

A REVIEW OF THE GENETICS MORATORIUM
AND WHAT MIGHT REPLACE IT:

**Prepared by Richard Walsh and Sandy Raeburn of
St Andrews Management Institute (SAMI) Consulting
for the Executive of the UK Forum on Genetics and
Insurance**

September 2009

**For more information on SAMI Consulting see
www.samiconsulting.co.uk**

EXECUTIVE SUMMARY

The UKFGI was inaugurated 10 years ago with the mission of analysing the implications for insurance of advances in genetic knowledge and of serving the public interest by reporting on its findings. The UKFGI is an independent expert group, founded with the support of the Royal Society, the Association of British Insurers, the Institute and Faculty of Actuaries, the British Society of Human Genetics, the Genetic Interest Group, the Nuffield Council on Bioethics and the Wellcome Trust. The UKFGI aims to encourage interdisciplinary discussions about genetic risk, to disseminate knowledge across specialist boundaries and to seek solutions to the differing anxieties of the public, of genetic specialists, of ethicists and of the insurance industry to the dilemmas posed by the implementation of genetic testing and screening and of genomic medicine.

In 2009 the UKFGI commissioned two senior researchers with St Andrews Management Institute Consulting to review the future of the genetics and insurance concordat and moratorium. In essence, the UK moratorium means that insurers can only use predictive genetic tests in underwriting insurance where the tests have been approved by a Government Committee and even then only for very high value policies. For a full history see Annexe 3 of this report. The review was particularly timely because it coincided with the publication of the House of Lords Select Committee report on genomic medicine which made recommendations on the subject. The review was informed by interviews with a wide range of stakeholders, desk research, and the authors' personal expertise in the area. The UKFGI has debated the report and endorses its findings including the eight recommendations in Part 4.

Of the eight recommendations, the key ones are:

- We believe we may have identified a way forward on the “test now buy later” issue which has dogged the moratorium since its inception, although this will require further work on quantifying the numbers of people who would need to be covered**

- **We recommend a re-examination of the ethical implications of different forms of predictive tests and in particular that these may be different for single gene disorders and multi-factorial conditions**
- **We recommend investigation into how a specialist insurance system might operate for people at risk of developing rare single gene disorders in the event of the end of the moratorium. This would form part of the work on the “test now, buy later” issue**
- **The UKFGI will continue to support exchange of research and debate between different stakeholder groups on this complex issue**

If these recommendations can be progressed effectively the end result would be a permanent solution and stability – removing the need for the current cycles of reviewing the moratorium. This would bring confidence to consumers and clinicians and “future proofing” for insurers and re-insurers.

I commend this report to you and hope it moves matters forward in the run-up to the next concordat and moratorium review

**Sir Walter Bodmer
Chairman of the UKFGI**

PART ONE – INTRODUCTION, AIMS & METHODOLOGY

BACKGROUND:

1. Compared with many other countries of the world, the United Kingdom has strengths and established expertise in six key elements which are important at the interface between medical genetic and insurance practice and in particular:
 - a. The NHS is renowned internationally as the most egalitarian approach to provision of coordinated national health care. This means that clinical care is available to everyone on the basis of need and is free at the point of delivery. In other countries, for example the USA, where a large proportion of the population is entirely dependent on private medical insurance legislation it has been necessary to prevent insurers from discriminating for individuals basic health care needs on the basis of the results of predictive genetic tests.
 - b. UK research in genetics, and its application in many fields, especially medicine, is long established and very highly rated.
 - c. The UK insurance industry has even longer traditions of risk assessment, actuarial science and of offering a wide range of insurance products, including life, critical illness and income protection insurance. Critical illness insurance, for example, is not available in some European countries where there is a tradition of strong state control of the factors that are allowed to be used in underwriting
 - d. The UK has many vibrant, very professional family/patient led self-help organisations which have made us a world leader in anti-discrimination law on grounds of disability.
 - e. The UK has strong ethical expertise and experience in this debate which is exemplified in the ground breaking report by the Human Genetics Commission in 2002 – “Inside Information”.

- f. The UK has a fair political/civil service culture with a long history of promoting fairness
2. However, these strengths have not always combined peacefully: indeed the period leading up to the introduction of the Government/ABI agreed moratorium in November 2001 was characterised by conflicts. We cover the history of these debates in more detail in **Annexe 3** of our report. And in **Annexe 4** we explain the principles of commercial insurance in the UK.
3. Since November 2001 the moratorium (and later the concordat – which unlike the moratorium is not time limited) has been regularly reviewed. The House of Lords Select Committee has revisited the issue in its report, published on 7th July 2009, which studied all aspects of Genomic Medicine. The report included 3 recommendations involving Genetics and Insurance including:
 - a. (para 6.47) ‘We recommend - - - a new clause - - - - in the moratorium - - **that prevents insurers from asking for the results of genetic tests which were carried out while the Moratorium was in place**’.
Often referred to as the “test now, buy later” problem.
 - b. (para 6.48) ‘**We recommend that the Government, together with the Association of British Insurers, should establish a longer-term agreement about the use of genetic test results for insurance purposes**’.
 - c. (para 6.50) ‘**Given that the Genetics and Insurance Committee is to be disbanded, we recommend further that the Government should put in place arrangements for monitoring the use of genetic tests for insurance purposes**’.

AIMS OF OUR RESEARCH:

4. The purpose of this research was to study what has happened during the moratorium, to identify successes which can be built on or problems to address and to find out if there is now any developing consensus on a longer-term policy solution. To achieve this we:
 - a. **reviewed the genetics and insurance moratorium and concordat in the UK.**
 - b. **interviewed a wide range of key stakeholders to ascertain their views on the legacy of the past, the current arrangements and ideas for the future.**
 - c. **developed some case studies of how other countries have addressed the issue and sought views from stakeholders on whether there were lessons for the UK.**
 - d. **reviewed the options for the future. We particularly wished to identify approaches to insurance provision for people with genetic risks that could clarify and enhance future policies.**

METHODOLOGY:

5. Key participants and stakeholders were selected from the groups listed below, attempting to ensure that each group was represented at least twice and that interviewees covered a range of UK locations:
 - Actuaries**
 - Ethical/social thinkers and advisors**
 - Geneticists**
 - Insurance industry**
 - Patient organisations and self-help groups**
6. We also held “off the record” conversations with others. The interviewees who participated are listed in **Annexe 1**. All interviews were carried out on a non-attributable basis – to allow for full and frank discussions. The questions we asked were drawn from a semi-structured interview brief which is attached at **Annexe 2**.

PART TWO - KEY FINDINGS FROM THE INTERVIEWS:

7. In this part we summarise the key findings from our interviews. As mentioned in the introduction, we have not attributed them but we have sought to identify levels of consensus (or not). In part three we survey some lessons from other countries and in part four we make recommendations for further work, based on the interviews and our desk research (including the material in Annexes 3 and 4)

A. THE IMPACT OF GENETICS AND INSURANCE ON DIFFERENT STAKEHOLDERS:

8. Interviews with different stakeholders showed that the impact of the issue varied over time and magnitude:
 - a. In the insurance industry there was a considerable workload (to ensure adherence to the ABI Code of Practice and the moratorium and evidence this). However, geneticists had required little time for insurance issues during the moratorium as it was no longer a big issue. One cancer genetic team had almost stopped mentioning the topic, partly due to the reassurance of the moratorium and partly because the new government standards in Health Service provision involved the target of seeing patients with cancer within a nine-week period.
 - b. In academic actuarial practice it was the work on the late onset single gene disorders which occupied time.
 - c. Epidemiologists were more concerned about the range of predictive tests (not just genetic) that were becoming available and their interactions with other factors such as lifestyle.
 - d. Patient organisations had to address many questions from their members, who were anxious about the implications of taking a genetic test **now** on future insurability. Several interviewees mentioned that it was issues of genetics and employment that were beginning to cause concern now, not insurance.

B. WHICH INSURANCE PRODUCTS WERE OF MOST CONCERN?

9. The insurance products of greatest importance were:
 - a. Life insurance (especially to protect a mortgage)
 - b. Critical illness insurance (especially for heart, stroke or cancer risks)
 - c. Long-term care insurance (especially for Huntington's disease or other conditions with a risk of dementia and progressive neurological degeneration). However, it should be noted that the current UK market for these products is tiny

C. THE SUCCESS OF THE MORATORIUM AND CONCORDAT

10. Everyone supported the moratorium. There were concerns about the "test now buy later issue", for example, but there was no enthusiasm for moving away from the moratorium in the near future for single gene disorders. Interviewees considered that the moratorium had been a success.

D. FAILURES OF THE MORATORIUM- INCLUDING TEST NOW BUY LATER

11. Only brief, anecdotal examples of misuse of the moratorium period by either patients, their families or by insurers were mentioned. In a few instances an insurer had misinterpreted the genetic information, this being easily resolved by an early appeal to the responsible company. The "test now, buy later" issue remains the biggest problem for clinicians and their patients. Clinicians were able to point to some rare instances when this problem had resulted in patients refusing a genetic test.
12. On the test now, buy later issue, some interviewees felt that this needed to be resolved sooner rather than later. Others were content that continuing to extend the moratorium well in advance of its end was sufficient. The nub of this problem is two issues of equity. First, what a clinician should say to a patient who takes a test during the moratorium, and has no need for say life insurance at that time but who may want it in the future – when the moratorium may have ended. While the clinician can point to the fact that the moratorium keeps being extended and there would be a three year period between its review and its ending that may not be enough for some young people. Then there is the position of people who take genetic tests post moratorium. If those who took the

tests during the moratorium had “protected rights” then two groups of people with identical test results would be treated in different ways.

13. Some argued that the longer the moratorium continues the larger the number of people who would have “protected rights”. Others pointed out that over time the numbers in this group would stabilise as individuals in the group aged, and either did or did not contract the condition or did not wish to purchase insurance cover.
14. Sometimes the best is the enemy of the good – it should be possible to resolve this issue by agreeing in advance what the transitional arrangements would be. This is a common public policy decision where there are winners and losers, for example changes to benefits entitlements. The key is usually to identify the numbers involved, the costs of providing post-change rights and agree how long these should stay in place. This would enable consideration to be given to another of the Committee’s recommendations, that a longer-term agreement should be achieved.

E. INFORMATION FOR PATIENTS ABOUT THE MORATORIUM

15. Some genetic services provided printed information about genetics and insurance at their clinics, but this was very brief. Referral of families to the ABI website (which was commended) for information was more likely. In contrast, the patient organisations had detailed printed information. In one, enquiries about insurance were directed to a specialised insurance broker via an interactive web-based ‘chat room’.

F. THE PRINCIPLES OF JUSTIFIABLE DISCRIMINATION AND GENETIC EXCEPTIONALISM IN THE MORATORIUM

16. There were different views to the questions about what discrimination was ‘justifiable’ and what was ‘unjustifiable’. For 200 years, insurers have based their business on understanding the degrees of risk of the insured event and then charging premiums commensurate with the risk (the underwriting principle). Geneticists and patient organisations tended to consider mutuality in insurance as a reason for not discriminating between the premiums charged for different degrees of risk. ‘All for one and one for all!’ was a common theme. The

disparity was recognised by geneticists as a tension; they hoped that even where there were greatly increased risks the cost of cover could be shared because they see insurance is about mutuality and sharing of risks'

17. A number of interviewees from across sectors considered that matters had moved on in terms of the practical reality of predictive tests (not just genetic) since the original debate in "Inside Information". At that time there was real concern that large numbers of new genetic tests would be discovered that would be highly predictive. This situation has not materialised. There was disagreement about the relevance of multi-factorial tests in the future, ranging from those who considered that their usefulness in clinical practice was decades away (if it happened at all) to those who saw more rapid progress in some areas.
18. Several interviewees had clearly given the issue of predictive tests, in general, a lot of thought. Typically the range of situations that could arise were put in a new construct – for example each person having a deck of cards (some of which e.g. lifestyle could be changed), which interacted with each other in highly complex ways. Another construct was a set of scales with a range of good and bad weights on either side. In essence, one interviewee suggested the range of predictive tests could be best described in the grid below, which has the advantage for example of clearly defining those tests which are predictive, inherited and genetic:

	"Inherited"	Complex
DNA/RNA/chromosomes	Mainly single gene disorders and with high impact on morbidity and mortality. Covered by moratorium as a clear case for genetic exceptionalism	Multi-factorial including whole genome analysis - how will knowledge develop??? – could be covered or not by moratorium?
Non-genetic	Some elements of family history including learned behaviour leading to obesity, smoking, drinking – not covered by moratorium	Non-genetic tests eg cholesterol

19. Insurers were content with genetic exceptionalism for the people in the top left hand part of the grid because the numbers are very small, providing they still had access to brief family history information. There was support for a new debate on the implications of multifactorial conditions.
20. There are few published data in the UK to compare the individual costs of offering the same premium to all of a widely varying group (in terms of risk of the insured event) with the current preference of insurers to identify the major different risk pools. Partly, this is due to the highly commercial nature of private insurance here. However in those countries which operate social insurance premiums there is evidence to indicate that fewer types of insurance product are available and that the premiums for those that are offered are bigger for most customers than in the UK. One key point of social insurance is that the insured does not choose the level of cover, or whether to take it out. This is important, as anti-selection is one of the key issues for insurers when considering the risks of asymmetry of information, as in the moratorium
21. Late onset single gene disorders which led to an early death, critical illness or severe disability were highly relevant to the moratorium. Although interviewees mentioned Huntington's disease (HD) in this respect, most qualified that by citing HD as atypical. The advantage of the moratorium was to allow for mutual sharing of costs so that such diseases did not lead, inexorably to family poverty to those with no other means of covering the financial impact of the insured event.
22. Common, multifactorial conditions were far more complex in terms of making individual (or group) risk assessments. However all interviewees pointed out that the differences in risk of common disease which were due to associations with genetic factors were insufficient to merit different insurance risk pools, within the foreseeable future.
23. There was general acceptance that the current levels of the thresholds above which genetic test results need to be reported to the insurer were 'about right'. Some participants indicated that an indexing formula would be important in any longer term solution. Patient organisations pointed out that there are low family income levels in many families affected by a genetic disorder with the result that applying for e.g. life insurance of quite low values (far below the threshold of

£500,000) would probably be precluded. The limits were chosen such that 97% of policies, by number, were for sums assured below that limit. It would be reasonable to review along these lines, as this would incorporate the influence of house prices, as many policies are related to house purchase.

G. THE PRACTICAL IMPACT OF GENETIC ADVANCES

24. There was some support for genetic screening in a public health or research context, with caution about any pre-employment screening or interpreting results of 'direct to public' tests. Any evidence-based preventive measures following screening were welcomed (but except in breast and colorectal cancers were poorly validated). However the reality was that useful screening was miles away for anything other than single gene disorders and a few clusters of genes.
25. Some interviewees considered that clarification of the use of genetic or other tests for colorectal cancer and their use or not by insurers, especially including the effect of screening of higher risk individuals by regular colonoscopies, would be useful. This might be a better model to study of environmental and genetic (both single gene and multifactorial) factors and of the possibilities for prevention than is breast cancer.
26. Collaboration between clinical geneticists and underwriters was welcomed, with a tendency to request that the industry assist in funding more research studies on risk assessment or on genetic prevention after testing. It was pointed out that, in general, underwriters did not conduct research and that competition between companies can reduce data sharing, except for the long-established Continuous Mortality Investigation (CMI), coordinated by the Institute of Actuaries.

H. THE FUTURE

27. The overwhelming response was that the interviewees wished the moratorium to be continued, long-term. There were no major elements of the present situation that needed changes but the “test now, buy later” issue needed to be resolved if possible. All participants welcomed the continuation of the moratorium until 2014 and hoped that it would continue, very much in the same format afterwards. It was thought to be ‘about right’ in its approach and a good compromise between different stakeholders.
28. There was a lukewarm response to the idea that those insurances which were identified as ‘social goods’ (e.g. life insurance to support the purchase of the family home) were handled differently from other insurances. Several respondents mentioned Huntington’s disease as a possible exception.
29. If commercial life and health insurance, as we now know it, did not exist, national tax-based solutions were suggested, but with the caveat that this could be very bureaucratic and expensive. The issue of the use of insurance to support house purchase would be highly relevant here. There is however a general issue about the extent to which greater and greater risk stratification between groups as opposed to retaining large pools of individuals obtaining insurance at “standard rates” is desirable or not.
30. Some interviewees considered that in practice the future relevance of a much broader range of predictive tests would be determined by the accuracy of risk modelling based on a whole range of factors such as age, genetic makeup including gender, and biomarkers (genetic, imaging and proteomic). More research was needed in this area and if successful this could change the climate of debate on genetics and insurance in general. Alternatively the situation for single gene disorders could remain an exception to the rest. Others took the view that this form of risk modelling was a long way away – as far as the genetic element was concerned.
31. There were concerns about unregulated sales of genetic tests and the impact that this could have on people’s lives. In addition the private sector companies that were driving this were acquiring population databases that would not be accessible to the NHS.
32. Some interviewees suggested that there should be greater collaboration between the different disciplines, and some specific innovations around tailoring

of insurance products to the needs of families with high risk genes, such as those for inherited cancers. Ideally, insurance should reflect the risk protection needs of individuals and might for example be a combination of life (and possibly critical illness also) and long term care insurance in which the person at higher risk of e.g. death would attract a lower premium rating for long-term care or annuities. Underwritten annuities are now well established. A more general point made by insurers was that only a commercial market can encourage insurers to develop new innovative products. For example for people with HIV, some countries have forced insurers to make cover available but it is very expensive, only covers a small number of people and for very limited terms. In the UK, re-insurers have studied the mortality data in depth and now offer affordable cover to a wide client base.

33. The responses consistently stated a dread of a return to the situation before the moratorium was negotiated. In addition, the industry would be anxious about losing, **as a result of legislation**, the right to use strong evidence, for ever, from genetic tests or the family history. They were also concerned about possible extensions of the boundaries of the moratorium.
34. On the other hand, geneticists feared that lack of a continuing agreement would prejudice future UK population genetic research because of long term concerns about how the research might be used. In practice it seems that, at present, the only stakeholder which would ever wish to end the moratorium is the insurance industry itself.

I. VIEWS ABOUT LESSONS FROM ABROAD

35. We cover the details of different approaches in different countries in the next part but interviewees did have views on this. Overall, our respondents did not consider that people with genetic risks were better off in other countries. Indeed, one patient organisation considered that the UK was leading the field in its evolving strategy to the issue of genetics and insurance. The key issue was that national health care systems, or a lack of these, differed to such an extent that the idea that 'one legislation fits all' was untenable. One geneticist pointed out that the proportion of specific mutations in certain genes (e.g. BRCA1 and 2) might be high in some countries and ethnic groups due to a founder effect, making testing for these specific mutations a cost-effective way of screening for

a large proportion of all mutations in the relevant gene in such populations, establishing a increased risk in mutation carriers. Likewise, comparisons of UK legislation and laws enacted in the USA (particularly the Genetic Information Non-discrimination Act, GINA, of 2008) were of dubious value, because of the UK National Health Service. It was pointed out that GINA only applies to Health Care insurance.

36. Notwithstanding the devolved element of health care in Scotland and Northern Ireland, there were no major differences in the way that insurance issues were addressed in the regions of the UK. The situation in Ireland is different in that they have moved to an outright ban. We found no evidence that individuals were moving to Ireland to take advantage of this. Indeed, the Irish response was criticised because their legislation does not allow companies to take account of negative tests (to over-rule family history).

PART THREE - LESSONS FROM ABROAD:

A. EUROPEAN DIVERSITY.

37. The UK debate, in part, led to a wider debate in the European Parliament and Commission in 2002. Many countries had settled positions banning both genetic tests and family history for insurers and employers because of past cultural problems – such as Germany. Others, like Ireland, had adopted positions similar to the UK although it has since changed its position. Yet others, treated genetics in the same way as any other medical information, e.g. Spain. The EU debate was also tied into a wider (and very heated) debate on other ethical biological issues, especially stem cell research. Following submissions by the European insurance trade body (the CEA) any attempt at harmonisation (and the lobby groups were for harmonising to a Europe-wide ban) was defeated. The situation remains one of country asymmetry.

B. CASE STUDIES

1. The USA

38. While most Americans are optimistic about the use of genetic information to improve health, many are concerned that genetic information may be used by insurers to deny, limit or cancel health insurance, and by employers to

discriminate in the workplace. They are worried that some insurers may choose not to insure people who are healthy but genetically pre-disposed to future disease: such people incur more health-related costs for the insurance company than individuals who are not predisposed. Similarly, they fear that some employers might only employ or retain individuals who are not pre-disposed to future disease onset, since healthy individuals are more productive (and as employers are often responsible for paying the premiums of health insurance it would be more expensive to employ an individual at higher risk if this could be taken into account by the insurer). Therefore, many lawmakers, scientists and health advocacy groups believed that there was a need for federal legislation to prevent genetic discrimination.

39. There are a number of laws that give individuals some protection from genetic discrimination. Forty-one states have enacted laws to protect the public from genetic discrimination by health insurance companies, and 32 states have laws protecting their citizens from genetic discrimination in the workplace. In 2000, an Executive Order was issued that prohibits genetic discrimination in the workplace for federal employees. The Health Insurance Portability and Accountability Act also provides some protection from discrimination. However, gaps remained. HIPAA does not:
 - a. Prohibit the use of genetic information as a basis for charging a group more for health insurance.
 - b. Limit the collection of genetic information by insurers and prohibit insurers from requiring an individual to take a genetic test.
 - c. Limit the disclosure of genetic information by insurers.
 - d. Apply to individual health insurers except if covered by the portability provision.
40. For over ten years, the US Congress has considered legislation to ensure comprehensive protection for all Americans. The U.S. Senate passed the Genetic Information Non-discrimination Act in 2003 by a vote of 95-0, but an identical bill was never introduced or passed in the House and the bill did not become law. A similar Senate bill, the "Genetic Information Non-Discrimination Act of 2005", was passed 98-0 in February 2005. Representatives introduced an identical bill on March 10, 2005.

41. The issue was finally resolved when The Genetic Non-discrimination Act of 2007 (GINA) was passed in the U.S. House of Representatives, and voted in by the Senate in 2008. It should be noted though that the Act only applies to health insurance (not life, or Critical Illness)

2. Australia

42. Australian health policies are set by the federal government which contributes about two thirds of the public hospital budget; the remaining third comes from the individual states and territories, which also administer health care provision in their health departments. Medicare Australia covers the costs of individual, publicly-provided health care. Private patients, who are often funded by health insurance, receive about 75% from Medicare for their health care costs, but they benefit from greater choice of the treating doctor. About 9.8% of Australian gross domestic product covers the total expenditure on health, both public and private.
43. Since 2000 the Institute of Actuaries of Australia has analysed data on the genetic tests reported to insurers in applications for life and health insurance (and also income protection and total permanent disability policies) initially every 6 months, latterly 12-monthly. The data are collected and collated by the Investment and Financial Services Association (IFSA) which has roughly the same roles as the Association of British Insurers. The data show, for example, that in the 12 month period to 30 November 2005 there were 387 genetic tests reported to insurers out of a total of 388,438 policy applications. These data came from 21 direct life insurers and 6 reinsurers, there being care taken to avoid double reporting.
44. The joint inquiry into the protection of human genetic information by the Australian Law Reform Commission and the AHEC ('the inquiry') commenced in February 2001. The terms of reference, with respect to human genetic information and the samples from which such information may be derived, were how best to:
 - a. protect privacy,
 - b. protect against unfair discrimination, and
 - c. ensure the highest ethical standards in research and practice.

45. The release in November 2001 of the inquiry's Issues Paper, *Protection of Human Genetic Information*, signalled the start of extensive national consultations. The final report--*Essentially Yours: the Protection of Human Genetic Information in Australia*, was tabled in federal Parliament in May 2003. The report covered an extensive range of activities in which genetic information currently plays (or potentially may play) an important role--including risk-rated, mutual insurance. The two-volume, 1200 page report made 144 recommendations about how Australia should deal with the ethical, legal and social implications of the 'New Genetics'.
46. The Report made a range of recommendations that were directed toward ensuring that the use of genetic information in insurance was fair and transparent, and that insurers kept to the terms of the exemption granted to them by anti-discrimination laws. Unlike in the UK, they did not recommend any moratorium on the use of genetic data. While the issue was raised in debate, there was no appetite in the Law Commission for such an approach.
47. That said, the Report did recommend an amendment to the *Insurance Contracts Act 1984* to clarify the nature of the obligation of an insurer to provide written reasons for an unfavourable underwriting decision upon the request of an applicant. Where such a decision is based on genetic information, including family medical history, the insurer should be required to give reasons that are clear and meaningful and that explain the actuarial, statistical or other basis for the decision.
48. One of the key recommendations in the Australian Government's 2005 report (which responded to the 2003 Commission Report) was that a statutory body be established to provide advice to Australian governments about current and emerging issues in human genetics. The Government agreed and has provided new funding of \$7.6 million over four years from 2005-6 to establish the "Human Genetics Advisory Committee" as the principal committee of the National Health and Medical Research Council. The Committee provides on-going advice to government on high-level technical and strategic issues in human genetics.
49. Crucially the Government took the view that genetic information is a type of information, but it is not a totally new type of information. Rather, it is a more

sophisticated form of information than we have been dealing with for a long time, such as in blood tests, fingerprinting and physical observation of familial characteristics. The Government agreed with the Law Commission report that a separate regulatory regime for genetic information is unnecessary. Instead, it considered that genetic information should remain within the protective framework that the Australian Privacy Act 1988 provides. It agreed that genetic information should be characterised as 'sensitive information' under the Act.

50. The privacy safeguards referred to in the Privacy Act are set out in the 11 Information Privacy Principles (IPPs) and 10 National Privacy Principles (NPPs) which have the force of law. The IPPs cover the collection, storage and security, use, disclosure and access to "personal information" by the Federal public sector, while the NPPs establish how private sector organisations should collect, use, and disclose personal information, maintain data quality and the security of personal information, all within an open and accountable operation. The NPPs provide special provisions for "sensitive information" and "health information", a subset of sensitive information. For example NPP 1.5 provides that if an organisation collects personal information about an individual from another individual, reasonable steps must be taken to ensure that the person is or has been made aware of the collection.
51. However, the Government acknowledged that additional legislative protection may be required to ensure appropriate safeguards in the uses that may be made of genetic information. But the fundamental concept that the Privacy Act does not prevent a person consenting to disclosures or uses of their personal information remains. This means that an individual may consent to his or her own genetic information being used for valuable research. The Government also agreed that in the area of discrimination, any potential misuses of genetic information should be dealt with within the existing context
52. Finally, since about 2001 there has been a 'Genetic Discrimination' project in Australia coordinated by a team at Melbourne University, with input from genetic counsellors, geneticists and some (selected) patients. Reports are now coming out and suggest that, despite the safeguards, the use of genetic data is causing insurers to restrict cover for some individuals; however the extent is small in comparison to the overall volume of insurance. These issues are

currently being debated by the media in Australia and are being considered by the Human Genetics Advisory Commission (of Australia) and also by the Australian Law Reform Commission. It is unclear whether this will result in Australia changing its position.

3. Ireland

53. Ireland used to have a similar position to the UK on genetic tests and insurance. It was covered by a Code of Practice issued by the Irish Insurance Federation (IIF). Under the Code, insurers were allowed to seek the results of any prior genetic tests taken by a person if the value of the life assurance policy exceeded 381,000 Euros. In the case of critical illness and income protection, insurers could seek the results of any genetic tests taken, regardless of the policy value.
54. Only the tests approved by the Genetics and Insurance Committee (GAIC) in the UK could be used in the underwriting process ie for Huntington's disease when underwriting life insurance.
55. A revised Disability Bill was published towards the end of 2004 and became law in mid-2005. Under the provisions of Part 4 of the Act (which came into effect on 31st December 2005) an insurer cannot request, take into account, or process the results of genetic tests. **This applies to both positive and negative tests** and is an exception to the normal duty of full disclosure of material facts which applies to insurance applications. However this exception does not change the legal obligation of applicants for life assurance to provide the insurer with full details of any symptoms experienced, non-genetic laboratory tests or investigations (the IIF have defined these for their Government), treatment and family history (although access to family information could also become regulated by the legislation at some point in the future – the Act contains regulation making powers which have not yet been used).
56. The IIF Code of Practice ceased to have effect when the legislation came into force.

PART FOUR – RECOMMENDATIONS:

57. **Our recommendations flow from the interviews we carried out with key stakeholders, desk research and the recommendations in the House of Lords Select Committee Report.**

RECOMMENDATION ONE:

58. **The moratorium and concordat applying to genetics and insurance in the UK should be continued for life, critical illness, income protection and long-term care insurance.**

RECOMMENDATION TWO:

59. **The ethical case for genetic exclusivity for multi-factorial conditions should be re-examined by an expert group, possibly set up by the HGC or the UKFGI.** Since all parties have appreciated the low additional risk of disease attributable to genetic associations, it is suggested that the use of genetic data from genome wide association studies is not used for underwriting for a period of 10 years unless insurers are able to make a convincing case otherwise to the HGC. The situation regarding the future impact of high throughput individual whole genome sequencing is less clear. Extensive testing may reveal new issues to be addressed and we recommend that developments in this area are closely monitored.

RECOMMENDATION THREE:

60. **The ‘test now, buy later’ issue should be resolved. Actuarial modelling should take place to establish the numbers of people who could benefit from it and for how long.** The aim is to build a model to predict the changes in the numbers of 'test now, buy later'(TNBL) subjects over time towards the expected equilibrium. Then it will be possible to assess the impact of the equilibrium numbers on potential insurance premiums and costs, as well as what happens before equilibrium is reached. We estimate there will be a gradual increase in the number of people with protected rights and then stabilisation when the numbers participating are balanced by those whose status (either definitely affected or unaffected) would preclude them from

buying this type of insurance contract. If these data were available, it could help the industry develop products which are part of a longer term solution.

RECOMMENDATION FOUR:

61. **The level of the thresholds above which genetic test results need to be reported to the insurer should be indexed regularly, keeping them relevant to the real needs of UK families.**

RECOMMENDATION FIVE:

62. **The practicality of developing a specialised insurance market for those at risk of relatively rare single gene disorders such as Huntington’s Disease (and perhaps the single gene forms of Alzheimer’s disease and breast cancer) in the event of an end to the moratorium, should be considered.** Because these conditions are rare, it should be possible to design a subsidised form of insurance provision for the families which reduces their risk of slipping into poverty. Work on this aspect could be taken forward, based on existing models of insurance for special insurance groups and could consider pooling arrangements between insurers and re-insurers. This would tie in with the work on the ‘test now buy later’ issue and achieving a longer term solution. A specialist insurance arrangement has been raised before – see **Annexe five for a proposal made by UKFGI member Nicholas Pawson in 2002.**

RECOMMENDATION SIX:

63. **Monitoring of the industry’s adherence to the ABI Code of Practice and the continuing moratorium requires a replacement for the now disbanded Genetics and Insurance Committee. We recommend that the HGC takes this on.** The UKFGI’s role is to spread research findings between different stakeholder groupings and encourage rational dialogue between them. This can include seeking evidence from patient organisations, clinical genetic services, public health practitioners and the insurance industry.

RECOMMENDATION SEVEN

64. **Consideration should be given to examining the impact of the moratorium on insurance buying behaviour and evidence of “adverse selection” if**

any, although this has been tried in the past without any compelling findings.

RECOMMENDATION EIGHT

- 65. All stakeholders should coordinate their efforts to carry out relevant research which explores the evidence for future risk assessments, based on family history, genetic testing and other biomarkers etc. Specifically, such research should attempt to record population risks accurately (and the practical reality of doing so), so that public health can be delivered more effectively and targeted to higher risk groups.** This is not an insurance specific recommendation. It relates to the wider risk assessment agenda.

RECOMMENDATION NINE

- 66. The UKFGI should undertake to organise open multidisciplinary meetings on genetics and insurance which report new research data, disseminate best clinical genetic and underwriting practices and publicise the moratorium and concordat - possibly in partnership with other organisations such as The Centre for the Study of Financial Innovation.**

KEY REFERENCES:

ABI (1999) **Genetics Code of Practice**, 1999 Edition, Association of British Insurers

ABI (2008a) **Code of Practice for Genetic Tests**, June, 2008, *ibid*

ABI (2005) **Genetics Information for Consumers**, *ibid*.

ABI (2008b) Guidance Notes on '**Non-disclosure and treating customers fairly**'.
ibid

Australian Law Reform Commission (2003). '**Essentially yours, the protection of human genetic information in Australia**'.

Australian Government **response to ALRC report**, (2005) accessed at:

<http://www.alrc.gov.au/inquiries/title/alrc96/agd.htm>

Butterworth A, Pharoah P, (2007) '**Family History as a risk factor for common, complex disease**: An independent epidemiological assessment of the evidence 'for familial risk of disease' Public Health Genetics Unit, Cambridge Genetics Knowledge Park.

Department of Health (2003) **Our inheritance, our future** - realising the potential of genetics in the NHS. Genetics White Paper

Ewald F, McGleenan T, Weising U. (eds) (1999) '**Genetics and Insurance**'

ISBN [0-387-91595-8](#)

Genetics and Insurance Committee (GAIC) minutes 2005- 2007 Accessed at:

http://www.dh.gov.uk/ab/GAIC/DH_087663

Godard B, Raeburn S, Pembrey M, Bobrow M, Farndon P and Aymé S. (2003)

Genetic information and testing in insurance and employment: technical, social and ethical issues European Journal of Human Genetics (2003) **11**, Suppl 2, S123–S142.

HM Government and Association of British Insurers, (2005) '**Concordat and Moratorium on Genetics and Insurance**' ABI, March 2005

Human Genetics Commission (2000) 'Whose Hands on Your Genes' Accessed at:

http://www.hgc.gov.uk/UploadDocs/DocPub/Document/business_consultations2maintext.pdf

Human Genetics Commission (2002) '**Inside Information: Balancing interests in the use of personal genetic data** - Summary document' Accessed at:

<http://www.hgc.gov.uk/client/document.asp?DocId=19>

Irish Insurance Federation (2006) **Annual Report**. Accessed at:

<http://www.iif.ie/Portals/1/Annual%20Report%202009.pdf>

Swiss Re Life and Health (2003) '**Genetics and insurance – a country by country analysis**'. Swiss Reinsurance Company, Zurich

Thomas G (2001) '**Genetics and insurance: an actuarial perspective with a difference**'. Submission to the HGC Consultation accessed at: <http://www.guythomas.org.uk/pdf/HGC27Feb.pdf>

Van Hoyweghen I; Horstman K (2008) '**European Practices of Genetic Information and Insurance: Lessons for the Genetic Information Non discrimination Act**' JAMA.2008; 300: 326-327. <http://jama.ama-assn.org/cgi/content/full/300/3/326>

Western Australia Genetic Health project. (2008) 'The Centre for Genetic Epidemiology and Biostatistics', accessed on 24/09/2009 At: <http://www.genepi.org.au/projects/waghp.html>

ANNEXE 1 – INTERVIEWEES (EXCLUDING OFF THE RECORD CONVERSATIONS)

Nick Kirwan, Assistant Director, Health and Protection, Association of British Insurers (ABI), London

Professor Patrick Morrison, Clinical and Cancer Genetics, South Eastern Health and Social Services Trust, Belfast, Northern Ireland

Dr Rosalind Eeles, Reader in Clinical Cancer Genetics, Royal Marsden NHS Foundation Trust, London

Professor John Burn, Clinical Geneticist and Director, Institute of Genetics, University of Newcastle

Professor Tim Bishop, Director of Genetic Epidemiology Laboratory, Cancer Research Institute, University of Leeds

Professor Angus Macdonald, Director of the Genetics and Insurance Research Centre, Department of Actuarial Mathematics and Statistics, Heriot Watt University, Edinburgh

Professor Ron Zimmern, Executive Director, Public Health Genomics Foundation, University of Cambridge

Professor Jonathan Montgomery, Chair, Human Genetics Commission and Professor of Health Care Law, University of Southampton

Professor Ian Tomlinson, Professor of Molecular and Population Genetics, Wellcome Trust, Oxford

Mr Gil Baldwin, Managing Director, Aviva Health Care, Norwich

Mr Alan Tyler, independent expert on genetics and insurance

Dr Virginia Warren, Assistant Medical Director, BUPA, London

Ms Julie Hopkins, Head of Underwriting and Claims Strategy, Hannover Life Re Insurance, Surrey

Mr Alastair Kent, Director, Genetic Interest Group, London

Professor C Michael Steel, Retired Professor of Medical Science, St Andrew's University

Baroness O'Neill of Bengarve, Chair Nuffield Foundation and Professor of Philosophy, University of Cambridge

Ms Cath Stanley, Head of Care Services, Huntington's Disease Association, Liverpool

Dr Susanne Sorensen, Head of Research, Alzheimer's Society, Devon House, London

Mr Mike Hobday, Head of Campaigns, Policy and Public Affairs, Macmillan Cancer Support

ANNEXE 2 – STRUCTURED INTERVIEW QUESTIONS

GENETICS AND INSURANCE ISSUES IN THE UK:

TOPICS FOR DISCUSSION:

- Past experiences of how people with genetic tests were assessed for insurance purposes.
- The present situation during the ‘moratorium’ – does it need to change? If not should it be made permanent?
- What are the future scenarios (who would be winners and who losers?)
- Genetics as part of the overall public health landscape and drives towards healthy lifestyles – to improve the health of the nation and offer insurance premiums based of lifestyle risk
- How to tackle the UK issues of genetics and insurance
- Are global issues relevant (both insurance and health care availability)
- On which diseases should we focus

INTRODUCTORY QUESTION:

In the past decade discussions of genetics and insurance have been perceived as adversarial issues with patient groups and geneticists on one side and the insurance industry on the other. Do you now consider there can be a collaborative approach, leading to win-win situations in which people at higher genetic risk can access the insurance products they need, genetic researchers and public health teams can gather population data central to their work and insurers can operate in competitive commercial markets for life and related insurance policies, basing their contracts on the degree of risk involved? Or alternatively, do you believe that the current moratorium is all that is required and could be made permanent?

LOOKING BACK:

1. Since the start of the moratorium, how much of your time has been related to this general issue?

2. What insurance products have been most involved?
 - a. Life insurance to cover housing loans
 - b. Other life insurance products
 - c. Critical illness insurance
 - d. Long term care insurance
 - e. Travel insurance
 - f. Health insurance
3. What successes or problems have you identified in this issue since the start of the moratorium?
4. Can you give specific examples of the misuse of genetic information during the moratorium period? Or that the moratorium has done any general harm to insurers or the insured?
 - a. Misuse by patients or their families
 - b. Misuse by insurers
5. When you raise the topic of genetics and insurance with the relatives of a person (with a significant genetic disorder) what do you cover in your discussion?
6. Does your answer differ from the above if the issue covers *term* insurance?
7. Do you have details of anyone who decided not to take a genetic test on account of the potential impact on future (or present) insurance?
8. Do you have details of insurers discriminating against healthy people with specific positive test results?
9. Your examples of justifiable discrimination are:
10. Your examples of unjustifiable discrimination are:
11. What aspect of genetic medicine has been the most relevant (or the most complex)?

WHERE ARE WE NOW?

1. When a person with a relative who has a severe progressive genetic disorder considers taking out a life or health related insurance policy, is there a systematic protocol in your team to manage the different nuances of the issue?
2. Are the present thresholds for allowing insurers to request genetic test information at the correct level?
3. If no please indicate an appropriate level:
 - a. A greater level for the life insurance threshold
 - b. A lower level for the life insurance threshold
 - c. A greater level for the critical illness insurance threshold
 - d. A lower level for the critical illness insurance threshold
 - e. A greater level for the long term care insurance threshold
 - f. A lower level for the long term care insurance threshold
 - g. Other aspects of the threshold issue
4. Are people (who are relatives of a person with a definite single gene disorder) better off in any other countries?
 - a. Which countries
 - b. Why?
5. Do you have any evidence that the situation differs in those parts of the United Kingdom with devolved governments?
 - a. Scotland
 - b. Wales
 - c. Northern Ireland
6. Do you have any information about the situation in Eire?
7. Increasingly, genetic tests are being considered for screening purposes, by means of either a search for specific mutations or a 'whole genome scan' for

higher risk patterns. In which of the following categories do you consider such screening is justified?

- a. Population genetic or public health research
 - b. Assessment prior to appointment to specific jobs (e.g. airline pilots, train drivers, the armed forces, those who work at heights)
 - c. 'On demand' testing as a privately purchased service by those who wish some predictive information.
8. If there were preventive programs that could follow-up the genetic screening process and reduce disease risks would that alter your views?
9. Do you think that critical illness insurance should be available to all?
10. Colorectal cancer (CRC) is prevalent in the UK and some sub-groups of the disease have single gene aetiology. Do you think the insurance issues here need to be clarified? For example, if a healthy person has a first degree relative with a known mutation in one of the genes which causes hereditary non-polyposis colorectal cancer (HNPCC) and the healthy person has a genetic test, positive for the same mutation, should that information be used in assessing the insurance risk?
11. Do you see ways in which clinical genetic services and the underwriting departments of insurers could collaborate to improve risk assessments?
Please list examples:

LOOKING FORWARD:

1. What element of the present moratorium do you most wish to preserve?
2. What element of the present moratorium do you most wish to change?
3. Should there be different arrangements for term life insurance (often regarded as a social good when used as mortgage protection) and other insurances (for example income protection, critical illness, PMI – sometimes regarded as being less of a social good)
4. Are there other good practices which you hope to retain?
5. Are there other practices which you hope to stop?

6. If in the future conventional life and health insurance products did not exist, what options would you suggest to fill any gaps?

OPTIMISTIC FUTURE OUTCOMES:

1. What three major outcomes would you like to see in future insurance products?
2. If risk assessment becomes much more refined as genetic research progresses, how do you think the insurance issue will be:
 - a. for insurers
 - b. for people at increased genetic risk
 - c. for researchers and public health teams

PESSIMISTIC FUTURE OUTCOMES:

1. Insurers have been caught up in the world recession and are under greater pressure than ever to discontinue products which are not profitable. Which of the following scenarios would you most/least wish to occur?
 - a. That insurers choose not to offer policies to individuals who have a family history of a genetic condition.
 - b. That people who have a family history of a genetic condition are offered insurance by the government in a subsidised system (as occurs now for certain members of the armed forces with life insurance).
 - c. That insurance companies amalgamate for most products and the resultant larger firms are controlled by the government.
 - d. That insurance as we know it ceases to be and the life and health protection of individuals and families is based on a central national service provider.

FINAL COMMENTS:

If you were able, without constraint, to dictate on the genetics insurance issue what change would you effect immediately?

ANNEXE THREE – THE HISTORY OF THE UK MORATORIUM

GENETIC TESTS AND INSURANCE – BACKGROUND BRIEFING

1. In principle, actuarial and genetic sciences can be partners in developing a better understanding of disease risk. Population studies have shown some communities and ethnic groups at higher genetic risk. Specific genetic studies can also provide better prediction of the individual disease risk. Combined application of family tree studies, individual mutation testing, epidemiology and actuarial analysis could also inform Health Service planning and help to individualise a person's health care.

2. When considering genetics and insurance, diseases can be thought of in two categories:
 - a. Where a single gene plays a major role in whether or not the individual develops the disease ("single gene disorders"). There are very few of these which affect people only as adults and which are reasonably common. It is these conditions which have attracted the most attention in the debate on genetics and insurance. The most prevalent ones are for HD, breast cancer (BRCA1 or BRCA2) and the group of single gene causes of colorectal cancer. It is important to note that only a small proportion of all cases of breast cancer arise because of BRCA1 and 2. In addition, with most cancers there are opportunities for reduction of the risk to individuals, by preventive measures ranging from lifestyle changes to prophylactic surgery. With Huntington's disease such risk reduction is not possible at present, although the age of onset can now be predicted more precisely by means of analysis of the size of the triplet repeats in the tested individual relative to affected family members.
 - b. Where the interaction of several genes and lifestyle/ environmental factors determine the risk of a disease or how the disease will progress in some population groups. With such "multi-factorial conditions", there are strong grounds for suggesting there is a genetic component (for example several cancers, stroke, and multiple sclerosis). However, neither genome wide association studies nor a

family history of affected first and second degree relatives provide alterations of specific risk data of sufficient magnitude to be taken into account for insurance purposes. Although insurers do use family history information on statistical, not causal, grounds.

WHERE WE ARE NOW

3. There has been a moratorium and concordat agreed between the UK Government and the ABI on the use of predictive genetic test results by insurers in the UK since November 2001. The practical effect has been to defuse the issues of:
 - a. insurers discriminating against people with no clinical symptoms of a disease that they may not get,
 - b. people refusing to take genetic tests when advised to do so by their doctor because of their concerns about the potential impact of the results on their insurability,
 - c. people buying high value insurance policies in the knowledge that they are likely to be able to make a claim and insurers not being able to charge for the level of risk that such individuals bring to the overall risk pool.

4. The moratorium and concordat have been reviewed and extended twice since then but there remain concerns about:
 - a. What happens to people who take a predictive test (with a positive result) during the moratorium and apply for insurance after it ends – known as the “test now buy later problem”.
 - b. The sustainability of the extremely diverse positions in different countries – ranging from outright bans (as in Germany and Ireland), to detailed supervisory controls (as in Australia) to treating genetic tests the same as other clinical data (as in Spain).
 - c. The insurability (especially for life insurance attached to a mortgage) for people with highly predictive positive tests (for example with the breast cancer BRCA1 gene) if the moratorium is ended. As genetic tests become a “normal” part of diagnosis will the special impact on

people with highly predictive tests be lost and their concerns thereby put aside?

5. A driver for ending the moratorium might be future advances in multi-factorial genetic conditions. Specifically, should there be reasonable levels of term life insurance available for such people as the quid pro quo of removal of the moratorium for the multi-factorial conditions. Insurers fear that if genetic tests become relevant for a large section of the population, they will not be able to absorb the extra costs without increasing all premiums significantly – which are, they will argue, not sustainable in a commercial market; they may withdraw from the market or from the moratorium.
6. Insurers may also want to offer better terms to people who have had a genetic test for multi-factorial conditions so long as they make appropriate lifestyle decisions (and worse terms if they come out at worse than average risk). Taking account of lifestyle choices has become more common in protection and health insurance in recent years but the key difference between these and genetic tests is that lifestyle choices are open to all and genetic tests are not – on grounds of clinical evidence, ethics and (for internet bought tests) affordability.

HOW DID WE GET THERE?

The build up to the moratorium in November 2001

7. The House of Commons Select Committee on Science and Technology has looked at genetics and insurance twice. The first time was in 1995 and the second in 2001. In 1995 the Select Committee recommended that the insurance industry be given one year to propose a solution that was acceptable to Parliament and that if it failed to do so a legislative solution should be sought. The Conservative Government of the time did not support legislation and the ABI worked with the then **Human Genetics Advisory Committee** culminating in the ABI Genetic Testing Code of Practice published in 1997 (and revised in 1999). The HGAC's report on 1997 decided that a permanent ban on the use of genetic test results would not be appropriate and they found that "a requirement to disclose results of specific genetic tests as a condition of purchasing a specific type of insurance would only be acceptable when a quantified

association between a given pattern of test results and events actuarially relevant for a specific insurance product has been established". This was, in effect, an affirmation of conventional insurance practice.

8. The new Labour UK Government responded in 1998 by agreeing that using tests should not be banned despite the Labour Party Manifesto to legislate, but they did have concerns about the controls in place on the use of tests by the industry. To address these concerns they set up (in 1999) the Genetics and Insurance Committee (GAIC) to inform Department of Health policy (plus the other two Government departments involved – HM Treasury and the then DTI – Office of Science and Technology). Its key roles were to publish criteria for evaluating genetic tests and to look at industry compliance.
9. In 2000 GAIC published its criteria for the insurers' use of **predictive** genetic tests (over time the debate had homed in on these – rather than diagnostic ones). The criteria (which still stand, albeit in augmented form) were:
 - a. **Technical relevance** – is the test technically reliable? Does it accurately detect the specific changes sought for the named condition?
 - b. **Clinical relevance** – Does a positive test have any implications for the health of an individual?
 - c. **Actuarial relevance** – Do the health implications make any difference to the likelihood of a claim under the proposed insurance product
10. In October 2000 GAIC announced that the genetic test for Huntington's disease was sufficiently reliable to be used for term life insurance. Finally things were getting "real" and the issue started to re-emerge as a major public policy issue. This was compounded by two separate but complementary developments. **First** - in 1999 the Government conducted a comprehensive review of the regulatory and advisory framework for biotechnology. One of the recommendations as to set up a single body to have oversight of this area. Hence the **Human Genetics Commission** (HGC) was born and the HGAC absorbed into it.
11. In November 2000 the HGC launched a discussion document "Whose Hands on Your Genes" which specifically addressed the insurance issue. The public consultation ran until March 2001 and a draft report was due in June 2001 but this was circumvented when they issued interim recommendations in May 2001.

One of the reasons for such an early statement by the HGC was the **second** of the two developments – the House of Commons Science and Technology Committee returned to the issue because of concerns about the GAIC decision on Huntington’s disease. Their new inquiry started in December 2000 and their report was published in March 2001.

12. During its hearings, the Committee took evidence from representatives of three insurance companies (the ABI or its Genetic Advisor were not invited to give evidence). Since each of the three companies gave different positions on whether they would use genetic tests or not and if so at what financial level they would start to take account of test results, this was taken as evidence of the failure of self-regulation
13. The scene was set for a battle which attracted much media interest:
 - a. The March 2001 Science and Technology Committee called for a moratorium on the use of all positive genetic test results by insurers for at least the next two years. During this time more research should be done on the actuarial and scientific relevance of the tests to insurance premiums and for research and healthcare. If a voluntary moratorium was not agreed the government should enforce it through legislation.
 - b. The HGC called for a three year moratorium except that insurers should be allowed to use tests for policies over £500,000 provided the tests were approved by GAIC. They also considered (as did the Committee) that self-regulation had failed and independent enforcement was required.
 - c. The ABI proposed a two year moratorium with a financial limit of £300,000. They also agreed that only GAIC approved tests should be used and companies were instructed to re-assess premiums of cases where the results of other predictive tests had been used

THE UK MORATORIUM – 1 NOVEMBER 2001 ONWARDS:

14. With the backdrop above, the **ABI** engaged in negotiations with:
 - a. **The Department of Health** (the lead department) – which was very concerned that the adverse effects of genetic tests on insurance might deter people from testing, with the loss of the potential health benefits.

- b. **The Treasury** – which had the same concerns but also wished to avoid setting social insurance precedents.
 - c. **The Office of Science and Technology** – which did not want insurance issues to impede scientific advance and research.
15. The ABI itself wanted a good period of stability (but not an open ended commitment). It also wished to end the very bad media coverage of the industry, to preserve the insurers' right to use the tests for high value policies and to ensure that all stakeholders recognised the general principles of commercial insurance.
16. The end result was a five year moratorium on DNA genetic tests such that customers would not be asked to:
- a. undergo a predictive genetic test in order to obtain insurance; re-iterating the previous position,
 - b. disclose another person's predictive genetic test results – another re-iteration,
 - c. disclose any predictive or diagnostic genetic test results acquired as part of clinical research – this was new but in line with GAIC's position on reliability of tests,
 - d. report test results not approved by GAIC,
 - e. report GAIC-approved tests if the policy was for less than £500,000 for life insurance, or £300,000 for critical illness insurance. An ABI survey of companies had demonstrated that over 97% of policies were below these levels. Later, the thresholds for income protection and long term care insurance were set at £30,000 annual benefit.
17. Other results were that:
- a. The ABI was to work with HGC, GAIC, and others to examine methods of improving access to insurance for people at risk of genetic diseases.
 - b. GAIC would monitor and publish data on trends on relevant NHS predictive genetic tests.
 - c. The ABI would publish its compliance reports, with GAIC having the role of checking their accuracy. This has been carried out annually.
 - d. Potentially unlimited fines were possible for companies breaking the moratorium.

- e. The moratorium to be reviewed in three years time – it has now been reviewed and extended twice.
 - f. The ABI would sponsor research into the accuracy of family history information for underwriting – this culminated in a report published by the Public Health Genetics Unit in Cambridge which did confirm their statistical accuracy.
 - g. The ABI would produce a leaflet for consumers explaining the insurance implications of genetic tests for them. This was produced and has been revised since and is available on their web-site.
18. The moratorium successfully brought to a close a very difficult period for the UK insurance industry and bought time for all sides. Over the period leading to this review, GAIC and others including the UK Forum for Genetics and Insurance fostered cross-sector debate. The result was a better understanding of different perspectives and re-building of respect.
19. The UKFGI was inaugurated 10 years ago with the mission of analysing the implications for insurance of advances in genetic knowledge and of serving the public interest by reporting on its findings. The UKFGI is an independent expert group, founded with the support of the Royal Society, the Association of British Insurers, the Faculty and Institute of Actuaries, the British Society of Human Genetics, the Genetic Interest Group, the Nuffield Council on Bioethics and the Wellcome Trust. The UKFGI aims to encourage interdisciplinary discussions about genetic risk, to disseminate knowledge across specialist boundaries and to seek solutions to the differing anxieties of the public, of genetic specialists, of ethicists and of the insurance industry to the dilemmas posed by the implementation of genetic testing and screening and of genomic medicine.
20. The seas were not always calm but the storm had subsided. GAIC re-affirmed its position on Huntington's disease but issued much stricter actuarial conditions for future approvals – and no-one forgot what happened last time it "went real". The ABI has submitted no further applications so the only predictive genetic test that can currently be used is for Huntington's disease and only for life insurance policies over £500,000.

ANNEXE FOUR – THE PRINCIPLES OF COMMERCIAL INSURANCE

A. BACKGROUND

1. Private commercial insurance is a means of converting the potential of individual catastrophic risk into manageable group loss. It is based on the principle of mutuality and is only commercially viable when uncertainty exists. If actuarial fairness were taken to its extreme conclusion and perfect information were available for each person then every individual would precisely fund their own risk. Of course this is not reality, and several long term insurance products have developed in the UK that individuals or groups (typically employers) buy to manage health risk. They include (in simple terms):
 - a. Life insurance that pays out on death or terminal illness
 - b. Critical illness insurance – that pays out if an individual gets one of the illnesses listed in their policy
 - c. Income protection insurance – that pays out if someone is too ill to work
 - d. Long term care insurance – that pays out if someone is admitted to a care home (a very small market in the UK but quite big in the USA, France, Germany and Spain). If the “partnership option” in the Government’s Green Paper on social care published in 2009 were to be implemented the market could become much bigger.
2. There are other health insurance products but these are short term and the implications of genetic information for these **in the UK** are limited. Examples include:
 - a. Private medical insurance – which pays the bills for acute medical treatment. It is because of its limited coverage and the underlying right to NHS treatment that (in the UK) genetics has not been an issue. This is in contrast with the USA and some EU countries.
 - b. Travel insurance – which pays out for medical treatment and repatriation for people on holiday abroad.
 - c. Payment protection insurance – which pays (for a short limited period) the interest on loans or mortgages when someone is too ill to work
3. In commercial mutual insurance, policy holders pay premiums into a mutual fund which is invested and the proceeds are distributed to those who make valid claims. The possibility of submitting a claim varies between individuals.

Insurers seek to determine the risk each proposer brings to the fund by the process of underwriting at the point they apply for a policy. **For long term insurance, this is usually the only opportunity to underwrite. If a person's health status changes later, then the fund bears that risk.** For short-term insurance the situation is different, here the policies are reviewed every year and the opportunity to re-underwrite arises.

4. **The commercial insurance market operates according to the principles of equity not equality.** Individuals pay different premiums depending on how much risk they bring to the fund. High risks pay higher premiums and vice versa. This principle of matching risk to premium is known as actuarial fairness. Social insurance schemes are based on equity. Here individuals pay a flat rate contribution whether they are high or low risk. The benefits of the scheme are then paid out in accordance with need. Such schemes are very common in the EU outside the UK and hybrid schemes exist where some risks can be taken into account and others not. Gender is a good case in point, where some EU countries, including the UK, have taken advantage of the Gender Directive opt out clause which allows them to continue to assess risk based on gender, whereas others, like Belgium, did not – and so can only assess risk on factors other than gender.
5. In theory the private insurance market operates under the following conditions:
 - a. The risk that any one individual claims is independent of the risk that any other individual claims.
 - b. The insured event must not be certain to occur (or the timing must be uncertain).
 - c. The probability of a claim must be open to actuarial estimation.
 - d. The policy holder must not be able to conceal any information from the insurer.
 - e. The applicant for a policy must not be able to manipulate the probability of claiming.
6. In practice, matters are more opaque. In the **UK the Financial Ombudsman Service (FOS), the Financial Services Authority (FSA) and the Association of British Insurers (ABI)** have set precedents or rules that make matters more lenient for policy holders (especially individuals as opposed to group purchases). For example four categories of non-disclosure have been identified

that have different consequences at the point of claim: “**innocent non-disclosure**” (full payout), “**negligent non-disclosure**” (usually partial payout), **clearly reckless non-disclosure** (no payout but premiums are refunded), **fraud** (no payout and no return of premiums).

7. The practical application of insurance and all these principles have also led to four commonly used terms which are particularly relevant to genetics and insurance and which are often referred to:
 - a. **Uberrimae fides (in utmost good faith)**: in effect this means that every material piece of information which is known to the insurance applicant must be passed on to the insurer and failure to do so may mean the policy does not pay at claim stage. In practice FOS and ABI guidelines only allow this to happen if the insurer has clearly asked a question that would cause the applicant to give the required information.
 - b. **Moral hazard**: this is where people behave differently when they have insurance compared to how they would have behaved without it, in such a way as to increase the probability of a claim.
 - c. **Actuarial fairness**: a common response of legislators is to tolerate “fair discrimination” in insurance but with the qualification that any risk classification must be actuarially relevant (this principle underpins all exceptions to anti-discrimination law for insurers in the UK (eg in the Disability Discrimination Act). The extent to which insurers are required to **prove** fair discrimination varies and is at its most extreme for predictive genetic tests (closely followed by gender).
 - d. **Adverse selection**: this can occur when the distribution of risk in a pool of insured people is skewed adversely eg when more high risk people find it worthwhile to take out insurance. The UK insurance industry raised serious concerns about adverse selection if they did not have access to genetic test results.
8. The Genetics and Insurance Research Centre in the Department of Actuarial Mathematics and Statistics, Heriot-Watt University, Edinburgh, has carried out a number of studies to put numerical values on possible genetic adverse selection and its impact. Three factors are important:

- a. The rate of insurance purchase (or insurance market size for any product for any one company) – if the rate is high then the impact of a small number of adverse selectors will be reduced. Stand alone critical illness insurance, for example, is a small market and therefore more exposed to this risk.
- b. The extent to which potential adverse selectors purchase insurance. The impact on families of some genetic conditions, such as Huntington's disease, can often mean less opportunity to be economically active and therefore insurance is less affordable.
- c. The extent to which adverse selectors insure their lives for more than normal amounts. Debate on this point led to the concept of financial limits and (eventually) the moratorium.

B. THE RELEVANCE OF INHERITANCE TO INSURANCE

9. Single gene disorders have limited significance for long term insurance because most of them have their onset in childhood, so if the patient survives to adulthood (and so becomes a potential purchaser of insurance) the disease is already diagnosed rather than a threat to their future health. However the single gene disorders with adult onset are significant although they affect only a very small number of people. Multifactorial conditions such as CHD, being much more common, are potentially much more significant in number but, as explained earlier, there are as yet no known reliable genetic tests in the vast majority of cases for them. In practice, insurers have three potential routes to assess genetic risk:
 - a. **Abbreviated family history information** – such information has been used for many years and the assessment is based on the number of first degree relatives (parents and siblings) who have suffered from a condition that is known to have significant inheritability. Family history (as collected by insurers) does not measure an individual's absolute risk of getting a disease. Rather it represents the chances of an individual getting the disease if he is a member of a pool of those with e.g. two affected relatives. In the health sector, epidemiologists are very familiar with this concept. A difference in understanding and defining risk between professions has been one of the major obstacles

to rational dialogue. A study (carried out at the behest of the Human Genetics Commission by the Public Health Genetics Foundation) assessed the evidence for the use of family history and found it largely justified

- b. **Pedigree or Mendelian analysis** – before the advent of genetic tests this was the only way of measuring an individual's absolute risk of getting one of the highly inheritable conditions. It is still used as a way of deciding whether to advise someone to have a genetic test. Geneticists are very familiar with the concept and express risk in these terms. Insurers do not ask for this information as it is very rarely available and highly intrusive. However one of the few complaints made to the Genetics and Insurance Committee was from a woman who had been rated at a higher premium because of a family history of breast cancer; after discussion she was then given normal rates, based on her family tree and an analysis from her geneticist showing she was at normal population level risk for breast cancer.
- c. **Predictive and diagnostic genetic tests** – it is these (and particularly the predictive ones) that have caused controversy in the UK and beyond and on which our paper concentrates.

ANNEXE FIVE – PROPOSAL FOR A CENTRAL INSURANCE BUREAU
DEVELOPED BY UKFGI MEMBER NICHOLAS PAWSON IN 2002

A. BACKGROUND

1. This note describes a proposal to assist those who have genetically inherited disorders that have been confirmed by genetic tests. This proposal is not relevant to those who already have symptoms of these disorders.
2. Because of its rigorous approach to underwriting and risk assessment, the UK Life Insurance Industry offers probably the most competitive rates in Europe. It is important that this position is not undermined by an inadequate response to the challenge produced by the knowledge of genetic test results.
3. Mistakes by the Life Insurance industry at this stage could lead to either seriously increased premium rates or an exodus of business from the UK to new subsidiaries set up by well known UK and Overseas Life companies. These subsidiaries would make full use of the Internet and be set up in offshore locations such as Bermuda with few restrictions on the use of genetic tests. They would insure the "genetically unscathed" lives and it must be remembered that it is those lives that are currently subsidising those with less fortunate genetic characteristics.
4. At present the Life Insurance Industry has agreed that applicants for life and various forms of health insurance for sums insured under £300,000/500,000 need not disclose genetic test results except those for the few tests that have been approved by GAIC. This **moratorium** is to be reviewed after 3 years and is scheduled to last for 5 years.
5. To aid readability, this proposal refers to mortality. This should be taken to mean mortality/morbidity/incidence of a trigger event as appropriate for the type of insurance being considered. Similarly "he" should be treated as meaning "he/she" etc as appropriate.

B. EXAMPLES OF THE CURRENT POSITION - MATHEMATICS

6. There are many genetic disorders where an individual, because of his family history, has a known chance (often 50%) of inheriting that disorder. Until it manifests itself, it is not known whether or not that individual has actually inherited the genetic disorder. The individual's children are in a similar position (though if the "at risk" parent is tested and found not to have the genetic disorder, then all the children should be free of that same disorder.)
7. If one assumes that a "fair premium" for a person with a particular genetic disorder was 5 times the normal rate (ie + 400% extra mortality) and that, based on the analysis of family history, an individual had a 50% chance of having the gene, then he would be charged an extra premium of + 200%. (This assumes that this individual has no other "adverse" disclosures on his proposal form and medical reports.)
8. If the above individual had a genetic test and was found not to have the gene then he would be able to buy insurance at normal rates (subject to the normal requirements of medical underwriting).
9. If the above individual had a genetic test and was found to have the relevant gene then, in the absence of the moratorium, he would have been offered insurance at an extra premium of +400%. With the moratorium in place, he would not have to disclose the results of his test and so would be offered insurance at the "normal" extra premium of +200%.
10. It should be noted that if the "fair premium" had been +900%, then, on the same basis, somebody with a 50% chance of having the gene would attract an extra premium of + 450%. Since insurance companies normally decline to take on cases with a higher than +400% extra mortality, that individual would not normally be offered insurance. However if this individual had a genetic test and was found not to have the gene then he would be able to buy insurance at normal rates (subject to the normal requirements of medical underwriting).

11. It should be noted that if the "fair premium" had been +700%, then, on the same basis, somebody with a 50% chance of having the gene would attract an extra premium of + 350%. If the above individual had a genetic test and was found to have the gene then, in the absence of the moratorium, he would not have been offered insurance as the calculated extra premium was +700% and this is higher than the +400% (self-imposed) limit. With the moratorium in place, he would not have to disclose the results of his test and so would be offered insurance at the "normal" extra premium of +350%.

12. A table of the above is as follows. This is drawn up on the basis that the individual has a 50% chance of inheriting the disorder.

	Case 1	Case 2	Case 3
Extra Mortality	+400 %	+900%	+700%
Extra Premium with no test	+200 %	+450% so declined	+350%
Extra Premium if test positive	+400 %	+900% so declined	+700% so declined
Extra Premium if test negative	+0%	+0%	+0%

C. EXAMPLES OF THE CURRENT POSITION - FAIRNESS

13. During the moratorium, it is possible that individuals who know that they have genetic disorders will take advantage of the fact that they do not have to disclose this knowledge to insurers. They will therefore buy insurance products at prices that are less than the expected costs of their delivery. This cost will cause all rates to be increased and so will be shared by the other purchasers of those products

14. This status quo has various disadvantages:

- a. Nobody knows the cost nor the effect of this inside information
- b. Individuals can take out policies via different offices and so avoid moratorium limits
- c. No central collection of this data is possible as the affected individuals are unknown to the insurance companies

- d. A climate of mistrust of insurance companies may develop
- e. It encourages companies to set up overseas subsidiaries that would offer business formerly written in the UK

D. PROPOSED SOLUTION

15. A Company, the Central Insurance Bureau "**CIB**", should be set up in the UK. It would be a company limited by guarantee and its members would meet its costs. It should become a statutory requirement that only members of the CIB would be authorised to write life and health insurance within the UK. This company would write the policies of individuals who would normally have been insured if they had not taken a positive genetic test. There would be limits on the total amounts that can be insured for any one individual.

16. This mirrors the situation of the Motor Insurers' Bureau "**MIB**" that was set up by some insurers in 1946. In 1960 it became a statutory requirement that only members of the MIB were authorised to write compulsory motor insurance in the UK. The MIB:

- a. Satisfies judgements in respect of any liability required to be covered by contracts of insurance or security under the Road Traffic Acts 1972 and 1988 (in respect of uninsured drivers)
- b. Makes awards to persons injured or dependants/relatives of persons killed as a result of the use of a motor vehicle on a road, in cases where the owner or driver of the vehicle cannot be traced.

D. COSTS

17. The MIB's costs are met by a levy on its members that is direct debited monthly and is calculated on a basis pro-rata to the compulsory motor insurance premiums received by its members. Formulae are used to determine the compulsory element of any premiums that include voluntary cover. This means that the extra cost of fire, theft and comprehensive (ie excluding third party) covers are ignored for this purpose. The current cost is about £30 a policy and the total cost is currently of the order of £250 million a year.

18. The costs of CIB would be met in the same way. However, CIB should aim to be fully funded from the beginning. This means that at the end of each year, there should be a full actuarial valuation to calculate the size of the fund needed to support all the policies in existence. This valuation should use mortality rates appropriate to the lives insured and so take into account the extra mortality risks that flow from the genetic characteristics of those lives.
19. CIB should be fully funded as this enables the proper cost of the CIB to be known each year. If this cost becomes too large and it is suggested that a levy of over 5% of appropriate premiums should be the threshold, then it would be necessary to look at the policies being issued and to perhaps reduce the maximum sums insured for future policies. This would cause the maximum sum insured to be a function of the cost of and degree of adverse selection experienced.
20. It is hoped that advances in medicine and a central database of those with genetic disorders will in time lead to faster and more appropriate treatment and hence to improved life expectancy and quality of life. It is also likely that more genetic tests will be developed and that therefore the number of individuals with known genetic impairments will increase. However this knowledge could lead to changes in behaviour /treatment and therefore contribute to the greater longevity of those affected and hence of the average population.
21. However it is appreciated that any individual who knows that he has genetic disorders will be able to exercise adverse selection by taking out a policy with the CIB and so benefit financially at the expense of other policyholders. This proposal makes all policyholders and insurers suffer this extra cost in a fair and equitable way.

E. UNDERWRITING POLICY

22. This part of the suggestion can be altered without affecting the advantages of this solution in general.

23. CIB should set up an Underwriting Panel. Life actuaries would staff this and a representative of the Department of Health could attend its meetings. This panel would be responsible for:

- a. Determining the insurance policies that would be written by CIB
- b. The underwriting rate book - this would be determined only by family history and non-genetic medical criteria. The objective is that the rates charged should be an average of those charged by competent UK underwriters that are not attempting to build market share by underpricing their products.
- c. What family histories and non-genetic medical criteria are such that proposals should be declined.

24. Administration would probably be subcontracted (at a fair fee) to other Life Company(ies). This would reduce the start-up costs and make use of the knowledge and expertise that already exists in a cost-effective manner.

F. ADVANTAGES OF THIS SOLUTION

25. For the majority of individuals (ie those who do not want policies above the thresholds), the insurance disadvantage of having a genetic test is removed. The moratorium could therefore be ended.

26. The administrative costs of this solution should be low. Only one company has any serious administration. No data for reinsurance pools needs to be kept and exchanged.

27. The cost is known easily and annually. No UK insurer can opt out, benefit or suffer at the expense of any of its competitors. There is great transparency in both the costs and the underwriting process.
28. Individuals will not be able to avoid moratorium policy limits by taking out policies via different offices. In addition, data on average sums insured will give information on the degree of adverse selection that is being carried out by individuals with particular genetic characteristics.
29. CIB will hopefully encourage more individuals to be involved in genetic research. This should increase the likelihood of cures and higher quality lives for those with what are currently considered to be genetic impairments.
30. CIB will have all the data about insureds who have genetic disorders and who have had at least one genetic test. In many cases, this will provide valid statistical data to evaluate the actual insurance and other risks involved.
31. With permission, it will be possible to use the data to help determine the efficacy of particular treatments. In addition a link to the Wellcome study should be explored
32. The UK would be able to remain a force in the science of genetics. The individuals, the medical profession and the insurance companies will all be pulling together to use and analyse the data collected to produce effective cures and solutions.
33. It would be possible to use CIB's website as a pointer to other websites that could bring together those with similar genetic characteristics. They would then be able to receive greater support and communication.