

4 October 2002

## **The Genetic Interest Group's response to:**

The supply of genetic tests direct to the public: A consultation document  
Human Genetic Commission July 2002

This response was drafted and then discussed by the Trustee Board of GIG before being circulated to the GIG membership for discussion and comment.

Since the publication of the Advisory Committee on Genetic Testing's report on this subject in 1997, there have been limited developments in this area in the UK. Indeed, leaving aside paternity testing (which is outwith this consultation), the only development of note is Sciona's marketing of 'lifestyle' genetic testing, of which only 500+ were sold in the year they were available.

The felt need to revisit the issue then is based as much or more on what *might* happen as on what has already happened. As with other commercial genetic companies, Sciona have now withdrawn their product from the direct-to-customer marketplace and switched to promoting their services to health professionals. Similarly in America, many of the commercial companies seem to be more interested in drumming up public interest and awareness for testing services that are later only available from a medical professional. A cynic might suggest that a period of direct marketing is a good way to raise a company's profile. Certainly, we should be aware of the complex factors that might limit, as much as the factors that might make possible, a viable commercial service supplied direct to the public.

Absent evidence that a number of companies are queuing up to market testing services direct to the public with potentially serious implications, the Genetic Interest Group's view is that it would be excessive to rush to legislation or strict regulatory restrictions in this area. Furthermore, as argued below, we can see positive reasons why people should be able to access testing services directly, if that is their wish.

**Q1: What role, if any, do you envisage for professional bodies in the regulation of genetic testing services supplied direct to the public?**

We do see a role for professional bodies, in particular in the monitoring of quality and the storage and use of data.

**Q2: What aspects of the existing controls on advertising would you wish to draw to our attention in conducting this review? In what way, if any, should adverts for direct genetic testing services be treated differently?**

It might be argued that the regulations listed in the consultation document lack teeth. However, alongside other forms of regulation and control listed later in the consultation, there do appear to be a fairly wide range of mechanisms to call companies to account, especially as regards technical standards. We would also expect that a vigorous public debate would accompany the entry into the marketplace of companies lacking in such expertise and competence.

**Q3: What other national controls or international instruments should we be considering during this review?**

**Q4: Do you have any comments or suggestions about the possible control on genetic testing services accessed via the Internet?**

Most international instruments require interpretation within national settings in order to generate sufficiently concrete guidance. We find it hard to see how, short of Draconian controls, it would be possible to control the use of genetic testing services via the Internet, unless that is controls were established within the country where the testing was conducted regarding the testing of people outside of that country.

**Q5: Should any controls or regulations be confined to tests carried out on the genetic material itself, or should they encompass tests on other aspects of body chemistry that might be directly determined by information stored in the genetic material?**

We agree with the consultation document (para. 31) on this. In general the question as to whether the information revealed by a DNA test is similar to other information (in kind or in its level of significance) can only be answered in a specific context. Accordingly, any controls or regulations would need to contain the flexibility to cover tests on more than just the genetic material itself.

**Q6: What are your views on which genetic testing services can be considered, now or in the future, to be defined as “direct to the public”.**

The definition adopted by the ACGT retains its usefulness for the moment. What will mark out a ‘direct to the public’ service will be the absence of official referral mechanisms. In our view, questions such as the availability of a comprehensive service, including, for example, pre- and post-test genetic counselling, are best understood as the components of a service, which we might or might not want to demand are provided by whoever is supplying the service. So, for example, if it were thought desirable to impose regulations on an Internet-based company regarding the components of the service that it should offer for testing for cancer risk, it would be equally appropriate to impose the same conditions on professional private medicine.

Perhaps this suggests that the only way to look at this is by considering the components of the service that should be offered as a part of a non-NHS service.

**Q7: What are the likely developments in the genetic knowledge and technology that might impact on the number and type of genetic tests offered direct to the public?**

The consultation document points to the complexity of offering an accurate and comprehensive testing service for the mutations linked to familial breast cancer. This might well prove to be a strong disincentive to the marketing of ‘direct to the public’ tests for this condition. The rarity of many of the highly penetrant single gene disorders which are not subsets of common disorders might also prove to be a barrier, even if the test itself is easy to do and the result fairly clear cut. In both cases it must be remembered that there are good reasons to believe that people will wish to continue to undergo testing within a medical context with a pre and post-test consultation. However, against such calculations must be set the possibility that if a commercial company (which might evolve out of an NHS context) developed a strong market position as a supplier of testing services to health professionals, it could run a direct to the public service in parallel, especially if the responsibility to provide extras to DNA analysis was minimal.

Some forms of genetic testing will not be so onerous or significant for the individual as those for risk or certainty of serious and / or difficult or impossible to treat conditions. ‘Lifestyle’ tests would be one example. GIG agrees with the views of many professionals regarding the limited usefulness of lifestyle tests based on current evidence. But such tests might be refined. Conceivably, the marketing of tests to healthy individuals for genes linked to conditions such as familial hypercholesterolaemia or haemochromatosis would be another category of tests.

**Q8: What distinction, if any, should be made between genetic tests and other medical or health-related tests which might be offered direct to the public?**

**Q9: If testing for non-genetic conditions is available direct to the public with few restrictions, then is there a case for restricting the availability of testing for genetic conditions?**

**Q10: What distinction, if any, should be made between genetic tests intended for:**

- predictive health purposes;
- diagnostic purposes;
- life-style or other purposes which have a limited impact on someone's life?

Distinctions should be made based on the implications of the information—for both the individual undergoing testing and for other family members. However, we do not feel that there are classes of tests that should not be offered direct to the public. For all conditions a company should have to prove that it has the competence to carry out the test at a technical level, and to provide an understandable interpretation of the results.

Furthermore, for conditions that have serious implications for the individual and / or other family members, a company should be obliged to offer a pre- and post-test consultation. However, individuals should not be compelled to take part in such discussions; there are some well-informed individuals who may wish to avail themselves of a DNA test and nothing more, and they should be allowed to do so.

**Q11: If people are interested in finding out personal genetic information about themselves, then should they be entitled to obtain such information in whatever way they wish?**

Ultimately the answer to this question has to be 'yes'. Many of the assumptions and presumptions that are common currency within the genetics and policy community have not been tested. For example, the absolute importance of genetic counselling has not been put to a real test in recent times simply because it is a part of practice and every study of practice. However, we do share some of the concerns expressed in the consultation, particularly about the marketing of tests when the implications are serious, and conversely about a pre-occupation with health and 'healthy living' without any clear evidence base for the usefulness of tests and the effectiveness of any 'remedies'. Some of these issues can and should be addressed through public debate. But we will also need to have more experience of the real decisions people make; at present the discussion is too speculative.

**Q12: Should direct genetic testing services be limited to adults capable of making informed consent?**

Leaving aside the question of *how* tests would be so limited, put baldly the answer must be No. We would expect that parents would want to consult a medical professional concerning their child's health. But, for example, we can foresee circumstances in which a parent might want to clarify questions concerning carrier status of family members, including children, through a direct to the public genetic test.

**Q13: With appropriate consent, should results from direct genetic testing be recorded in the GP record? Should this be encouraged within any future regulatory system, and if so, how might this be done?**

If there is a health implication of the result, people should be encouraged to take the results to their GP.

**Q14: What are your views on the arrangements for retaining and using samples and data?**

We think that the current arrangements are satisfactory.

**Q15: Do you consider that there should be some independent process to review the accuracy and reliability of some or all types of genetic tests that are available direct to the public? If so, how might this be achieved?**

**Q16: Should the value of any pharmaceutical or life-style intervention that is linked to a genetic test be considered as part of any accreditation process? How would this relate to established mechanisms for professional self-regulation?**

We would expect to see any laboratory offering a genetic testing service meeting internationally accepted norms and their European and British equivalents, as happens now with those operating in the public and private sector. As to the value of the intervention, existing regulations cover the safety of pharmaceutical products and lifestyle interventions. In the grey area of non-harmful but perhaps of no real benefit, we would expect some controversy and public debate, but doubt that this could be addressed through regulation.

**Q17: For which types of test should access to appropriate pre- and post- test counselling be a requirement? Who should undertake this?**

**Q18: What are your views on the need for more general consumer information or education about the issues raised by direct to the public genetic testing?**

The company should be under an obligation to offer pre- and post-test counselling for those tests where this is the case within the NHS currently. It should have its own qualified staff available to do this or have an arrangement with professionals able to provide the service.

So far the public seems to have shown a strong degree of scepticism about directly marketed genetic tests. The issue of public knowledge and attitudes should be monitored as and when any new tests become available.

**Q19: Do you believe that the option of no specific regulation is desirable?**

**Q20: If you believe that there should be some form of regulation, then is a voluntary code of practice the best way to achieve this? If not, how else could this be done?**

**Q21: If a new voluntary Code of Practice were to be introduced, what issues do you think it should cover?**

**Q22: What are your views on who should be responsible for introducing and administering any new Code of Practice?**

**Q23: Should any new voluntary code of practice stipulate that certain tests should not be offered direct to the public? If so, which type of tests should not be offered?**

**Q24: If certain tests were not to be offered direct to the public, what process or criteria should be used to identify such tests?**

**Q25: Do you think that a strict regulation system, of the sort described in Option 4 above would be desirable?**

Broadly speaking we would favour option 2 as outlined in the consultation—voluntary regulation. If serious problems were to emerge in time more stringent controls could be introduced. Such a code, an extension (though in some ways a relaxation) of the existing



*Working to benefit all people  
affected by genetic disorders*

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ACGT Code of Practice, should be drawn up by the HGC in consultation with companies and individuals known to be interested in offering direct to the public genetic testing services.

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