

# ***Genes direct: Ensuring the effective oversight of genetic tests supplied directly to the public***

***(A report by the Human Genetics Commission, March 2003)***

**SUMMARY:** Below is a five-page summary of the UK Human Genetics Commission's document: *Genes Direct*. The purpose of this report was to carry out a review of current available direct-to-the-public genetic testing services and advise the government on how best to regulate these services. This summary is arranged in a *question and answer* format to make it easier to access the information you are specifically looking for. To view the whole 78 page document click here:

[http://www.hgc.gov.uk/genesdirect/genesdirect\\_full.pdf](http://www.hgc.gov.uk/genesdirect/genesdirect_full.pdf)

The Human Genetics Commission was established in 1999 as an advisory body to the UK government on issues concerning new genetics technologies. The HGC believes that *some* oversight is necessary in the regulation of direct-to-consumer genetic tests, but emphasises that the individual's "right to know" information about oneself must not be infringed upon. This summary includes definitions of genetic testing, information about current legislation and important social, ethical and cultural issues to consider regarding genetic testing.

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## **1. INTRODUCTION**

The purpose of this report was to conduct a review of current genetic testing services supplied direct to the public, and thereby make recommendations to Ministers on if, and how, those services should be regulated. The HGC did this by setting up a Working Group in early 2002, and this report is the outcome of a year of close examination of the social and ethical issues associated with new genetic testing services. HGC concluded that *some* effective oversight is needed to ensure consumers have adequate advice and guidance, and to prevent misuse of an exciting, new technology. One of the major issues considered was how to balance individuals' right to know information about themselves, whilst protecting vulnerable individuals from inappropriate testing, exploitation and discrimination.

## 2. ABOUT THE HUMAN GENETICS COMMISSION (HGC)

Established in December 1999, the HGC is the UK Government's advisory body on how new developments in human genetics will impact people and health care. They aim to provide advice that will inform Ministers' decisions on the broad social and ethical issues related to human genetics, and to ensure an open and transparent public dialogue on these issues. To find out more about the HGC visit <http://www.hgc.gov.uk/>.

## 3. DEFINITIONS OF GENETIC TESTING

For the purposes of this document, the HGC defines *direct* genetic testing as:

- “Any test to detect differences in DNA, genes or a chromosome that is not provided as part of a medical consultation” (p.7).

And genetic testing in general as:

- “A test to detect the presence or absence of, or change in, a particular gene or chromosome, including an indirect test for a gene product or other specific metabolite that is primarily indicative of a specific genetic change” (p.21).

## 4. WHAT ARE THE CURRENT LAWS/LEGISLATION AROUND GENETIC TESTING?

- In April 2003 a new over-arching body, known as the **Council for the Regulation of Health Care Professionals**, was established by the NHS Reform and Health Care Professions Act 2002, to oversee aspects of professional self-regulation.
- The **1997 ACGT Code of Practice** outlines the legal requirements for consent and storage of DNA or tissue, but the legal basis underpinning these requirements is constantly changing.
- The 1997 Code states that direct genetic testing services should not be supplied to those under the age of 16, and parents or guardians should consult their GP or medical practitioner for referral to a specialist before doing so.
- The HGC is currently awaiting the government's response regarding legislation protecting individuals from genetic discrimination and stigmatisation.
- The MDA is not responsible for approving medical devices. This is the responsibility of approved '**Notified Bodies**' in the UK and other EU countries.
- The Secretary of State has power to restrict availability of medical devices for public health reasons.
- The Department of Health's **Genetics Commissioning Advisory group (GenCAG)** was formed in 2001 to ensure that appropriate services are available in the NHS. A new sub-group of GenCAG – the **UK Genetic Testing Network (UK GTN)** has been set up to advise on the implementation of the UK genetic testing network.

## **5. WHAT GENETIC TESTING SERVICES ARE CURRENTLY AVAILABLE AND HOW RELIABLE ARE THEY?**

- In 1996, 200 labs provided 175,000 genetic tests for over 300 diseases or conditions in the USA, and these figures are growing rapidly. The big companies offering genetic testing services are **Myriad Genetics** (tests for susceptibility to breast cancer) and **Sciona**.
- Several important scientific reviews concluded that there was “little or no direct health benefit associated with screening for variations in some of the common genes” (p.18).
- Genes are poor predictors of complex diseases and there is still considerable uncertainty about the role of genes and the environment in the progression of common complex diseases.
- Carrying a faulty gene may only present a risk of developing a condition in 30-60% of patients.

## **6. WHAT ARE THE RISKS AND CONSEQUENCES TO CONSIDER BEFORE GETTING A GENETIC TEST?**

- The HGC recommends that all consumers need to **embrace a healthy degree of scepticism** regarding genetic testing: “if it sounds too good to be true, it probably is!” (OFT slogan).
- Although the results are still unclear, many studies have indicated the possibility that positive (abnormal) or negative (normal) genetic test results may engender a sense of **fatalism** or **invulnerability**.
- **Informed Consent**: make sure you know the researcher’s or doctor’s agenda and all the possible implications for you AND your family.
- The **rights of children** and embryos: as a parent/guardian it is important to consider the implications for your child of having this genetic information circulating in society.
- **Counselling** is seen as essential for serious disorders.
- The Nuffield Council on Bioethics has expressed concern over the increased **medicalisation of personality traits** by pharmaceutical companies in order to sell more drugs.
- **Confidentiality**: Do you want your genetic test results to appear on your medical record; do you have a choice? The results could be viewed by potential insurers and employers, and without laws in place to protect you this could potentially lead to discrimination.
- Will your test results be used for **direct-marketing** of medicines, supplements or vitamins?
- Be aware that commercial companies might **over-simplify** the complex process and overstate the evidence.

## **7. HOW MUCH POWER SHOULD THE STATE HAVE TO REGULATE THE AVAILABILITY AND MARKETING OF GENETIC TESTING SERVICES?**

*“A balance must be sought between respecting that individuals are entitled to health information about themselves and protecting vulnerable individuals from inappropriate testing” (p.12).*

- Because a considerable **financial burden** could be placed on the NHS in terms of resources and labs needed for genetic testing services, government input is important.
- The main argument against regulation in focus groups was that preventing someone from obtaining knowledge about themselves infringes their **right of autonomy**. An important value in our society is that we have the right to make decisions about our personal lives, and that this

power to decide should only be restricted when our decisions **might adversely affect the interest of others.**

*“The fact that the consumer might be willing to purchase a product and may regard the purchase as an exercise of individual self-determination is not sufficient to outweigh the need to protect individuals from self-harm. In particular, the need to protect vulnerable persons from harm is a strong factor at work here” (p.48).*

- Some individuals and organisations argued that “rapid advances in our knowledge of genetics, and the understandable public interest in advances, could be misused as a powerful marketing tool by unscrupulous companies in support of misleading claims” (p.49). It was felt that the government is responsible from protecting individuals from such manipulation.

## **8. WHAT RECOMMENDATIONS HAS THE HGC MADE TO THE GOVERNMENT REGARDING THE REGULATION OF DIRECT-TO-CONSUMER GENETIC TESTING?**

*“We feel strongly that there should be a well-funded NHS genetics service supported by a genetically literate primary care work force, which can properly manage and allow access to new predictive genetic tests that are being developed” (p.53).*

- The HGC does *not* believe in banning direct access to genetic tests, but sees the need for some effective oversight.
- The HGC supports most genetic tests as long as they are ‘prescription only’ or part of a consultation with a registered medical practitioner.
- Genetic tests for behavioural traits should be subject to strict regulation.
- The best way of protecting the public is through a combination of legal controls on the sale of tests and professional self-regulation of those who might supply the tests.
- Commercial companies *must* be subject to appropriate regulatory oversight, and if they want to sell a self-testing kit, they must convince a regulator that it is safe and meets appropriate standards.
- HGC believes every person has a right to obtain information about oneself, and the **government should only be involved if there is risk of harm**, particularly regarding children and the elderly.
- Non-consensual testing of children or adults should be made a criminal offence.
- Genetic tests and results should be of a high **quality**.
- Consumer support such as **follow-up counselling** should be offered with all genetic testing services.
- The government must **prevent the misuse of power** of modern genetics and profits must not be allowed to overrule the best interests of patients.
- There should be strict controls, but *access* should not be difficult.
- **Training and expertise** for ALL healthcare providers must be improved to an excellent standard.
- There is a need to ensure responsible **advertising** as:
  - Lack of scientific validity in ads could lead to unnecessary expense or worry.
  - Advertising Standards Authority should act as regulators.
  - *“Advertisements should be legal, decent, honest and truthful and prepared with a sense of responsibility to consumers and society” (p.32).*

- The HGC recommends the development of a **Medicines and Healthcare Products Regulatory Agency (MHRA)** and a **Human Tissue Authority** that will provide statutory regulation in the areas of consent, storage and disposal of most types of human tissue.
- Regulations need to be flexible to adapt to changes.

*“We believe that funding should be made available to an independent consumer body in order to prepare specific and impartial information on any direct genetic testing services that are being marketed” (p. 60).*

## **9. WHAT REGULATORY APPROACHES HAVE OTHER COUNTRIES TAKEN?**

### **AUSTRALIA:**

- A major review of the law relating to human genetic samples and information is currently under way by The Australian Law Reform Commission (ALRC).

### **CANADA:**

- Genetic tests marketed as a ‘kit’ must be approved by Health Canada.
- Direct to consumer advertising for prescription medications and professional services are prohibited, but still penetrate the market via US broadcast media and the Internet.

### **GERMANY:**

- Still debating the issues, particularly regarding consent. No firm conclusions reached yet.

### **JAPAN:**

- Voluntary guidelines only. Because they are not enforceable, they are often ignored.

### **NETHERLANDS:**

- Completely reject regulation, pro - “user’s right of self-determination”

### **USA:**

- The FDA is involved in the regulation of genetic tests.
- Kits must have pre-market approval by the FDA.
- ‘Home Brew’ tests are illegal but there are loopholes in the system which cause problems.
- Controlling the sale of genetic tests via the Internet poses a huge problem.
- Quality standards have been established.

## **10. WHAT OTHER RESOURCES WERE MENTIONED IN THIS REPORT, WHICH MIGHT BE USEFUL FOR FINDING OUT MORE ABOUT GENETIC TESTING?**

**GeneWatch UK** (ethics and risks of genetic engineering):

<http://www.genewatch.org/>

**Christian Medical Fellowship** (uniting Christian doctors and pursuing highest ethical standards):

<http://www.cmf.org.uk/>

**Nuffield Council on Bioethics** (identify, examine and report on the ethical questions raised by recent advances in biological and medical research):

<http://www.nuffieldbioethics.org/home/>