Strategies of Regulation: Illustrations from the work of the Human Genetics Commission

Not all regulators are alike. Nor do all regulatory issues require the same approach. This piece reflects on factors that affect the selection of regulatory options in the context of the work of a UK body that was not a 'regulator' in the sense of formally overseeing the activity of others. The Human Genetics Commission (HGC) did not directly wield legal power, but it had a recognised place in UK bioethical governance. It was established in 2000 to provide the UK Governments with advice on the ethical, legal and social issues arising from Human Genetics and it adopted different approaches in various pieces of its work. It was disbanded in 2012 as part of the reconfiguration of non-governmental bodies, colloquially known as the 'bonfire of the quangos' (an acronym for quasi-autonomous non-governmental organisations), and partly replaced by an internal expert committee of the Department of Health in England to be known as the Emerging Science and Bioethics Advisory Committee (ESBAC).

The Commission can point to a number of regulatory successes in the instigation of legal interventions, such as the crime of DNA theft under the Human Tissue Act 2004. However, in other pieces of work different modes of regulation have emerged. Its interim recommendation in 2001 that there should be a moratorium on the use of predictive genetic testing in insurance led to such a moratorium being announced by the Association of British Insurers later that year, which has been periodically renewed by agreement with the Governments of the day. In other areas the Commission has not been able to convince its audiences of the wisdom of its views, as in the need for legal protection against genetic discrimination. Here, the Commission recommended in 2002 that consideration needed to be given to the need for specific legislation protecting people against discrimination on the basis of genetics. It considered that existing discrimination provisions (specifically the protections against unequal treatment on the basis of disability or the perception of disability) were inadequate to achieve this (a view that persisted even after the amendment of the Disability Discrimination Act 1995 following the EU Employment Directive 2000). The Disability Rights Task Force (1999) was not convinced. The Human Genetics Commission's suggestion that the UK's Equality Act 2010 should include specific genetic discrimination provisions was also rejected. Nevertheless, the Commission sought to keep the issue alive by convening a high level seminar with the Arts and Humanities Research Council and recommending in its consideration of the report of that seminar that the Equality and Human Rights Commission should continue to monitor evidence of genetic discrimination and keep the need for legislative change under review (*The Concept of Genetic Discrimination: A Seminar Report and Reflections and Recommendations* 2011).

These examples illustrate how the Commission needed to consider the opportunities for both short and longer term intervention and also a range of regulatory options. In some cases a specific and immediate legal intervention can be promoted. Where that failed it was necessary to consider how influence might be brought to bear over a longer time frame or through less direct regulatory approaches. Thus, it is necessary to consider the type of normative intervention that is ultimately most likely to promote the activities and behaviours that have been identified as desirable. Such regulatory strategies are sometimes obscured by the more explicit consideration of substantive

issues in the final published reports, which are the activities that generally receive the most attention. It may, however, be equally important

to consider how decisions were taken on how best to frame enquiries when they are established and also how recommendations are championed once the conclusions of the deliberations have been reached. These can be messy and difficult to disentangle; the context in which a report is published may be different from that in which it was initiated, the degree to which the 'regulator' can control the reception of its reports is limited, the conclusions that are reached may be unanticipated. Nevertheless, some scoping of how choices of regulatory strategy may be made is possible.

It will be grouped here under two headings. The first concerns issues relating to the art of the possible that result in the investigations being framed on the basis that some possibilities that are theoretically open are to be regarded as fixed for the purpose of the enquiry. This would include an assessment of the constraints put in place by aspects of the regulatory framework that are regarded as given (at least at the point of time in question), the realities of technological possibilities in the proximate future (distinguishing hyperbolic speculation from plausible developments within the regulatory time horizon), socio-political and economic contexts that are not expected to be amenable to influence within the time frame of the enquiry.

The second concerns which actors' behaviour recommendations the regulator should set out to influence. This might cover both providers and consumers of services. It could address governmental, professional and trade bodies. It might be concerned to shape the terms of public debate, either directly or through opinion formers such as various media. Each of these aspects of consideration is likely to colour the prudent selection of regulatory measures to that are likely to be effective. The regulator's task in this is neatly captured by Reinhold Niebuhr's prayer to be granted the serenity to accept the things that cannot be changed, the courage to change the things that should be changed and the wisdom to tell the difference.

These points can be elaborated in relation to the issue of genetic tests directly available to consumers without the intermediary of health service provision. The Human Genetics Commission had explored issues arising from the possibilities of widely available genetic testing in *Genes Direct* (2003) and *More Genes Direct* (2007) before it embarked on a specific piece of work on direct-to-consumer tests that led to the publication of *A Common Framework of Principles for Direct-to-Consumer Genetic Testing* (2010). Rather than proposing the extension of formal regulation beyond that already in place under the EU In Vitro Diagnostic Devices Directive, this framework sought to establish a consensus on high level principles through a collaborative process involving stakeholders from mainland Europe and the USA as well as the UK who represented public, professional, regulatory bodies, Governments and charities, as well as companies providing direct testing services. The principles included standards of scientific quality, marketing, the categorisation of tests including those where results should only be communicated by an appropriate health professional, issues relating to the genetic testing of children.

The proposal of a code of good practice were criticised by some for lack of courage, shying away from recommending a ban of a practice in which it saw many pitfalls. However, a number of features of the context were significant in explaining why this approach made sense to the Commission. First, the market about which concerns had been raised was a transnational one. Test kits might be

bought and marketed in the UK but it was highly likely that the actual testing would be carried out abroad, especially in the USA. Given the nature of internet marketing it was also possible that the marketing and purchase would also occur in the USA, swabs of samples being taken by the consumers in the UK when kits were sent to them, and then sent abroad for analysis. In this context, development of agreed principles for a code of practice had a better chance of securing acceptance from US providers of services than proposing regulatory restrictions at either UK or European level (even without taking into account the time that it might take to implement such restrictions). Once standards were in existence, they would also enable responsible testing companies to differentiate themselves from less reputable providers by using their compliance as a selling point and thereby giving a market advantage to good practice. Indirect force might be given to the standards where health professionals were involved via the requirements of professional ethics. In a world where there was clear demand for the services, the framework of principles might also serve to educate consumers to make better informed choices so that they were less likely to over-estimate the reliability, accuracy or significance of results.

This could be achieved more quickly than a more formal regulatory approach would have permitted. This approach did not preclude the adoption of further regulatory option in the future. The intention of the Commission had been to return to the regulatory questions, but its abolition ended its work in the area. However, even in the absence of such interventions, the principles have already had an impact in international discussions and can therefore be seen as providing the foundation for further regulatory action but nevertheless as powerful in their own right. Further, they created an environment where interventions by regulators in different countries were more likely to adopt a common approach and consequently more likely to establish a consistent regulatory framework that had a chance to work robustly in a global cross-border market. Thus, in both the case of genetic discrimination and the direct-to-consumer testing, it could be said that Commission was playing a long game – seeking to frame and influence the policy debates of the future even where it thought that early progress was unlikely. In part, this was a reaction to limitations placed on the authority and shelf life of the Commission following the announcement that it was to be wound down after the General Election of May 2010. However, this is not the whole picture. All regulators need to consider influencing strategies as part of their work and to shape the environment in which they work in order to achieve their long-term goals.

Jonathan Montgomery was Chair of the Human Genetics Commission between 2009 and 2012. The views expressed here are personal and do not represent the formal view of the Commission.