Dear Sir Norman,

Re: Direct to Consumer Genetic Testing

I am writing to you to address the Committee’s questions on the College’s stance on direct-to-consumer genetic testing. As you are aware, the College is the largest membership organisation in the United Kingdom solely for GPs. Founded in 1952, it has over 53,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline. The College is an independent professional body with expertise in patient-centred generalist clinical care.

- Are more people seeing their GP as a result of taking commercially available genomics tests?

The College does not currently have quantifiable evidence that direct to consumer (DTC) genetic testing is leading to more patients seeing their GP, however anecdotally we are aware of patients seeking clarification of the results, and information about how they impact on an individual and their family.

There is a lack of academic research on how much private screening results are presented to NHS services and the level of burden this presents. However, a survey, via social media (and therefore with attendant biases of sampling) of 500 doctors in 2018 found that, in the previous year, 91% of doctors had experienced seeing a patient, in an NHS appointment, to discuss the results of a private health screening. Only 13% of the time the professional thought this was a reasonable use of NHS resources. 75% of the time further resources – such as follow up appointment, blood tests or imaging – were arranged within the NHS.

- Do GPs have sufficient training when it comes to interpreting these results, and to support individuals who have taken these tests?

At present, GPs are not sufficiently supported to interpret the results of DTC tests, and we believe that GPs should exercise caution in interpreting the results from these tests. This is not least because the analytical validity and clinical utility of such tests is often lower than may be popularly perceived. Indeed, some DTC testing kits are marketed as being able to test for conditions where there is not sufficient evidence.

As the availability of these tests to the wider public is a new phenomenon it is understandable that GPs and their teams may not have sufficient knowledge and training of all areas around DTC testing to be able to interpret the results and appropriately support their patients.

We believe it is likely that further education or training will be required for clinicians to help them understand the principles and terminology of genomics, as well as to understand the ethical issues that may arise; and to support patients, and implement appropriate management, and navigate new clinical pathways. The RCGP is currently working with Health
Education England’s Genomics Education Programme to develop a genomics toolkit for primary care professionals.

The College also believes that it is the role of the Government and NHS England to educate patients about the limitations of DTC testing, and recommend that regulators should be asking that DTC testing companies provide clinical support as part of the models informing patients of the limitations of DTC testing.

- **Do the results supplied by the commercial providers offer enough information to GPs? What information would it be helpful for the commercial providers to supply?**

Different commercial providers supply different levels of information, and the College has not audited the information that all the different commercial providers offer. The level and depth of genomic testing varies considerably between tests and commercial companies, and generally doesn't involve the whole genome being sequenced, meaning these commercial tests cannot provide all the information on a person. Given the limited analytical validity and clinical utility of DTC tests, the College advises GPs to exercise caution if interpreting the results of such tests.

- **Do the College have any concerns about the public purchasing these tests? Are there any benefits for consumers?**

The College has several concerns about the public purchasing DTC testing kits. We are concerned that the current accuracy of the tests is often poor and therefore will result in either false positives, or false negatives due to the way such tests work. Indeed, some DTC testing kits are marketed as being able to test for conditions that there is not appropriate scientific evidence to support. This places increased pressure on already overstretched primary care services, and also feeds unrealistic patient expectations of healthcare. The probabilistic nature of genomic testing is not widely understood by the public, and the results from such tests may have a significant and unnecessary detrimental impact on the mental wellbeing of patients. We are further concerned about the related workload and cost implications this may have on the NHS, such as providing follow-up care and in some cases counselling. Finally, we are concerned by the privacy implications of providing genomic information to private companies; and how that information may be used by these companies in future.

- **Do we have any proposals or views on the regulatory framework for these tests? Do we have any views on the shape of future regulation?**

Currently, private companies are offering screening that is not approved by the UK NSC or NICE. People seeking private screening are not routinely told that the screening they are offered is either available within the NHS, if evidence-based; or not available within the NHS on the grounds of a lack of evidence.

There are no regulations on private companies to prevent them from undertaking screening that is not evidence-based. In England the Care Quality Commission do not regulate the information provided by private companies in advertising or information leaflets, or validate the evidence for the services they provide; and nor does HIS in Scotland, the Regulation and Quality Improvement Authority in Northern Ireland, or the Healthcare Inspectorate in Wales.

Guidance from the Department of Health and Social Care (DHSC) in England and the BMA states that the NHS should not be used to subsidise private healthcare services. The College
believes that the regulatory framework should:

- Remind private providers that it is their responsibility not to put the NHS at risk of subsidising private care.
- Ensure information provided through advertising and consent is fair, accurate, acknowledges what is available on the NHS and why other screening is not recommended, ensure that standards of consent are in keeping with GMC guidance.
- Ensure private clinics routinely arrange follow up at their cost.
- Encourage reporting of unjustified use of NHS services to them for their action.

The College believes that the regulatory framework for DTC genomics testing should take account of information governance and privacy issues around the use of patients’ genomics data by private companies. There are further privacy issues to be addressed since by implication the information gained about one patient also provides information about other individuals they are related to.

Further to this, the College's governing Council recently adopted a position statement on direct-to-consumer testing written jointly with the British Society for Genetic Medicine, and another position statement on screening by organisations which have not been approved by the UK National Screening Committee. These are both attached for reference by the Committee.

Please do not hesitate to contact me if we can be of further assistance to the Committee.

Kindest regards,

Prof. Helen Stokes-Lampard FRCGP
Chair of Council