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Dear Dr Bale

I am writing to draw to your attention to a number of issues that the Human Genetics Commission would like to see handed over to the new Emerging Science and Bioethics Committee (ESBAC) or another relevant Committee or policy team.

In its Final Report, which I enclose, the Commission's monitoring groups made a number of recommendations regarding issues they believed required follow-up or monitoring by either ESBAC or another appropriate body. I would therefore also like to take this opportunity to highlight some of our key recommendations from that report.

Databases and consent

The Commission had a long-standing interest in the ethical, legal and social issues associated with genetic and genomic data processing and consent.

We are now entering a new and crucial phase regarding the ethics and governance of storing, accessing and sharing genetic and genomic information. Next generation sequencing technologies are already generating large amounts of genomic data, both in research and in clinical settings. In order to draw the maximum benefit from this information, further

annotation with phenotypic or pathogenic status will be important, raising some concerns regarding potential identification of data subjects. The prospect of global genetic data sharing make these issues ever more pertinent.

At its plenary meeting in December 2011, following a request from the Human Genomics Strategy Group, the Commission discussed a possible generic consent model for genomic studies in the NHS. The Commission's opinion was submitted to the HGSG for consideration as part of the HGSG's report.

Had the Commission continued to exist, it would most likely have played a leading role in developing any future policy positions on these issues. It would therefore be appropriate for ESBAC, or an expert working group, to consider these issues and to provide advice.

Incidental Findings

The above issues are closely linked with the issue of whether, and if so how, to disclose incidental findings in clinical genetic testing. In September 2011, the Commission held a joint workshop with the Economic and Social Research Council (ESRC) Genomics Forum to explore this area. Unfortunately, due to time constraints it was not possible for the Commission to publish the workshop report. However, I am completing this work under the auspices of the ESRC Genomics Forum and would be pleased to share a report of the workshop with ESBAC at a future date.

Genetic Services

In recent years, the Genetics Services monitoring group published two key reports. *A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services* sets out a helpful governance framework for an area that is currently lacking regulation. The Framework has been welcomed internationally, with some countries building on its content to develop national guidelines and regulation. While it appears that uptake of DTC genetic testing services in the UK currently remains low, as sequencing costs continue to fall, it is possible that this may increase, with a possible concomitant impact on NHS genetics services as consumers seek support and advice on their test results. It would be useful if ESBAC could monitor the uptake of DTC testing, its potential impact on NHS services and how consistently the Framework is being applied by companies operating in this market.

In its report *Increasing Options, Informing Choice*, the Human Genetics Commission responded to a request for advice from the UK National

Screening Committee on the ethical aspects of preconception genetic testing. The report found that there were no specific social, ethical or legal principles that would make preconception genetic testing within the framework of a population screening programme unacceptable. The Commission was not able to follow-up its report with the Screening Committee but it would be useful to monitor the impact, and possible implementation, of the Commission's advice.

Genetics and Insurance

The Commission was fortunate to be provided with expert advice on issues relating to genetics and insurance from co-opted members of its Genetics and Insurance Monitoring Group.

In the Commission's final scrutiny exercise of the ABI Compliance Report, a number of issues were raised in relation to the 2011 review of the Concordat and Moratorium on Genetics and Insurance. Firstly, there was a view that the new compliance monitoring arrangements under the revised Concordat will be insufficient to reassure consumers that predictive genetic information will be processed fairly by insurance companies, as it appears that no data will be collated under the new agreement. The Commission agreed that it would raise issue this with the Department.

The Commission also expressed concern about the continued uncertainty regarding the 'test now, buy later' issue. The Commission welcomed the proposed measures to strengthen the Concordat, with future reviews always taking place three years before any potential end date of the Concordat so that consumers will always have three years to prepare for any potential change. However, the Commission also felt that consideration should be given to a 'sunset clause', i.e. if a consumer took a predictive genetic test under the Moratorium and a number of years had passed, it should no longer be possible for an insurance company to ask about the result of the test many years later. The Commission felt that there was something intrinsically unfair about the fact that consumers could not 'undo' a predictive genetic test but the insurance companies could 'undo' the Moratorium. I understand the next review of the Concordat will take place in 2014 and, as stated in the Commission's final report, it is hoped that the Government and the Association of British Insurers, perhaps with input from ESBAC, will give due consideration to finding a long-term solution to this issue.

Public Engagement

The HGC had a long history of public engagement, from its innovative Consultative Panel to citizens' inquiries on issues such as the National DNA Database. In its report the Human Genomics Strategy Group recommended the continued provision of high quality public engagement on the ethical, legal and social issues associated with further integration of genomic technology into mainstream healthcare provision. The Commission welcomed this recommendation but was unclear about who would be taking forward this role and what funding would be available for these activities.

The Commission's experience was that it was important to engage early on any proposals or in any process and that high quality public engagement did not come cheap. It therefore hoped that suitable funding would be found for these activities in the future. On the issue of consent, the Commission felt that there was value in engaging people early not only on the model but also on its implementation.

I hope these points are helpful. On behalf of the Human Genetics Commission, I would like to wish the Emerging Science and Bioethics Advisory Committee every success with its work and with developing its advice.

With best wishes,

Yours sincerely



Professor Sarah Cunningham-Burley
Former Acting Chair, Human Genetics Commission

cc Professor Sir Alasdair Breckenridge CBE, Chair ESBAC

Encl Human Genetics Commission Final Report, April 2012