This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Medical profiling and online medicine: the ethics of 'personalised' medicine in a consumer age* between April 2009 and July 2009**.** The views expressed are solely those of the respondent(s) and not those of the Council.

Tom Finnegan
Nuffield Council on Bioethics
28 Bedford Square
London
WC1B 3JS

21 July 2009

Dear Mr Finnegan

I am writing on behalf of the British In Vitro Diagnostics Association (BIVDA) with our response to your consultation on medical profiling and online medicine: the ethics of 'personalised' healthcare in a consumer age.

BIVDA is the national trade association for companies with major involvement and interest in the *In Vitro* Diagnostics (IVD) industry. IVDs are the tests used for:

- Early detection or diagnosis of disease
- Screening for disease pre-disposition
- Monitoring of treatment and disease management

As the representative organisation for the sector, BIVDA works to raise awareness of the clinical and cost utility of diagnostics in the provision of effective healthcare in the UK. The diagnostics industry has been a leader in healthcare innovation in recent years and it is committed to developing more efficient, effective and accurate diagnostic tests to aid and improve patient treatment and care.

The membership of BIVDA currently represents over 95% of the industry with more than 100 member companies. Membership includes UK subsidiaries of multinationals, UK SMEs and a number of start-up companies. We supply diagnostic tools to the NHS for a range of disease areas, including diabetes and cancer.

BIVDA welcomes the opportunity to respond to this consultation on the use of commercial medical profiling technologies and we have selected the most appropriate questions from the consultation paper to which we can contribute our expertise.

Q1. If an increasing number of medical products and services are becoming available as consumer goods – that is to say, as commodities which customers may choose to purchase provided they can meet the costs – is this development, on balance, desirable?

It is to be welcomed that developments in diagnostics are allowing greater choice for individuals who may wish to find out more about their own health and, potentially, change their lifestyle to improve their health and wellbeing. BIVDA believes that every person has the right to carry out a self-test if they want to find out more about their health. Self-tests provide personalised information about an individual's health, which can offer peace of mind where someone has previously had a concern. They can also highlight health problems and therefore encourage individuals to seek help from health professionals and other services. Self-testing fits into the wider health

policy agenda where the Government is actively encouraging people to take more responsibility for engaging in decisions about their health.

It is, however, critical that consumers can be assured of the safety, accuracy and reliability of the tests which they may use. People need to be able to have confidence in the method of administering the test, and most importantly the accuracy of the result. The test should also clearly signpost individuals to support once they have received a test result. It is important that an individual has the opportunity for follow-up with health professionals after the test, and that this is timely and sensitive to his/her needs regardless of the result. This could include a letter to inform of an unusual result, and a phone call with a health professional where there may be a concern. Some BIVDA industry members have health professionals on hand to discuss individual test results, who will direct the person to their own health professional for further advice.

At present, direct to consumer testing services are unregulated – there is no legislation regarding setting up and operating a medical testing laboratory provided that the information generated is not entering the NHS. These private laboratories must use tests which are CE marked indicating that the test meets all the requirements of the relevant EC Directive for *In Vitro* Diagnostics, including those relating to safety, quality and performance. However, because the operations and systems of these private laboratories are not currently regulated, there is no guarantee that only CE marked tests are being used and therefore that the results are safe and accurate for patients. A market exists for direct to consumer testing because these are tests that cannot be simplified enough to be done by a lay individual and/or without the need for laboratory equipment, unlike tests such as pregnancy kits which are routinely used by women at home.

Q**2. While much health related information is freely available to individuals, this varies greatly in quality and accuracy. Many of the lifestyle and health books and magazines that are currently available may contain medical information that is misleading or even incorrect from a scientific point of view. Do you think that information provided by DNA profiling and body imaging services raises different questions and should be subject to different regulations?**

It is BIVDA's view that all direct to consumer testing should be subject to appropriate regulation, so that consumers can be assured of the safety, accuracy and reliability of the test result. This is particularly important as individuals may make significant life-changing decisions based on the information from the test result. An inaccurate diagnosis can cause much anxiety, for example a positive diagnosis of the presence of a Hepatitis virus, which may be incorrect.

There should also be regulatory steps taken to provide support to, and protect the confidentiality of, individuals using these tests. Procedures should be in place to ensure the highest standards of patient confidentiality, so that information about an individual's health is treated with respect at all stages of the test and results process.

Q12. Do you think it is satisfactory for DNA profiling and body imaging services to have to pass stringent evaluations before they are provided in the NHS, but for them to be readily available on a commercial basis without having to go through such evaluations?

All commercial tests must, by law, be guaranteed by the CE mark. This indicates that the test meets all the requirements of the relevant EC Directive for self-testing, including those relating to safety, quality and performance. It is a requirement that all commercial diagnostic tests used within the NHS have the CE mark to indicate that they have been designed, and can be used, according to the rigorous procedures associated with the CE mark. (However, NHS laboratories can currently design and manufacture their own tests without any need for the same rigorous testing required for commercial products; this is in itself a loophole that BIVDA believes is a patient safety issue).

This should be extended to all direct to consumer testing service laboratories in order to ensure that individuals can be assured that the test result generated is accurate for the purpose for which it is intended, and that patient safety remains paramount.

It is important to stress also that genetic tests should not necessarily be treated as a distinct group of diagnostics apart from any other form of consumer self-test. Some genetic tests can give an individual information which will not have significant implications on his/her health and wellbeing or on decisions about their future lifestyle. There are diagnostic tests which are not based on genetics, whose results could be equally, or more, devastating to the individual, for example a positive diagnosis of HIV.

Q13. The results of DNA profiling and body imaging may lead people to seek appropriate treatment. But it may also lead to harmful actions, such as inappropriate self-medication, or people may become more fatalistic, believing that there is no point in altering their lifestyles. In the most extreme cases some people could become suicidal as a result of the predictive information they receive. Should providers ever be held responsible at law for such harms?

Providers of diagnostic tests should always work to uphold the highest standards of safety, reliability and accuracy in the tests which they manufacture. It is BIVDA's view that all direct to consumer tests should be subject to appropriate regulation. Where regulations are met, providers should not be responsible at law for such harms which individuals may take as a result of the information they receive. This issue was also publicly debated at length at the time when pregnancy self-test kits were first available to the public.

Q14. Some have criticised current commercially-available body imaging and DNA profiling services for giving information that is of limited quality and usefulness. Do you think more should be done to improve the quality and usefulness of body imaging and DNA profiling services?

BIVDA supports all appropriate regulation of direct to consumer tests in order to ensure that these tests are of the highest quality, safety and accuracy for the purpose for which they are intended. Our member organisations are constantly working to develop tests in new areas and to deliver improvements in existing diagnostics. As an organisation, BIVDA is also working with our members from across the *in vitro* diagnostics sector to uphold the highest standards of quality in tests available.

If you have any queries or would like any further information, please do not hesitate to contact me on 020 7957 4633 or by email at Doris-Ann@bivda.co.uk.

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Yours faithfully

Doris-Ann Williams
Director General