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# Why Should I be Concerned About Human Genetics?

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Nowadays, whether it is cloning animals, or the latest gene linked to disease, human genetics is always in the news. Genetics has become a central strand in medical research, and huge international projects, such as the Human Genome Project are said to promise a medical revolution through which we will all live longer and healthier lives. Governments and industry have invested massively in genetic research, believing it will be a key driver of economic growth in the future.

Human Genetics Alert (HGA) believes that this some of this research will bring medical benefits. However, it often seems that scientific and commercial developments are rushing ahead faster than our ability to deal with their ethical and social consequences. This briefing paper examines some of the key issues raised by human genetics, and outlines HGA's responses.

## What are they doing it for?

Amongst the promised benefits of human genetics research are:

- Better understanding of disease, leading to better drugs: by understanding which genes are involved in diseases, it may be possible, for example, to distinguish between different mechanisms which lead to the same disease symptoms. Identifying the key molecules involved in disease may allow scientists to design drugs that work better.
- Personalised preventive medicine, based on prediction of our genetic susceptibility to disease: it may be possible to build up a 'genetic profile' for each individual, detailing which diseases they are most likely to get, so that they may take preventive measures, such as lifestyle changes or drugs to avoid them.
- Gene therapy: in some cases it may be possible to directly 'fix' genes that are responsible for disease, by introducing correctly functioning versions of those genes directly into the relevant organs.
- Pharmacogenetic drug prescription tailored to our individual genetic profiles: there are genetic differences between people that may determine whether we respond well to certain drugs or if they will have dangerous side-effects. By testing these genes, doctors may be able to prescribe the right drug for the patient first time and avoid side effects.

### Some principles

- *Genetic research should be driven by genuine need, not commercial imperatives or social and cultural prejudices*
- *Genetic technologies must not exacerbate existing social inequalities, or create new ones*
- *Social problems should not be subjected to 'genetic fixes'*
- *People must not be seen simply as determined by their genes*
- *The public must be able to democratically control human genetics*

## Will it work?

Genetics has already led to medical benefits, but it is very uncertain whether it can live up to the hype which currently surrounds it. For example, after more than a decade of research into gene therapy, we are only now beginning to see a few small successes. Research on

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working out the molecular basis of disease, and on pharmacogenetics is still at a very early stage, while new drugs arising from the Human Genome Project are at least ten years away. Both companies and academic scientists sometimes exaggerate their success in order to gain more funding, and the media, which likes to report 'break-throughs', often does the same.

### Genetic determinism

A more fundamental problem is the complexity of disease. Although there are relatively rare genetic diseases that are due to mutations in a single gene, in most cases, our susceptibility to disease is determined by a complex mix of multiple genes interacting with the environment. Unfortunately, both scientists and the media often fall into the 'genetic determinist' trap of simplistically over-emphasising genetic causes. It is very possible that the complexity of genetics and environmental factors will frustrate attempts at accurate and reliable prediction of whether someone will suffer from a particular disease. This uncertainty may also mean that scenarios of genetic discrimination and eugenics (see box, 'What is eugenics?') are exaggerated, since they may not be technically feasible.

Not only is genetic determinism bad science, but it may result in a downgrading of research into social and environmental causes of disease which, in most cases, play a larger role than genes. Traditional public health approaches aim to improve environmental and social conditions for everyone, but the genetic approach of focusing on people with high susceptibility may give the false impression that others need not be concerned about their lifestyle and diet, and that society need not worry, for example, about income differences that are a major cause of ill health.

An example of such 'technical fix' strategies is the possibility that people identified to have high genetic susceptibility will be prescribed preventive drugs for their whole life. While this might benefit them, this strategy would make healthy people dependent on drugs, and seems to be primarily designed to make money for drug companies.

A related concern is that hi-tech genetics will be much too expensive for Third World countries, where the majority of the world's disease burden is to be found. Drug companies already focus almost exclusively on the markets of industrialised countries.

***HGA advocates a review of medical research funding, and a re-direction of funds towards addressing social and environmental causes of disease.***

## The ethics of medical genetic testing

The genetic testing of people for susceptibility to disease is a key promise of genetic medicine. This may be useful where there are clear medical interventions or changes of lifestyle and diet that could be made in response to test results. Where there are no treatments available, and the only benefit is knowing what may happen in the future, most people prefer not to know, and their right to make this choice must be respected. Children should not be forced to take genetic tests by their parents, unless there is some immediate medical benefit to them, since this may burden the children with knowledge that they do not want. Since family members will share genetic predispositions, knowledge by one member of a family can help others, but can also increase tensions in families. Genetic testing must be voluntary and there should be access to genetic counselling, both before and after taking a genetic test.

Delivery of genetic testing services contains pitfalls. Counselling is time-consuming and expensive, but it is vital that it is adequately funded. There is room for doubt that general practitioners, who are seen as being central to future genetics services in the NHS, will have the knowledge to do this adequately. In the absence of proper counselling, people may take irreversible, life-changing decisions (e.g. to undergo surgery)

### What is eugenics?

The meaning of the word eugenics is hotly contested in debates about human genetics. It is sometimes used to stigmatise scientists, which is not our aim here. Many people, especially scientists, assume that eugenics was mainly confined to the first half of the 20<sup>th</sup> century, and was a right-wing movement aimed at eliminating disabled people and certain ethnic groups from society. Eugenics in that period often operated by forced sterilisation and even murder. According to this definition, the key characteristic of eugenics is coercion of people's reproductive choices by doctors or the state.

However, many eugenicists opposed coercion, and the movement embraced all shades of political opinion. Eugenic attitudes and practices, including coercive, state sponsored forms, have persisted to the present day. A broader definition, which captures more of the essence of eugenics in modern societies, is 'the attempt to control human reproduction, in order to 'improve' the genetic characteristics of the next generation'. The key word here is control: the basis of modern technological societies is the control of natural processes, through technology. Many of the negative attitudes towards disabled people are still present in our society. Thus, eugenics can be seen as an ongoing social process, whereby social and economic forces and technological changes create results similar to those that the earlier eugenics movement aimed for. The section 'prenatal screening and disability rights' discusses how this works in more detail. It is important to note that this is not a matter of any conspiracy of scientists, doctors or politicians, but rather something that our entire society must take responsibility for.

without properly understanding the risks they are facing. In the USA, genetic testing is supplied directly to the public by commercial companies, often without counselling. This has already led to concerns about misleading advertising and the marketing of ethically dubious genetic tests, such as sex selection. In the UK, although far fewer genetic tests are being marketed, there is no legal regulation of genetic testing.

***HGA has called for genetic testing to take place within public health services. Genetic tests should not be introduced until there is adequate access to genetic counseling.***

### Privacy and genetic discrimination

It is sometimes argued that personal genetic information is not different to other medical information about a person. However, because of its ability to predict the future, its impact on families and reproduction, the possibility of discrimination and its role in determining a person's individual identity, most commentators argue that personal genetic data are especially sensitive. There is currently little legal protection of medical privacy in Britain, and no special legislation on genetic privacy.

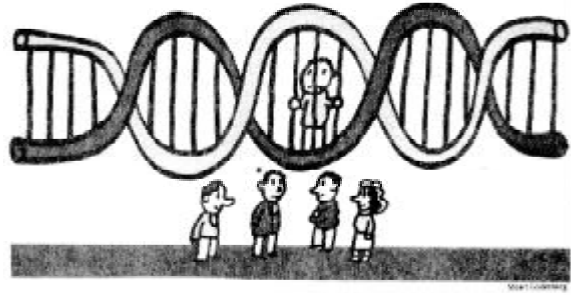
The police now routinely store 'genetic fingerprints', from anyone arrested for a crime. Although at present this information is purely for identification and does not allow the police to determine physical characteristics, like disease susceptibility, there is considerable concern about the lack of external regulation of police activities. Civil liberties organizations are concerned about an apparent tendency to gradually expand the range of reasons for storing samples.

Genetic predictions about our future health or other characteristics may also be of interest to insurers, employers and a range of other institutions. In the USA, there are already many examples of people being denied insurance as a result of genetic testing. In the UK, there are also examples of genetic discrimination, although the problem is less widespread. For example, people who have the gene for Huntington's Disease

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generally find it impossible to obtain life insurance, which makes it impossible for them to get a mortgage. The possible expansion of this problem to include people with susceptibility to common diseases, has raised fears that large numbers of people may be affected, raising the spectre of a 'genetic underclass'. Surveys in the US have shown that fear of discrimination by insurers is preventing people from taking genetic tests that may benefit their health, eg. by predicting whether they may develop cancer.



Public opinion is strongly against allowing insurers access to genetic information. However, insurers argue that if they are not allowed access, people who know they are likely to become ill or die will take out large insurance policies, potentially damaging the industry and raising premiums. There is little hard evidence that this will happen. Insurers also argue that genetic information is merely a form of family history information, which is already a standard part of insurance forms. This issue is still being debated.

It is clear that people should not be penalised because of their genes, and a number of international agreements now state that genetic discrimination is wrong in principle and must not be permitted. However, there is still much opposition from insurers to putting this principle into practice. Many US states, and a number of European countries have passed laws banning the use of genetic tests by insurers, but to date insurance industry lobbying in Washington has prevented comprehensive federal anti-discrimination legislation. In Britain, the insurance industry has declared a five-year voluntary moratorium on the use of genetic test results, except for very large life insurance policies. A previous voluntary industry moratorium was flouted by some companies.

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*Everyone opposes genetic discrimination in principle - but insurers are still opposing legislation to ban it*

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In employment, the use of genetic tests is further off, although in the 1970s, African Americans were discriminated against by many employers because they are more likely to carry genes for sickle cell disease. In 1996 the US Equal Employment Opportunities Commission passed regulations preventing employers from using genetic information to discriminate, and recently it prosecuted a railroad company that was doing this. In Britain, there is no legislation governing the issue. A report by the Human Genetics Advisory Commission (HGAC) suggested that where a worker could put others at risk, for example by suddenly collapsing, genetic testing was acceptable. There is much research into genetic variation in susceptibility to environmental and workplace chemicals, and it is possible that employers will use genetic tests to exclude susceptible workers. The HGAC stated that this would be acceptable on the grounds of protecting these workers. The Trades Union Congress has argued that employers should concentrate on reducing the level of pollutants in the workplace, which would protect all workers, not just those who are especially susceptible.

***HGA has called for increased legal protection for genetic privacy and for a ban on genetic discrimination in both insurance and employment***

## Prenatal screening and disability rights

Whilst the medical benefits of human genetics research are still mostly in the future, one of the most immediate applications that is being offered is prenatal testing. Nowadays, pregnant women are routinely offered ultrasound scanning and blood tests to

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detect conditions such as spina bifida and Downs Syndrome. Most women who are told that the child they are carrying will be affected by these disorders terminate their pregnancy. In future, it may be possible to screen for many genetic disorders.

Many disabled people feel that such screening programmes are part of society's negative attitude towards them. They argue that prenatal screening is based on a false medical model of disability, which attributes their problems to their physical conditions. Instead, they argue that their main problems in life are due to able-bodied people's ignorance and discrimination against them, and the lack of accessibility of buildings and services. They see prenatal screening programmes as part of an ongoing history of eugenic attempts to rid society of disabled people. In some cases these programmes are justified by health service officials in terms of financial savings to health services from reduced numbers of disabled people.

This is a very difficult issue. Many women feel that they could not cope with bringing up a disabled child, and that they have a right to make such choices in their pregnancy.

Women still carry the main burden of caring for children in our society. Geneticists argue that women are not pressured into abortion, but should be given non-directive genetic counselling that simply informs them about the condition and the choices available to them. Philosophers have argued that there is no contradiction between having respect for disabled people and seeking to prevent the birth of children who will suffer and impose extra burdens on their parents.

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*Women must be allowed to choose, but are they really being given a free choice?*

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Whilst women's right to choose to terminate pregnancy must be preserved, it is far from clear that women are genuinely being offered free choices. Research has shown that doctors often give biased information that exaggerates the extent of physical impairments, and assume that women will be bound to choose abortion. Disability rights activists have called for women to be given information directly from disabled people. They point out that if financial and other support for families with disabled children was adequate, women would feel more able to cope. Whilst there may be no contradiction in principle between respect for disabled people and screening, it seems likely that there would be much less interest in screening in a society that genuinely viewed disabled people as equal members.

### Embryo selection and slippery slopes

The relatively new technology of pre-implantation genetic diagnosis (PGD), which involves genetic testing and selection of embryos produced by in vitro fertilization (IVF), raises similar concerns. Because it involves IVF, use of this technology is regulated in the UK by the Human Fertilisation and Embryology Authority (HFEA). It is currently used relatively rarely, to select embryos free of genetic disease, in families where there is a known risk of such conditions. The justification for using it is that it offers the chance of (near) certainty that the child will be free of genetic disease, and is less traumatic for these women than repeated pregnancy and abortion. Because it does not involve abortion, and offers the chance to select amongst ten or more embryos, PGD opens up greater possibilities than prenatal screening for families to go beyond avoiding serious disease, and to select on the basis of characteristics such as sex (which is already common in some countries), appearance or intelligence. Recent cases, in which families are selecting embryos to create children to be bone marrow donors for existing ill children, suggest we may have already started on such a 'slippery slope'. (These cases also raise major issues about having children as means to an end, rather than as an end in themselves.) Although the HFEA insists that PGD will only be used for severe and life-threatening genetic diseases, market forces, threats of legal action by consum-

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ers, and technical improvements in IVF make it questionable whether this line can be held. Many people fear that these technologies will lead to a reduction of diversity, and a narrowing of what is seen as normality in society. This would seem unacceptable: there is a clear need to prevent 'reproductive consumerism', but there are difficult questions about where to draw the line between allowing women to choose to avoid disability and creating a 'genetic supermarket'.

***HGA has been supporting the positions of disabled people's organizations in this debate. We believe that genetic screening programmes should not be introduced without full public debate, and that regulation must ensure that prenatal screening is only used for very serious conditions. Society must work to improve access for and attitudes towards disabled people.***

## Psychiatric and behavioural genetics

Genetic research on mental health and behaviour raises special issues, both for individuals and society. This is partly because mental illness carries a particular social stigma, as do certain behaviours. Behavioural genetics makes claims about the fundamental nature of human beings and society, which have often been associated with right-wing and authoritarian attempts to control society.

The current scientific and media emphasis on genetics is leading to the belief that our

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***We must not fall into the trap of trying to treat social problems with a genetic technical fix***

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personality, behaviour and even life history are determined by our genes. In many cases, the media talk uncritically about 'happiness genes' or 'genes for aggression'. Genetic determinism was very unpopular after the Second World War, but has become increasingly part of popular 'common sense' in the last 20 years. As noted above, such 'genetic

determinism' cannot be scientifically supported. Nowadays, most scientists agree that our characteristics are determined by the interaction of both nature and nurture. Of course, in the case of behaviour, free will plays a major part.

### Behavioural genetics

There is much research into the genetic basis of mental health problems such as schizophrenia. This field has been plagued by many cases where strong claims are made for genes, which later have to be retracted, because other scientists cannot confirm them. This may be because the diseases themselves are very hard to define precisely. In the area of mental health, the boundaries between normality and disease are unclear, and in many cases it seems there is pressure from the pharmaceutical industry to redefine certain characteristics as diseases. An example is Attention Deficit Hyperactivity Disorder (ADHD), which is often claimed to have genetic causes, and the diagnosis of which has escalated rapidly in the US over the last 20 years. Around 10 percent of American children are now prescribed Ritalin to treat ADHD, and parents are often pressured into accepting the drug, even though the World Health Organisation has stated that it is radically over-prescribed.

Behavioural genetics, and the genetic determinism which is often associated with it, has historically been the basis of some of the worst excesses of eugenics. For example, there are claims that certain ethnic groups are genetically inferior in intelligence, or are more likely to be violent. Although there is variation between ethnic groups, it is impossible to determine their cause, because of social and economic differences, including the pervasive influence of racism. Many behavioural geneticists are conscious of this unfortunate history and avoid making claims about inter-group differences. However, researchers are still attempting to identify genes involved in sexuality,

IQ and violent behaviour. It is important to guard against the tendency, which such research may encourage, to believe that social success and social problems, such as crime, are caused by genes and therefore cannot be changed by social measures such as improved education. Genetic research tends to imply medical intervention, and when the researchers claimed to have found the 'gay gene', some newspapers published articles looking forward to its use for prenatal testing to avoid homosexuality. Even seemingly more benign interventions have problems. For example, it is often proposed that if we can identify children at risk of antisocial behaviour, this could be prevented by treating them with drugs before the problems emerge. It seems unlikely that such approaches could avoid coercion of children and may actually worsen the problem, since targeting children in this way may damage their self-esteem and lead to them getting a 'bad name'.

***HGA questions whether behavioural genetics is a good use of limited taxpayers' money. We have been calling for a public information campaign designed to combat the pitfalls of genetic determinism.***

### Cloning and stem cell research

In 1997, the cloning of a sheep, Dolly, created a furore about the possibility of cloned human beings. The scientists transferred the nucleus, containing the DNA, of a sheep's udder cell into an unfertilised egg, which then started dividing and grew into Dolly. Since then mice and farm animals have been cloned, and in November 2001 the US biotechnology company, Advanced Cell Technologies claimed the creation of the first cloned human embryo. The Italian fertility doctor, Severino Antinori and a US colleague have announced their intention of cloning a human being in 2002, and there are companies offering human cloning on the Internet for \$ 200,000.

There are many problems with human cloning. Firstly, the technology very unsafe, creating many animals that die at birth or have subtle or gross abnormalities: this is the consequence of breaking the fundamental rules of mammalian reproduction. For most people, cloning is simply an unacceptably unnatural way of reproducing. A key part of the problem with cloning is that it removes the element of random genetic mixing that creates unique individuals. In this sense, cloning exemplifies the industrial/consumerist approach to human reproduction: the creation of a precisely specified product rather than the unique and random outcome of the union of two people. It can be argued that completely controlling another person's genetic inheritance in this way turns them into a designed object, which must have an inferior status, relative to its designer. Although we cannot absolutely predict the psychological consequences of this, it is likely that whereas normal parents will have hopes for their child, cloners will have expectations. It is often objected that 'identical' twins are clones, and that in any case, clones will not 'photocopies' of the cloned person. However, it should be clear that the problem is not genetic sameness as such, but the attempt to impose it through the control of reproduction.

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***Human cloning is an industrial-style and dehumanising form of reproduction***

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The main argument for the use of cloning is for infertility treatment in couples where one member produces absolutely no sperm or eggs. We would argue that relief of infertility does not justify crossing this line, with all the profound consequences for society, especially when there are alternative ways for such couples to have children, including adoption. While we can sympathise with couples who wish to 'replace' a dead child, it is a fundamental misunderstanding to think that the same child will be born.

Finally, supporters of cloning argue that it would be unacceptable restriction of repro-

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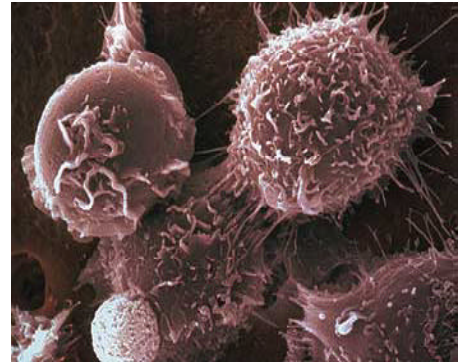
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ductive liberty to ban cloning. But although the state should not interfere with people's right to have children, that does not imply that people have rights to reproduce 'by any means necessary', no matter what harm this does to society. The UK has, legitimately, banned commercial surrogacy, for example, on the grounds that this means of reproduction harms society and the individuals involved. A similar type of argument can be made with cloning.

Internationally, there is a strong consensus against reproductive cloning, and many countries have already passed legislation banning it, including the UK in December 2001. The UN General Assembly is currently preparing an international Convention to ban on reproductive cloning.

### Stem cells and 'therapeutic cloning'

Although the vast majority of scientists oppose reproductive cloning, scientists and patients' groups have lobbied to allow the creation of cloned embryos, for the purpose of extracting embryonic stem (ES) cells. These cells, taken from 10 day old embryos, are believed to be capable of turning into all the different types of cells in the body, (e.g., nerve cells). Thus it is hoped that cells created from ES cells could be used for transplantation to treat a range of diseases. If the ES cells are taken from an embryo created by cloning a cell from the patient, the transplanted cells will be genetically identical to the patient, and so should not be rejected by the patient's immune system. This proposed method of treatment has been dubbed 'therapeutic', or non-reproductive cloning, and is said to have great potential by many scientists. In January 2001, Parliament legalised non-reproductive cloning. In early 2002 the US Congress is debating this issue.



**Human embryos**

Because extracting ES cells destroys embryos, it has attracted opposition from those who believe embryos, like fetuses, have the same rights as human beings. However, there are other reasons for at least delaying this research. Firstly, once techniques for creating cloned embryos were developed, it would be easy for scientists elsewhere to use these techniques to clone a child. Secondly, UK law is based on the principle of respect for embryos, even though they are not full human beings. It is hard to see how creating embryos purely as a source of biological raw material (ES cells) is compatible with respect: it seems part of the trend of turning human life into a commodity. Thirdly, recent research shows that stem cells from adult tissues may have the same potential for treating disease, without involving embryos or cloning. Finally, the full 'therapeutic cloning' scenario is widely agreed to be unrealistic as a general treatment, since the supply of human eggs needed for cloning is so small. Currently, government policy in Britain is to support research into both adult and embryonic stem cells.

***HGA has argued for a moratorium on non-reproductive cloning until there is a global ban on reproductive cloning, and until there has been a full public debate on the ethics of cloning embryos.***

### Gene therapy and human genetic engineering

A major hope of genetic medicine is the direct use of genes to correct genetic diseases or diseases like cancer, which are not inherited. The patient's cells are genetically engineered by inserting a correctly functioning copy of a gene into cells where the patient's genes are not working properly, perhaps because they are mutated.) For example, to alleviate cystic fibrosis, which affects the lungs, scientists are trying to insert a working copy of the cystic fibrosis gene into patients' lungs. Although much has



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been written about the medical promise of gene therapy, and billions of dollars have been invested, this research is still at a very early stage and has had very few successes.

In 1999, the death of a young man, Jesse Gelsinger, in a gene therapy experiment triggered a major controversy in the USA about the way commercial considerations appeared to lead the scientists to take unnecessary risks. The research project has since been halted by the US Food and Drug Administration, and the father of the young man is suing the scientists. The US biotechnology industry is still resisting efforts by regulators to force it to disclose adverse reactions in its clinical trials, on the grounds that this will lead to the disclosure of commercially sensitive data. In Britain, gene therapy is regulated by a government advisory committee, although it has no legal powers.

If gene therapy can be made effective, it is likely that a market will be created for its use for 'enhancement', for example of athletic ability. There are already reports that athletes are using the genetically engineered human protein, erythropoietin, to enhance performance.

### Germ line engineering

In contrast to gene therapy, which only seeks to genetically engineer a patient's body cells, in 'germ line engineering' it is proposed to engineer eggs, sperm or embryos, so that the genetic changes are present in all the cells of the individual that develops from these 'germ cells', and in the cells of that person's descendants. This is similar to the genetic engineering of plants and animals, but to date there are no genetically engineered humans. In Europe, germ line engineering is widely seen as ethically unacceptable, and is prohibited by the European Convention on Biomedicine and Human Rights, which the UK has still not signed. In the USA, there is a growing lobby arguing for it to be used, in the first place for correcting genetic diseases. Some advocates even argue openly for its use to create 'enhanced', 'designer babies', tailored to the parents' whims. At present, scientists are not attempting germ line engineering because of fears that the technology is unsafe: random insertions of genes can disrupt chromosomes, leading to new genetic disabilities. This constraint is likely to disappear in a few years as the technology improves.

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*Germ line engineering could lead to a free market version of eugenics*

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Opponents of germ line engineering argue that there is no need to use this technology to avoid the birth of disabled children. Even if we agree that this is ethically legitimate (see 'prenatal screening and disability rights'), parents may adopt children, use donated eggs or sperm, use prenatal testing or, as a last resort, genetic screening of embryos. It would seem, therefore, that the real market for this technology will be for the 'enhancement' of normal characteristics, and once this technology is sanctioned for treating genetic disorders, it will be impossible to prevent its use for creating 'designer babies', and the development of a commercially-driven consumer eugenics. Since such technologies will be expensive, and available on the basis of ability to pay, it is likely that they will further increase the gap between the children of the rich and the children of the poor.

Another objection to germ line engineering centres on the rights of the child. As with cloning, by designing our children, we would turn them into just another consumer object, and thereby undermine their rights to determine their own future.

***HGA is opposed to the use of gene therapy for enhancement. It is also calling for a global treaty banning germ line engineering.***

### Commerce, research and patents

Unlike most scientific fields, there is no clear separation in genetics between fundamental research and its commercial application. For example, the Human Genome Project became a race between a publicly-funded consortium, committed to free access to its data, and a private company, Celera, which restricts access to its data, and sells access to the pharmaceutical industry at high prices. Commercial involvement in such basic discovery research is commonplace, and every major pharmaceutical company is investing heavily in human genetics, which is seen as key to more efficient drug development.

The involvement of business in basic science, often through collaborations with universities, raises many difficulties, such as restriction of scientists' freedom to publish their data. It also can create suspicions of bias in the research and other conflicts of interest. This has become a major issue in medical research publishing, with journals trying to ensure that scientists disclose the sources of their funding. Studies have shown that links between industry and scientists are especially strong in genetics.

#### Gene patenting

An especially sensitive issue is the patenting of genes. Both companies and universities are patenting human genes - there are now over 4 million patents applications on human DNA sequences, the majority for small sub-gene fragments. Patenting of genes and living organisms was legalised by the EU in 1998, despite prolonged campaigns against it by many consumer, environmental and Third World development organizations. Many geneticists also oppose gene patents, because they tend to inhibit research: the issue was central to the acrimonious dispute between the Human Gene Project and Celera. The opponents argue that genes are part of nature and should not be patented, since they can only be discovered, rather than invented. Patenting of genes, which are parts of the human body also violates the rule that the human body should not become a commercial commodity.

There is now much concern that a small number of companies could control over the future of medicine through the ownership of large numbers of human gene patents, obtained with little invention, simply by using DNA sequencing machines. Many governments are now arguing that patents should only be allowed on DNA sequences when there is clear evidence of the function of the gene. Companies are already using

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*The patenting of genes may allow a few players to control the future of medicine*

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patent monopolies to charge large royalties on genetic tests. This has led to the closure of genetic testing programmes for rare genetic diseases. In the US a genetic disease society has claimed a share in a patent, after several cases in which scientists, having done research on people with a genetic disease, used ownership of a patent on the disease gene to charge large fees for genetic tests.

In essence, the problem arises from allowing the patenting of discoveries, which gives control over a wide range of possible applications based on a gene. Although the pharmaceutical industry argues that gene patents are essential for investment, the industry could protect its investments by patenting its products, such as drugs or



genetic tests, as other industries do, rather than patenting basic discoveries. This would allow others to market different products based on the same gene. However, patenting of medicines must always allow compulsory licensing in the public interest, for example in order to provide essential medicines cheaply in Third World countries.

The commercialisation of human biological samples has also led to the exploitation of indigenous peoples. Several cell lines from indigenous tribes have been patented by US government institutions, without the consent of the people from whom the samples were derived, although some of these patents were withdrawn, following protests by the tribespeople. Concern over such 'biopiracy' has led countries such as India to try to restrict foreign scientists' access to their wealth of human genetic diversity.

***Human Genetics Alert is opposed to patents on genes.***

### Gene banks

A major current focus of genetics research is the construction of large 'gene banks', containing thousands of samples of people's tissue and DNA, together with data about the donors' medical history and lifestyle. By correlating genetic variations with lifestyle and medical history data, it is hoped to identify the genes involved in common diseases and to clarify how they interact with the environment. Many drugs companies have constructed such gene banks, and in Iceland the health records and DNA samples of the entire population have been placed in a gene bank owned by a biotechnology company, DeCode Genetics. In Britain, the Wellcome Trust and the Medical Research Council are planning a collection of 500,000 samples taken from middle-aged people, which will be known as Biobank UK. The public's trust in medical research has been undermined by recent scandals involving high-handed actions by doctors. Yet unlike in Iceland, where there was a national debate over legislation to create the national gene bank, in the UK there has been little debate about the proposed Biobank.

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***If the ethical safeguards are inadequate, gene banks threaten to worsen the public's distrust of doctors***

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Gene banks raise tricky issues about consent. In Iceland, people who do not wish to participate must actively opt out, turning the usual rules of informed consent on their head. It is difficult to fully inform people about all the different research projects which their sample will be used for, but this emphasizes the need for guidelines on the type of research which can be done. One gene bank in the UK, for example, refuses to allow people's samples to be used for behavioural genetic research; other types of research might offend particular ethnic groups. Informed consent should ensure that people understand that companies may commercialise and even patent research based on their genes.

The involvement of drugs and biotechnology companies in such research raises important issues. However good the safeguards, it does not seem in the public interest for an entire nation's DNA to be in the hands of a private company, which has its own interests. Gene banks should be independently controlled by a body that represents sample donors and other stakeholders. In addition to ensuring security of the data, so that breaches of privacy and genetic discrimination do not occur, this body should ensure that companies are not allowed to know who donated particular samples. The doctors who collect samples must have no financial interests in the results of the research that might bias the information they give to patients.

***HGA has campaigned for more public consultation for the proposed Biobank, and for the necessary safeguards on ethical issues to be in place before the project is launched.***

## Further reading (Note: these sources were not chosen to necessarily agree with HGA's positions.)

### General

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Council on Genetics and Society [www.genetics-and-society.org/](http://www.genetics-and-society.org/)  
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