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Human genetic testing and the influence of the pharmaceutical industry

Drug companies are seeking to use genetic tests to define 'at risk' groups who would be advised to take (their) medication to prevent a predicted future illness. This approach would be hugely profitable for the pharmaceutical industry, but does not have a good scientific foundation. Many people could take medicine unnecessarily, and some could suffer side-effects. Public health approaches to tacking problems such as obesity and smoking could also be undermined.

Unregulated genetic testing could lead to the drugs industry, rather than the medical profession, defining who is at risk and needing medication in the future. This would represent a profound increase in the influence of the industry over our approach to health care. Regulating genetic testing is the key way in which such excessive influence can be prevented.

The Health Select Committee is conducting an inquiry into the influence of the pharmaceutical industry. It is taking evidence from the Department of Health and the Department of Trade and Industry at 10.30am on 9th September in Portcullis House. GeneWatch believes that the need to regulate genetic testing should be part of the inquiry.

Predictive genetic testing: unreliable and misleading

Genetic disorders are caused by rare changes in the sequence of the DNA called "mutations". These are often inherited, but can also arise spontaneously. Most people with genetic disorders have symptoms in early childhood. More common differences in genetic make-up are called "polymorphisms". Each polymorphism occurs in 1- 50% of the population and does not necessarily cause an illness, but may be linked with an increased risk of illness in the future. Tests for polymorphisms are "predictive" rather than diagnostic and are increasingly being developed and marketed, either directly to the public or via medical professionals. People taking this type of test are likely to be told that they are "genetically predisposed" or "susceptible" to a future illness.

Drug companies are seeking to extend their influence in genetic testing by defining 'at risk' groups who would benefit from [their] preventive medication.

Most people get common illnesses because of lots of complex factors, including social, economic and environmental factors, biology and chance. Therefore, the predictive value of genetic tests in most people is usually

low and often not well understood. Trying to predict future health in this way is much more complicated than diagnosing an existing genetic disorder: it is more like trying to predict the weather.

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The majority of links between genes and common diseases later turn out to be exaggerated or wrong, so there is a real danger of misinformation if the clinical validity of the test has not been established. One study found that only 6 of 600 published links between genes and common diseases had been shown to be robust[1]. For example, although some rare genetic forms of extreme obesity are known, so far none of the dozens of genetic factors that have been linked to 'normal' obesity have been confirmed[2,3].

Marketing genetic tests

> *"Roche is committed to integrating resources in the field of genetics and genomics to find new individualised solutions that address predispositions* ***long before an ailment even starts****."* [Emphasis added]. Roche "Predisposition" Movie[4].

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Professional bodies, such as the American College of Medical Genetics, oppose direct-to-consumer sales of genetic tests because they may harm health[5]. However, given the massive marketing potential, it is not surprising that some biotech companies are already selling genetic tests combined with other products, mainly via the internet or alternative healthcare providers[6,7] . The customer takes a swab of DNA from inside their cheek and posts it to the company. A number of DNA-based laboratory tests are then made on the sample and a report sent back. Companies are already claiming to identify genetic susceptibility to conditions including obesity, heart disease, addiction and some cancers. A common approach is to sell "customized" nutritional advice and supplements, based on the test results.

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Most of these tests are sold by small US companies which take advantage of a loophole in US regulation allowing individual laboratories to conduct unregulated tests. So far, the big pharmaceutical companies have not begun to market tests for common genetic variations, but this could soon change. Roche and GlaxoSmithKline have recognised the potential to expand the drug market to healthy people identified as "predisposed" to future illness[8,9,4,10]. Roche is lobbying the FDA to allow it to sell genetic test kits without having to provide any scientific data[11]. If its proposal is approved, genetic test kits could be widely sold without any evidence that the gene increases risk to health. Even if the tests are marketed through doctors, the lack of data could mean that people are misled about their health.

Genetic testing – the best approach to health care?

A focus on the 'wealth-generating' potential of genetic testing may lead to wider social and health consequences:

- With the whole population potentially 'at risk' and eligible for preventive medication, the cost implications of 'genetic susceptibility' testing have been described as *"staggering"*[12].
- People may dislike preventive medication and prefer alternatives, such as lifestyle changes[13,14]. Population-based measures (such as banning tobacco advertising) are generally more effective than individually targeted measures[15].
- Genetic testing may wrongly imply that only a minority of the population with 'bad genes' need to stop smoking or to eat a healthy diet.
- An over-emphasis on genetic risk factors can divert resources from addressing the major social and economic determinants of ill health[16].
- In the US, direct-to-consumer advertising of prescription-only drugs focuses on fears of death or disability to sell preventive medication[17]. Such advertising is banned in Europe, but there are no controls to prevent the advertising of genetic tests, which provide a potential mechanism for the 'marketing of fear'[18].

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Lack of regulation

"*No test should be introduced in the market before it is established that it can be used to diagnose and/or predict a health-related condition in an appropriate way*". The US Secretary's Advisory Committee on Genetic Testing (SACGT)[19].

In Europe, there is no regulatory assessment of any clinical data relating to genetic tests. Legislation covers only analytical validity (whether the test is technically accurate and identifies the correct DNA sequence). It does not cover clinical validity (the claimed link between the gene and the disease and the test's ability to accurately predict risk) or clinical utility (the test's usefulness in deciding what kind of action to take). Assessing clinical validity and utility are important because the implications of a particular DNA sequence for someone's health are so poorly understood.

The Human Genetics Commission (HGC) has considered the issue of the sale of genetic tests direct to the public and concluded that "*most genetic tests that provide predictive health information should not be offered as direct genetic tests*" and that companies wishing to sell genetic tests should have to "*convince a regulator that the test is suitable*". The HGC has not considered tests marketed through private practice or the NHS, although these tests also need assessment.

The HGC recommended that the Medicines and Healthcare Products Regulatory Agency (MHRA) should oversee the wider issues such as clinical validity, clinical utility and the advice given to customers but opposed giving the MHRA the necessary statutory powers to undertake this task. The MHRA has neither the necessary structure, remit nor the resources to assess the clinical validity or utility of genetic tests. No Government response to the HGC has yet been published.

Conclusions

Genetic tests are already being marketed to people without proper medical advice and interpretation, or any independent assessment of the claims made for the test. As a result, people will be given health-related information which is inaccurate and misleading. Taking 'preventive' treatments or supplements associated with genetic tests could even prove harmful to their health.

All genetic tests should be subjected to a pre-market approval system to ensure they are useful for health. Clinical validity, clinical utility and social consequences all need to be assessed. Tests should be offered only via health professionals who can give advice based on knowledge about the whole person, not only their genes.

The first genetic tests from the big drug companies are expected on the market in the next 2 to 3 years, combined with advice to take preventive medication[20]. Unless steps are taken to introduce regulation quickly, the pharmaceutical industry is likely to create a health care system based on drugs for prevention, rather than more effective public health interventions. The Wanless report on population health has already warned that expanding the use of medicines for disease prevention would have "*considerable financial implications"* and that the bias against funding public health research needs to be addressed[21].

The Health Select Committee could make an important contribution to future public health if it included recommendations to regulate genetic tests and to address the bias in research funding in its report.

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