcare over the next two decades*”.

In his book, Sykes predicts that within 20 years there will be fully developed ‘predictive medicine’, based on the integration of genetics, diagnostics and medicines, and an emphasis on “*pre-symptomatic treatment*” in developed countries (page 112), shifting the “*boundary between the individual and the patient*” (page 119). He states (page 119): “*Especially once effective interventions have been established, it will be reasonable to screen the population for genetic susceptibility to diseases such as diabetes and heart disease. The genetic information derived from these screens can then be combined with known conventional risk factors – such as inactivity, diet and smoking – to assess the population risk of disease with much*

greater knowledge than has previously been possible. This in turn will enable counselling and preventative measures to be initiated, such as encouraging regular monitoring, lifestyle changes and preventative medicine". Sykes claims this plan will both help "manage the future disease burden" and cut costs. However, he also argues (Chapter 5) that the UK population spends too little on medicines and that the NHS needs to be reformed to "deliver innovation" and "allow patients ready access to the medicines they want outside NHS funding" (page 195), stating that "The individualisation of patients by genetic profiling will add to their demand for greater control over their care..." (page 190).

The Medical Research Council

The Government allocated £20 million to the MRC (its initial share of the funding for the UK Biobank) in November 2000. In its Annual Report for 1999/2000 and accompanying press release the MRC claimed that the UK Biobank will lead to "*individualised risk assessment and preventative advice or treatment*" and "*a major shift in emphasis from treatment towards prevention*".¹⁶² On its website, the MRC stated that the understanding developed using the biobank "*will be used to predict the likelihood that an individual will develop a disease so that medicines can be used to prevent its onset rather than as a treatment for symptoms once a disease develops*"¹⁶³. Lifestyle advice could also be targeted at those identified as 'genetically susceptible' to future illness.

Evidence to the House of Lords Science and Technology Committee

On November 8th, the House of Lords Science and Technology published the written evidence it had received in response to its Genetic Databases inquiry, including evidence from Glaxo Wellcome, SmithKline Beecham, Paul Debenham of LGC (see Box L), Professor John Bell (Box C), the Wellcome Trust and the MRC.¹⁶⁴

The memorandum from Glaxo Wellcome states¹⁶⁵: "*The UK has an opportunity through the National Health Service (NHS) system of "tracking" patients and using electronic medical records to establish a valuable genetic research database. This would capitalise on advances in genetic science and technology and has the potential to attract investment in supporting and sustaining the UK's pharmaceutical and life science sector*".

A letter to the Committee from SmithKline Beecham states¹⁶⁶: "*We would expect to see DNA sequencing technologies advancing in the next 10 years, to a level that enables sequencing a substantial proportion of an individual's genome in a short time-frame. This will lead to the ability to diagnose diseases or the potential risks to health on an individual basis based on the variants occurring in a particular genome*" and "*...the British NHS represents a singular but under-utilised resource for population genetics, and healthcare informatics more generally. It has the potential to offer unparalleled access to areas of sample acquisition, such as across primary care, that is not possible in more fragmented health systems or in the smaller cohorts studies hitherto. A national structure could provide homogeneity of data acquisition that is essential for large-scale studies*".

Giving oral evidence to the Committee in December 2000¹⁶⁷, Professor Sir John Pattison (Box K), then Director of Research and Development for the NHS, admitted: "*...The strategy, of course, is not to go to a national genetic database as a first step, the strategy is to join the MRC and the Wellcome Trust in assembling a large cohort of approximately half a million people...There is an element of this which is going to be, as it were, worked out with a large research study*".

Box K: Department of Health officials involved in UK Biobank

Sir **John Pattison**¹⁶⁸ was Senior Medical Adviser to the MRC Chief Executive from 1995 to 1999 and chairman of the government's advisory committee on BSE ('mad cow disease'). He was knighted in 1988. In 1999 Sir John left University College London to become Director of Research, Analysis and Information and Head of Genetics at the Department of Health. He was made Senior Responsible Office (SRO) for the NHS National Programme for IT (NpflT) from October 2002, until he retired in 2004. He also chaired the 2004 Research for Patient Benefit Working Party.

Dr **Peter Greenaway** was Assistant Director of Research and Development at the Department of Health during the development of the UK Biobank proposal. He is now Director of the private consultancy Horus Research Management Ltd, but continues to act as consultant to the Department of Health and is Director of the National Research and Development programme on New and Emerging Applications of Technology (NEAT) and the genetics research portfolio.¹⁶⁹ At a 2005 conference, he stated that "*the UK biobank is a paradigm for the future NHS*", and went on to discuss how the UK Biobank may provide information which lends itself to a shift from diagnosis and treatment to prediction and prevention.¹⁷⁰ He is co-ordinator of the EUHEALTHGEN project, a 250,000 Euro project led by the Wellcome Trust which was funded by the European Commission from 2005-06 to organise a conference to develop a strategy for harmonising biobanks across the EU.¹⁷¹

Criticisms of UK Biobank begin

In December, the limitations of the data likely to be collected for UK Biobank – particularly the use of medical records for follow-up – led the Chief Executive of Gemini Genomics to comment: "*Garbage in, garbage out*"¹⁷².

Healthcare 2020

In December, the DTI's Foresight Programme published a new report: Healthcare 2020.¹⁷³ The panel was chaired by Professor Sir Michael Peckham of University College London. The industry representatives on the panel were from Pfizer (Dr Gill Samuels), Celltech, Smith and Nephew PLC, BUPA Ltd, Schroder Venture Life Sciences, and the Association of British Healthcare Industries. The report states that "*It is crucially important for the biotechnology sector in the UK to flourish and there is concern that other EU countries are taking over the UK lead in this field*" and that the NHS must "*be proactive towards the take-up and purchasing of key innovations in order to avoid R&D and other capacity being lost to other countries*". It emphasizes the role of public private partnerships – including with the Wellcome Trust (Recommendation 18) - and closer links between universities and industry to support 'technology transfer'. Paragraph 24.1 states: "*The perception of the biotechnology and pharmaceutical industries is of a lack of understanding within health care of what developments in genetics could offer. This is compounded by a lack of clarity about responsibilities for integrating genetics into medicine and health care more generally and by inadequately informed committees with which health care industries work. If the UK is to be at the forefront of exploiting genome research and other rapid growth areas in science and technology, an environment favourable to industrial innovation and R&D investment is a crucial requirement*".

The report predicts that "*Genetic screening and support will be predominantly a primary care responsibility*" (paragraph 3.2) and that "*In due course on the basis of*

genetic profiling it will be possible to devise a 'life' plan including diet and lifestyle" (paragraph 19.3). However, it cautions that "For most common conditions such as heart disease and cancer, genetic constitution and probably the interaction of many genes, plays a role in causation but extrinsic factors such as environmental pollution, diet and lifestyle are likely to be as important if not more so" and recommends that "Government should ensure that there are well-defined criteria for genetic testing and screening" (Recommendation 23). Nevertheless, the report envisages genetic predisposition data becoming part of individuals' healthcare records (paragraph 25.1): "Sequencing the entire genome of individuals is unlikely to be either desirable or usable. However, broader screens may prove useful in assessment of the individual's future health risks, for example, using single nucleotide polymorphism maps in genome "scanning". Such maps which could suggest predisposition to conditions such as cancer, diabetes and cardiovascular disease, and could become part of an individual's health biographical record". It states (paragraph 27.1) that: "By 2020 scans across the genome of individuals are likely to produce profiles of risk for many conditions".

The report also highlights the role of the NHS in implementing this vision (paragraph 28.1): *"The National Health Service is ideally placed to exploit opportunities to be derived from the successful integration of clinical and genetic information. This will be beneficial to the efficiency and performance of health services as well as to UK health care industries. The requirements for achieving this include a strong presence in clinical research/documentation, efficient information systems, good clinical trials networks, well developed knowledge management, methods for data extraction and analysis, and the build up of a tissue resource". It recommends a "high-profile" research initiative (Recommendation 28) and a national strategy for clinical trials (Recommendation 29): "This should jointly involve the Medical Research Council, Wellcome Trust, other charities, industry and NHS Research and Development. It should be associated with the national co-ordination and collection of donated blood samples for disease-related genetic study. Such action could provide a unique genetic blood pool from which to conduct research that would place the UK in a strong position commercially as well as academically. A DNA-based drug surveillance system is also needed to ensure post-approval monitoring of patients who have their blood stored. This will permit adverse events to be reported and interpreted in relation to genetic features and allow the development and design of future safer medicines".*

The report advocates more public engagement in the NHS but is also critical of information only being made available for research with the consent of patients (Recommendation 11). On electronic medical records, it states:
*"10.1 For individuals to hold and own their health records would signal a profound change in relationship between the public and health services. We anticipate that each person will have his or her own health biography held in an encrypted form on the internet and include clinical, genetic, and other relevant personal details. The individual will be able to add to the record, for example about the course of chronic ill-health and responses to treatment.
10.2 Ways will need to be found of maintaining confidentiality while allowing the record to be supplemented automatically by evidence-based recommendations. The individual would gain access to information through a smart card or biological identifier. Patients will authorize doctors or other professionals to have access to all or part of their records. Since the record would be owned by the individual it would be theirs to divulge or even sell selected aspects of information for example to commercial companies. Linkage between care in hospital or in the community including pharmacy use, will be crucial.*

10.3 Each record will have a unique number and confidentiality/privacy assured. One possibility will be to make use of approaches such as hashing algorithms where health service number, credit card and other numbers are combined to produce a unique number that cannot be traced back to the individual. This would permit records to be linked including if necessary monitoring the purchasing of food and alcohol while maintaining the privacy of the individual. Anonymised records could be used for automated data extraction for research and policy development.”

The report recommends that prototype models of electronic patient-owned health records created and maintained on the internet, are designed, piloted and evaluated and states that “*One way forward would be for consortia composed of people from the health sector and from other fields including commercial companies, to bid for development funds ear-marked for this purpose*”. It envisages that by 2020 the first point of contact with the NHS will be through a ‘virtual’ cyber-physician and that: “*Access to part or all of the user’s health biography would require use of a smart card or a biological identifier such as retinal vessels*”. It also states (paragraph 35.2) that “*Improved patient surveillance will result from miniaturisation of physical and chemical sensing devices, along with smarter biohybrid (“biosensor”) structures*” and (paragraph 35.4): “*Whatever its technical power, ultimately data processing will need to be assessed alongside any other health technology in regard to clinical benefits. It could be an important means of enhancing mass screening, disease risk assessment and predicting individual prognosis*”.

2001

A national biobank in Estonia

In 2001, Estonia became the second country to seek to establish a health and genetics database of its citizens, amid promises that this would “*increase quality of health care while lowering costs*”.¹⁷⁴ The Estonian Genome Project began as an independent foundation established by the Estonian government and almost fully financed by foreign and local private venture capital.

Harnessing genomics

On 13th February, the UK Government White Paper ‘Opportunity for All in a World of Change’ announced a new £25 million, 5 year programme on ‘Harnessing Genomics’.¹⁷⁵

The Human Genome and gene patenting

On 15th February, the scientific publication of the draft human genome sequence^{176,177} estimated that humans have only 30,000 to 40,000 genes, only about twice as many as in a worm or fly, and far fewer than the 100,000 originally predicted. This finding cast doubt on the ‘central dogma’ that one gene makes one protein. It also undermined the idea that common variations in a single gene were likely to explain common diseases (known as the ‘common-variant hypothesis’), adding to other evidence that the genetics of common diseases was likely to be much more complicated than this. As well as having scientific implications, the question of whether the ‘central dogma’ is valid has implications for gene patenting, which is based on the idea that discovering the function of a gene means it can be claimed as an ‘invention’.¹⁷⁸

UK Biobank consultation with healthcare professionals

In April 2001, a further consultation with primary healthcare professionals about UK Biobank was published by the Wellcome Trust and MRC, which found that they felt that the patenting of genes should be avoided.¹⁷⁹

The House of Lords Science and Technology Committee publishes its report

The report of the House of Lords Science and Technology Committee, published in March 2001¹⁸⁰, is highly enthusiastic about a genetic “*revolution*” in healthcare (para 1.1) and “*impressed by the vision of Dr George Poste*” (para 6.3). However the Committee was concerned “*that NHS Trusts continue to have autonomy to decide on their own computing strategy and protocols, making for unnecessary complications in the essential task of extracting and linking data across Trusts and across different data sets*” (para 6.25) and that the “*current strategy [for electronic patient records] would not yield a single national system*” (para 6.18) or meet the need for the large-scale computational infrastructure envisaged by Poste (para 6.6).

The report refers to evidence from the Academy of Medical Sciences, that advances in genetic technology will allow the identification of groups of individuals who may be more susceptible to certain diseases (para 4.8) and notes that “*Sir John Pattison was clear that these advances would transform the assessment of the risk of developing certain diseases and communication of this information to patients and their families (together with possible preventive action)*” (para 4.9).

The report also notes that Sir John Pattison (Department of Health), Sir George Radda (MRC) and Dr Dexter (the Wellcome Trust) “*all stressed the importance of industry in exploiting the benefits of genetic research*”, and, “*An important role for industry was also envisaged in the proposed UK Biomedical Population Collection [now called UK Biobank], although not in funding the core data collection for the study*” (para 8.11).

In relation to electronic medical records, the report recommends: “*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*”. In addition: “*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.*”

Writing in a letter to the British Medical Journal, at a time when Iceland’s deCODE project (Box H) was being criticised by many academics in the UK, researcher Jane Kaye noted that¹⁸¹: “*Only after reading the report in depth does it become clear that the recommendations would lead to the establishment of a British national population collection, which would link identifiable NHS clinical information on the 58 million people in the United Kingdom for genetic research. The proposed British biomedical population collection of 500,000 volunteers being established by the Wellcome Trust, the Medical Research Council, and the NHS would be a test run for this much bigger and more ambitious project*”. A joint response to Kaye’s letter from Dexter, Radda and Pattison, on behalf of the Wellcome Trust, MRC and Department of Health states

that her claim may “mislead readers” and “this is an independent research project and not linked to the establishment of any more extensive national collection”.¹⁸²

Government announces a new policy Green Paper on genetics in the NHS

In a speech at Newcastle University on 19th April, Health Secretary Alan Milburn announced that the Government would be publishing a Green Paper on genetics in the NHS, stating: “Above all, our task now is to determine how best we can harness the potential of genetics for the benefit of all our people and for all parts of our country”.¹⁸³ He claimed: “In time we should be able to assess the risk an individual has of developing disease - not just for single gene disorders like cystic fibrosis but for our country's biggest killers - cancer and coronary heart disease - as well as those like diabetes which limit people's lives”.

The advisory group for the Green Paper was chaired by Lord Turnberg (see Box J). It later became a White Paper (finalised policy document) without any consultation. Its members included Dr Paul Debenham head of Head of Life Sciences and Forensics at LGC (Box L). The minutes of the first Advisory Group meeting, held on 12th July 2001, were leaked, along with papers from the panel members, including Debenham, and from Crispin Kirkman, then Chief Executive of the BioIndustry Association.¹⁸⁴ An article in the Observer about the papers¹⁸⁵, published in September, states “The genetic secrets of millions of Britons could be sold off to private drug companies under highly controversial proposals outlined in leaked government documents”.

Box L: LGC

LGC was a partner company with Newcastle University in one of the new “Genetics Knowledge Parks” announced by Milburn in his speech.¹⁸⁶ The company was founded over 150 years ago as the Laboratory of the Government Chemist, but privatised in 1996. The Government cites LGC as a “bioscience success story”, for developing a prototype genetic testing technology called HyBeacon, which allows rapid testing of common variations in people's genes (known as SNPs) outside a laboratory.¹⁸⁷ LGC is one of the companies currently analysing DNA samples for the police and is also exploring the use of this technology for forensic purposes. In 2006, GeneWatch and the Observer newspaper revealed that LGC had kept a “mini-database” of people's information sent to them by the police.^{188,189}

Dr **Paul Debenham** is the Director of Technology and Innovation at LGC and is a member of the Human Genetics Commission (HGC).¹⁹⁰

Regulating the processing of patient information without consent

In May, the Health and Social Care Act 2001 was adopted. Section 60 allows the Secretary of State for health to regulate the processing of patient information without consent in some cases, when it is deemed to be in the public interest.¹⁹¹ The Patient Interest Advisory Group (PIAG) was set up to advise the Secretary of State on the use of these powers.

Scientific criticisms of UK Biobank

On 17th April 2001 a Protocol Development Workshop for UK Biobank was held at the Royal College of Physicians.¹⁹² There were widespread criticisms from scientists at the Workshop, where UK Biobank was described as “a poor vehicle for study of cardiovascular and metabolic disease”. The Workshop noted that there may be crucial changes in exposures (including environment and lifestyle) over time and recommended that returning to the people taking part in the study for updated

exposure information should be budgeted for from the outset. Participants noted that the true costs of meeting the academic objectives of the study might be in excess of £1000 per participant, and that the costs of sub-group studies needed to be included from the outset. At the Workshop, a much more detailed nested study of between 20,000 and 100,000 individuals was proposed, without which many scientists believed that the usefulness of the biobank, particularly for studies of heart disease, was “very weak”. Funds for this study, or other nested studies, have not been allocated, although they could be expected to cost many millions. Commenting on UK Biobank, the US geneticist Joseph Terwilliger stated: “*I don’t know any statistical geneticist in the UK who supports it*”¹⁹³.

In the medical journal, *The Lancet*, in October 2001, geneticists David Clayton (from the Department of Medical Genetics, Cambridge University) and Professor Paul McKeigue (from the London School of Hygiene and Tropical Medicine) examined UK Biobank’s scientific justification, arguing that: “*The scientific value of focusing on gene-environment interactions has not been established, and in any case, the technical advantages of cohort studies over case-control studies in detection of statistical interactions between genetic and environmental effects are less clear than has been assumed.*”¹⁹⁴

In scientific journals, other scientists continued to criticise the underlying premise that genetic testing could provide meaningful and useful predictions of the risk of common diseases, such as heart disease and cancer, in most people.^{195,196}

Government response to the House of Lords Committee

On 13th June 2001, the Human Genetics Commission sent a memorandum to the House of Lords Science and Technology Committee.¹⁹⁷

On 19th June, the Secretary for Health, Alun Milburn, claimed that genetic tests would be so predictive that they would destroy private health companies because insurance risks could be no longer pooled.¹⁹⁸

On 23rd July, the Government responded to the House of Lords Science and Technology Committee’s biobanks report, stating:¹⁹⁹ “*The Government accepts that the United Kingdom is ideally placed to establish the proposed large-scale prospective study [now known as UK Biobank] 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*”.

Shifting the boundary between the individual and the patient: and expanding the drug market

Despite the scientific criticisms, the idea of genetic ‘prediction and prevention’ of disease remained attractive to the biotech and pharmaceutical industries.

In May 2001, George Poste (Box G), by then based at Health Technology Networks, Arizona, published a paper about the role of genetic tests in healthcare, arguing that tests to predict the future risk of an individual will be developed and will transform healthcare.²⁰⁰ In the paper, Poste also states that the ability to patent genes and

other disease-associated biomarkers will make developing and selling diagnostic and predictive tests much more attractive to commercial companies. However, he warns that the lack of regulation of genetic tests is a matter of concern and that the launch of poorly validated predisposition tests could harm patients.

In September, Dr Ian Gilham, Vice President Pharmacogenetics and Applied Diagnostics at GlaxoSmithKline, and his colleague Dr Tom Rowland, writing in the International Journal of Medical Marketing, described the integration of diagnostics and pharmaceuticals - including genetic prediction as well as diagnosis of disease - as an area of significant added value for healthcare companies²⁰¹. The authors identified predisposition profiling - "*the ability to assess an individual's risk for a disease or diseases so that medicine can be given to prevent illness*" - as one key area of the new 'predictive medicine' and argued that integrating genetic testing and pharmaceutical products will increase market size for pharmaceutical products and services and "*the boundary between an individual and a patient will shift*". In addition, "*Once an individual is determined to be at risk, health status monitoring comes into play*", implying the need for further tests and services.

Commercial gene tests sales begin

In late 2001, the UK company Sciona began marketing gene tests combined with dietary advice directly to consumers via the Body Shop (Box M).

Box M: Sciona

In 2001, the UK company Sciona won a DTI "SMART" award (for small businesses) of £130,000 for its plan to commercialise the human genome by selling genetic tests linked with dietary advice. It withdrew its tests from sale in Body Shop stores in 2002, following an investigation by GeneWatch UK and criticism from leading scientists.^{202,203,204,205,206,207} Sciona subsequently relocated to the USA, obtained new investment from the major food ingredients companies DSM and BASF, and relaunched its product as the Celf genetic test kits, marketing the tests to use a loophole in US law which means they do not undergo an assessment by the FDA. In July 2006, an investigation by the US Government Accountability Office (GAO) concluded that genetic tests marketed via four US websites mislead people by making predictions that are medically unproven, and that the test results may needlessly alarm consumers into thinking that they need to buy a costly supplement in order to prevent an illness.²⁰⁸ Three of the four websites investigated by the GAO were marketing Sciona's genetic tests. The company is now exploring the Asian Pacific Market and has partnered with an Australian laboratory to pursue its Asian business further.²⁰⁹

2002

The genetics revolution underway?

On 15th January, 2002, a debate was held in the House of Lords on its biobanks report.²¹⁰

On 16th January, the Secretary of State for Alan Milburn made a speech to an international conference on genetics and health, reaffirming that later in the year he would publish a Green Paper setting out the Government's vision of how the genetics revolution could transform treatments and services available to NHS patients. He again claimed²¹¹: "*The genetics revolution is already underway...In time we should be able to assess the risk an individual has of developing disease - not just for single*

gene disorders like cystic fibrosis but for our country's biggest killers – cancer and coronary heart disease – as well as those like diabetes which limit people's lives” and highlighted to role of UK Biobank and the need for a “partnership with science and industry, medicine and the National Health Service”.

Streamlining consent?

On 12th February, the Academy of Medical Sciences held a symposium on consent and confidentiality, in an attempt to find a “middle way” to use data for research without necessarily requiring full informed consent.²¹² In one paper, Lord Turnberg (Box J) argued that Section 60 of the Health and Social Care Act 2001 was “*an awkward solution to the problem of data use without specific consent*” and that more work should be done to educate the public and increase trust so that general public knowledge of the uses to which their data is put is sufficient.²¹³

Blair's sofa meeting: approving the NHS National Programme for IT

On 18th February 2002, Sir John Pattison, Director of both Genetics and Information at the Department of Health, and Health Ministers Alan Milburn and Lord Hunt, met Prime Minister Tony Blair in Downing Street.²¹⁴ Others present at the meeting included the new ‘e-envoy’ Andrew Pinder, the NHS Chief Executive Nigel Crisp, and the civil servant leading the team working with Sir Derek Wanless to review the NHS.²¹⁵ This was the meeting at which Blair approved the new NHS National Programme for IT (NpflT). Pattison later told the BBC that he was given only ten minutes to make the case and did not make clear that the £2.4bn budget was only for the first phase.^{216,217}

The NHS Information Authority then initiated development of an ‘Output Based Specification’ (OBS) for the planned IT system – a specification of the functions that it was intended to perform.

UK Biobank's scientific protocol

The UK Biobank's Scientific Protocol was also published in February²¹⁸, stating that its main aim is “*to investigate the separate and combined effects of genetic and environmental factors (including lifestyle, physiological and environmental exposures) on the risk of the common multifactorial diseases of adult life*”, and that it would also examine whether or not the risk of adverse events relating to the use of certain medications varies according to an individual's genotype (genetic make-up). The Protocol claimed that “*The more precise identification of individuals at increased risk of disease through both exposure and genotype will allow improved targeting of various interventions*”.

For the first time, the Protocol provided some details of the science behind the study and it soon became the target of much behind-the-scenes scientific criticism, echoing many of the concerns previously raised at the Protocol Development Workshop in April 2001. In the Lancet, the authors of the protocol stated that “*We believe the extent to which the targeting of interventions in accordance with genotype will ultimately prove useful is as yet unclear*”, but proposed that the problems raised in 2001 would be addressed a studying a smaller group of 20,000 to 100,000 UK Biobank's participants in more detail (although funds for such a study have not been allocated).²¹⁹ However, the authors of the 2001 Lancet paper which criticised the study argued that funding this type of smaller study on its own would not require the larger UK Biobank and would provide much better value-for money and a better test of the causes of disease.²²⁰

Electronic medical records move ahead

On 20th March, Sir John Pattison, NHS Director for Research, Analysis and Information, announced the new fast-track corporate approach to electronic medical records that had been agreed at February's breakfast meeting with Blair.²²¹

Also on 20th March, in a speech to the Social Market Foundation, Chancellor Gordon Brown argued that the more accurate risk predictions enabled by genetics would cause problems for private medical insurance.²²²

Concerns about commercial companies and UK Biobank

In March, further focus group research regarding UK Biobank for the MRC and Wellcome Trust²²³ reported that "*The idea of access by commercial organisations raised concerns and generally the first reaction was to reject the idea*" although the researchers then noted that "*Further debate brought the realisation that if medicines are going to be developed, pharmaceutical companies must have access*" and that some participants therefore "*became resigned to their involvement*".

Delivering the NHS Plan

In April, the Department of Health published 'Delivering the NHS Plan', setting out the Government's modernisation agenda and vision for the NHS.²²⁴ It stated that a greater share of the new NHS funding would be used on training new health professionals for the future, and on capital infrastructure and modernised information technology rather than current spending.

The Wanless report

The Wanless Report to the Treasury: 'Securing Our Future Health: Taking A Long-Term View' was also published in April 2002.²²⁵ The report is described as the first ever evidence-based assessment of the long-term resource requirements for the NHS. A major finding was that lifestyle changes such as stopping smoking, increased physical activity and better diet could have a major impact on the required level of health care resources. The report assumes a doubling of spending on Information and Communication Technology (ICT) "*to fund ambitious targets of the kind set out in the NHS Information Strategy*", and recommends that these budgets should be ring-fenced. It also states that the scope for greater future cooperation between the NHS

and the private sector in the delivery of services should be explored, building on the concordat set out in the NHS Plan. The report concludes that in order to meet people's expectations and to deliver the highest quality over the next 20 years, the UK will need to devote more resources to health care and that this must be matched by reform to ensure that these resources are used effectively. It describes three scenarios:

1. *Solid Progress*. People become more engaged in relation to their health and life expectancy and health improve. In the NHS, there are high rates of technology uptake, extensive use of ICT and more efficient use of resources;
2. *Slow uptake*. No change in the level of public engagement and slow rates of technology uptake in the NHS.
3. *Fully engaged*. Levels of public engagement in relation to their health are high. Life expectancy and health improve dramatically. The health service is responsive with high rates of technology uptake, particularly in relation to disease prevention and use of resources is more efficient.

The fully engaged scenario was the least expensive scenario modelled and delivered better health outcomes. In absolute expenditure terms the gap between the best and worst scenarios was large – around £30 billion by 2022/23, or half of current NHS expenditure.

UK Biobank announced

On 29th April, the MRC, the Wellcome Trust and the Department of Health announced the allocation of £45 million start-up funding to the UK Biobank²²⁶.

On 6th May, Professor Sir David Weatherall of Oxford University told the Telegraph: “[UK Biobank] is a big gamble... People who opt into this study have to know exactly what is being done with this DNA. They need to know its relationship to any industrial exploitation.”²²⁷.

Blair’s science speech

On 23rd May, Prime Minister Tony Blair gave a major speech to the Royal Society in London, in which he stated that “*science is vital to our country’s continued future prosperity*”.²²⁸ In his speech and in the press, Blair criticised “irrational” protests against GM crops and animal experiments as harmful to science.²²⁹ Blair also repeated the vision of genetic ‘prediction and prevention’ of disease popularised by the Wellcome Trust: “...we can now see a future where the doctor will swab a few cells from inside your cheek, put them into a DNA-sequencing machine and a computer will spit out a complete reading of your unique genetic makeup - all 30,000 or so genes that make you who you are. From that, doctors could pinpoint flawed genes and gene products and predict what diseases you are likely to develop years in advance of any symptoms - and how to help you avoid them”. He then added: “We have a unique resource in this regard in the national health service. There are crucial issues of privacy of genetic information that we need to deal with. But our national, public system will enable us to gather the comprehensive data necessary to predict the likelihood of various diseases - and then make choices to help prevent them”.

Regulating patient information

On the same day, the Health Service (Control of Patient Information) Regulations 2002 were adopted in England and Wales, making provision for the processing of patient information, including confidential patient information, by persons or organisations approved by the Secretary of State for Health, provided they inform the Patient Information Advisory Group (PIAG).²³⁰

The HGC’s Inside Information report

In May, the Human Genetics Commission (HGC) published its report ‘Inside Information’.²³¹ The report considers ethical issues relating to personal genetic information, including: general principles for how genetic information should be treated; protecting personal genetic information; its use in clinical practice; consent and confidentiality; medical research; insurance and employment; forensic uses; parentage testing and family relationships. The report makes a number of recommendations for safeguards, including preventing police access to medical research databases “*by legislation if necessary*”. The summary states: “We want to ensure that the exciting prospects for genetic research will not be impeded by public anxiety” and the report endorses the concept of broad consent (to “medical research”, rather than specific studies), combined with a right to withdraw from the study. It states (in Chapter 5) that: “Access to samples and personal genetic

information may need to be made available to commercial organisations engaged in health-related research of public benefit. Our consultation revealed some disquiet over this, but the development of medicines and treatments is largely a commercial undertaking and the usefulness of genetic research and large databases would be severely limited if commercial access were denied". The HGC concludes that "best practice requires that the question of commercial involvement in research or access to genetic databases should be fully explained at the time of obtaining participants' consent. This should include a brief explanation of any intellectual property issues. In order to allay concern about wider uses it might be necessary to give commercial access only to companies engaged in health-related research".

The NHS National Programme for Information Technology (Npfit)

In June 2002, Ministers launched the new National Programme for Information Technology in the NHS (NPfIT), developed by John Pattison.²³² The core part of the Programme is the NHS Care Records Service, intended to make relevant parts of a patient's clinical record available to whoever needs it to care for the patient. Other elements include making X-rays available by computer, electronic transmission of prescriptions and electronic booking of outpatient appointments ('Choose and Book').

UK Biobank and gene-environment interactions

Also in June, the Department of Health's advisory Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC) published a statement on gene-environment interactions in cancer, including a lay summary and background papers.²³³ The Committee concludes (paragraph 37) that gene-environment interactions studied to date "were likely to be of little importance for public health or risk assessment", although this did not exclude the possibility that others might be discovered in the future.²³⁴ The report is also highly critical of poorly designed research in this area. It highlights the need for adequate assessment of exposures and states that it is "essential that such studies should involve a priori hypotheses" so that they do not give misleading results – two criticisms which are highly relevant to UK Biobank.

Sainsbury's speech

On 2nd July, science minister Lord Sainsbury made a speech to the Science Council (a membership body of scientific societies and professional institutions)²³⁵, stating: "We must all work to create a sustainable environment, and evolve a way of life which is in harmony with it, and not destructive of its future. One of the ways we can do that, of course, is to take measures to improve our own health. Any work which you undertake to improve the speed and accuracy of medical diagnosis, as recommended in the 'Healthcare 2020' Foresight exercise will contribute to that goal. I consequently look forward to reading your findings in this area, which I understand are due to be reported in the autumn. Diagnosis of course is the first step to deciding what must be done to cure the patient. Our capacity to do that should increase immeasurably once we have identified the relationship between diseases, the environment, and particular sequences in the human genome. In future it should become possible not only to identify which members of the population have a genetic propensity to particular diseases, but also to develop medicines suitable for an individual patient. That is why the Medical Research Council, the Department of Health, and the Wellcome Trust are together providing an initial £45 million for the UK Biobank project – the world's largest study of the role of nature and nurture in health and disease."

In July, the NHS Information Authority published a revised draft Output Based Specification (OBS) for consultation, requesting comments by September 2002.

UK Biobank raised in parliament

On 3rd July, the Chair of the House of Commons Science and Technology Committee, Dr Ian Gibson, MP, raised concerns about UK Biobank in an adjournment debate in Parliament.²³⁶

Government and Wellcome Trust jointly fund more science

On 15th July, Chancellor Gordon Brown announced a further 10% per year increase in science funding. A separate joint initiative with the Wellcome Trust involved a £280m joint investment to improve science teaching; awards totaling £90m to selected universities and Wellcome Trust-funded researchers; £30m for scientific equipment, a £95m award to the Wellcome Trust Sanger institute, and £40m to convert discoveries into medical treatments.²³⁷

Investing for Innovation

On 23rd July, the Treasury launched its 'Investing in Innovation: a strategy for science, engineering and technology' report²³⁸ at the Wellcome Trust. The Strategy notes that the Wellcome Trust provided £525 million towards the recent Joint Infrastructure Fund and the Science Research Infrastructure Fund in partnership with the Government. They have also, alongside the Medical Research Council and the Department of Health, provided an initial £45 million for the UK Biobank project – "*a study of genes, environment and health that will capitalise on the knowledge from the Human Genome Project*". In addition, the Wellcome Trust has committed £110 million to the Diamond Synchrotron project, and £360 million over five years for genomic research at the Wellcome Trust Sanger Institute. In parallel, industry collaboration with, and use of, university research has grown in real terms from £135 million to £242 million (in 1999-00 prices) between 1988-89 and 1999-2000 (paragraph 3.20).

UK Biobank impacts on other research funding

In August, the journal Nature reported that the MRC had refused funding for some top-rated medical research projects because of the resources required for UK Biobank²³⁹.

The Nobel prize for medicine

In October 2002, geneticists Sydney Brenner, Robert Horvitz and John Sulston (Head of the Wellcome Trust Sanger Centre) won the Nobel Prize for medicine.²⁴⁰

NHS IT, NHS numbers for babies, and the secondary use of data for research

Also in October, the Deloitte consultant Richard Granger was appointed as the first Director General for NHS IT, responsible for procuring and delivering the IT systems needed for the NPfIT. All of the contracts were procured between February 2003 and February 2004. The four principal suppliers (supported by numerous others) are: BT, Accenture, Fujitsu and CSC.

The NHS Information Authority and Health Which? published the results of qualitative and quantitative research with patients and the public.²⁴¹ When given a series of potential safeguards and asked “what would reassure you most that the NHS is careful with your health information?”, 45% said a published sharing agreement. This led to the development of the Care Record Guarantee (see May 2005).

On 29th October, the new NHS ‘Numbers for Babies’ (NN4B) scheme went live, ensuring that all babies born in England and Wales are issued with an NHS number at birth – a significant step towards electronic medical records for all.^{242,243}

On 1st November, the Nuffield Trust published its report ‘Learning from Experience: Privacy and the Secondary Use of Data in Health Research’²⁴⁴, written by the Geneva-based ethics consultant Dr William Lowrance – the former Director of the Life Sciences and Public Policy Program of the Rockefeller University, who was later appointed to Chair UK Biobank’s Interim Advisory group on Ethics and Governance - and funded by grants from GlaxoSmithKline and Pfizer, Inc. The report considers under what conditions data not collected specifically for research, such as primary medical data, may be re-used for health research. The report advocates broader forms of consent (or “non-objection”) to the use of personal data *“to make this both fairer and more practical”* and argues that the motivations of *“social solidarity, altruism, and unselfishness”* need to be developed as regards *“willingness to let others learn from the record of one’s experience or from one’s genetic material”*.

The House of Commons Science and Technology Committee scrutinises UK Biobank

In September 2002, the House of Commons Science and Technology Committee announced that it would be holding a scrutiny session on how the Medical Research Council (MRC) spends its money, including consideration of the UK Biobank proposal.

In its evidence²⁴⁵, the Human Genetics Commission (HGC) stated: *“Before considering the detailed consideration of the proposals for UK Biobank, the Commission would like to formally record that we believe that this is an extremely important and valuable research project if the benefits of advances in genomics are to be converted into a more detailed understanding of complex diseases. We believe that this is possibly a unique opportunity and that it must succeed”*.

In his oral evidence to the Committee on 4th December, Sir George Rada, Chief Executive of the MRC, stated that the Biobank’s policy is that genes with known functions have to be patentable as a safeguard for industry²⁴⁶. He also claimed that ‘science’ and ‘ethics’ are separate and only the latter requires public input – implying that the claimed benefits of the project would not be open to public scrutiny.

2003

The Bioscience Innovation and Growth Team

In January 2003, Lord Sainsbury, then science minister, and Lord Hunt, then a minister at the Department of Health, launched the Bioscience Innovation and Growth Team (BIGT), in partnership with the BioIndustry Association. Its mandate was to formulate a strategic approach to the future of the UK’s bioscience industry (Box N).

Box N: The report of the Bioscience Innovation and Growth Team (BIGT)

BIGT involved representatives of the biotechnology industry, government and investors, chaired by Sir David Cooksey (Box F). Its report, 'Bioscience 2015 – Improving National Health, Increasing National Wealth', was published in 2003.²⁴⁷

Key recommendations of the report are:

- 1) Build a mutually advantageous collaboration between the NHS and industry for patient benefit;
- 2) Create a public and regulatory environment supportive of innovation;
- 3) Ensure sufficient and appropriate funding is available;
- 4) Build a strong bioprocessing sub-sector;
- 5) Develop, attract and retain a high quality scientific and managerial talent base;
- 6) Making it happen: create the Bioscience Leadership Council.

The Bioscience Leadership Council (BLC), was set up and headed by **Sir Richard Sykes** (Box D), but was wound down in January 2006.

Dr **Gill Samuels** CBE, previously Executive Director of Science Policy & Scientific Affairs (Europe) at Pfizer led the work of its subgroup, the **Bioscience Futures Forum** (BFF).²⁴⁸

Ownership and access to medical records

In 2003, the Health and Social Care (Community Health and Standards) Act²⁴⁹ was adopted, allowing the Government access to all medical records in the UK, and the new contract offered to GPs moved ownership of family doctor computers to Primary Care Trusts.²⁵⁰

The Royal Society's People's Science Summit on genetic testing

On 4th March 2003, the Royal Society held a People's Science Summit on genetic testing. Nobel prizewinner Sir Paul Nurse initiated a discussion based on a scenario that newborn children could be given "genetic identity cards" at birth in 20 years.²⁵¹ When asked what their top recommendations were, 41% of forum participants wanted more regulation of genetic testing, 13% wanted more education about genetics and 11% wanted a ban on genetic identity cards. When asked directly if genetic identity cards should be allowed, a small majority were against.²⁵² The main recommendations that emerged were²⁵³:

1. That a regulatory body be set up to oversee legislative and other issues surrounding genetic testing;
2. That the profiling of the genomes of children at birth should not proceed because as many people were against the idea as were in favour;
3. That a strong effort be made to increase education about genetics for both the public and healthcare professionals;
4. That the impact of environmental and lifestyle factors on health continues to be considered alongside genetic factors.

Genetics and health: Visions of the future

On 24th March, the Wellcome Trust and the Royal Society published a report 'Genetics and health: Visions of the future', based on a meeting of approximately 50 participants including life scientists, members of the policy community and representatives of the clinical and social sciences.²⁵⁴ The report states that "*The usefulness of genetic screening was a matter of much debate in the meeting*".

Although some participants believed that in 20 years time, technological advances would mean that it will be feasible in terms of cost and speed to sequence the entire genomes of individuals on a routine basis, not everyone could see what the merits of

a total genome scan for everyone would be. There was much discussion about the pros and cons and significant social and ethical questions were raised.

The HGC's Genes Direct report

Also in March, the Human Genetics Commission (HGC) published its report 'Genes Direct: Ensuring the effective oversight of genetic tests supplied directly to the public', which highlighted the danger that people might receive misleading medical advice as a result of companies overstating the role of genetics in common complex diseases; the difficulty of ensuring informed consent when tests are offered direct to the public; and the impact on NHS resources if patients were to seek advice from their doctors before or after private tests, or if patients were to require confirmatory testing within the NHS.²⁵⁵ The report concluded that the Medicines and Healthcare Regulatory Agency (MHRA) should oversee the scientific quality and clinical utility (usefulness) of genetic tests and the advice that is given to customers. However, the report stopped short of recommending new legal powers.

The DNA double helix anniversary

In April, the 50th Anniversary of the discovery of the DNA double helix structure was celebrated at the Royal Society.²⁵⁶ In a speech at a reception organised by the BioIndustry Association, Science Minister Lord Sainsbury concluded: "*What form that impact [of the discovery] will take, we can only imperfectly see today, but what we can be certain about is that exciting times lie ahead and that Tony Blair was clearly right when he said that biotechnology is likely to be the 21st Century what IT was to the 20th*".²⁵⁷

NPfIT's output specification

On 1st May, the first version of NPfIT's final Output Based Specification (OBS1) was issued to potential suppliers. Originally marked 'restricted', the documents have now been published together with the later OBS2 version (published in August 2003).²⁵⁸

UK Biobank – a politically driven project?

In February, UK Biobank appointed an Interim Advisory Group on Ethics and Governance, chaired by Dr William Lowrance.

On 31st March, UK Biobank's first Chief Executive, John Newton, was appointed.

In March 2003, the House of Commons Science and Technology Committee, published the results of its investigation into the MRC²⁵⁹. The report states: "*The Biobank is an exciting project and we commend the MRC's efforts to ensure that the UK is taking the lead in harvesting the fruits of the human genome. We are concerned, however, that funds were allocated to the project before the scientific questions over its value and methodology were fully addressed... It is not clear to us that Biobank was peer reviewed and funded on the same basis as any other grant proposal. Our impression is that a scientific case for Biobank has been put forward by the funders to support a politically driven project*".

The Committee recommended that the MRC publish the peer reviewers' comments anonymously "*to build confidence that the project is fully justified and supported by the scientific community*".

On 4th April: UK Biobank held a consultation meeting with the Association of the British Pharmaceutical Industry (ABPI).

In April, the Prime Minister, the Chancellor and the Secretary of State for Health asked the banker Derek Wanless to begin investigating the challenges involved in implementing the fully engaged scenario set out in his 2002 report on long-term health trends.²⁶⁰

An article in the medical journal in the Lancet in May89 reported widespread concerns about the UK Biobank project amongst geneticists, stating:
“Some scientists are broadly supportive of the [UK Biobank] project, and feel it is a scientifically valid, potentially valuable resource, although they still have reservations over the details of the current protocol. Others see it as an ill-conceived, politically motivated project, in which consultations have only been done to give an appearance of legitimacy and in which the scientific case has not been made for its design”.

On 7th May, the University of Manchester was selected for the new headquarters of UK Biobank, and Professor John Bell (see Box C) was appointed to chair its Science Committee.²⁶¹

In June, the Government responded to House of Commons Science and Technology Committee’s concerns about UK Biobank, stating that it would not be appropriate to peer review the project like “any other grant proposal”.²⁶²

In July, the UK Biobank’s Science Committee held its first meeting, chaired by Professor John Bell.

Publication of the Genetics White Paper

In June 2003, Lord Warner was appointed as a junior health minister (Box O).

Box O: Lord (Norman) Warner

Appointed as Under-Secretary of State for health in June 2003, Warner was given responsibility for genetics and IT policy in the NHS, including the implementation of electronic medical records. He was promoted to become Minister of State for Reform at the Department of Health following the May 2005 election²⁶³ and resigned in December 2006.²⁶⁴ Downing Street denied accusations that his departure was linked to the growing difficulties over the NHS IT programme, and delays to the implementation of the national electronic record system.²⁶⁵

In February 2007, NHS London’s Provider Development Agency – part of the NHS ‘modernisation’ agenda Warner helped to develop as minister - appointed him as its chairman.²⁶⁶ In late 2007, he became an advisor to five companies, including Apax Partners Worldwide (see Box A), joint owners of the private health company General Healthcare²⁶⁷; and three companies – including Deloitte – involved in the NHS IT programme. General Healthcare owns BMI Hospitals (the largest owner of private hospitals in the UK) and Netcare UK, which provides specialised clinical services to patients under contract to the National Health Service, including diagnostic centres. In 2006, Netcare UK was awarded contracts to provide two of the seven NHS Treatment Walk-in Centres, as well as the London Diagnostic services contract, won with InHealth.

In January 2008, Warner also became Non-executive Chairman of UK HealthGateway Ltd, which helps US companies gain access to the UK healthcare market.^{268,269,270}

In June 2003, the Government's White Paper on genetics in the NHS was published.²⁷¹ In its foreword the Secretary of State for Health, John Reid states: *"Advances in human genetics will have a profound impact on healthcare. Over time we will see new ways of predicting and preventing ill health, more targeted and effective use of existing drugs and the development of new gene-based drugs and therapies that treat illness in novel ways. Above all, genetics holds out the promise of more personalised healthcare with prevention and treatment tailored according to a person's individual genetic profile"*. The White Paper claims (para 1.4) that in Britain *"We are well placed to lead the world in the discovery and realisation of the maximum benefits of genetics in healthcare"* and states (para 3.19): *"As genetic testing technology becomes simpler and faster, common tasks in primary care such as the prevention of CHD [coronary heart disease] and the management of asthma or diabetes could involve the carrying out and interpretation of genetic tests. Information from such tests could provide clinicians and patients with more accurate, personalised information about their health problems"*.

In relation to IT the White Paper states (para 4.19) that: *"The effective utilisation of genetic knowledge will receive a major boost through 'Information for Health', the NHS Information Strategy"* and that: *"In future, genetic features (such as family history, inheritance patterns, test orders and results, diagnoses detailing genetic subtypes of disease, estimates of future risk) will need to be recorded in patients' electronic records to inform subsequent treatment decisions"*. The White Paper also reiterates the Government's commitment to funding UK Biobank, jointly with the Wellcome Trust (para 5.34), stating: *"This project aims to obtain comprehensive data on the combined effects of genotype, lifestyle and environmental exposure to assess the risk of developing the common multi-factorial diseases of later life"*.

The Genetics White Paper also included a controversial proposal to collect and screen DNA from every baby at birth (paras 3.36 to 3.38), so that *"it could then be used throughout their lifetime to tailor prevention and treatment regimes to their needs as further knowledge becomes available about how our genes affect our risk of disease and our response to medicines"*. This proposal was subsequently rejected by the Human Genetics Commission (HGC) on the grounds of its excessive cost, lack of benefit to health, and concerns about ethical issues such as lack of consent and potential misuse of the information.^{272,273} However, the HGC recommended that the proposal should be revisited in 2010.

In August, a second version of the Output Based Specification for NHS IT (OBS2) was provided to contractors.

The Academy of Medical Sciences: 'Strengthening clinical research'

In October, the Academy of Medical Sciences published the report of a working group led by Professor John Bell (Box C) and assisted by its Senior Policy Advisor, Dr Robin Fears (Box G). The report, 'Strengthening clinical research' is funded by the Kohn Foundation and GlaxoSmithKline.²⁷⁴ Members of the working group (page 43) included Lord Turnberg (Box J). The report argues (paragraph 2.4) that *"the dramatic expansion in molecular medicine has created a crisis in clinical research by producing a pipeline of new interventions and technologies that need now to be evaluated in a clinical setting"*, including new genetic susceptibility tests and other biomarkers (paragraph 2.16), as well as new drugs. The report also highlights the UK Biobank as providing *"one opportunity"* to use better IT infrastructure within the NHS (paragraph 2.23) and states (paragraph 3.9) that: *"Current plans to improve IT within the NHS must take into account the needs of research"*.

The NHS Code of Practice on Confidentiality

In November, the NHS Code of Practice on Confidentiality was published²⁷⁵, replacing the previous guidance HSG(96) 18/LASSL 96(5) - The Protection and Use of Patient Information. The Code of Practice had been put out for Department of Health stakeholder and public consultation between October 2002 and January 2003. It states: *“Preventative medicine, medical research, health service management, epidemiology etc are all medical purposes as defined in law. Whilst these uses of information may not be understood by the majority of patients, they are still important and legitimate pursuits for health service staff and organisations. However, the explicit consent of patients must be sought for information about them to be disclosed for these purposes in an identifiable form unless disclosure is exceptionally justified in the public interest or has temporary support in law under section 60 of the Health & Social Care Act 2001”*. The Code states (paragraph 34): *“Whilst it would not be reasonable and proportionate to disclose confidential patient information to a researcher where patient consent could be sought, if it is not practicable to locate a patient without unreasonable effort and the likelihood of detriment to the patient is negligible, disclosure to support the research might be proportionate. Other factors e.g. ethical approval, servicing and safeguards, anonymisation of records and/or clear deletion policies etc. might also influence a decision on what is proportionate”*.

More criticism of UK Biobank

On 1st October, Professor Steve Jones of University College London wrote an article criticising UK Biobank in the Telegraph. In the article, Jones states: *“The first problem is that the degree of inheritance expected for life-expectancy and of the miseries of advancing years is, for good evolutionary reasons, limited. The old adage ‘If you would live long, choose your parents well’ is correct but has little to do with DNA. Surrey parents and children live longer than those in Somalia: but that’s largely because of conditions”*. He also raises practical problems with recruitment, potential costs (up to £1,000 a head) and the limitations of collecting dietary information using a survey.²⁷⁶

On 24th November, UK Biobank published its draft Ethics and Governance Framework for comment.

In December, UK Biobank was established as a charitable company.

NHS IT contracts awarded

Also in December, Health Secretary John Reid announced the award of three key contracts to deliver the National Programme for IT (NPfIT) for the NHS.²⁷⁷ An extra £2.3 billion was also pledged to kick-start and fund the national programme up to 2005-06.

2004

UK Biobank’s Board appointed

In January, the UK Biobank’s Board of Directors was appointed. The Board is chaired by Sir Alan Langlands, former Chief Executive of the NHS in England (1994-2000), and includes Professor Sir John Bell (Box C), and Professor Mike Pringle, the National Clinical Lead for General Practitioners at ‘Connecting for Health’.²⁷⁸

The second Wanless report

In February, the second Wanless Report for the Treasury was published: 'Securing good health for the whole population'.²⁷⁹ It found that people need to be supported more actively to make better decisions about their own health and welfare because there are widespread, systematic failures that influence the decisions individuals currently make, including significant inequalities related to socio-economic differences. However, it found generally little evidence about the cost-effectiveness of public health and preventative policies or their practical implementation and states: "*The dearth of [public health] evidence is not unrelated to the lack of funding of public health intervention research - with funding from research organisations and the private sector heavily directed towards clinical, pharmaceutical, biological and genetic research – and the lack of a clear and coherent set of Government priorities for the public health research which does exist*". For example, less than 0.4% of current academic and research output is relevant to public health intervention research²⁸⁰.

In relation to ICT the Wanless report states; "*To improve understanding of prevalence of disease and to enable proactive management of personal risk factors, much greater use needs to be made of primary care data systems. The potential of the Electronic Patient Record and new General Medical Services (GMS) contract to begin to collect this type of information and use it to guide both national understanding and local activity must be fully realised*". It also anticipates that "*Information Management and Technology (IM&T) will be a massive driver of change and the big commitment which is being made to improved technology in the NHS will have, as part of its justification, the possibility of helping the identification of personalised risks from the information stored about the individual*". However, elsewhere the report warns: "*A possible consequence [of the low status of public health] is that pharmacological solutions might become the focus of primary prevention with considerable financial implications. Substantial investment, or reprioritisation, is necessary if this imbalance in research funding is to be addressed*".

Pattison retires

In March, Pattison retired and his role as Senior Responsible Owner of the NPfIT and the role was given jointly to Richard Granger and the Deputy Chief Medical Officer, Dr Aidan Halligan.²⁸¹

Increased budget for medical research

On 17th March, the Chancellor announced in his Budget speech that the combined budget for medical research and research and development within the NHS would rise, to approach £1.2 billion a year by 2008.

New UK Biobank appointment

In April, Dr Tim Peakman became director of operations at UK Biobank.²⁸² He is now Executive Director for UK Biobank and has overall responsibility for the day-to-day running of the organisation. He has ten years' research experience in the pharmaceutical industry and as a senior consultant in drug discovery. As a consultant, at PricewaterhouseCoopers, he advised discovery organisations in the pharmaceutical and biotechnology industries on a variety of projects. Steve Walker was also appointed as Information Officer. He worked as an assistant director for the National Programme for IT, with responsibility for primary care, between September

2003 and April 2004. From September 2001 to August 2003, he was involved in the negotiation of the new contract for GPs in the UK and responsible for the delivery of new information systems to support that contract. Between March 2000 and September 2001, he worked as the NHS national programme director for Project Connect (an NHS project to connect the computer systems of GPs and local hospitals). He is also co-leader, with Professor Jan-Eric Litton, of the proposed EU work package 'Harmonising Population-based Biobanks and Cohort Studies to Strengthen the Foundation of European Biomedical Science in the Post-Genome Era'.

Implementing the BIGT report

On 28th May 2004, the Government (Lord Warner and Lord Sainsbury) published its response to the 'Bioscience 2015' report, led by the Bioscience Innovation and Growth Team (BIGT) and confirmed that it would create a new UK Clinical Research Collaboration (Box P).²⁸³ The response concludes: "*We will continue to progress activities across Government to support the development of the medical bioscience sector in the UK, and will meet biannually with the Chairman of the Bioscience Leadership Council, Sir Richard Sykes, as the implementation of the BIGT recommendations progresses*".

Box P: The UK Clinical Research Collaboration (UKCRC)

An outcome of the bioindustry's 2003 BIGT report, the UK Clinical Research Collaboration brings together the NHS, research funders, industry, regulatory bodies, Royal Colleges, patient groups and academia. Members include the Wellcome Trust, the MRC, the Academy of Medical Sciences, the Association of the British Pharmaceutical Industry (ABPI), the BioIndustry Association (BIA) and the Association of British Healthcare Industries (ABHI).^{284,285} Its Board is chaired by Professor Sally Davis of the Department of Health and its members include Dr Richard Barker of the ABPI, Dr Peter Arnold of the ABHI, Dr Mark Walport (Box E) and Dr John Pattison (Box K)²⁸⁶. The UKCRC Partners are implementing "a comprehensive UK-wide strategy which is putting in place infrastructure to support all aspects of clinical research", including "Realising the research benefits of NHS IT Programmes"²⁸⁷.

The NHS improvement plan and the data 'Spine'

In June, the Department of Health published its NHS Improvement Plan.²⁸⁸ It states (para 5.14) : "*Reflecting the urgency of developing diagnostic capacity and encouraging innovative solutions, the next wave of independent sector procurement is likely to include diagnostic services. The Department of Health will also be looking to expand diagnostic provision in primary care and "high street" settings, and via the letting of one or more major contracts to new providers to process electronic and routine diagnostic test results remotely*". It also reiterates the view that "*The National Programme for IT is an essential element in delivering The NHS Plan*" (para 7.2).

On 29th June, the National Data Spine for the NHS Care Records Service went live. Despite delays to creating a fully functioning system, the plan remained to achieve full implementation by 2010.

The Science and Innovation Investment Framework

In July, the 'Science and Innovation Investment Framework 2004 – 2014' was published as part of the Treasury's 2004 Spending Review.²⁸⁹ The Wellcome Trust

pledged to at least match government by investing £1.5 billion on science projects thus taking overall increases in science spending between 2004/05 and 2007/08 to £2.5 billion.²⁹⁰

New UK Biobank appointment

In August, Dr Tim Sprosen became chief scientific officer for UK Biobank.⁹⁴ Before joining UK Biobank, he was director of product development and acting director of clinical operations for Health Decisions Limited in Oxford. He has also worked as associate director of clinical development for Baxter Healthcare at their European headquarters in Brussels; as the first clinical trials manager at the MRC; and with two US West-coast start-up companies.

Revised draft of the Human Genome published

In October, a revised draft of the human genome was published.²⁹¹ The number of genes was again revised downwards, at 20,000 to 25,000 (about the same as a roundworm).

Systems biology: DNA plus monitoring

In October, Leroy Hood of the Institute for Systems Biology in Seattle published a paper in the journal *Science* arguing that both genomic data and other molecular measurements (made using blood samples) “*will allow for the determination of a probabilistic future health history for each individual*”.²⁹² Rather than relying on DNA tests alone, this would require building a fundamental understanding of systems biology and the development of new technologies, such as (extremely small) nanotechnology devices to measure genes and proteins. Hood claimed: “*Predictive and preventative medicine will lead naturally to personalized medicine that will revolutionize health care*” and “*Health care providers will move from dealing with disease to also promoting wellness (prevention)*”. However, the vision had shifted to include ongoing surveillance as well as genetic make-up.

The Healthcare Industries Task Force

The Healthcare Industries Task Force (HITF), set up in October 2003, reported in November 2004. It was co-chaired by Health minister Lord Warner and Sir Christopher O'Donnell, Chief Executive of Smith and Nephew PLC. Members and participants included the Association of British Healthcare Industries (ABHI) and representatives of numerous small technology firms, including Dr Paul Debenham of LGC (Box L). Its aim was to identify areas for closer co-operation between government and the healthcare industries, in the context of new policy developments, such as the use of privately run Independent Treatment Centres (ITCs) in the NHS. The focus of the final report was on medical devices (which include medical tests, such as genetic tests, but also a wide range of other medical technologies, excluding pharmaceuticals). It identified market access; R&D and the industrial base; regulatory issues and international trade as the key areas for investigation (paragraph 1.4).

The HITF report strongly endorsed Sykes' vision for a partially-privatised NHS, in which healthy people are treated on the basis of their supposed risk of common diseases. It states (paragraph 4.1): “*As we understand more of the origins of disease, both genetic and environmental, we realise that we are on the verge of a new model. This will be based upon helping individuals understand and maintain their health throughout their lives, rather than simply treating disease after it has taken hold. The emphasis will shift from 'late' to 'early' and will expand from treating*

disease to maintaining health". The report then claims (paragraph 4.2): "*Technology has a central role to play in enabling this vision, but its success will be critically dependent on establishing the right mechanisms of interaction and partnership between scientific innovators, the healthcare industries, the NHS and individual patients*". As part of this shift, it notes (paragraph 4.9): "*providing prophylactic treatments for predictive conditions could be used more extensively to avoid ill health*". "*Pharmacogenomics, pharmacogenetics and genetic screening will have an enormous impact on our ability to identify those members of the population who are at increased risk of disease*" and "*the early health approach will allow individuals to understand their own genetic propensity to key treatable diseases, so that they can receive regular selective screening...allowing rapid intervention through surgery, drugs or lifestyle improvement*" (paragraphs 4.13 and 4.14). In addition: "*Remote monitoring technologies will allow the health of at-risk patients to be monitored as they go about their daily lives and treatment to be provided when there is an indication of need emerging*" (paragraph 4.24).

The HITF report also identifies the National Programme for IT (NpfiT) as the means to facilitate the delivery of these new services and track individual patients (paragraph 4.28.2). Echoing Poste and Fears' paper in *Science* in 1999, it argues that the NHS is a uniquely valuable asset which could "*provide an engine for industrial development based on the knowledge economy*" (paragraph 4.35).

Also in November, an obscure review of the Department of Health's 'arms length bodies' (ALBs), recommended the transfer of the Device Evaluation Service of the Medicines and Healthcare Regulatory Agency (MHRA) to the NHS Purchasing and Supply Agency (PSA) (page 27)²⁹³. This effectively undermined the Human Genetics Commission's 2003 proposals in its report *Genes Direct*, that the MHRA should undertake pre-market reviews of genetic susceptibility tests. This change was endorsed by the HITF report (paragraph 5.10), on the grounds that device evaluation is not a regulatory function, but is a matter for NHS procurement only. Instead of acting as a regulator, the transferred advisory group is intended to work with a proposed new Innovation Centre to facilitate the adoption and diffusion of new technologies. The report also recommends the establishment of Healthcare Technology Co-operatives (HTCs), collaborations between clinicians, patients, academia and industry that act as a focus for 'technology pull' into the NHS.²⁹⁴

The 'Choosing Health' White Paper

On 16th November, the Department of Health published its 'Choosing Health' White paper.²⁹⁵ The policy included a commitment to a 'health-promoting NHS' and to developing and implementing a comprehensive public health information and intelligence strategy.

Clinical leads for NPfiT

Seven National Clinical Leads were also appointed in November to represent GPs, hospital doctors, nurses and allied health professionals in the NPfiT. The National Clinical Lead for general practitioners (GPs) is Professor Mike Pringle, a member of the Board of UK Biobank.

More gene test marketing

In December 2004, the Oxfordshire-based company G-Nostics began marketing a pharmacogenetic test, linked to a smoking cessation programme, online (Box Q).

Box Q: G-nostics and ‘the smokers’ gene’

The UK company G-Nostics is a ‘spin out’ company from Oxford University which markets a genetic test kit to smokers. The company was created in July 2004 by Isis Innovation, the University of Oxford’s wholly owned technology transfer company, with the university as a shareholder.²⁹⁶ Prior to its spin-out, approximately £3.5m was invested in the technology, and a total of £2.1m has been invested in the company since.²⁹⁷ The test is based on research by Dr Robert Walton in the university’s Department of Clinical Pharmacology, who became a co-founder of the company. The academic research was part-funded by the charity Cancer Research UK.

G-Nostics began marketing Nicotest, a test of two common genetic variants, combined with advice on quitting smoking, in December 2004. It claimed that its test included a gene which predisposed people to nicotine addiction, and provided advice on the best smoking cessation method to use. The test was launched amid a blaze of publicity which claimed that Oxford University scientists had identified ‘the smokers’ gene’ and that: “*Smokers can now test themselves to find out if they carry a gene that predisposes them to heavy smoking and nicotine addiction*”.^{298,299} However, the claimed nicotine addiction gene does not have a statistically significant association with smoking, and the company had also published misleading information about smoking cessation rates on its website.³⁰⁰ Both Oxford University and Cancer Research UK subsequently distanced themselves from the company and its claims.^{301,302} In 2008, a review of the genetics of nicotine addiction concluded: “*Nicotine genomics is a very new and underdeveloped field. On the evidence to date, its advocates would be wise to avoid extravagant claims about its preventive applications*”.³⁰³

The Estonian Genome Project’s funding collapses

By the end of 2004 private funding had been pulled from the Estonian Genome Project and activities were more or less frozen for two years, leaving the project’s subsequent maintenance and development to be funded by the government.³⁰⁴

2005***NHS Connecting for Health and the Care Record Guarantee***

In April, the Department of Health’s IT unit became an agency of the Department, called NHS Connecting for Health.

In May, Ministers published the NHS Care Record Guarantee (revised versions were subsequently published in 2006 and 2007). The publication of the Guarantee followed drafting begun in 2003 by sixteen people from patient and citizen groups who formed a Public Advisory Board to the Programme, and completed by the Care Record Development Board (CRDB), a group of patients, the public and clinicians established by the Department of Health in 2004. The key principles of the Care Record Guarantee adopted in 2005 are:

- Only authorised people will be allowed access to patient records
- Only those involved in a patient’s care will have access to records about identifiable individual patients
- A record will be kept of everyone looking at a patient’s record
- Patients will be able to check their own care records and ask for factual inaccuracies to be corrected
- Patients cannot opt out of having information recorded altogether
- Patients will be able to opt out of information being shared

- Clinicians can withhold information on a patient's record from the patient.

UK Biobank's first peer review revealed

On 13th May, following a Freedom of Information request by GeneWatch UK, the MRC finally published the peer reviewers' comments on UK Biobank, made in November 2001.³⁰⁵ Some peer reviewers were positive about the project, others criticised various aspects: including inadequate measurements of environmental factors and of phenotype (the observed state of a person, such as whether they are ill or overweight); and the lack of statistical power to detect gene-environment interactions (the original purpose of the study). Several noted that electronic medical records in the NHS would provide a unique a resource for tracking patients, although many questioned the assumed recruitment rate of 50% of those approached.

One reviewer argued that any protocol should be preceded by “a list of the types of question one would like to answer”, with only some questions (those requiring detailed environmental measurements) requiring a large prospective study like UK Biobank. The same reviewer states: “The humility that in the end long-term disease prediction (except in small sub-groups) will ultimately remain as fundamentally impossible as long-term weather prediction, might be a pervasive attitude in this project. It might also help not to oversell the expectations, neither to the public, nor to the scientists involved”. Another reviewer stated: “It seems to be recognized that there are not enough public monies to carry out all potential investigations and industrial relations will be necessary. However, ‘big pharma’ could conceivably ‘pay for’ and control all of the data. The MRC must protect itself and the vested investigators from such an outcome.”

Lord Warner becomes responsible for NHS IT

In May, Lord Warner (Box O) became the Department of Health minister responsible for the the National Programme for IT (NPfIT) in the NHS.

McKinsey report on NHS-Industry collaboration

In August, a report on strengthening UK clinical research was prepared for UKCRC by the consultants McKinsey.³⁰⁶ The report builds on the work of the Pharmaceutical Industry Competitiveness Task Force (PICTF), the Bioscience Innovation and Growth Team (BIGT), the Healthcare Industries Task Force (HITF), and the Academy of Medical Sciences (AMS) review and argues that: “If UK plc and its National Health Service aspires to be a leader in commercial clinical research, then, having understood the criteria that matter to industry, and how the UK is performing against them, it must develop a distinctive value proposition for commercial clinical research”. In particular it notes: “The UK’s system-wide cradle-to-grave healthcare provision offers a unique opportunity to examine a wide range of approaches to disease and health”. One of its recommendations is: “A commitment to involving industry in Connecting for Health as demonstrated by influencing its design, exploring the potential of an interface between Connecting for Health and industry, and piloting NHS-industry collaboration”.

Connecting for Health’s Secondary Uses Service (SUS)

Also in August, a Strategy was developed for Connecting for Health’s Secondary Uses Service (SUS) – which includes research uses of electronic medical records. The Strategy was amended to take account of Programme developments in July 2007.³⁰⁷ It outlines one potential use of the SUS as providing public health

information, including screening, surveillance and epidemiology to support the Public Health Information Strategy, announced in the Choosing Health White Paper in 2004.

Device Evaluation becomes procurement support

On 1st September 2005, the Centre for Evidence-based Purchasing (formerly the Device Evaluation Service) was transferred from the Medicines and Healthcare Regulatory Agency (MHRA) to the NHS Purchasing and Supply Agency (PSA), as recommended by the IHTF report.^{308,309} This effectively removes the prospect of any regulatory oversight for genetic tests.

Professor Rory Collins (Professor of Medicine and Epidemiology at the University of Oxford), was appointed Principal Investigator and Chief Executive of UK Biobank, with effect from 1st September, replacing its previous Director, John Newton, who left in January 2005.³¹⁰

Harmonising biobanks across the EU

In September 2005, a consortium of researchers held a conference at the Wellcome Trust Conference Centre, funded by the European Commission's Health Research Directorate and the Wellcome Trust. The conference was held as part of the EUHEALTHGEN project, to develop a strategy for harmonising biobanks across the EU, to be representative of the entire EU population.^{311,312} One of the project's aims (paragraph 2.6) is to: "*Promote the anticipated paradigm shift in healthcare from disease diagnosis and treatment to the identification of personal disease risk and the development of appropriate personalised prevention strategies*". In the Conference's press release, Dr Bill Baig from the Health Research Directorate of DG Research at the European Commission said: "*From a personal viewpoint, I think this should be the start of visualising the 21st century mode of health care where new elements such as susceptibility to disease, response to treatment, tolerance of medication, and a host of other attributes could be linked to the patient's medical record Europe wide*".³¹³ In his foreword to the conference report, Baig refers to "*the significant investments made in sequencing the human genome and the need now to harvest the results*" and states that access to databases containing genotypic, clinical, environmental and lifestyle information on individuals, along with corresponding clinical specimens (biobanks) is essential.

The project co-ordinator is Dr Peter Greenaway, of Horus Research Management Ltd, formerly of the Department of Health (Box K). Representatives of numerous research institutes, plus GlaxoSmithKline, Roche, DeCode Genetics and UK Biobank, attended the conference. Delegates included Professor Mike Pringle, the National Clinical Lead for General Practitioners at "Connecting for Health", a member of the Board of UK Biobank, and Scientific Officer for the European Collaboration, Electronic medical records for Health Indicator Data (eHID).^{314,315,316}

Newborn babies' blood spots

In October 2005, the Institute of Education's Social Science Research Unit (SSRU) held a consultation, funded by the MRC, and conducted in collaboration with Carol Dezateux (Institute of Child Health, University College London) about uses of the newborn blood spots that are collected routinely as part of newborn blood spot screening.³¹⁷ Also included on these cards is basic information about the baby, such as the baby's name, date of birth, contact details and NHS number. The consultation website states that, once no longer needed for screening tests, the blood spots provide valuable material for research and public health. The consultation document

sought views on whether the cards should be stored beyond the five years needed to help improve the screening programme and used for other types of research, including genetic research.³¹⁸ It states: *“In the future commercial organisations may be interested in accessing whole collections of blood spots”* and asks whether the blood spots should be used to develop new tests and whether researchers should be able to link them with new information from other databases, and if so, what safeguards are needed. It also states that the police may access the blood spot cards of specific deceased or missing persons for forensic purposes only if they first obtain a court order, and seeks views on whether police use should be expanded.

In November 2007, GeneWatch UK contacted the SSRU to find out what had happened to the consultation and was told that publication of the findings had been delayed.

Concerns about electronic medical records and patient confidentiality

In November, the findings of a poll of more than 200 organisations worldwide, including almost 50 in England, by Health and Social Campaigners News International (HSCNI) - a global network of patient groups – highlighted concerns that electronic patient records would undermine medical confidentiality.³¹⁹

The CST’s report on better use of personal information

Also in November, the Government’s Council for Science and Technology (CST) published a report ‘Better use of personal information: opportunities and risks’.³²⁰ The CST is the Government’s top-level advisory body on science and technology issues, with members appointed by the Prime Minister. The report was prepared for the CST by a subgroup comprising Professor Janet Finch (co-chair of the CST), Professor Wendy Hall and Dr Mark Walport of the Wellcome Trust (convenor of the group). It states: *“The government – through its White Paper on Transformational government - enabled by technology - has made clear its ambitions to deliver more effective and personalised public services. CST believes that the ability to fulfil these ambitions is dependent on the intelligent use of personal information about individual people. Government should provide the focus and drive to improve the linkages between, and access to, personal data, while at the same time recognising that there are significant risks which need to be minimised”*. Professor Wendy Hall CBE, is a computer scientist, who stated in a recent interview³²¹: *“I’m convinced that in the future when babies are born they’ll each have a Uniform Resource Identifier or URI and a digital profile that will grow with them. Everything they do in life will be documented digitally: their health and education records, legal documents, insurance details, certificates of birth, death, marriage, family information, photos, archives...”*.

A ‘new deal for medical research’

In December, the Chancellor, Gordon Brown, and the Health Secretary, Patricia Hewitt announced a ‘new deal for medical research’.³²² In the press release, Brown stated: *“How much stronger we will become from the announcement today – thanks to the work of Sir David Cooksey – of a strengthened clinical research partnership linking our universities, our biomedical companies and our NHS.”*

The framework included:

- a commitment to implement key measures proposed in ‘Best research for best health’ including the National Institute for Health Research (NIHR).
- a *“new commitment to develop the capability within the NHS National IT System to facilitate, strictly within the bounds of patient confidentiality, the recruitment of*

patients to clinical trials and the gathering of data to support groundbreaking work on the health of the population and the effectiveness of health interventions”;

- a series of further reforms “*to improve performance and streamline unnecessary regulatory procedures that hold back the research community*”.

2006

The AMS report ‘Personal data for public good’

In January, the Academy of Medical Sciences published its report ‘Personal data for public good’.³²³ It notes that identifiable data can be used for medical research without consent, provided that such use is “*necessary and is proportionate with respect to privacy and public interest benefits*” and recommends that the UK Clinical Research Collaboration, set up following the BIGT report (Box N), should lead the bodies involved in governance of research using personal data in “*developing a simple scheme of assessment for proposals*” and issuing “*clear guidance on the approval process*”. The report expresses concerns (page 5) that the current wording of the Care Record Guarantee to members of the public, could prevent many research projects from using Connecting for Health data.

‘Best Research for Best Health’

On 25th January, the Department of Health published ‘Best research for best health’, setting out the goals for research and development over the next five years, with the aim of demonstrating “*the commitment to creating a vibrant research environment that contributes to the health and wealth of England*”.³²⁴

In February, a new Knowledge Transfer Network for medical devices was launched.

UK Biobank launches pilot study

On 15th March, UK Biobank began recruiting participants in Manchester for its pilot study.³²⁵ The journal Science reported: “*Proposed in 1999, the \$106 million effort has been criticized for its size and for the possibility of turning up spurious associations between genes and disease. Principal investigator Rory Collins of the University of Oxford says these are ‘misconceptions’ and that the study’s large size will make false associations unlikely. But organizers now emphasize that UK Biobank is a broad medical study and that biological markers such as blood protein levels may yield as much information as genes*”.³²⁶

In April, the biobank’s Director, Rory Collins told the Guardian “*Its not a genetic study, it’s not a DNA study. It’s an epidemiological study, a study of public health, and its looking at a range of different factors. If you’re interested in genes, then why do a prospective study? If you’re solely interested in genetics, then you do family-based studies to identify new genes that are causing disease*”.³²⁷ One of the project’s scientific critics, Sir Alec Jeffreys is cited as changing his view of the project in response: “*Biobank is a straight epidemiological project. It does not have a focus on genetics, which is my real concern. As soon as you view Biobank in that sort of light, then I have no major problems with it*”.

Undermining the Care Record Guarantee

In May 2006, the NHS Care Record Guarantee underwent its first revision. The new version states that the service will: “*allow only those involved in your care to have*

access to records about you from which you can be identified, unless you give your permission **or the law allows**" [emphasis added].

The National Audit Office report

On 16th June 2006, the National Audit Office (NAO) published its report on the National Programme for IT (NPfIT) in the NHS. The report estimated (para 1.19) that the total spending on the programme would be £12.4 billion (at 2004-5) prices, over the ten year life of the main contracts to 2013-14.³²⁸ Local NHS expenditure on IT over this time would exceed central expenditure and the two together would total some £20 billion (para 1.17). It noted that the main aim of the programme was to improve services rather than to reduce costs. Although the report is upbeat about the programme, saying it has "*the potential to generate substantial benefits for patients and the NHS*", it notes that it has not been possible to put a financial value on these claimed benefits. The Treasury had therefore approved all expenditure although "*it was not demonstrated that the financial value of these benefits exceeds the cost of the Programme*" (para 5b) – a process normally required according to the rules in the Treasury's Green Book. The report also notes (para 1.8) that: "*In developing the Spine (which will hold summary information about every patient's care and support the transmission of information between other systems), the Programme is developing a system not being attempted elsewhere on this scale*".

Criticism of genetic 'prediction and prevention' of disease

Also in June 2006, the International Journal of Epidemiology published a series of articles by leading experts, which criticised the concept of individual genetic risk prediction; the validity of the genetic association studies being used to identify links between genes and diseases; and the use of twin studies to claim that common conditions are highly heritable.^{329,330,331}

In August, the journal Nature Biotechnology published an article highlighting the growing commercial market for genetic tests and the lack of regulation.³³²

Proposals for use of personal data in research

The British Medical Journal published an article co-authored by the director of UK Biobank, Rory Collins, which argued that: "*Privacy of individuals should be respected, but disproportionate obstacles to using personal data in research may adversely affect public health*".³³³ In another article, the Chair of the Academy of Medical Sciences working party on personal data in health research, Robert Souhami, argued that: "*Regulating bodies should accept that the law permits the secondary use of data without consent or full anonymisation provided that the likely benefit to the public is demonstrably proportionate to the risk of identification and the consequent distress caused*".³³⁴

UK Biobank's second peer review

On 22nd August, UK Biobank announced that it had unanimous backing from an international panel of peer reviewers for the study.³³⁵ The press release states that: "*UK Biobank will gather, store and protect a vast bank of medical data and material that will allow researchers to study in depth, in decades to come, how the complex interplay of genes, lifestyle and environment affects our risk of disease. It is the first time that such a project has been attempted in such fine detail on such a vast scale*". It states that the panel concluded that: "*UK Biobank has the potential, in ways that are not currently available elsewhere, to support a wide range of research,*

particularly investigations into complex interactions of various exposures, including genetic and lifestyle factors in the pathways to disease and health." The International Review Panel was chaired by Professor Thorkild Sørensen, from the Institute of Preventive Medicine in Copenhagen, Denmark. Sørensen's research area is the genetics of obesity and he has undertaken work with Nestlé, the Dutch food ingredients company DSM, and in collaborations involving biotech companies.³³⁶

Growing concerns re Connecting for Health

In September, Computer Weekly questioned whether the National Audit Office's report on Connecting for Health had been truly independent.³³⁷

On 1st November, the Guardian published the concerns of the critics of Connecting for Health, including critical GPs, who argued that the central "spine" was unnecessary and carried grave risks to civil liberties and public health. They argued that electronic records should be shared locally when necessary, rather than being uploaded to a central system.³³⁸

The Cooksey Review

In December, Sir David Cooksey's Review of UK Health Research³³⁹ identified a need (paragraph 8.23) *"to ensure that research is fully embedded in and integral to the NHS IT programme, and prioritised on a par with other service uses for the system."* In his foreword, Cooksey states that *"first and foremost"* amongst the new opportunities for pharmaceutical, devices, diagnostics and biotech companies in the UK *"is the potential offered by the new 'connecting for Health' IT database which will contain the medical records of the 48+ million inhabitants of England and should be accessible for important research..."* He recommends the establishment of a new Office for Strategic Coordination of Health Research (OSCHR) to set the government's health research strategy and budget, monitor the delivery of the strategy against objectives, and encourage a stronger partnership with the health industries and charities (such as the Wellcome Trust). Projects that meet the OSCHR objectives will become 'UK Priority Health Research Projects' (PHRPs) and OSCHR should also establish a joint MRC/NIHR Translational Medicine Funding Board to increase translation into health and economic benefit.

European biobanking

In September 2006, the European Strategy Forum on Research Infrastructure (ESFRI)'s annual report was published.³⁴⁰ Page 48 describes the European Biobanking and Biomolecular Resources project (EBBR) which aims to build a coordinated, large-scale European infrastructure of biobanks. It states: *"Following the rapid progress of genomic research in humans and their ancestors, biomedical and health research has expanded from the study of rare monogenic diseases to common, multifactorial diseases. However, most complex diseases are elusive as they do not root in single defects, but are caused by a large number of small, often additive effects from genetic predisposition, lifestyle and the environment. Discovery, i.e. separating the signal from the noise, will depend critically on the study of large collections of well-documented, up-to-date epidemiological, clinical and biological information and accompanying material from large numbers of patients and healthy persons, so-called biobanks. Biobanks are widely considered as a key resource in unravelling the association between disease subtypes and small, but systematic, variations in genotype, phenotype, and lifestyle"*.

UK Biobank's new scientific protocol

On 21st November, UK Biobank published a new scientific protocol.³⁴¹ The protocol recalculates the likely size of genetic and environmental effects on the risk of common diseases that the Biobank may be able to identify statistically.

Chancellor welcomes Cooksey report

In his Pre-Budget Report on 6th December 2006, the Chancellor announced that he and the Secretaries of State for Health and for Trade and Industry (now Innovation, Universities and Skills) welcomed Cooksey's report and would work to take forward its recommendations.

Government assurance on the 'Spine'

On 18th December, the government was forced to give an assurance that NHS patients would have an absolute right of veto on any part of their medical records being uploaded to a national database (the 'Spine'), following concerns raised by patients and staff about confidentiality.³⁴²

2007

The economics of gene testing

In February 2007, a paper published in the journal *Health Policy* concluded: "*Based on current evidence, an era of healthcare consisting of gene technology built on widespread predictive testing is not desirable from a health economic viewpoint*".³⁴³

The AMS report on systems biology

In February 2007, the Academy of Medical Sciences and the Royal Academy of Engineering published a new report on systems biology³⁴⁴, which concedes (page 26): "...*the promise of personalised medicines is still a widely debated issue and a large divide exists between those who are enthusiastic about it and the sceptics who believe that it is still a remote possibility*". Although the report does not abandon the idea of sequencing people's genomes in order to predict disease susceptibility, it accepts that: "*The sequencing of the human genome, although of fundamental importance, does not even provide a complete parts list of the protein molecules that exist in a biological organism because of complexities...To tackle this problem requires an iterative application of biomedical knowledge and experiment with mathematical, computational and engineering techniques to build and test complex mathematical models...This new approach is now termed "Systems Biology"*."

The report argues that the potential of systems biology will only be realised "*if the UK government takes determined and prompt action*", requiring new investment in science by government and industry. Echoing earlier demands for increased science funding, the authors claim that the UK leads the world in the science, but could lose out in terms of public health and economic benefits and that, unless their recommendations are implemented, "*Industry could also look to the US, South Asia and the Far East for research and development opportunities*".

The House of Commons Science and Technology Committee comments on the Cooksey report

In March 2007, the House of Commons Science and Technology Committee commented on the Cooksey review in March 2007 – broadly welcoming it but raising concerns about too much emphasis being placed on the pharmaceutical sector (neglecting medical engineering and technology, preventative and public health research).³⁴⁵

The Strategic Implementation Group (SIG) of the Healthcare Industries Task Force

Also in March 2007, the Strategic Implementation Group (SIG), led by Lord Hunt (Minister of State for Quality at the Department of Health) and Sir Christopher O'Donnell (Chief Executive of Smith & Nephew PLC), reported on progress towards implementation of the recommendations of Healthcare Industries Task Force (HITF).³⁴⁶ Members included Professor Kent Woods, Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA); Professor Sir Ara Darzi, Adviser on Surgery to the Department of Health; John Jeans, GE Healthcare; and Ray Hodgkinson, British Healthcare Trades Association. Reported developments include the new Centre for Evidence-based Purchasing (CEP) and the National Innovation Centre, based in the NHS Institute for Innovation and Improvement. The report states that procurement issues lay at the heart of the HITF SIG discussions: a large group of stakeholders from industry, the NHS and the Government met regularly to create mechanisms that would promote the NHS's adoption of innovation. Another key area of work that has emerged under SIG has concerned gaining a better understanding of what helps UK-based medical devices companies prosper. The report also states that: "*On regulation, there is commitment to continued development of the dialogue between industry and government*" and reports one highlight of implementation as the "*Development of key messages to communicate to health professionals and the public on the regulation and safety profile of medical devices*".

The SIG report recommends that a ministerial industry strategy group of senior representatives from government and industry should be set up to consider progress, including how to take forward the implications of the Cooksey Review as they affect medical technology.

UK Biobank begins recruitment

On 21st March 2007, UK Biobank issued its first invitations for recruitment to the main study, to potential participants in Manchester.³⁴⁷ In April, invitations were issued to potential participants in Oxford.³⁴⁸ In June, recruitment for UK Biobank began in Scotland (linked with another project known as Generation Scotland)³⁴⁹ and the project announced that its automated system for storing and analysing blood samples was up and running.³⁵⁰ In September, recruitment began in Wales and in October the project opened an assessment centre in Cardiff.^{351,352} In the original protocol, recruitment of 500,000 participants to the study was due to begin in April 2003 and to take five years, with the project aiming to recruit "*40 to 50% of the eligible population from each practice*".⁹² In practice UK Biobank is achieving recruitment rates of around 10%.³⁵³ Recruitment letters contain a pre-booked appointment and do not mention genetics or DNA.³⁵⁴

Some scientists continue to criticise UK Biobank's approach, particularly the lack of detailed measurements of environmental exposures³⁵⁵, and social scientists have questioned UK Biobank's public engagement exercises, stating, for example³⁵⁶:

“UK Biobank’s ‘engagement’ efforts thus far convey the impression that these have been largely about managing perceived mistrust and engineering consent rather than creating the conditions for trust”. Others have noted that “The public were regularly consulted as the project developed in order to find out what would increase public interest and confidence and ensure enough people would participate”. However, “The public were not invited to consider more fundamental questions about Biobank itself, for example, the priorities of commercial users versus the public interest, the likelihood of benefits set against other possible uses of those resources, the content of regulations and who would be enforcing them”.³⁵⁷ UK Biobank’s policy on access and Intellectual Property (IP) has still not been finalised.³⁵⁸

Evidence to the Health Committee on electronic medical records

The written evidence to the House of Commons Health Committee’s inquiry into electronic medical records (announced in February) was published in April 2007.³⁵⁹

In its evidence, the Wellcome Trust argues that *“a secure system of access for biomedical researchers should be seen as an integral part of patient record use”* and that this will *“help to ensure that the UK maintains and builds on its global lead in biomedical research, attracting inward investment from the bio-pharmaceutical research sector”*. The Trust claims that: *“When combined with information from cohort studies, use of platform technologies and other developments, the patient data available through the Secondary User Service could improve our understanding of the heterogeneity of diseases and population, accelerating the move towards pharmacogenetics/personalised medicine”*.

The Association of the British Pharmaceutical Industry (ABPI) states: *“Whilst CfH [Connecting for Health] is a very considerable undertaking, it should be recognised that there is an international race for benefit and competitive advantage in research where the UK could have a significant Unique Selling Point (USP), if research interests are given priority”*.

Evidence submitted by the Academy of Medical Sciences – whose President is John Bell (Box C) - states (para 20)³⁶⁰: *“We are concerned that the current version of the [Care Record] Guarantee seems to be based on the assumption that all work with identifiable data will be accomplished within SUS [Secondary Uses Services] and that research and public health users will be only supplied with anonymised output from SUS. It includes statements that seem to preclude any use of CRS [Care Record Services] data outside the NHS for research purposes. We welcome the mention in the document that data might be used to ‘help with research’. However, we are concerned about the explicit pledge that the new IT system will ‘allow only those involved in your care to have access to records about you from which you can be identified’. A public statement of this kind invalidates the legal basis on which public health professionals and clinical researchers currently access identifiable data for research and is therefore of grave concern”*. However, this comment appears to refer to the May 2005 version of the Care Record Guarantee.³⁶¹ The wording of the 2006 (and subsequent 2007) Care Record Guarantee has been modified, stating that the service will: *“allow only those involved in your care to have access to records about you from which you can be identified, unless you give your permission **or the law allows**”* [emphasis added].

Healthcare innovations conference

In April 2007, a major conference “*Healthcare Innovations: the Next Frontier*”³⁶² opened with a presentation by Andrew Witty, President, Pharmaceuticals Europe for GlaxoSmithKline on the ‘Pharmaceutical Industry’s Vision for the Future’, followed by the Chief Executive of MRC Technology, Dr Roberto Solari, who claimed that UK Biobank would lead to a future in which “*everyone in this room will have their whole genome sequenced*”.³⁶³ The conference was addressed by two ministers: Lord Hunt for the Department of Health³⁶⁴ and Malcolm Wicks from DTI, as well as the Chief Executive of UK Biobank, Rory Collins.

Meeting on the use of electronic medical records for research

The UK Clinical Research Collaboration (UKCRC, see Box P) and the Wellcome Trust held a meeting “Use of Electronic Patient Records for Research and Health Benefit” on 24-25 May 2007.³⁶⁵ Speakers included Professor Ian Diamond, Chair of the UKCRC R&D Advisory Group to Connecting for Health, and Chief Executive of the Economic and Social Research Council (ESRC) and Richard Barker, Director General of the Association of the British Pharmaceutical Industry (ABPI). Prior to becoming Director of the ABPI, Dr Barker was Chief Executive of the diagnostic division of biotech company Chiron, General Manager of IBM’s worldwide healthcare business and leader of McKinsey’s European healthcare practice³⁶⁶. Dr Philip Burstein of GlaxoSmithKline, who is also a member of UKCRC’s Research Advisory Group for Connecting for Health, also gave a presentation.

In his introduction to the report of this meeting³⁶⁷, Wellcome Trust Director Mark Walport states: “*Many of our speakers agreed that the UK has three to five years to set up a working system of linked medical records. If it takes any longer, we will have lost a crucial competitive advantage.*” Controversially – in a reference to the recently discovered FTO gene (Box R) - the report states “*Patient data has been used for the first time to uncover a common genetic predisposition to obesity which, in turn, increases the likelihood of the development of diabetes in later life. It will be important to understand the mechanisms of genetic susceptibility to obesity in order to design optimal preventive strategies and interventions*”. The report also highlights the importance of being able to track every patient using their NHS number and states: “*This number would accompany every person in the UK throughout life and should be used in transactions with private healthcare providers as well as the NHS. It is important that it is not confused in the public imagination with the controversial issue of UK identity cards*”.

Box R: The FTO gene, obesity and diabetes

The recently discovered FTO gene is the first common genetic obesity susceptibility gene to have been confirmed in multiple data sets³⁶⁸, despite numerous previous published claims to have identified such genes. However, the FTO gene accounts for less than 1% of the variance (differences across the population) in body mass index (BMI) – the usual measure of whether someone is overweight for their height - in the UK. Testing for the gene is not useful to decide who should take action to reduce their weight, because it does not make any difference to advice on eating healthily and getting enough exercise. Similarly, newly discovered genetic variants linked with type 2 diabetes – which is strongly linked with being overweight - do not provide sufficient diagnostic accuracy, either alone or in combination, to be clinically useful.³⁶⁹ Genetic tests for the FTO gene are being marketed in Britain by the controversial company Genetic Health, based in Harley Street (see also main report).³⁷⁰

A further revised version of the Care Record Guarantee was published in May 2007.³⁷¹

UKCRC promotes research access to ‘sealed envelopes’

On 7th June, the UKCRC R&D Advisory Group for Connecting for Health published its report of ‘Research Simulations’.³⁷² The Group is chaired by Professor Ian Diamond, Chief Executive of the Economic and Social Research Council (ESRC). Members include Dr Mark Walport, Director of the Wellcome Trust, Dr Richard Barker, Director General of the ABPI and Dr Philip Bernstein, Head of the Electronic Information Healthcare Initiative, GlaxoSmithKline. Members of the Simulation Subgroup included representatives of the Wellcome Trust, UKCRC, MRC, Connecting for Health, ABPI and Dr Louise Wood, the Head of Innovation and Industry R&D Relations at the Department of Health.

The report claims that: *“The UK can significantly enhance its clinical research capability by using, strictly within the bounds of patient confidentiality, the electronic patient data that the UK’s National Programmes for IT in the NHS have the potential to allow. This will have enormous benefits for all types of clinical, public health and health services research and for many aspects of patient care”*. It included four simulations based on four research applications: surveillance of drug response (led by Dr John Parkinson, Medicines and Healthcare Products Regulatory Agency and Steve Mott, DataPharm Ltd.); interventional clinical trials (led by Rob Thwaites, GlaxoSmithKline Research & Development Ltd.); prospective tracking of an identified cohort of patients (led by Andy Harris, UK Biobank); and observational epidemiological research (led by Professor Carol Dezateux, and Professor Catherine Peckham of the Institute of Child Health, University College London, and Great Ormond Street Hospital for Children NHS Trust).

The report argues for the data in NHS Care Records to be linked widely to other databases and that *“There should be formal recognition by NHS CfH [Connecting for Health] that research is a core, not secondary, component of the development of the NHS Care Records Service as it benefits patients directly”*. It also notes that: *“In order to achieve its objectives UK Biobank requires access to the complete medical record of consented participants. This information will come from a range of sources but the NHS Care Record Service is expected to be the primary source. Information required includes that which is contained in the ‘sealed envelope’ and the ‘sealed and locked envelope”*.

‘Informing healthier choices’

On 11th June, the Department of Health published ‘Informing healthier choices: Information and intelligence for healthier populations’³⁷³, following the recommendation made in the 2004 ‘Choosing health’ report.

Granger resigns as Chief Executive of NHS IT

On 17th June, Richard Granger announced his resignation as chief executive of the NHS Connecting for Health IT project.³⁷⁴

Evidence to the Constitution Committee's Surveillance Society inquiry

On 26th June, Professor Carol Dezateux, of the Institute of Child Health, University College London, Dr Ian Forbes of the Royal Academy of Engineering, and Professor Simon Wessely of the Academy of Medical Sciences, gave evidence to the House of Commons Home Affairs Committee's inquiry 'A surveillance society?'. They argued that applying the principle of "consent or anonymise" to people's medical information would be highly detrimental to medical research. Professor Dezateux stated: "*I think that we need to understand that after the Cooksey Report, there is a real recognition that unless we make the most of these electronic health records, we will not be able to maintain globally our competitiveness in terms of our science, and that will have economic implications for society*".

MRC and Wellcome Trust publish public opinions of research without consent

Also in June, the Medical Research Council (MRC) published the findings of its public consultation on the use of personal health information in research (launched in response to the Academy of Medical Sciences' 2006 report 'Personal Data for Public Good'). The MRC's press release states³⁷⁵: "*Two of the UK's biggest medical research organisations: the Medical Research Council and Wellcome Trust are calling on researchers, funders and medical charities to do more to convince the public of the benefits to society of allowing personal health information to be used in important medical research*". The research included an Ipsos MORI survey of 2,106 people³⁷⁶ and qualitative research (involving focus groups and in-depth interviews) by the Wellcome Trust/University of Surrey.³⁷⁷ Ipsos MORI reported: "*The key factor that might make people more inclined to allow their personal health information to be used for medical research is information. If the public had more information specifically about the purposes of medical research, they are likely to be more inclined to allow their personal health information to be used for that purpose*". The majority of members of the public felt that consent should always be sought to use their personal information. People taking part in the Wellcome Trust study indicated they were not unwilling to provide personal data for research if they understood why it was wanted and had confidence in the integrity of the research process, but this confidence could be undermined by a variety of factors. Public acceptance depended greatly upon expectations of how information is used and how well its use is regulated. Other concerns were over who can view the data, with particular resistance to the police and security services having access.

UK Biobank: problems solved by pooling data internationally?

In June 2007, a commentary published in the Lancet³⁷⁸ noted that "*Objections [to UK Biobank] include: that specific disease-focused case-control studies would be more efficient; only limited deep phenotyping (objective physiological measures) is being done; the age-range is not representative of the general population and many of the relevant exposures will have occurred previously; and that the projected time-lines to develop sample sizes of incident cases with sufficient power to detect realistic effect sizes are too long (at least 10 years for most diseases)*" and that: "*The study is also predicated on the common-disease common-variant hypothesis*" (the idea that a single common genetic variation – rather than multiple small effects - explains a person's genetic risk of a common disease). However, the commentary notes that the value of the study could be enhanced with more comprehensive phenotyping and that "*Many of the other objections might be resolved by the vigorous international biobank harmonisation and data-pooling strategies underway...*".

The UK company Genetic Health

On 1st August 2007, GeneWatch UK supplied the Medicines and Healthcare Regulatory Agency (MHRA) with detailed evidence regarding misleading genetic information being sold by the UK company Genetic Health, based in Harley Street.³⁷⁹
³⁸⁰

The Department of health's 'Investing in Innovation' strategy

In August 2007, the Department of Health launched a consultation, as part of a Government Office for Science "science review", which is exploring the department's role in fulfilling the 2002 "*Investing in Innovation*" strategy, taking account of the Cooksey Review. Professor Tom Meade, who developed the original protocol for UK Biobank, is a member of the review's Steering Panel.³⁸¹

Review of the Secondary Uses Service

Also in August, a further review of the Secondary Uses Service (SUS) was published following the Care Record Development Board (CRDB)'s 2006 request to Professor Sir Robert Boyd to chair a group looking at the ethical use of patient information for secondary purposes (purposes other than the direct delivery of care), starting in May 2006.³⁸² Members of this group included Dr Mark Walport, Director of the Wellcome Trust and representatives of UKCRC and the Academy of Medical Sciences. The Boyd Report was submitted to the CRDB in July 2007 and a final approved version was issued in August 2007.³⁸³

The Health Committee's report on electronic medical records

In September, the Health Committee published its report on electronic medical records³⁸⁴ and the further written and oral evidence it had received.³⁸⁵ One of the Committee's recommendations is: "*Information in 'sealed envelopes' should not be made available to the Secondary Uses Service under any circumstances; this will allow patients to prevent data being used for research purposes without their consent*".

The Science Horizons project

Also in September, the UK Government published the reports of the three strands of its Science Horizons project (a deliberative panel, facilitated public events and small group discussions).³⁸⁶ The project was part-funded by GE Healthcare, a \$17 billion unit of the US multinational General Electric Company, specialising in medical imaging and information technologies, medical diagnostics, patient monitoring systems, performance improvement, drug discovery, and biopharmaceutical manufacturing technologies. Its website states: "*Our vision for the future is to enable a new "early health" model of care focused on earlier diagnosis, pre-symptomatic disease detection and disease prevention*".³⁸⁷

The future scenarios for the Science Horizons 'Mind and Body' theme included: an Alzheimer's Disease patient whose clothes had been electronically tagged and whose jogging cap was tracked by satellite, and a computerised health check-up for a busy professional using miniaturised sensors and chips.³⁸⁸ The major areas of policy relating to biosciences which were raised by the discussions were:

- Regulation of personal genetic information
- Protection of personal data on computer and DNA databases

- Insurance issues relating to increasing genetic understanding and medical profiling
- Public confusion and apprehension about genetics and biotechnologies
- Support for advanced vaccine technology being made affordable and available to people in need in developing countries.

Overarching issues raised by the Deliberative Panel³⁸⁹ included:

- trust in expertise - who can be trusted?;
- concerns about the security, privacy and integrity of personal information (IT- or genetically-based);
- concerns about safeguards against abuse of technologies by authorities or by criminals;
- and fears about loss of the 'human touch' in everyday interactions, for example in relation to health, and in work.

There was a "*striking trust deficit*" and some people saw expert priorities for research investments as inevitably not the same as those of the average citizen.

Brown's speech to the Labour Party Conference

On 24th September 2007, in his first speech to the Labour Conference as Prime Minister, Gordon Brown referred to "*Our great ambition now: a National Health Service that is also a personal health service*" and said that "*following the review by Professor Darzi, my aim for the next stage of an NHS personal to you: for every adult a regular check up on the NHS*".³⁹⁰ He also stated: "*Over the next ten years: I am proud to announce that through the medical research council and the NHS together, Britain will invest more than ever before - £15 billion of public money - financing the genius of British researchers and doctors as they convert breakthroughs in genetics, stem cell research and new drugs into cures and vaccines to combat cancer and the deadliest of diseases*".

The National Information Governance Board (NIGB)

At the end of September 2007, the Care Record Development Board was taken over by a new body, the National Information Governance Board (NIGB) for Health and Social Care.^{391,392,393}

Brown visits Imperial College

On 4th October 2007, in Gordon Brown's first visit to a UK university since becoming Prime Minister, Imperial's Rector, Sir Richard Sykes (Box D), and its Professor of Surgery, the Department of Health Parliamentary Under Secretary, Lord Darzi, took him on a tour of the College's newly launched Institute of Biomedical Engineering³⁹⁴, where a project called SAPHE project is based³⁹⁵. According to the newly created Department for Business, Enterprise and Regulatory Reform (BERR): "*The SAPHE project team is developing a new generation of telecare networks with miniaturised wireless sensors worn on the body and integrated into homes, offices and hospitals to allow for continuous healthcare monitoring*".³⁹⁶ Imperial College is the lead partner in the project, which also involves BT, Philips and two smaller companies, as well as the University of Dundee. The 'UbiCare Centre' (Ubiquitous Computing for Healthcare in the Community) at Imperial was established with the support of the DTI/NextWave Technologies Research Centre initiative and "*aims to bring together academic researchers and key industrial expertise to develop the future technologies for 'everywhere' healthcare*".³⁹⁷

Lord Darzi's interim report

On the same day, Lord Darzi launched his interim report 'Our NHS, Our Future'³⁹⁸. Its press release, which included a quote from Mike Walport of the Wellcome Trust, welcoming its emphasis on innovation, launched a new Health Innovation Council (Box S), together with a fund of up to £100m to help the NHS develop and deploy hi-tech healthcare such as medical devices and diagnostics.³⁹⁹

Box S: The Health Innovation Council (HIC)⁴⁰⁰

In 2007, the DoH announced that membership of the HIC would include⁴⁰¹:

Sir David Cooksey, Chair of Advent Venture Partners

Sir Mike Rawlins, Chair of the National Institute for Health and Clinical Excellence

Dr Mark Walport, Director of the Wellcome Trust

Professor John Bell, Chair of the Office for Strategic Coordination of Health Research

Andrew Witty, President, GSK Pharmaceuticals Europe

Professor Graham Spittle, Chair, Technology Strategy Board

Professor Bernard Crump, Chief Executive, NHS Institute of Innovation and Improvement

It first met in November 2007 and is chaired by Lord Darzi, with a total of 20 members. The minutes of the first meeting record that: "*We need to factor genetics and IT within the overall scope of the HIC*".

Concerns re the lack of regulation of genetic tests

On 6th October, New Scientist reported concerns about the lack of regulation of genetic tests.^{402,403}

First meeting of the Ministerial Medical Technology Strategy Group

On 24th October 2007, the Ministerial Medical Technology Strategy Group (MMTSG), held its first meeting.^{404,405} The background paper claims that: "*Prediction and early diagnosis, followed by timely intervention, are well established as a way of reducing lifetime mortality, morbidity and cost of disease management*", and "*In promoting 'early health' with a strong technology foundation, there is the potential for the UK to make a yet broader and deeper contribution, to the world's health economy as well as to public health*".⁴⁰⁶ It also states that: "*Technology could help to offset scarcity of skilled staff...*". The MMTSG was established to develop the agenda in the Healthcare Industries Task Force report, following the March recommendation of the Strategic Implementation Group (SIG).⁴⁰⁷ The meetings are co-chaired by Dawn Primarolo, Minister of State for Public Health and John Jeans, Vice-President International Life Sciences & Chairman UK, GE Healthcare. Membership of the group includes ministers from the Department of Business, Enterprise, Regulatory Reform (BERR - formerly DTI), Department of Innovation, Universities and Skills, senior officials across Whitehall and "*leading international players from the industry*".

Brown asks Walport and Thomas to conduct data-sharing review

On 25th October 2007, the Government announced "*a review of the way we share and protect personal information in the public and private sector. The review and any recommendations will be produced by Richard Thomas, the Information Commissioner and Dr. Mark Walport, Director of Wellcome Trust, and published in the first half of 2008*".⁴⁰⁸ The Prime Minister announced the review in a speech on Liberty, stating that its aim was "*to assess whether [the framework for the use of*

information] is right for today's landscape and strikes the right balance — giving people the protection they are entitled to, while allowing them to make the most of the opportunities which are being opened up by the new information age".⁴⁰⁹

The Wellcome Trust's touring exhibition 'Inside DNA'

In November 2007, the Wellcome Trust launched a £1.5 million five-year project entitled 'Inside DNA: A genomic revolution' - the first UK major touring exhibition on genomics. The exhibition continues to promote the idea that 'genetic susceptibility' to common diseases is important in determining an individual's future health – leading to a 'genomic revolution' in healthcare. Feedback from members of the public visiting the exhibition will feed into policy advice via the Human Genetics Commission (HGC).^{410,411}

'The Killer in Me'

On 8th November an ITV programme called 'The Killer in Me' featured the Harley Street company Genetic Health providing four celebrities with health advice based on its genetic tests. The celebrities included GMTV presenter Fiona Phillips, who admitted shortly afterwards that Prime Minister Gordon Brown had offered her a job as health minister.^{412,413} The programme was the subject of complaints by the British Society of Human Genetics to ITV and OFCOM.^{414,415,416} The complaint states: "*The programme portrayed these genetic tests as useful predictors of future ill health without any discussion around the scientific basis of the testing offered. Analysis of common genetic variants to predict disease susceptibility may have some potential but most scientists and doctors who have expertise in this field would agree that the scientific evidence is currently preliminary and the performance of this type of test in health risk discrimination is unsubstantiated and unvalidated. In summary the programme amounted to undeclared advertising for the company without sufficient detail or discussion to allow that audience to properly weight the content.*" Geneticists and health professionals subsequently warned the public that genetic tests that claim to predict the risk of developing life-threatening diseases are a waste of money and can frighten healthy people.⁴¹⁷

Government response to the Health Committee

On 12th November, the Government published its response to the Health Committee's report on the electronic patient record.⁴¹⁸ In its response, it notes that so far 1.5 million records have been added to the Secondary Uses Service (SUS). The Government rejects the Health Committee's recommendation that patients should be able to prevent data being used for research purposes without their consent stating that this is not required by law and: "*The Committee received strong evidence on the need for health information to be made available for research from a number of organisations. The design of the Secondary Uses Service ensures that patient confidentiality is protected*".

Home tests to predict and prevent diseases?

On 14th November 2007, Leroy Hood of the Institute for Systems Biology in Seattle told the BBC's Today Programme that home tests would soon allow the prediction and prevention of diseases, using a combination of gene sequencing and systems biology. Hood's philosophy is summed up on ISB's website: "*The common theme running through all of this research and its application to medicine -- the predictive and preventive potential of systems biology -- is personalization. On average, each human differs from another by less than one percent of their genetic makeup. But*

*these genetic differences give rise to our physical differences, including our potential predisposition to various diseases. So the ability to examine each individual's unique genetic makeup and thereby customize our approaches to medical treatment is at the heart of this new era of predictive, preventive, personalized medicine. As a result of this personalization, medicine will become participatory. Patients will actively participate in personal choices about illness and wellbeing. Participatory medicine will require the development of powerful new approaches for securely handling enormous amounts of personal information and for educating both patients and their physicians".*⁴¹⁹

NHS IT: concerns re costs and confidentiality

On 20th November 2007, a poll by the Guardian newspaper revealed that 70% of GPs and family doctors did not think that the £12.4bn programme to modernise the NHS's IT systems is a good use of NHS resources, and the majority had major concerns about protecting confidentiality.⁴²⁰

On the same day Richard Jeavons, Director of IT Service Implementation at the Department of Health, informed the House of Commons Home Affairs Committee⁴²¹: *"Most recently we have had two quite major joint pieces of work which are now guiding what we are doing. Those pieces of work are the Joint Report with the UKCRC that was commissioned, which Ian Diamond led for us, and the recommendations of that were accepted, and the Boyd Report, which was commissioned by the predecessor of the National Information Governance Board, and again the recommendations were accepted".* Jeavons also admitted: *"You cannot stop the wicked doing wicked things with information and patient data..."*.

Technologies for health

Also in November, the Medical Research Council (MRC) announced that it would join forces with the new Technology Strategy Board (TSB), by making calls for proposals in cell therapy research and technologies for health, to strengthen its support for translational research. The second call, technologies for health, *"seeks to improve healthcare provision by bringing medical diagnosis, condition monitoring and care and analytical capabilities closer to the patient community"*.⁴²² The Technology Strategy Board states: *"This call seeks to improve healthcare provision by bringing medical diagnosis (self- or professional), condition monitoring and care, and analytical capabilities closer to the patient community. It applies advanced hardware systems and miniaturisation technologies to develop more portable and lower-cost medical equipment, and new test methods to speed up drug development and evaluation. There are close links between topics in this area and the Assisted Living Innovation Platform launched by the Technology Strategy Board in November 2007"*.⁴²³

Biobanking across Europe

Also in November 2007, the European Grant Agreement (under the EC's Framework 7 Programme, FP7) 'Biobanking and Biomolecular Resources Research Infrastructure' (BBMRI) was published. This states that the Preparatory Phase for a pan-European Biobanking and Biomolecular Resources Research Infrastructure will focus on technical, legal, governance, and financial issues to prepare to construct the proposed BBMRI. It states that, although currently established national biobanks and biomolecular resources are a unique European strength, valuable collections typically suffer from fragmentation of the European biobanking-related research community and *"This hampers the collation of biological samples and data from different*

biobanks required to achieve sufficient statistical power". UK Biobank is one of the institutions involved, as is DeCode in Iceland (Box H).⁴²⁴ The aim is to build "A pan-European and broadly accessible network of existing and de novo biobanks and biomolecular resources. The infrastructure will include samples from patients and healthy persons (with links to epidemiological and health care information), molecular genomic resources and biocomputational tools to optimally exploit this resource for global biomedical research".⁴²⁵ The timeline and estimated costs: are Preparatory phase: Years 1-3 (70 million Euros). Construction phase: Years 2-7 (100 million Euros). Operation: total over years 3-10 (100 million Euros).⁴²⁶ The BBMRI was officially launched at a meeting held at the Wellcome Trust Sanger Centre in Cambridge from 10th-12th February 2008.⁴²⁷

The creation of the UKCMRI

On 5th December 2007, the creation of the UK Centre for Medical Research and Innovation (UKCMRI) in the heart of London was announced by the Government-funded Medical Research Council, Cancer Research UK, The Wellcome Trust and UCL (University College London).⁴²⁸

Consultation on the data-sharing review

On 12th December 2007, Mark Walport and Richard Thomas published a consultation on the Data-Sharing Review that they had been asked to undertake by Prime Minister Gordon Brown.⁴²⁹

'More Genes Direct'

Also in December, the Human Genetics Commission (HGC) published 'More Genes Direct', a follow-up to its 2003 'Genes Direct' report, prompted by the number of new tests coming on the market and concerns about their reliability and usefulness.⁴³⁰ It states that "*The recommendation in Genes Direct that certain genetic tests are only offered by a suitably qualified health professional should be implemented*" and again calls for better oversight of genetic tests. The Government's response encourages the HGC to "*work with relevant stakeholders to develop a comprehensive code of practice or guidelines*", rather than to adopt a pre-market approval system.⁴³¹

OSCHR established

As a result of the Cooksey Review, the Office for Strategic Coordination of Health Research (OSCHR) was set up in 2007 to take an overview of the budgetary division and research strategy of both the MRC and NIHR (Box T). In December it established its E-health records research board.

Box T: The Office for Strategic Coordination of Health Research (OSCHR)⁴³²

OSCHR was established in 2007 as a Government office jointly by the Department of Health (DH) and the Department for Innovation, Universities and Skills (DIUS), headed by a non-executive Chair who is appointed by, and reports to, the Secretaries of State for Health and for Innovation, Universities and Skills. Its membership is:

Professor Sir John Bell (Chair, see Box C);

Professor Adrian Smith (Director General of the Research Councils, DIUS) – who replaced Sir Keith O'Nions on his departure from DIUS;

Professor Sally Davies (Director of Research and Development, Department of Health);

Sir Leszek Borysiewicz (Chief Executive of the MRC);
Dr Russell Hamilton (Department of Health/NIHR);
Professor Sir John Savill (Chief Scientist, Scottish Government) – who replaced Dr Harry Burns;
Professor Mike Harmer (Deputy Chief Medical Officer, Welsh Assembly Government)
Dr Mark Walport (Director of the Wellcome Trust, see Box E);
Sir Alan Langlands (Chairman of UK Biobank Ltd and former Chief Executive of the NHS in England);
Mr Andrew Witty (President of Pharmaceuticals Europe for GlaxoSmithKline).
(Scotland)
In December 2007 OSCHR established its **E-Health Records Research Board** (EHRRB), chaired by Professor Ian Diamond, CEO of the Economic and Social Research Council (ESRC). Its members 22 members include: Dr Richard Barker (Director General of the ABPI); Dr Charles Brigden (Amgen); Dr Paul Cload (GE Healthcare); Professor Rory Collins (Chief Executive, UK Biobank); Professor Carol Dezateux (Institute of Child Health, UCL); Professor Paul Elliott (Imperial College); Dr Cathy Emmas and Dr Alan McDougal (both from AstraZeneca); Dr Tim Hubbard (Wellcome Trust Sanger Institute); Dr David Roblin (Pfizer); Dr George Sarner and Dr Janet Valentine (both from the MRC), Mr Rob Thwaites (GlaxoSmithKline).⁴³³

DNA included in UK household survey

On 30th December, it was announced that more than 100,000 people, including children as young as 10, will be asked to provide saliva tests and DNA samples in a new annual survey of the lives, behaviour and beliefs of people in the UK.⁴³⁴ The UK Household Longitudinal Study (UKHLS) will replace the long-running British Household Panel Survey, costing an initial £15m and covering 40,000 households. The study will incorporate the existing survey, which has been running since 1991, but will ask those taking part to allow interviewers working for the National Centre for Social Research to take a saliva sample and allow a range of physical examinations. Professor Nick Buck from the Institute for Social and Economic Research at Essex University, which is developing the study, told reporters, “*The sample could be sent to a medical laboratory to look at indicators of health, such as sugar and cholesterol levels, and for genetic tests that use the DNA contained in saliva*”. The study is funded by the Economic and Social Research Council (ESRC), whose Chief Executive is Professor Ian Diamond.⁴³⁵

New poll of doctors re electronic medical records

On 31st December, the Times reported a poll showing that only a fifth of doctors believe that a national electronic system for storing patients’ records will be secure⁴³⁶, following the loss of a reported 168,000 patient records by nine NHS Trusts.⁴³⁷

2008

Personalised services via the National Identity Scheme

In January 2008, a leaked document about the National Identity Scheme⁴³⁸, probably written in late 2007, revealed that: “*The NIS [National Identity Scheme] will become an identity ‘utility’ to deliver public services and will in time support the implementation of personalised services*”. The NIS will also support the delivery of “identity services” to the private sector and “*It is recognised that the market will be*

the most efficient mechanism to innovate in the development of services based on the NIR [National Identity Register]”.

Brown’s health speech

On 7th January 2008, Prime Minister Gordon Brown announced the third stage of the Government’s reform of the NHS⁴³⁹ in a speech in which he stated: “...*I am delighted to support Europe’s largest medical science centre here in London - developed under Nobel Prize winner Sir Paul Nurse: public and private sectors working together to pioneer new technologies and new treatments.*” A key theme of Brown’s speech was the ‘prediction and prevention’ of disease, including the use of genetic screening: “*With new tests to identify women who are at heightened risk of breast cancer, new drugs aimed at preventing allergies, and the discovery of new genes that are key to the progression of conditions like Alzheimer’s - to give just three examples - we are at the dawn of a whole new era:*

- *with growing understanding of individual risk factors;*
- *the possibility of anticipating the development of future illness;*
- *and perhaps even that of pre-empting such illness with specific advance interventions.”*

He stated: “*Over time everyone in England will have access to the right preventative health check-up.*”

However, the proposal was greeted with some scepticism by doctors and the press. For example, the Times commented: “*There are also searching questions about the possible consequences that the public should want answered. These include how British screening compares with international standards, whether more screening ultimately means more treatment or less and if, as the suspicion must be, it is the former, what the longer-term cost implications are of adopting this strategy*”.⁴⁴⁰ Its health editor’s analysis noted: “*Wider screening has often been proposed but on close examination has been shown to be poor medicine or a poor use of resources. That may be changing, but patients and taxpayers would be wise to look carefully into the mouth of this particular gift horse*”.⁴⁴¹

23andme and other US companies

In January 2008, despite the poor predictive value of genetic tests for common diseases, the US company 23andMe – co-founded by Anne Wojcicki, wife of Google co-founder Sergey Brin - launched a web-based gene testing service to compete with the one offered by DeCode Genetics (Box H) and offered 1,000 delegates at the World Economic Forum in Davos free tests.^{442,443} Later in the year 23andMe cut its prices and continued to market its genetic tests as a loss-leader, in an as yet unproven market, with the aim of profiting from its customers’ genetic information in the future.⁴⁴⁴ Another US company, Knome, signed up its first two customers for whole genome sequencing, at \$350,000 each. Leading UK psychiatrists also denounced plans by other US companies to market genetic tests claiming to identify susceptibility to bipolar depression or schizophrenia on the internet.⁴⁴⁵

The Science Council report on diagnostic technologies

On 25th January, the Science Council (chaired by Sir Tom McKillop, see main report) published its report ‘Integration and Implementation of Diagnostic Technologies in Healthcare’.^{446,447} The report was produced by the Council’s Science in Health Group chaired by Professor Stephen Holgate, and the project received financial support from the Department of Health. The report recommends that all the available

evidence about a new diagnostic test is systematically assessed before its introduction into the wider NHS and that “*some form of regulation or accreditation should be introduced into the independent sector to ensure diagnostics are performed to defined standards*”. It also recommends that “*imaginative and efficient use is made of information technology*” to improve the use of new diagnostic tests. This includes self-care testing, the use of patient-structured interviews and image libraries, and links to patients’ electronic records.

BMA poll on patient data

On 1st February 2008, the British Medical Association published a further poll conducted by *BMA News*, revealing that nine out of ten doctors have no confidence in the government’s ability to safeguard patient data online.⁴⁴⁸

Release of papers re Blair’s sofa meeting

On 4th February, 2008, Computer Weekly reported that the Government would shortly be releasing papers containing details of the February 2002 seminar in which the then Prime Minister Tony Blair approved the launch of what became the National Programme for IT in the NHS.⁴⁴⁹ The papers revealed that Blair told the meeting at Downing Street that taking the programme faster than currently planned would help underpin the reform agenda and provide visible evidence of NHS modernisation to patients and the public.⁴⁵⁰

Wellcome Trust boosts spending on genetics of common diseases

On 5th February 2008, the Wellcome Trust’s Director Dr Mark Walport announced that it would boost its spending on biomedical research by 60% - to £4bn over the five years, stating “*One of our priorities is to increase our understanding of common human diseases at the genetic level*”.⁴⁵¹ Announcing the finding increase, Walport told the BBC: “*The genetic influences on health are very profound*”.

Growing concern about Direct-to-Consumer genetic tests

In February 2008, the journal *Nature Biotechnology* published an article about direct-to-consumer marketing of genetic tests, which highlights the disconnection between “*the mushrooming number of tests on offer and their quality*” and reports that changes may be made in the US regulatory system, following an investigation by the Secretary’s Advisory Committee on Genetics, Health and Society (SACGHS), due to be published in April.^{452,453} The SACGHS investigation followed a 2006 Government Accountability Office (GAO) investigation into genetic tests marketed on-line (Box M).

UK Biobank admits withdrawal is impossible

Also in February, UK Biobank issued a statement that “*although data from participants can be made unusable, it is not possible to destroy it completely*”, contrary to claims in its information materials.⁴⁵⁴ The statement explains: “*While we can absolutely guarantee that data from participants who choose the ‘No further use’ withdrawal option will cease to be used for any research purpose, it cannot be deleted entirely from UK Biobank records*”. The Information Leaflet has been rewritten.

The House of Lords Science and Technology Committee launches inquiry into genomic medicine

On 28th February 2008, the House of Lords Science and Technology Committee announced a new inquiry into 'Genomic Medicine'.⁴⁵⁵ The inquiry states that it will provide an assessment of genome technologies and their actual and potential impact on clinical practice. The sub-committee established for the inquiry is chaired by Lord Patel, the former Chairman of the MRC's Genetics Advisory Committee who was a member of the Committee's inquiry into genetic databases which first adopted George Poste's idea for a national DNA database in 2000. Members include the former health minister Lord Warner (Box O).⁴⁵⁶

Criticisms of genetic 'prediction and prevention' and lack of regulation

On 3rd March, scientists from the Netherlands and from the US National Institutes of Health – including the Director of the National Office of Public Health Genomics at the Centers for Disease Control and Prevention - published a critical appraisal of the scientific basis of commercial genomic profiles, in the *American Journal of Human Genetics*⁴⁵⁷. They conclude: "*There is insufficient scientific evidence to conclude that genomic profiles are useful in measuring genetic risk for common diseases or in developing personalized diet and lifestyle recommendations for disease prevention.*"

On 11th March 2008, the PHG Foundation (formerly the Public Health Genetics Unit at Cambridge) and the Royal College of Pathologists published a report of a 'Diagnostic Summit' held in January on the evaluation of diagnostic tests.⁴⁵⁸ Launching the report of the meeting, the PHG Foundation's Director, Dr Ron Zimmern, said⁴⁵⁹ "*In the UK, around 1 billion laboratory tests are performed each year. NHS laboratories have sophisticated systems to ensure the analytical accuracy of the tests, but no systems for ensuring that individual tests are clinically effective and useful. This is akin to pharmaceutical companies having tight control over the chemical purity of drugs, but there being no formal requirement for them to prove that the drugs produce any benefit for patients*". The report recommends that a new body should be established to ensure the evaluation of laboratory diagnostic tests and the creation of a database of new and existing laboratory tests, including genetic susceptibility tests. However, it stops short of proposing statutory regulation, beyond requiring that evidence is put in the public domain. It also encourages "*policy makers and all stakeholders*" to address issues around funding to gather the necessary evidence and says they "*should consider the establishment of public-private partnerships to increase industry involvement*".

This workshop report was published alongside a shorter report from Sense about Science⁴⁶⁰, aimed at the general public, which stated that "*Many doctors and scientists don't agree with the increasingly promoted idea that well people need to be tested for diseases*". Based on the views of a number of medical professionals, it states that:

- Most tests are not designed for use by people with no symptoms or elevated risk.
- Most tests on well people won't accurately predict the diseases they will get.
- Some tests on well people will suggest diseases that they will probably never get.
- What a test claims to do for your health or tell you about a disease isn't adequately regulated or fully researched.

- Diagnosis is complex, based on clinical experience and research, signs, symptoms and context. These determine which tests to do and how to understand their results.
- Information from many home testing kits and full body scans is usually not clinically useful.
- There is a growing business selling new genetic tests based on very preliminary research - the evidence is far too flimsy to be accepted by evidence-based medical practice.
- Testing for a disease before symptoms appear can even harm in ways people may not have considered.

The workshop report was also accompanied by an academic research report on the factors influencing how new genetic tests for common disease susceptibility enter routine clinical practice, and the need for appropriate clinical evaluation.⁴⁶¹ This report is based on over 80 interviews with “*opinion leaders from all the key parties involved in the clinical use of genetic tests for common conditions*”. It identifies “*major areas of weakness*” in the existing regulatory system for genetic tests, accompanied by disagreement about the appropriate scope of regulation, and advocates a ‘light-touch’ pre-market review of evidence by regulators.

A new biomedical research centre for Manchester and funding for biomarkers

On 19th March, the Government announced a new biomedical research centre for Manchester, focusing on genetic testing for complex diseases and adverse drug reactions.⁴⁶²

Also in March 2008, a call for proposals in biomarkers was announced by the MRC, with a planned £10 million budget to develop or to evaluate potential biomarkers for their predictive and prognostic capability for the diagnosis of disease, disease heterogeneity and underlying mechanisms, susceptibility, exposure or response to interventions.⁴⁶³

The House of Lords Science and Technology Committee’s inquiry into genomic medicine

In April, written evidence to the House of Lords Science and Technology Committee’s inquiry into Genomic Medicine was published.⁴⁶⁴ Oral evidence continued to be taken until January 2009.⁴⁶⁵

The MRC provided figures of total spend on genomic medicine of £49m (2003/04); £36m (2004/05), £52m (2005/06), £50m (2006/07).⁴⁶⁶ In the financial year 2006/7, the major scientific categories were, Genetics of specific disease, Genetic epidemiology, Genome instability (all more £9m a year), followed by Global Health and Gene therapy (£3m - £4m a year). Spend on genetic biomarkers and pharmacogenomics was less than £2m a year.

The written evidence of the Academy of Medical Sciences (AMS) claims that “*Genomic medicine holds the promise to revolutionise care and prevention of common diseases*”.⁴⁶⁷ The submission outlines a vision in which everyone in the population will be classified as at high genetic risk of at least one disease: “*Making the simplifying assumption of independence across diseases, then simple probability calculations show that across 50 diseases:*

- ~95% of people will be in the top 5% of genetic risk for at least one disease.

- ~40% of people will be in top 1% of genetic risk for at least one disease.
- ~5% of people will be in the top 0.1% of genetic risk for at least one disease.

Therefore, while the predictive power of genomic tests for any one disease might be limited, for most people, across 50 diseases, there will be a few diseases for which the individual is at particularly high risk. Personal genomic screening might therefore be more usefully viewed as a way to identify the 2 or 3 diseases for which an individual has the highest risk”.

In the uncorrected transcript of his oral evidence⁴⁶⁸, Professor Sir John Bell (of the AMS and OSCHR) admits that *“the concern about predictive testing and the relevance of the whole genome association data from predictive testing is fair; we do not yet know what that will do if you add up all those very small risks, what it will do in a population to identify people and what you would do if you had that information anyway”*. However, he argues that within five years it will be possible to generate a whole genome sequence for \$1,000 and that *“we are going to be at the receiving end of almost unlimited amounts of genetic information”*. Bell admits that individual gene tests are unlikely to be cost-effective in a screening programme but states: *“In my view the best way to do this will be to bundle it; the great thing about genetics is you can get the answers to all the questions in one test because you answer all the questions on one chip or you answer all the questions on one genome sequence, and then you extract the information you need out of that. If you say there are about 100 things that would be interesting to know, that would be useful in clinical practice, and for 1,000 bucks we could sequence the genome and stick it on a chip and extract the information, then the cost-effectiveness starts to change quite dramatically because basically you are bundling all the information a person might need in their entire lifetime in a single test”*. Asked whether every newborn baby should be tested, Bell states: *“I think there is an ethical discussion you have got to have before you start testing newborn babies but the idea is that at some stage during life*

...My suspicion is that that would be a very efficient way to do it and one can now see for the first time how you might do that in the relatively near future”. He also states: *“...one of the reasons that Biobank will be successful is because of our ability to manage and handle data in large numbers of people, which really relates to the Connected for Health programme, and the research capability programme analysis alluded to. If it evolves as we all hope it will, given the ready access to that kind of data, I am not sure why we would not expand the Biobank concept much more widely in the UK, where one gave all patients an opportunity to deposit a bit of DNA that would be used in an anonymised fashion, to link the data system...I see Biobank as phase one, a pilot study. We may end up eventually with ten million people who are all participating in the programme. The IT makes it possible”*. When asked whether the key industrial players been talked to or involved, he replied: *“I have not directly approached people but I know Google has been involved in discussions at the Department of Health”*.

In the same uncorrected transcript of evidence, Professor Sir Alex Markham, speaking as Chair of the OSCHR Translation Medicine Board, and Chair of NHS Connecting for Health’s Research Capability Programme, said: *“All of the efforts that are now going in through OSCHR, through its e-Health Board, and through the Department of Health through the Connecting for Health process with this new programme called the Research Capability Programme, that is all about setting up the systems that will enable us to handle this tidal wave of information under the right limitations of good governance to ensure all of those vital components of this game, that patient confidentiality is maintained, that this is not on the front page of the*

newspapers on a daily basis when data is lost". Asked whether he thinks in the long run it is going to be possible to combine personal health care records with genetic data, he replied "yes" and explained the process being developed by UK Biobank.

The Wellcome Trusts' written evidence states: "*The NHS provides a unique research resource – offering potential to link large-scale genomic data with information on health outcomes and responses to treatments captured in electronic patient records*" and that "*The Government must plan effectively for the implementation of genomic medicine in the health service*".⁴⁶⁹

In the uncorrected transcript of his oral evidence, Dr Mark Walport, Director of the Wellcome Trust argues that although other research can be done in the meantime: "...*there is no question of the opportunity that large databases bring; they offer a huge potential competitive advantage for the UK and indeed Europe for advancement in healthcare through this type of research. I do not for a second underestimate the ethical issues here, but this is research which does not depend on identifying information, it can be done with anonymised or pseudo-anonymised data sets. The opportunities are huge and I think the research community has been pressing very hard on Connecting for Health*". Asked about the data-sharing review he is conducting with the Information Commissioner, Walport says: "*I have deliberately not talked about it so far, although the work is highly relevant.... All I can say at this stage is that I think some of our recommendations will be germane to the issues of data sharing in the context of research and statistics because it comes up as a clear issue*".

In the same uncorrected transcript of oral evidence, Professor Peter Donnelly, Director of the Wellcome Trust Centre for Human Genetics and Chair of the Wellcome Trust Case Control Consortium, claimed: "*We will move from the stage where we do [genetic tests] in a kind of ad hoc condition by condition way to just thinking that it is much more efficient with current technology to type their genome at, say, a million SNPs and through that with future technology their DNA sequence. I think in the long term that will be part of routine practice*". In his written evidence⁴⁷⁰ Donnelly notes: "*For a particular disease, and a typical individual, their genetics is unlikely to have a major impact on their disease risk. Put another way, these genetic markers are not yet good predictors of disease outcome, as has been widely noted. But there is another perspective.*

Across the population as a whole there will be some individuals at greatly increased risk of disease, based on their genetics". He then cites the examples of Type 2 Diabetes and Crohns' Disease and argues: "*Here genetics has the potential to identify individuals at greatly increased risk. It is not yet known how best to intervene to improve outcomes, and more research is urgently needed, but it seems wrong to ignore a method for identifying such high risk groups – many of the risk factors of current focus in medicine identify subgroups with much less increased risk. From an individual's point of view, for most diseases the genetic risk is about average, but over 50 or more diseases the chance of being in the top 5% for one or more is 95%. So a potentially helpful perspective on "consumer genomics" is that for the individual it can identify the small subset of diseases for which their genetics puts them at much increased risk*".

In the uncorrected transcript of his oral evidence, Nobel Prizewinner Sir John Sulston (acting chair of the Human Genetics Commission, HGC) stated: "*I think we are going to have to get used to having our genome known just as we have credit cards and we have mobile phones and they are intrusions on privacy if misused. In my opinion – this is not HGC opinion – is that the ethical dilemma will actually reduce as a result of doing these things and we may then at some point say what does it matter, yes,*

*sure, sequence at birth, we will do it, but how to get from here to there is a rough road because right now it is going to be unusual, we have privacy issues and, as we are coming to I hope later in the discussion, we have discrimination issues which are very real and have not been dealt with and until we have dealt with those then the ethical problem stands very starkly”.*⁴⁷¹ Asked about the implications for family relationships he stated: *“All of that will come out, absolutely. This is what I mean about getting real and getting used to it. There will be no secrets about paternity anymore”.*

The Government’s written evidence to the Committee endorses the 2003 Genetics White Paper vision *“that the NHS should lead the world in taking maximum advantage of the application of the new genetic knowledge for the benefit of all patients. New genetic technologies are increasingly going to revolutionise the delivery of targeted health care and prevention of ill health. Over the past decade, the Government has set out a clear strategy for research into the link between genes and disease and to prepare the NHS to make maximum use of the new knowledge.”*⁴⁷² The evidence also states that BERR has a strong interest in genomic medicine because of its impact on the competitiveness of UK pharmaceutical and biotechnology industries three major initiatives - the Pharmaceutical Industry Competitive Task Force (PICTF), the Bioscience Innovation and Growth Team (BIGT) and the Healthcare Industries Task Force (HITF) and refers to the fact that BIGT concluded that that the bioscience-related industries would play a major role in population screening to identify the proportion of the population affected by a specific condition or disease. It also states that: *“Improved algorithms for assessing the interactions between an individual’s genes, environment and lifestyle will result in the development of an increasing number of prediction and prevention strategies”* and that: *“The outcomes of this [further epidemiological research] will improve our understanding of the influence of genetic variations on the risk of common chronic conditions. This will become increasingly important to people making lifestyle choices to reduce their risk of these diseases. This underlines the importance of health professionals having better access to both information about genetic conditions and management support to incorporate genetics advances into their practices”.* However, the Government’s evidence also notes that *“it is important to manage public expectation on the predictive capacity of these genetic variations”.*

In her uncorrected oral evidence, Professor Sally Davies, Director-General, Research and Development and Chief Scientific Adviser to the Department of Health, stated⁴⁷³: *“We would agree with you that the potential is absolutely enormous. How will genetics impact on health care? Through finding genes or their expressions; to give profiling for people, either as patients or even as a population, for screening that will lead to prevention of disease/health promotion.”* However, she admits that for complex disorders *“we do not have very much that is relevant to clinical implementation yet”.* Nevertheless: *“We are trying to mainstream genetics into education because it will be fundamental, in its broadest definition, to a vast amount of the work of the NHS in the future, particularly as we move towards more preventive issues”.*

The second meeting of the Ministerial Medical Technology Strategy Group

On 18th June the Ministerial Medical Technology Strategy Group (MMTSG) held its second meeting.⁴⁷⁴ The meeting discussed the Health Innovation Council; clinical research in the NHS on medical technology; procurement; consultation on the recast of the EC Medical Devices Directives; industry’s perspective on Health Technology Assessment; and the UK Life Science Marketing Strategy for international trade and investment. An industry paper discussed at the meeting states that within 10-15

years “a new model of delivery will evolve reflecting a change in emphasis from the relatively late diagnosis and treatment of disease to a focus on the ‘Early Health’ of individuals and population groups”.⁴⁷⁵ The industry claims this will not only improve patient outcomes but “moderate growth in healthcare expenditure” and reduce the estimated £103 billion cost of ill-health to the UK economy. The paper states that the key elements are:

“The prediction and prevention of disease;

Early (pre-symptomatic) diagnosis;

Minimally invasive treatments;

Post treatment monitoring;

Information flows which connect all the elements.

In each element the Medical Devices and Diagnostics Industries are currently investing in new technology platforms to help materialize this new model”.

In relation to “Prediction and Prevention” the paper claims:

“As the cost of gene based predictive technologies decline their routine application to identify high risk individuals and populations will be invaluable. Linking such identification to tailored prevention programmes will improve personal and public health”. Regarding “Information” the paper claims:

“The ubiquitous electronic patient record and database connectivity are the cornerstone of this element and, through Connecting for Health (CfH), the UK is already in an enviable position to take advantage of the opportunities it offers.

In future, the ability to mine data generated from this environment will bring about a true revolution in the practice of medicine, opening new industrial as well as healthcare horizons”.

The paper concludes: *“From wealth comes health”.*

The MMTSG meeting papers also include a paper from the Association of British Healthcare Industries (ABHI) opposing attempts to approve regulation of genetic tests and other medical devices at an EU level, via revision of the Medical Devices Directives.⁴⁷⁶ In discussion, the industry’s position was supported by the Medicines and Healthcare Regulatory Agency (MHRA).⁴⁷⁷

Lord Darzi also gave a presentation to the meeting, and another paper proposed a change in the group’s terms of reference to enable it to play a role in implementing the proposals expected in his forthcoming report.⁴⁷⁸

Lord Darzi’s final report

On 30th June, Health minister Lord Darzi published the Final Report of his vision for the NHS.⁴⁷⁹ It states (paragraph 18): *“With the advances currently underway in genomic testing, we may be able to predict future disease rather than simply understand present illness”.*

Publication of the Data-sharing Review

On 11th July 2008, the final report of the Data-Sharing Review led by Walport and Thomas was published.^{480,481} Over 200 responses to the consultation were also published, including submissions from the Academy of Medical Sciences (led by John Bell), the BioIndustry Association, GlaxoSmithKline, the ABPI and the Wellcome Trust.⁴⁸² The report recommends (Recommendation 8(a)) *“that where there is a genuine case for removing or modifying an existing legal barrier to data sharing, a new statutory fast-track procedure should be created. Primary legislation should provide the Secretary of State, in precisely defined circumstances, with a power by Order, subject to the affirmative resolution procedure in both Houses, to remove or modify any legal barrier to data sharing by:*

- *repealing or amending other primary legislation;*
- *changing any other rule of law (for example, the application of the common law of confidentiality to defined circumstances); or*
- *creating a new power to share information where that power is currently absent”.*

The report recognises (para 8.45) that its proposals are not consistent with the fourteenth report in Session 2007/08 of the Joint Committee on Human Rights, which expressed concerns about the use of secondary legislation to authorise information-sharing schemes. However, it argues that the proposed safeguards in the report (involving scrutiny by the Information Commissioner) are adequate. The report also makes a series of recommendations (Section IV) to allow greater access by researchers to ‘pseudonymised’ data: coded datasets that no longer contain explicit identifiers, but ultimately allow the data to be linked to a particular individual. This type of data is the same as that likely to be released by UK Biobank, where there will be limited access to the codes and identifiers (such as name) but wide access by researchers – including commercial companies – to medical data linked with genetic information.

In August 2008, a paper was published in the Public Library of Science, showing that individuals or their relatives could be identified from the limited statistics based on individual genotypes that are often shared between researchers.⁴⁸³ The authors state: “*Though counter-intuitive our findings show a clear path for identifying whether specific individuals are within a study based on summary level statistics...*”. The study led to access to some data from genome-wide association studies (GWAS) being restricted.⁴⁸⁴

Review of the Police and Criminal Evidence Act

In August, the Government published its proposals in response to its review of the Police and Criminal Evidence Act.⁴⁸⁵ It reported (paras 9.11 & 9.12) that an interdepartmental working group had concluded that: “*Subject to an overriding public interest test and judicial oversight, the police should be able to obtain access during a criminal investigation to material held by third parties that is currently barred to them by the Police and Criminal Evidence Act 1984, such as medical, social services or educational records*”, and stated that “*The working group’s findings are currently under consideration with a view to a possible public consultation exercise*”.

The Sunday Times finds conflicting gene test reports

On 7th September 2008, an investigation by the Sunday Times found that the Harley Street company Genetic Health and two other companies – 23andMe and DeCode – gave wildly differing assessments of individuals’ genetic risk, based on the same DNA.⁴⁸⁶

Genetics of common diseases ‘is not working’

On 16th September 2008, geneticist David Goldstein of Duke University told the New York Times that the effort to nail down the genetics of most common diseases is not working, and: “*There is absolutely no question that for the whole hope of personalized medicine, the news has been just about as bleak as it could be*”, producing just a handful of genes that account for very little of the overall genetic risk.⁴⁸⁷ “*It’s an astounding thing,*” Dr. Goldstein said, “*that we have cracked open the human genome and can look at the entire complement of common genetic variants, and what do we find? Almost nothing. That is absolutely beyond belief.*” In the article, Goldstein argues that the ‘missing heritability’ is due to rare genetic variants that

cannot be found by current studies but might be tracked by thoroughly studying the genome of specific patients.

Connecting for Health consultation

On 17th September, Connecting for Health launched a consultation on ‘additional uses of patient data’, via its Secondary Uses Service (SUS).⁴⁸⁸ The consultation asks a series of questions about access to electronic medical records for research and suggests various circumstances in which records might be shared with ‘researchers’ without consent. It does not mention genetic information or the role of researchers from commercial companies. The Human Genetics Commission’s submission to the consultation notes that *“easier access to patient information also increases the risk of unauthorised access without appropriate consent”* and reports that: *“A majority of members of our Consultative Panel who responded to our request for feedback felt that anonymisation of patient information would always be difficult, if not impossible, for people with rare genetic conditions or other conditions that are visible. For such conditions, information about a person’s sex and age used in combination with the reduced postcode could lead to that person’s identification rendering anonymisation almost meaningless. There was one view that for conditions which would prevent the patient from ever being effectively anonymised, the patient should retain the right to restrict use of their information”*.⁴⁸⁹

Redacted human genome data can be reconstructed

In October, the European Journal of Human Genetics published a paper about the whole genome sequence of James Watson – one of the discoverers of the DNA double-helix.⁴⁹⁰ Watson’s genome has been published with his consent online but with some information missing at his request, relating to whether he has a variant of the APOE gene which has been linked to increased risk of Alzheimer’s Disease. The authors conclude that the redacted part of the genome could be deduced from the rest of the sequence and other public information and state: *“In summary, hiding genetic information in an otherwise fully disclosed genome sequence is not straightforward because of the availability of genomic data in the public domain that can be used to predict the missing data. We believe the potential for such indirect estimation of genetic risk has considerable relevance to concerns about privacy, confidentiality, discriminatory and defamatory use of genetic data, and the complexities of informed consent for both research participants and their close genetic relatives in the era of personalized genomics”*.

‘The case of the missing heritability’

On 6th November, the journal Nature published an article called *“The case of the missing heritability”*, which stated: *“When scientists opened up the human genome, they expected to find the genetic components of common traits and diseases. But they were nowhere to be seen”*.⁴⁹¹ It reports that *“...even when dozens of genes have been linked to a trait, both the individual and cumulative effects are disappointingly small and nowhere near enough to explain earlier estimates of heritability”*. Most of the geneticists cited are optimistic that they can find more of the missing heritability (which is a calculation of the genetic proportion of the variance – or how much of the differences between individuals are explained by inherited genes). But the article also admits that the calculations (which are made from twin studies using several very controversial assumptions^{492,493}) may be wrong. If the missing heritability exists, it must be caused either by much rarer mutations, or by common variants that individually each have a much smaller effect on risk: but these would be much harder to identify. Interactions might also be important, requiring complex modelling of

networks of different genes. The article reports that Francis Collins, the former head of the US Human Genome Project, “*agrees that the picture for disease prediction remains bleak, but is still optimistic about therapeutic intervention*”.

The third meeting of the Ministerial Medical Technology Strategy Group

On 25th November 2008 the Ministerial Medical Technology Strategy Group (MMTSG) held its third meeting.⁴⁹⁴ The meeting discussed its role in the implementation of the NHS Next Stage Review (NSR) innovation outputs on medical technology^{495,496} and an update on the recast of the Medical Devices Directives. A further paper from the Association of British Healthcare Industries (ABHI) states that the industry is opposed to any pre-market approval system for genetic tests or other diagnostic devices under the Medical Devices Directives.⁴⁹⁷ The minutes of the meeting are not yet available.

The OSCHR’s first report

Also in November, the OSCHR (chaired by Sir John Bell, Box C) published its first report.⁴⁹⁸ It states that “*A Funders’ Group, with membership from Cancer Research UK, EPSRC, ESRC, the MRC, the NIHR and the Wellcome Trust, has been established to facilitate coordination of funders’ strategies in the area of E-health records research in order to maximise preparedness of the research community for exploitation of the RCP’s Health Records Research Service when it is launched. The Group, which has met three times to date, will report to the EHRRB in November with a draft paper outlining the strategic implications of the Research Capability Programme for E-health records research in the UK*”.

Further criticisms of gene tests sold by Genetic Health

In December 2008 an article in the Guardian cites experts who describe the predictions and advice from the Harley Street company Genetic Health as “*poor*”, “*flawed*”, “*misleading*” and “*baloney*”.⁴⁹⁹

The decision of the European Court of Human Rights

On 4th December, the European Court of Human Rights ruled that Britain’s police National DNA Database contravened human rights law. The court found unanimously that the retention of both DNA profiles and DNA samples collected by the police interferes with the right to respect for private life, and that the blanket and indiscriminate nature of the powers of retention of the fingerprints, samples and DNA profiles of persons suspected but not convicted of offences fails to strike a fair balance between the competing public and private interests.⁵⁰⁰

2009

Data-sharing without consent: the Coroners and Justice Bill

On 14th January 2009, Justice Minister Jack Straw introduced the Coroners and Justice Bill in the House of Commons.⁵⁰¹ Part 8 of the Bill proposes amendments to the Data Protection Act, which include a power to enable information sharing, as recommended by the Thomas-Walport Data-Sharing Review.^{502,503} The proposed power would allow ministers to issue ‘information-sharing orders’ to enable any person to share information which consists of or includes personal data, for any purpose with which their department is concerned. Critics warned that the Bill was a new “*building block of the surveillance state*”.⁵⁰⁴ DNA and genetic information is

generally considered to be personal information under the Data Protection Act and information in electronic medical records also counts as personal information. The data-sharing proposals have major implications for genetic privacy and health and could allow a 'back door' national DNA database to be developed, linked to electronic medical records in the NHS, with access to the data later given to the police.

Ministers give evidence to the Lords' Science and Technology Committee

On 21st January, the Rt Hon Dawn Primarolo MP, Minister of State for Public Health, gave evidence to the House of Lords Science and Technology Committee's Inquiry on Genomic Medicine. In the uncorrected transcript she states: "*I should start by saying I rely very heavily on the expert advice that is provided to me*".⁵⁰⁵

Accompanying the minister, Professor Dame Sally Davies, Chief Scientific Adviser at the Department of Health asked the rhetorical question: "*At what point will we want to link an individual's genome data with their health data?*" and noted that this would raise both technical and ethical issues. Asked about the Data-Sharing Review, Dame Sally told the Committee that the Department of Health had accepted the recommendations in the Thomas-Walport report and that: "*Everyone in front of you and the Government is absolutely determined to exploit this research opportunity. In fact, Lord Drayson and I were discussing how unique it is in this country that we have this cradle to grave community inter-specialist care data and to link that to genomics is very powerful as a way of learning how to improve public health and individuals' care. That is why we are making substantial investment in this Research Capability Programme for NHS Connecting for Health...*". When former health minister Lord Warner (Box O) stated that: "*the great prize for researchers in this area is being able to access the current data that is in the medical record plus the new genomic data as it emerges for individuals*", the Minister replied "*I think the long-term objective would be yes*", and Dame Sally added: "*I agree. If they are linked for clinical purposes then the only issue is about access and as long as we develop safe havens effectively to pseudo-anonymise...then we'll be all right*". However, the minister refused to be drawn on whether Government would revisit legislation to make access easier, stating "*At the moment it's two steps*".

Science Minister Lord Drayson told the Committee that "*The whole area of genomics has the potential to transform healthcare*", and both ministers argued that the OSCHR (Box T) was key to providing strategic oversight.

Follow-up to the BIGT report

On 22nd January, a follow-up to the BIGT report (Box N) was published by Sir David Cooksey (Box F).⁵⁰⁶ The report notes that there have been no biotechnology IPOs anywhere since November 2007 and that an analysis of the 2007 stock market performance showed that UK biotechnology was by far the weakest in Europe. It argues for various forms of tax relief and forming a UK investment fund to match venture capital with government subsidy. The report criticises the slow roll-out of the Connecting for Health IT programme "*particularly as an R&D tool*" and argues that it could be used to help industry do pre-competitive research to stratify genetic sub-groups of patients who respond differently to different drugs. It notes that: "*Stratified medicine is distinct from the concept of 'personalised medicine' which raises potentially unrealistic and probably unaffordable expectations of treatments tailored to the individual*".

6. Conclusions

The history of the decision to fund UK Biobank and a centralised system of electronic medical records in the NHS provides a striking example of how science funding decisions are driven by a small group of unaccountable advisors. The idea of a national DNA database linked to electronic medical records was first proposed by Sir George Poste, then at SmithKline Beecham, and subsequently Bush's bioterrorism advisor and a board member or CEO of several US biotechnology companies. It was supported and promoted by Sir Richard Sykes of Imperial College, formerly Chairman of GlaxoSmithKline; Sir David Cooksey, founder of Advent Venture Partners; Professor Mark Walport of the Wellcome Trust; Professor John Bell of Oxford University; and members of the House of Lords Science and Technology Committee. They advocated a 'genetic revolution' in healthcare, which would transform the NHS into a service based on 'prediction and prevention' of common diseases, such as heart disease and cancer. They have been members of virtually every advisory committee established to consider innovation in the NHS and the role of the biosciences in health, and have repeatedly sat on committees or given evidence to inquiries established by each other.

UK Biobank was developed as a pilot project for the much larger national DNA database proposed by Poste, and the Wellcome Trust is now leading plans to share genetic data and health data internationally, including across the EU. The data-sharing proposals in the Coroners and Justice Bill, and proposals contained in the consultation on the Secondary Uses Service (SUS) held by Connecting for Health, would allow this to take place without the consent or knowledge of individuals in the NHS. Over time, the database could be expanded to use the blood spot cards which are already taken routinely from every baby at birth in the NHS and linked to their electronic medical records. Current legislation would not prevent police access to this data, which could also be used to check paternity. Research has shown that privacy cannot be protected if individuals' genome sequences are widely accessible.

Sir George Poste's proposal was intended to allow Britain to take the lead in commercialising the human genome and to massively increase the drug market by shifting the boundary between the individual and the patient, leading to an emphasis on the 'pre-symptomatic' treatment of healthy people. Access by private companies to electronic medical records in the NHS, linked to biological samples, was seen as Britain's 'unique selling point' to encourage commercial investment in research and create a 'knowledge-based economy' to compete with India and China. However, no common genetic variants that meet medical screening criteria for the general population have been identified and very little of the differences in disease risk observed between individuals has been explained by genetic factors.

The potential contribution of genetic 'prediction and prevention' to reducing the incidence of common diseases is therefore extremely questionable and the problem is compounded because genetic tests are largely unregulated, so 'genetic information' – combined with medicines, supplements, foods, skin creams, lifestyle advice and additional tests - can be marketed even when it is not valid or useful. This has the potential to harm health by:

- targeting the wrong advice at the wrong people;
- confusing healthy-eating messages or advice to quit smoking;
- leading to the costly over-treatment of healthy people;
- undermining public health approaches and diverting resources from the social, environmental and economic changes that are needed to prevent ill-health.

Numerous consultations and public engagement exercises have identified public opposition to research without consent; concern about the lack of regulation of genetic tests and about protection of personal data; and a “*striking trust deficit*” regarding whether research is being conducted in the public interest. Concerns about the role of commercial companies have been repeatedly dismissed, because a commitment to sharing NHS patient data with industry has always been central to the plan.

Policy decisions reflected the New Labour government’s strong commitment to the knowledge-based economy, as described in the main report. This included:

- adoption of a strong intellectual property regime, so that ‘knowledge’ can be patented and traded – in this case by supporting the patenting of genes;
- ‘light touch’ regulation, which focused on the needs of a claimed future business, accepted claims made by vested interests that regulation would ‘stifle innovation’, and ignored repeated calls to regulate the misleading health claims made about genetic susceptibility tests;
- closer links between industry and the public sector aimed at facilitating access by commercial companies to people’s personal health information contained electronic medical records, linked to their DNA;
- a narrow definition of wealth-creation and innovation as the main focus of public research spending, combined with an assumption that broader benefits will also be delivered (in this case, benefits to health);
- total dependence on ‘expert’ advice supplied by vested interests;
- sidelining and dismissal of concerns, leading to the loss of public trust.

The Government has provided an enormous public subsidy to a science fantasy: involving a total transformation of the NHS to facilitate the ‘prediction and prevention’ of disease. Its failure to attempt to evaluate the costs and claimed benefits to health of centralising electronic medical records – ignoring its own rules in the Treasury Green Book – has led to the entire risk of the ‘public-private partnership’ being borne by the taxpayer. The decision to create a centralised system (the ‘Spine’) is estimated to cost at least £11 billion more than the localised system which was originally planned. In addition, risk assessment of every individual in the UK population means turning healthy people into patients and could lead to massive over-treatment and huge financial burdens on the NHS, as well as causing major privacy concerns. No Government analysis of the cost-effectiveness, impact on health, or impact on the NHS has ever been undertaken to support this plan.

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