

“GENOVATIONS” GENETIC TEST KITS

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The first genetic tests linked with dietary advice have been withdrawn from sale on the UK high street following concerns that they were misleading and unethical.

However, a US company is now trying to market a new series of genetic test kits via alternative health practitioners and some GPs^{i,ii}. Genetic tests remain unregulated and GeneWatch UK recommends that you *do not take the “Genovations” tests*, which are being marketed in the UK by Health Interlink Ltd on behalf of the US company Great Smokies Diagnostic Laboratory (GSDL).

GeneWatch UK is particularly concerned about:

- unsubstantiated and misleading claims that the tests can identify your genetic risk of illnesses such as heart disease, hormone dysfunction and rapid bone loss;
- recommendations for supplements and medicines to “treat” the common variations in genetic make-up identified by the tests;
- the lack of provision of proper medical advice and counselling or full information about the implications of taking a genetic test.

Everybody’s genes are different (unless you have an identical twin) and you cannot change your genetic make-up. Common variations in genetic make-up do not mean that you are going to become ill, although a few common genetic variations have been linked with a higher risk of some diseases. Many of these links are unreliable and later scientific studies have often contradicted earlier ones. For most people, genetic make-up is a poor predictor of future illness. GeneWatch believes that many claims to test and treat people based on their genetic make-up are driven by a cynical marketing strategy designed both to sell genetic tests and to expand the market for supplements and medicines to people whether they need them or not.

What are the “Genovations” tests?

GSDL’s “Osteo”, “Cardio” and “Immuno” genomic profiles are currently being marketed. These tests of your genetic make-up look for common genetic variations known as “polymorphisms” in a sample of cells taken using a mouth wash rinse. In the UK, the kits (which come packaged like a box of chocolates) are being marketed via alternative health practitioners and some GPs. Once they have analysed your sample, GSDL provide an interpretation of your genetic test results which claims to:

- identify the disease risks associated with your genetic make-up;
- suggest possible dietary, environmental and lifestyle changes, and vitamin supplements or drugs to take;
- identify the need for follow-up assessment.

These claims are misleading and unethical because:

- the risks associated with particular genes are still poorly understood and for most people diet, lifestyle and environment will be much more important than genetic make-up in the development of common future illnesses;
- selling supplements, medicines and follow-up tests to people based on their genetic make-up means treating them for illnesses they do not have but are worried they will get. At best, this is exploiting people’s fears in order to make a profit. Taking unnecessary medication could also be harmful to your health, as could being unnecessarily worried or

falsely reassured about your risk of future illness;

- you may be informed of risks you didn't want to know about without proper counselling or advice (for example, an increased risk of Alzheimer's Disease has been associated with one of the genes in Genovations' "Cardio" genetic test).

"Neuro", "Gastro", "Metabolic" and "Dental" genomic profiles are under development by GSDL and a detoxification profile is expected to be available in the next few months. Health Interlink also market nutritional supplements and may gain financially from recommending supplements for those with particular genetic variations.

Which genes are being tested?

1. "Osteo Genomic Profile"

GSDL claims that this test reveals potential genetic susceptibility to bone diseases such as osteoporosis, low bone mineral density, osteopenia (low bone mass), age-related bone fractures, and arthritis. However, the definition of osteoporosis is controversial and bone mineral density is not necessarily an accurate predictor of future fracturesⁱⁱⁱ. Some have argued that encouraging the testing of bone mineral density in menopausal women is already *"the marketing of fear"*^{iv}. Tests of the genetic make-up you are born with are likely to be even poorer predictors of future fractures in old age.

Bone mass and bone strength are in part genetically determined, but many different genes are probably involved in complex interactions that are not fully understood, and environmental factors such as diet and exercise are also important. Although some common variations in the genes in the "Osteo" profile have been statistically linked with differences in bone mass density, other links are disputed. For example, although some studies have found a link between common variations in the VDR gene and bone density, others have found no link and one study has concluded that testing the VDR gene is of no practical use in predicting the most serious fractures associated with osteoporosis^v.

Osteoporosis is largely preventable by eating a healthy diet including sufficient calcium and by taking weight-bearing exercise, particularly in adolescence^{vi}. Taking these actions to help grow healthy bones are important whatever your genetic make-up.

2. "Cardio Genomic Profile"

GSDL claims that this test reveals potential genetic susceptibility to hypercholesteremia, atherosclerosis, obesity, hypertension, coronary artery disease, myocardial infarction (heart attack), thrombosis, endothelial dysfunction (dysfunction of the blood vessel lining), and stroke. However, genetic tests are poor predictors of complex diseases such as heart attack and stroke in most people^{vii}. Although genetic variation plays a role, the majority of cases of cardiovascular disease are caused by unhealthy diets, lack of exercise, and smoking. Air pollution can also be a factor^{viii}. Tobacco control and promotion of healthy diets and exercise for the whole population, including tackling underlying social and economic factors, are likely to be much more effective means of prevention than trying to identify those individuals at the highest risk^{ix}.

In many cases, links between the genes included in the "Cardio" test and cardiovascular disease are poorly established. For example, studies have found a complex and confusing link between the MTHFR gene and levels of folate and homocysteine – and no link between common variations in this gene and heart disease. Some studies have found a link between

the less active form of the MTHFR gene and high levels of homocysteine – but if you have sufficient (average or above) levels of folate in your diet, the form of the gene you have does not seem to matter^x. The less active form of the MTHFR gene does not seem to be associated with an increased risk of heart disease, even when folate and B vitamins are low^{xi}.

GeneWatch is particularly concerned that the Genovations' "Cardio" profile includes a test for common variations in the ApoE gene. Some variability in cholesterol levels does appear to be associated with variations in the ApoE gene, although a link with heart attack risk is controversial. But genetic variations in ApoE have also been associated with an increased risk of Alzheimer's Disease. Predictive genetic testing for Alzheimer's using ApoE is not recommended due to the uncertainty of the prediction and the lack of a cure^{xii}. GSDL does not seem to have considered the implications of testing for this gene, particularly without providing patients with proper information or counselling.

3. "Immuno Genomic Profile"

GSDL claims that this test reveals potential genetic susceptibility to asthma, autoimmune disorders, certain cancers, allergy, infectious diseases, bone inflammation, arthritis, inflammatory bowel disease, *Helicobacter pylori* (the organism causing stomach ulcers), heart disease, and osteopenia. Again, genetic make-up is likely to be a poor predictor of these complex diseases. GeneWatch also believes that predictions of heightened susceptibility to cancer – even when highly uncertain - should not be made without appropriate genetic counselling.

GSDL has implied that genetic research results are more certain than the evidence suggests. For example, although common variations in the IL-4 gene may be linked to asthma, research results have been inconsistent with different studies reporting different outcomes. There are more variants of this gene than originally supposed, making the links with disease very complex to study^{xiii}.

Asthma is now the most common chronic disease in children and has been increasing in developed countries in the past few decades. Although the causes are disputed, environmental or lifestyle factors – outdoors or in the home - must underlie the increase, not an increase in genes linked with asthma. It is important to tackle these underlying causes if the number of children with asthma is to be reduced.

Conclusions

Unless genetic testing is regulated, there is a real risk that people will be subjected to inappropriate, unnecessary or dangerous medication through the spread of poorly understood genetic tests^{xiv}. The current unregulated sale of genetic tests is misleading and unethical and can detract from the real steps that should be taken to prevent ill health. Health practitioners cannot be expected to assess individually the many complex and often contradictory research studies linking genetic make-up to future diseases.

Necessary safeguards include:

- the creation of a statutory regulator to assess the validity and utility of all genetic tests before they are used (other than for medical research);
- medical oversight (via GPs or genetic counsellors) of genetic testing to ensure that those taking tests have given fully informed consent to every test and have access to counselling if needed;
- legislation to control the collection, storage and use of genetic information and to prevent

genetic discrimination (for example, by insurers or employers).

The Government has failed to take action to protect people from unscrupulous sales of genetic tests, despite being alerted to the problem several months ago. The Government must act quickly or the marketing of genetic testing will escalate rapidly and lead to an increasing number of people being misled about their health.

References

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