Reforming the Governance of Human Genetics: the Politics of Public Trust

KEY FINDINGS

As an emerging field of biotechnology, human genetics is regarded as saviour by some sections of the public and as villain by others. The aim of the project was to assess the ability of the new advisory and regulatory framework for biotechnology to deal with these tensions and the consequent issues of public trust in the field of human genetics. Data was gathered from policy documents on human genetics, the internet, media monitoring and interviews with key stakeholders in the regulatory bodies, civil society organisations and media. Evidence from the regulatory experience of the United States and the European Union provided an international context for the UK case.

RESEARCH FINDINGS

- There is a dual system of governance consisting of the advisory bodies (relatively open) and the core policy community (closed).
- The 'core' policy community of the Department of Health, the Office of Science and Technology, and the Cabinet Office is fragmented.
- Many of the growing number of civil society groups with an interest in human genetics perceive a divided system of regulation, still heavily influenced by industry, to which they have fragmented and partial access.
- These groups form into policy networks which generated their own internal dynamism and instabilities, particularly when engaging with the media.
- The Human Genetics Commission has created a counter and open dynamic to the traditional secrecy of the departmental civil service.
- The UK's regulatory system for human genetics at present supports the UK's international competitive advantage and European leadership in this field. However, regulatory initiatives by the EU may well challenge the format of the UK system.
- Some UK civil society groups are already developing a presence at the EU level where political access is more open.
- Bioethics is emerging as a new form of expertise which challenges the central role of science in human genetics regulation.

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The Problem of Governance

The pace of change in biotechnology in general and the field of human genetics in particular is placing the governance machinery under considerable strain as it attempts to deal with the consequent political and economic pressures. As *The Advisory and Regulatory Framework for Biotechnology: Report from the Government's Review* clearly recognised, following as it did hard on the heels of the controversy over the governance of genetic modification for agricultural purposes and in the midst of the BSE inquiry, public trust in both the field of genetics itself and its institutions of governance is problematic. Since then, continuing and widespread interest from the media and public lobby groups in similarly controversial issues such as stem cell research, cloning, and genetic testing for insurance purposes has ensured that, for the foreseeable future, the politicisation of the field is here to stay.

The reforms emerging from the government's review are intended to ensure the legitimacy of biotechnology in the eyes of the public and to enable the UK to benefit economically from a lead position in its global development. The technical and strategic functions of biotechnology governance have been reorganised under the Human Genetics Commission (HGC), the Food Standards Agency (FSA) and the Agriculture and Environment Biotechnology Commission (AEBC) and their respective committees and agencies. Each of these is intended to embody the best practices for reformed governance as laid out in the report: streamlined processes, transparency, public consultation, and broadened committee membership.

A Divided Policy Community

The research found that the ability of the new regulatory framework to cope with the political pressures from a growing number of interested groups is limited by a number of factors. What may be termed the 'core' policy community of the Department of Health, the Office of Science and Technology and the Department of Trade and Industry, and the Cabinet Office have yet to evolve a coordinated approach to the formation and implementation of policy on human genetics. The relationship of this community to the advisory and regulatory framework is obscure as are the interrelationships of the formal bodies which constitute that framework. In a sense this is not surprising because it is, after all, a new policy arena where the rules of engagement are still being developed. Nonetheless, what remains is the impression of a dual system of governance consisting of the advisory bodies (relatively open) and the core policy community (closed).

The Limits of Open Government

The number of organisations with an interest in this field is growing in response to its expanding scientific and therapeutic possibilities and placing increasing and more varied political demands on the regulatory apparatus. These 'policy networks' generate their own internal dynamism and instabilities, particularly when exposed to, or colluding with, media interest. Promises of more open government have been received with some scepticism by many of these groups which perceive a divided system of regulation, still heavily influenced by industry, to which they have fragmented and partial access, albeit more than to the core policy community.

The Emerging Role of the Human Genetics Commission

In terms of the future adaptability of the machinery of regulatory policy making, much depends on a further finding: the ability of the Human Genetics Commission (HGC) to capitalise on its reputation among policy networks as relatively open and prepared to engage with their interests. As a new player in the politics of governance in this field the HGC has demonstrated its ability to create a counter dynamic to the traditional secrecy of the departmental civil service. With its broader representational base and range of expertise it can draw on new sources of regulatory legitimacy. To that extent its political utility to the state increases considerably.

International Pressures and EU Politics

However, the state's response to these difficulties and opportunities is complicated by the international dimension. The project's findings indicate the unavoidable impact of both international economic competition and the European Union's (EU's) highly politicised debate on human genetics on the UK's domestic regulatory politics. As the European leader in key aspects of human genetics R and D the UK is competing with other countries, and in particular the United States (US), for global advantage. In this situation regulatory politics becomes the crucible where the search for that advantage collides with other interests. Thus the stem cell regulations introduced by the US, for example, have already benefited the UK's relative attraction to scientists in this field given its liberal regulatory regime. However, this position may not be sustainable if possible EU moves on the regulation of human embryo and human tissue research take a particular form. The UK therefore has to engage in some detail with the internal politics of EU regulation to protect its stake in human genetics. As it does so our research indicates that it may well find familiar faces at the political table as the national policy networks of civil society develop their EU profile. Indeed, the nature of multi-level governance, and the permeability of EU institutions when compared to the defences of the UK policy community, have already encouraged some policy networks to take this course.

From Technocracy to Bioethics

The 1999 reforms represent a move, at least at the rhetorical level, away from technocratic regulation towards a different and only vaguely articulated form of open governance. The project's findings indicate that this has generated what may be termed an 'authority vacuum' into which new forms of expertise, and in particular bioethics, are attempting to insert themselves. Supported by a range of international and EU agencies and networks, bioethics is laying claim to the roles of both informant and arbiter of an increasingly ethical policy discourse. What remains to be seen is how far the UK's advisory and regulatory framework is able to incorporate - and authorise - such new forms of expertise in a systematic fashion.

The Policy Implications

- The effectiveness of the advisory and regulatory framework is partially dependent on the ability of what we have termed the core policy community to coordinate its policy formation activities. At present those activities are fragmented. A single administrative unit should be given the responsibility and the power to enable (a) cross-departmental coordination and (b) explicit linkage with the appropriate advisory/regulatory bodies.
- The four elements of open governance listed in the 1999 Review (streamlined processes, enhanced public consultation, broadened committee membership, and transparency) provide a convenient means for the evaluation of the framework's progress. Drawing on the evidence of this project, in 2004 the HGC should introduce a five year review of progress towards open governance with reference to itself, its associated committees and the core policy community of human genetics.
- Given the emergent role of bioethics as a source of regulatory expertise and legitimation, as the responsible strategic body the HGC should formally reflect on the role of bioethics at the international, European and national levels and consider how best to integrate it into its own operation and the committees under its aegis.
- The variable access to the advisory and regulatory framework accorded to different policy networks is a continuing source of political tension. Efforts should be made to ensure that the full range of networks are engaged in the regulatory policy process particularly with regard to building a stronger culture of exchange between the civil service and the advisory groups. Such a development may also offset the scepticism among policy networks regarding the continuing influence of industry.

About the Project

The project was funded as part of the ESRC Innovative Health Technologies Programme and carried out between April 2001 and July 2003.

Data was gathered from policy documents on human genetics, the internet, media monitoring and 53 interviews with key actors in the regulatory bodies, civil society organisations and media. The interviews were semi-structured and organised around a model of the policy process in the governance of human genetics. Evidence from the regulatory experience of the United States and the European Union collected by policy analysis and 30 interviews provided an international context for the UK case. Two workshops were held with stakeholders in human genetics at the midpoint and end of the project in order to reflect on the data, inform the analysis and disseminate information.

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