ACADEMY OF MEDICAL ROYAL COLLEGES _____



Andrew Lansley CBE MP Secretary of State for Health Department of Health Richmond House 79 Whitehall London SW1A 2NS

24 June 2010

Dear Andrew

The British Medical Association (BMA) and Academy of Medical Royal Colleges (AoMRC) have today issued a joint statement calling for the strengthening of the existing regulatory framework on the provision of information for direct-to-consumer screening tests. A copy of the joint statement is enclosed for reference.

This was developed following a stakeholder event hosted by the BMA in February 2010 and in light of concerns expressed by healthcare professionals regarding ad hoc, non-quality assured screening practices. The event was attended by a range of organisations including the AoMRC, the UK Genetic Testing Network, the Nuffield Council on Bioethics, the Medicines and Healthcare products Regulatory Agency, the Faculty of Public Health, the UK National Screening Committee, and the Patients Association.

We are writing to seek your views on how this matter can be progressed and look forward to hearing from you.

Yours sincerely

Dr Hamish Meldrum

Chairman of Council British Medical Association **Professor Sir Neil Douglas**

Chairman

Academy of Medical Royal Colleges

und C.P. Meean

Doctors call for an end to misleading advertising claims on health tests

A joint statement from the British Medical Association and the Academy of Medical Royal Colleges

Individuals are being increasingly encouraged and choosing to improve their own health by making lifestyle changes and participating in blood pressure and other screening checks. In parallel with this the private marketing of "health tests" directly to healthy people is becoming common practice. These tests are marketed with the implied promise that testing for a risk marker or early disease process can lead to a reduction in future risk.

The NHS has safeguards in place to ensure that tests are only offered as part of high-quality screening programmes supported by sound research evidence. This ensures that participants are aware of the benefits, risks and limitations of a test, and are therefore able to make informed choices. Such safeguards often do not exist in the private sector which makes it impossible for people to distinguish between private testing services that may do some good, and those that are of no value or even potentially harmful.

There are significant risks with direct-to-consumer tests. Many are unreliable and inaccurate. Patients may be falsely reassured, or undergo unnecessary and sometimes invasive follow-up tests and treatments. Unnecessary procedures may have long-term or permanent complications. These problems often create unnecessary burdens for mainstream NHS services.

The current system of regulation has gaps and areas of weakness that mean misleading marketing claims are not effectively challenged. Regulatory control can be exerted through complaints to the Advertising Standards Authority (ASA) but only after an advertisement is in the public domain. This does not protect against unbalanced or missing information; in addition the penalties for breaching the ASA code are an ineffective deterrent.

Doctors have a professional obligation to promote and protect patient safety. Doctors want their patients to be well informed and enabled to take responsibility for managing their own health. Doctors have a professional duty to prevent patients from being exploited, and to ensure they have access to the information they need and deserve when deciding what tests to choose.

The UK governments must strengthen the existing regulatory framework on the provision of information for direct-to-consumer screening tests. This must ensure that the marketing is factual and balanced through:

- a mandatory requirement that all marketing material includes information on:
 - the risks and limitations associated with the test
 - the implications of the results and any follow up that might be required
 - the procedures that are and that are not included in the price of the test
 - a statement of the health benefit from the test and of the nature and quality of the evidence for this health benefit
 - any financial gain or conflict of interest by those providing or recommending the tests
 - the advisability of seeking independent medical advice before taking a final decision to have the test.
- a robust system to monitor compliance with these regulations, including strong penalties for transgressions.

Notes

The BMA first called for action to address ad hoc, non-quality assured screening practices in its 2005 report *Population screening and genetic testing*. This call for action was repeated at the 2009 BMA Annual Representative Meeting. In February 2010, the BMA hosted a stakeholder event to explore the need to strengthen the regulation of direct-to-consumer health screening tests, in particular in relation to marketing claims to consumers. This included representation from the following organisations:

Academy of Medical Royal Colleges Bupa Clinical Genetics Society Faculty of Public Health Genetics Interest Group Gengage Human Genetics Commission Medicines and Healthcare Regulatory Authority **Nuffield Council on Bioethics** Patients Association **PHG** Foundation Royal College of Physicians Royal College of Radiologists Science Council Society for Genomics, Policy and Population Health **UK Genetic Testing Network UK National Screening Committee**