Change in the policy community of human genetics: a pragmatic approach to open governance

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Abstract

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The 1999 Review of biotechnology regulation launched a policy designed to deal with the politicisation of GM foods and agriculture and enable the policy community of human genetics to deal with similar pressures through a new and open approach to governance. In implementing this policy of self-reform, the policy community of human genetics is obliged to reconcile conflicting political demands from the policy networks of civil society, science and industry as it seeks to establish and maintain the legitimacy of the new regulatory apparatus. Drawing on documentary and interview evidence, this paper employs the case of human genetics to explore the way in which policy community change may be limited by the nature of its existing culture and policy networks in ways not predicted by existing theory. It reveals a pragmatic approach to change characterised by a Whitehall core policy community employing a closed, elite model of policy making and an outer periphery composed of the Human Genetics Commission and its associated agencies where the tenets of open governance hold sway. Policy networks enjoy reasonably open access to the periphery but a highly selective access to the inner core dependent on their ability to resonate with the dominant policy paradigm of scientific and industrial advance. Whilst politically functional at present, this arrangement is unlikely to provide the policy community with the flexibility to deal with any high profile politicisation of human genetics.

Introduction

Propelled by the difficult experience of genetically modified (GM) foods and agriculture, the 1999 Review of the governance of biotechnology published in *The advisory and regulatory framework for biotechnology* set out a new vision of an open style of policy community better equipped to address the recognised tensions between civil society, science and industry in this new, and valuable, knowledge field (Cabinet Office and Office of Science and Technology (OST), 1999). The reformed policy communities of biotechnology were to be transparent, consultative and accessible to a broad range of civil society interests. Without such a shift in the official culture of policy formation and implementation, the report argued, public trust in the new technologies of food, agriculture and health would be fragile and easily undermined.

In theoretical terms, the approach of the Review is not new. Policy community and network theory suggests that over time policy communities should be prepared to change the sources of expertise they consult and the policy networks with which they engage if they are to remain flexible in the face of new political demands from a changing policy environment. An oft quoted example is that of food policy in the late 1980s where, under pressure from the outbreak of salmonella in eggs and other food scares, the consensual policy community was obliged to evolve into more pluralistic 'issue networks' to deal with consumer pressures (Smith 1991). But policy community adaptation is not always straightforward. Established practices, networks and policy paradigms can generate a reliance on the familiar that creates an inertia opposing the good intentions of governance reforms and may undermine the policy community's ability both to change itself and to produce policies relevant to the needs of new constituencies of interest.

Within biotechnology human genetics constitutes a domain that posed a particular challenge to the policy community's development and its ability to deal with the pressures created by the new science. The unravelling of the human genome and the therapeutic promise of areas such as stem cell research, pharmacogenetics, gene therapy and predictive diagnostics had stimulated interest from civil society, the scientific community and industry. However, unlike the other biotechnology domains, health was as yet unpoliticised. The high profile experience of GM foods and agriculture had left it unscathed and the government's intention was that the governance reforms would keep things that way. But the case of human genetics was

unlikely to prove straightforward: it was a new and still developing policy community, its core identity was uncertain and the positive and negative implications of human genetic science had activated a broad spectrum of new and existing policy networks with little stability in their relationships either with each other or with the policy community. Regulatory politics in this field were decidedly unroutinised.

Furthermore, policy community change was taking place in the aftermath of the Phillips Inquiry into bovine spongiform encephalopathy (BSE) and the pressures generated by its recommendations for the reform of the scientific advisory system. Following the well-documented failures of scientific advice throughout the BSE crisis, government policy emphasised that there must be a shift towards greater openness and public consultation if the trust of citizens in its regulatory arrangements was to be maintained (HM Government, 2001). However, there was always likely to be resistance to this policy of reform from a scientific advisory system traditionally characterised by isolated scientific networks with a consensual, inward looking and essentially private style of operation (Wynne, 2001).

Policy community change was therefore likely to be problematic and it is the nature of this problematic that forms the focus of this article. In analysing the engagement between the policy ambition of the Review and the obstacles which lay in the path of its implementation, the paper begins by exploring the theoretical relationship between policy community change and policy networks. Secondly, it outlines the structures of the human genetics policy community in terms of an inner Whitehall 'core' and an outer periphery of advisory and regulatory agencies. Thirdly, it examines the implications of this divided policy community for policy formation on two issues: genetics in the NHS and stem cell research. To what extent is the policy goal of open governance applied in these examples and how far is it constrained by traditional civil service values? Finally, the degree of policy community change is measured in terms of the reformulation or stability of the relationship between policy community and policy networks.

Policy community change

The pressure for change in the policy community of human genetics from civil society, science and industry is a product of their interest in the creation of human genetics knowledge, its industrial application and its therapeutic potential. Sometimes

those interests may overlap, on other occasions they may be completely incompatible. It is the role of policy on the regulation of human genetics to promote the means for negotiating and resolving the tensions between the different interests. A key measure of success is the degree of public trust not only in human genetics science itself but also in the procedures and institutions which regulate it. If the policy fails and public confidence declines, there will be costs to pay in terms of the political exposure of the regulatory institutions, the economic vulnerability of the emerging industry of human genetic technologies and the likely escalation of critical media interest. As the 1999 Review and its recommendations for reform well illustrate, there is much to play for.

In this context, how do we conceptualise the problem of policy community change? Stable policy communities can be seen to emerge when the state's engagement with a particular set of policy networks becomes routinised, boundaries are established to identify 'insiders' and 'outsiders' in the policy domain, and a policy paradigm is institutionalised (see, for example, Marsh and Smith, 2000; Wright, 1988). Underpinning a policy community are shared values, a common understanding of 'the rules of the game', trust between its members, and an acceptance that cooperation is the best way to achieve common goals (Borzel, 1998; Hindmoor, 1998). Over time its membership tends to become highly restricted and hierarchical (Marsh and Rhodes, 1992). Once stability is established, a policy community may come to dominate all phases of the policy process: agenda-setting, evaluation of alternatives, policy formulation, policy implementation, and policy evaluation (Coleman, 1999). To maintain its stability, the efficient delivery of policy and a secure and dominant policy paradigm, a policy community favours some networks over others. Those policy networks granted most legitimacy by the policy paradigm become the core actors participating in the sub-government of policy community (Coleman, 1999: 6).

Policy communities and networks are related but distinct concepts. A 'policy network' describes relationships across a broader range of actors (politicians, bureaucrats, interest group representatives, professional bodies, etc.). Network activity entails the mobilisation and sharing of resources (funds, information, space, time, expertise, social capital, etc.) both within and across networks, for the purposes of shaping policy outcomes. The affinities which form the basis of these network interactions usually derive from actors' identification of similar goals and values. An affinity of approach, process, or discursive style may also inspire co-operation. This

recognition of affinities is a key strength the network approach has in comparison to rational institutionalist approaches: 'not only do ideas, beliefs, values, identity and trust matter in policy networks; they are constitutive for the logic of interaction between the members of a network' (Borzel, 1998: 262). Network interaction is characterised by routinised patterns which in turn shape behaviour, simplify the policy process by excluding certain directions the policy agenda could take, and thereby limit the range of both problems and solutions. In this way they may relieve policy-makers of some of their burden such as information gathering and synthesis (Marsh and Smith, 2000:2-3). Further, the policy community can benefit from the integration of policy networks into policy making processes because networks are capable of both legitimating those processes and outcomes and enabling policy implementation.

One significant consequence of this interdependence is that policy community change may require alteration not only in the membership of that community but also in the pattern of its policy network relationships. In their study of the GM crops issue, Toke and Marsh showed how the reconstitution of the membership of key committees in this policy field was accompanied by a realignment of policy networks (Toke and Marsh, 2003). Driven by the previously passive Department for the Environment. Transport and the Regions (DETR), in 1998-99 the membership of the Advisory Committee for Releases into the Environment (ACRE) was radically overhauled to replace its pro-biotechnology industry composition with experts more attuned to the issue of environmental protection. At the same time, a 'Scientific Steering Committee' (SSC) was established to judge the results of the GM crop trials. Its membership consisted of independent scientists and scientists from the Royal Society for the Protection of Birds (RSPB), English Nature and the Game Conservancy Trust – respectable and insider members of the environmental lobby who became important players in the new DETR sponsored policy community. In parallel to these changes, the access afforded to the farming and biotechnology industry networks diminished, as did their influence over policy. Radical environmental groups such as Greenpeace and Friends of the Earth however remained on the fringes of the policy community with access to the new Agriculture and Environment Biotechnology Commission (AEBC), a body that was to prove more adept at debate than influence.

The GM crops example shows how a determined department of state can re-engineer a policy community in terms of its membership, its dominant policy paradigm (environmental protection rather than economic benefit) and the relative position of competing policy networks. However, the policy domain of human genetics in the wake of the 1999 Review appears to be rather different. While public interest in human genetics was undoubtedly present the controversies of the field were few and low key, and political pressure a potential rather than an actual problem for the policy makers, not least because of the youth of the science and the distance still to travel to its therapeutic applications. Furthermore, there was no obvious department of state with a burning ambition to implement the open governance policy and, in particular, administer its requirement that the membership of the policy community be reconfigured (or at least re-examined) and the policy networks of civil society be accorded a more significant presence in the policy community.

In examining how the human genetics policy community dealt with a policy that aimed at its own reform, we draw on data gathered and analysed by the 'Governance of human genetics project' between April 2001 and July 2003. Using the internet for much of the work, policy documentation was gathered from the regulatory and advisory bodies, government departments, and a range of organisations with an interest in the field of human genetics. At the same time the media was monitored for policy issues relevant to the research and applications of human genetic science. Having thus established the broad outlines of policy community and networks, semi-structured interviews were conducted, tape recorded and transcribed with 53 political actors with key roles in the policy process thus defined. In part these actors were identified through their structural position as officers or members of particular organisations and in part through a 'snowball' approach based on their political reputation as described by other interviewees.

The policy community of human genetics

Taking the Review of the advisory and regulatory system for biotechnology at its face value, it was the intention that its proposed measures would reconcile the interests of civil society, science and industry by 'strengthening the protection of public health and the environment, while allowing the biotechnology industry to develop and demonstrate its potential benefits' (Cabinet Office and Office of Science and

Technology (OST), 1999: 1). To achieve this political alchemy, strategic issues on human genetics were to be dealt with by the Human Genetics Commission (HGC) which, with the Food Standards Agency (FSA) and the Agriculture and Environment Biotechnology Commission (AEBC), was to provide,

> strategic analysis of biotechnological developments, addressing broader issues including ethical considerations regarding the acceptability of genetic modification, identifying gaps in the regulatory and advisory framework and building up a wider picture from the lessons learned from individual regulatory areas (Cabinet Office and OST, 1999: para 8).

Specific regulatory and technical issues were allocated to the HGC's five associated committees, including the regulation of medicines and the pharmaceutical industry. The specialist committees are: the Genetic Therapy Advisory committee (GTAC), the Genetic and Insurance Committee (GAIC), the UK Xenotransplantation Interim Regulatory Authority (UKXIRA), the Human Fertilisation and Embryology Authority (HFEA), and the Committee on the Safety of Medicines (CSM). (The HGC has absorbed the Advisory Committee on Genetic Testing (ACGT), the Advisory Group on Scientific Advances in Genetics (AGSAG), and the Human Genetics Advisory Commission (HGAC)). (There is no line of accountability between these specialist committees and the HGC.) The Review is emphatic that the ethos of the new arrangements should be one of openness, consultation and improved lay representation. If the policy community and its agencies are to deal with the pressures they face, the report argued, then they must be flexible and responsive.

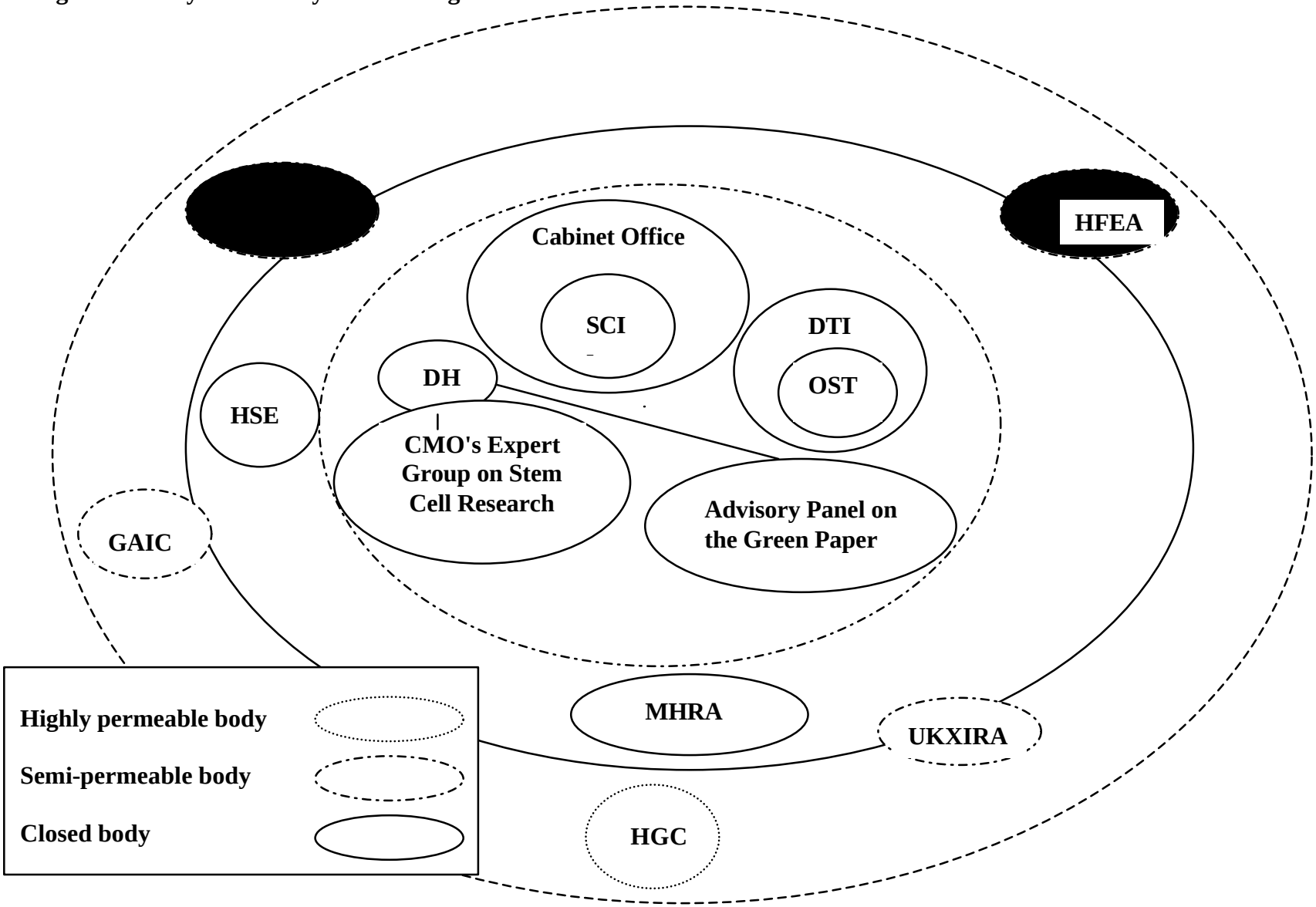
This neat policy statement of formal structures with the HGC in an apparently central strategic role has to be matched against the way in which the human genetics policy community actually evolved as part of the government's broader response to biotechnology politicisation. Recognition of the need for a policy community to address the political needs of biotechnology came in Autumn 1998 following the public protests and wide scale media interest in GM foods and agriculture. In response to this issue, and given that there was no 'natural' institutional locale for a new knowledge domain which spanned departmental concerns (food, agriculture, health, science), the Cabinet created the Ministerial Committee on Biotechnology and Genetic Modification (subsequently shortened to the Ministerial Committee on

Biotechnology – SCI(BIO)) with the brief to 'consider issues relating to biotechnology –including those arising from genetic modification, biotechnology in healthcare and genetic issues – and their economic impact; and to report as necessary to the Committee on Science Policy' (Privy Council Office, 2004). As its first chairman, Dr Cunningham (then Minister of Agriculture), explained to the Select Committee on Science and Technology, 'the Government felt, that we would benefit from….more joined up thinking, more inter-departmental communication and more focus on these issues'. He presented the Cabinet Office as 'it often does in cross departmental matters [as] holding the ring in these matters, taking the responsibility for ensuring co-ordination across the Government in our thinking about the issues and the development of policy on those issues' (Select Committee on Science and Technology, 1999: question 784). One of the first decisions of the new committee was to establish the Review of the regulation of biotechnology, to be carried out by officers of the Office of Science and Technology (OST) of the Department of Trade and Industry (DTI).

As a result of the Review and the continuing work of SCI(BIO) which meets on a three weekly basis, the organisations involved in the formation and implementation of policy on the regulation of human genetics became those outlined in Figure 1. These structures in turn formed part of the complex map of biotechnology regulation as a whole which also includes the territories of the Department for the Environment, Food and Rural Affairs (DEFRA) and its associated agencies (e.g. the Advisory Committee on Novel Foods and Process (ACNFP), Advisory Committee on Releases to the Environment (ACRE)) (DTI, 2003). Our interviews indicate that what can be termed the 'core' policy community of human genetics has a Whitehall identity consisting of SCI(BIO) itself, the OST, the DTI and the Department of Health where there is a degree of routinised interaction and the regular exchange of information on genetic issues. Less central are the Medicines and Healthcare Products Regulatory Agency (MHRA – accountable to the Department of Health) and the Health and Safety Executive (HSE – accountable to DEFRA), established and statutory agencies which would expect to be consulted on genetic issues relevant to their area of responsibility. Following the Review, the HGC and its associated agencies were positioned on the periphery of the policy community.

Given the policy ambition of the 1999 Review for a reformed human genetics policy community characterised by an open approach to governance in the pursuit of robust public trust, the question then becomes one of how far the core and periphery of the policy community were able to interact to achieve that ambition. How did they deal with the policy pressures for policy community change? It was the stated policy intention of the Review that strategic issues on human genetics should in future be dealt with by the HGC which was given the broad brief 'to advise on applications of biotechnology in health care, and the impact of human genetics on people's lives' (Cabinet Office and OST, 1999:1). One might therefore assume that the HGC would assume a lead position in the policy community, or at least be built into the consulting process of the core of that community. However, what emerged instead as the

Figure 1. Policy community for human genetics



dynamic of the new arrangements took effect was a clash of political cultures between periphery and core.

The Review made it clear that transparency and openness were to be the watchwords of the HGC's style of operation. From the outset the Commission accepted this recommendation and took the view that in order properly to 'advise the government on developments in human genetics and the social and ethical implications, [it] will promote debate and achieve effective representative dialogue with a wide cross-section of people' (HGC, 2002: 1). It formally adopted a Public Involvement Strategy and engaged in a series of very public policy consultations on issues such as the use of personal genetic data and preimplantation genetic diagnosis (HGC, 2002; 2001a and 2001b). In addition it commissioned work on public attitudes towards human genetic information and on international law and regulations concerning the protection of genetic information (HGC, 2000a and 2000b) and was energetically promoted in the media by the independent style of its chair Baroness Helena Kennedy.

Ironically, by implementing the policy recommendation on open governance so literally, the HGC thus offended the culture of secrecy characteristic of the civil service and aroused the suspicions of the core policy community. The resistance to change in the way in which policy is formed is formed is palpable. A member of the Commission commented that:

> The civil servants were jittery about open meetings I think, and understandably, it's not a culture they understand here….I know from speaking to civil servants who are attached to the HGC that their bosses in the DoH and DTI are not really happy about everything. One of them said to me "they're worried we've gone native". It's because the civil service is so secretive about everything - and so when people were actually talking about public meetings and public involvement, they get a bit worried about it….And it's a very strong cultural thing about not giving anything away. (Interview 2)

To explore in detail the implications of this culture clash for the goal of policy community change, we examine the way in which policy was formed on two issues: genetics in the NHS and the new legislation on stem cell research. Together they

illustrate how the rift between the HGC and the Whitehall departments has created a divided policy community in human genetics. Policy community change is taking place, but not in the way envisaged by the 1999 Review. Rather, there is a process of pragmatic adaptation in train, driven by the core policy community and acquiesced in by its periphery.

Policy formation in human genetics

In a speech on 19th April 2001 at the opening of the Institute of Human Genetics, Newcastle-upon-Tyne, the then Secretary of State for Health Alan Milburn announced the establishment of an Advisory Panel to inform the production of a Green Paper on the development, funding and regulation of genetics in the NHS: a large and substantial policy issue (Department of Health, 2001). In the course of time the status of the Panel's brief changed and, instead of inputting to a Green Paper, it provided advice for the production of the White Paper *Our inheritance. Our future. Realising the potential of genetics in the NHS* (Department of Health, 2003). At the same time, its role in the creation of policy diminished and was largely replaced by contributions from permanent officials in the Genetics Unit of the Department of Health. Nonetheless, given the invisibility of the Department's policy work, it was the Advisory Panel on the Green Paper (the 'Green Paper Committee' as it was known) which attracted the interest of the other potential actors in the policy process.

Chaired by Lord Turnberg, for all of its two year life the Advisory Panel operated in secret using selective consultation with particular individuals and organisations which, revealingly, in the initial stages did not include the HGC. From outside the HGC this seemed a distinctly odd way to proceed. As one interviewee observed,

> The DoH is writing a Green Paper and that has been such a different experience from the approach of the HGC. It hasn't been open at all, it hasn't invited people to submit their views on what they think the focus of the Green Paper should be. It's development has all taken place behind closed doors. From discussions held at some of its open meetings, I don't think the HGC was aware of what was happening for a long time from many of the meetings they had….You have a lot of expertise on the HGC so why isn't government consulting straight away with HGC? If you are going to have a commission that has an overarching capacity then it should be the first resource to be approached. (Interview 1)

From inside the HGC it seemed even odder:

> When the government set up the committee under Lord Turnberg to do this Green Paper, that was all behind closed doors. We weren't told it was going to be set up. All of a sudden it happened. I said 'What the hell is this all about? They're doing similar things to us'. And they said 'Well its about the NHS'. And I said 'What are *we* [his emphasis] doing? Human genetics, well where does this take place? Do me a favour, it's not something people sell on the street'. So that was worrying. And I got some real nasty stuff from some civil servants about this, because I made such a fuss….And even Turnberg, who I met, was embarrassed about this….Then they said 'Well we'll work together'. And I said 'Well how can we work together when you're working in secret and we're working in public? What's all that about?' And I never got an answer and still don't know what's going on. (Interview 2)

The conclusion reached by this and other interviewees was straightforward: 'If at any point the government decides that they want something done that might be questioned in public, they will just bypass us [the HGC].' (Interview 2)

In the second example, the case of stem cell research, the scientific and industrial pressures on the core policy community of human genetics again produced a response characterised by a closed, elite model of policy formation. By the late 1990s, scientists working with human embryonic stem cells (ESCs) had reached the point where, in their view, they needed their research freedom to be extended beyond the existing statutory limits. In particular, they needed to apply cell nuclear replacement (CNR) techniques requiring the cloning of human embryos – which took them beyond the limits of the Human Fertilisation and Embryology Act 1990 and beyond the regulatory capacity of the Human Fertility and Embryology Authority (HFEA). Given the claimed potential of stem cell research to produce therapeutic benefits for such intractable diseases as Parkinson's and Alzheimer's, British industrial interests were also very interested in this field. Yet the sensitivity of civil society to human cloning posed a handling problem for the policy makers. Some European countries had already banned it and the European Parliament had regularly opposed its use whether for reproductive or therapeutic purposes (Salter and Jones, 2002a, 2002b).

In response the government established an ad hoc Expert Group chaired by the Chief Medical Officer Sir Liam Donaldson, composed chiefly of scientists in the field, with no lay representation, operating independently of the HFEA, that did not engage in any extensive or systematic public consultation (consultation information was available on the World Wide Web and submissions were received from non-scientific interested groups and individuals, but this was very limited in terms of accessibility and scope) and which duly produced recommendations favourable to embryonic stem cell research in 2000 (Department of Health, 2000). These recommendations were implemented by the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 and mean that research on human embryos up to 14 days old can be conducted which (in addition to the provisions of the Human Fertilisation and Embryology Act 1990 allowing research for reproductive purposes) increases knowledge about the development of embryos, about serious disease, or enables such knowledge to be applied in development treatments for serious disease. (Additional legislation in the form of the Human Reproductive Cloning Act 2001 was introduced to ensure that the new regulations could only allow human embryo cloning for therapeutic purposes.) In an interesting move to enhance the legitimacy of the new policy, the actual issuing of licenses by the HFEA to conduct ESC research was made contingent upon a review of stem cell research by the House of Lords Select Committee on Science and Technology (Science and Technology Committee, House of Lords, 2002). On 13 February 2002 that review concluded that embryonic stem cell research was justifiable and two weeks later the HFEA issued the first licences for such research to proceed. In statutory terms, the UK had created the most liberal regulatory regime for human embryo research in the world.

Although both the NHS genetics and stem cell policy initiatives were driven by the Department of Health and the core policy community, the relationship between core and periphery was different in the two examples. In the first case, as a member of the periphery the HGC was completely excluded from the core policy community's deliberation. The Commission's drawbacks for the core policy community were that it was open, transparent, composed largely of non-scientists and therefore likely to challenge the preferred policy agenda . However, in the second example, the cohesive power of an overlapping network of stem cell scientists ensured that there were strong links between the core policy community and the HFEA. As experts, the scientists formed the dominant membership of the CMO's committee on stem cells and were, and are, strongly represented on the HFEA. As a component of the policy making

process, the scientific network was therefore employed in its traditional role as a source of expertise and, it was hoped, of authority. The clear inference of this evidence on two important policy issues is that the core policy community is content to rely on its customary mode of policy formation and include or exclude the periphery on a case by case basis.

The changing relationship between policy community and policy networks

The decision of the core policy community not to follow the advice of its own Review of biotechnology regulation and adopt a more open, inclusive approach to policy making in this field raises some important theoretical questions regarding its ability to deal with civil society pressures through a process of policy community change. Quoting the example of the Thatcher government, Marsh and Rhodes argue that the 'rejection of consultation and negotiation almost inevitably led to implementation problems because those groups/agencies affected by the policy, and who were not consulted, failed to cooperate, or comply with, the administration of the policy' (Marsh and Rhodes, 1992: 181). Inflexible policy communities, it is argued, risk incurring high political costs. Whilst the Review suggested that at one level the state had learnt this lesson, the behaviour of the human genetics policy community over the NHS genetics and stem cell policy issues indicates that, at another, it had not. When faced with instability and new issues in the political environment the policy community was not willing (or able), as Coleman puts it, to change the membership of the central actors within the policy community and thus the range of possible policy outcomes. The policy community did not accept that:

> Faced with conflicting opinions from experts, politicians will have to decide whom to regard as authoritative, especially on matters of technical complexity, and the policy community will engage in a contest of authority over the issues at hand…. Most likely, the groups or advocacy coalitions granted most legitimacy by the policy paradigm become the core civil society actors who participate in the sub-government or actor constellation of the policy community (Coleman, 1999: 697).

Instead, the analysis of two policy issues suggests that the policy community of human genetics worked through its established scientific networks and largely excluded from the business of policy formation those policy networks that might oppose its intended policy direction. How valid is this view if we generalise from it

and examine in detail the relationship between the human genetics policy community and its policy networks?

In his review of conceptions of policy networks Borzel comes to the view that a minimal definition is 'a set of relatively stable relationships which are of a non-hierarchical and interdependent nature linking a variety of actors, who share common interests with regard to a policy and who exchange resources to pursue these shared interests acknowledging that co-operation is the best way to achieve common goals' (Borzel, 1998: 254). Applying this definition, our project created a profile of ten policy networks of civil society, science and industry in human genetics based on the ideological affinities of the constituent organisations as identified from their publicity material and the interviews with their officers and members (Figure 2). They are a combination of existing organisations that have adapted their activities in response to the emergence of human genetics and new organisations summoned into being by the unique opportunities and threats of the new knowledge. The networks are not static but activated (and deactivated) by particular issues.

One measure of the nature of the engagement between policy networks and policy community, and in particular the extent to which networks have penetrated that community and thus rendered it more 'open', is the formal involvement of network members in policy community structures. Data on the membership of the core policy community is limited but we do have the committee membership relevant to the two policy issues quoted earlier: the 'Green Paper' on genetics and the NHS and stem cells. In the former case, the Advisory Panel (as it was termed) on the Green Paper was chaired by Lord Turnberg, former President of the Royal College of Physicians. Including the chair, its 14 person membership consisted of eight senior genetic or medical scientists, two industrialists (Bioindustry Association and Association of British Pharmaceutical Industry), two members of the 'Advocacy, patients' civil society policy network (Genetic Interest Group and Breakthrough Breast Cancer – both 'pro' genetics research), one biethicist and one nurse counsellor (Department of Health, 2002). With the possible exception of the latter two, none of the membership was aligned with networks hostile to human genetics research and development. The policy community had faithfully recruited members sympathetic to the dominant policy paradigm supportive of genetics research. The second example is yet more clear cut. The CMO's 'Expert Group' on stem cell research had 14 members of whom ten were senior genetic or medical scientists, one a bioethicist, one a lawyer

Figure 2 – The policy networks of human genetics

Civil Society

Ethics, faith based. Promotes values associated with religious belief systems regarding the sanctity of human life. It has emerged primarily in response to the implications for prenatal human life of technologies stimulated by human genetics knowledge. Examples are Comment on Reproductive Ethics (CORE), Christian Action Research and Education (CARE), the Pro-life Alliance.

Ethics, commercialisation. Focuses on the effects of global capitalism and commercialisation of human tissue and genetic material as part of a larger social justice concern. It is particularly interested in how the market potential of genetics could outweigh its risks in the formation of policy and therefore promotes policies which place strict limits on the ability to market and profit from biological matter (e.g. genes). Examples of participants are The Institute for Science and Society and Genewatch.

Ethics, utilitarian. Representatives from a variety of academic disciplines who have received training in ethics derived from a pragmatic model. It acts in support of regulatory decision making based on service provision and strictly delineated risk-benefit guidelines for decision making.

Social sciences. Academics drawn largely from the disciplines of science and technology studies (STS), the sociology of scientific knowledge (SSK) and the public understanding of science engaged in the study of genetics and society. Provide a critique of the problematic nature of science and its relationship with society and are sometimes called on for policy advice.

Advocacy, the disabled. Motivated by the marginalisation of the disabled. Its interest in genetics is founded on the belief that the identification of genes linked to physical and mental disorders will lead to prenatal or in vitro genetic testing followed by selective abortion or implantation. These practices are seen to reproduce marginalisation by devaluing the lives of people with disabilities and undermine the network's progress on behalf of its members in other fields. Groups that participate include the British Council of Disabled People (BCODP) and Disabled People International.

Advocacy, patients. Acts on behalf of those who suffer from or are carriers for disorders or diseases with a genetic component. Its activities support regulation that protects and nurtures the advancement of the science of human genetics. It is the most salient of the policy networks and features advocacy groups for sufferers of specific diseases such as Parkinsons, Diabetes, and Altzeimers many of which lobby under the umbrella of the Genetic Interest Group (GIG). Infertility advocates such as Infertility Network UK, the Progress Educational Trust and the National Gamete Donation Trust also participate.

Advocacy, consumer. Overlaps with the previous network but takes a more cautious approach and is more inclined to investigate and weigh the risks and benefits of advances in human genetics. Its interest is part of a larger agenda of protecting the consumer or patient and it includes the Consumers Association and the Progress Educational Trust.

Advocacy, animals This network is issue specific focusing on the abolition of the use of animals in laboratory studies and advocating alternative models of biological research. Its interest in human genetics is directed not only towards the use of genetically modified animals in research into human disorders but also in the development of genetically modified animals for the purpose of organ harvesting (xenotransplantation). Participants include the British Union for the Abolition of Vivisection (BUAV) and Uncaged.

Industry

Corporations and organisations of the pharmaceutical and biotechnology sectors promoting self-regulation or limited state intervention. Individual organisations such as GlaxoSmithKline are large enough to generate their own policy input or work collaboratively with the Association of British Pharmaceutical Industries. Biotech SMEs work through the BioIndustry Association (BIA).

Science

Largely professional associations promoting the advancement of the science of human genetics. These include the Medical Royal Colleges, the Biological Societies and, a declining force, the Royal Society. New groups such as Save British Science, the Science Media Centre and Sense about Science are emerging to counter the appeal of new civil society networks to the public and fill what they perceive to be the gap created by the less mobile, and more formal, institutions of science.

and one a member of the HGC. No civil society networks, pro- or anti- stem cell research, were present on the Group (Department of Health, 2000: Annex A). The heavy reliance of the core policy community on its established networks of science and industry for its policy agenda setting means that its ability to accept the Review's agenda for change and thus move towards a new policy paradigm is heavily restricted.

But what of the peripheral policy community of the HGC and its five associated committees? When analysed in similar fashion, is this equally impervious to the representation of new civil society interests or is it more able to adopt the inclusive assumptions of policy community change? It is apparent from Figure 3 that as one moves from the core to the periphery of the policy community, so a broader range of policy networks become formally involved in the apparatus of human genetics regulation. However, the pattern and allegiances of policy network representation strongly suggests that, with the exception of the HGC arena, there is likely to be little challenge to a policy paradigm oriented to the interests of science and industry. Rather it is clear that the political support for that paradigm has been broadened so that the pervasive presence of science and industry networks is reinforced by those of patient groups advocating genetic research in the interests of their members. The policy community is changing through a selective process that allows some new networks to enter its periphery provided these act to legitimise the existing policy agenda.

This interpretation of policy community change is reinforced by evidence from interviews with the civil society networks which question or are opposed to human genetic science. From these networks a picture emerges of scientific and industrial influence over policy formation matched by a mirror image of their own exclusion. Industrial influence is seen as inevitable, not least because of the economic imperatives of government:

> Whoever is in power, there are some things where nothing changes. I see the government as very conservative. There is a strong link between government and business. There is no doubt about that because business has resources to lobby government effectively. (Interview 4)

Figure 3. Policy networks and the peripheral policy community (2003)

Network	Committee	Member
Ethics, faith-based	GTAC	Rev Lee Rayfield, Vicar
	HFEA	Rev Michael James Nazir-Ali, Lord Bishop of Rochester
Ethics, commercialisation	None	
Ethics, utilitarian	HGC	Prof Brenda Almond, Hull Prof John Harris, Manchester (+ co-opted member of sub-group)
Social sciences	HGC	Prof. Martin Richards, Centre for Family Research, Cambridge
Advocacy, the disabled	HGC	Dr Bill Albert
Advocacy, patients	HGC	Alastair Kent, Genetic Interest Group Philip Webb, Genetic Interest Group
	GTAC	Ann Hunt, Tuberous Sclerosis Association Fiona Sandford, Patient Advocate
	HFEA	Clare Brown, CHILD
	GAIC	Susan Watkin, Huntington's Disease Association Julie Foxton, Heart UK
Advocacy, consumer	GAIC	Brian Yates, Consumers Association
Advocacy, animals	None	
Industry	HGC	Celia Brazell, GSK (+ co-opted member of sub-group)
	GTAC	Dr Peter Harris, KuDOS Pharma
	GAIC	Prof David Latchman, BioVex Ltd. (+ four from insurance industry)
	UKXIRA	Janet Dewdney, AdProTech (biotech startup)
	HFEA	None, two members are clinicians with consultancies and shares in industry
Science	All	

> Well certainly industry goes direct to the policy community. They don't bother with all this mediation, they'll mediate when they feel they need to but industry clearly wants a specific outcome. They don't mess around. They go to government and they go to the people who they think will affect government directly. (Interview 5)

At the same time, policy formation is seen by such networks to be characterised either by a lack of consultation with organisations hostile to genetic science or by a judicious filtering out of information which might undermine or challenge the pre-determined policy agenda. For example, although the House of Lords Select Committee on Science and Technology conducted what it regarded as a broad consultation exercise on stem cell research, not all were convinced of its impartiality. One interviewee commented:

> We were very concerned that when you looked at the [House of Lords] Select Committee on stem cell research, it was incredible the way that that Committee was stacked….If you looked at their registered interests, it was clear a lot of them have involvement and interest in the research community and the scientific community. Clearly no one is neutral. (Interview 7)

Some pro-life groups opposing human embryo research and supporting adult stem cell research maintained that their evidence submitted to the Committee was excluded from discussion. This bred a scepticism regarding the legitimacy of the consultation process. Referring to the House of Lords review, the director of Comment on Reproductive Ethics (CORE) observed: 'This was just a placatory exercise, undertaken after the legislation had been passed. The only purpose was to reassure the public that safety issues were being adequately addressed. There was no possibility of any alterations being made to the law.' (Interview 3).

In some cases, exclusion from the formal policy process is self-imposed, part of a conscious strategy by an oppositional policy network to wield influence from without the policy community as well as from within: 'We [the BUAV] feel strongly that as a pressure group totally opposed to animal testing, it's our role to be there on the outside campaigning, lobbying and pushing for change rather than becoming part of a system that exists in order to inform the process of licensing animal experiments.'

(Interview 6). In other instances the BUAV's judgement on the political costs and benefits of participation in the policy process can produce a different decision and active membership of committees such as the UK Chemicals Stakeholders Forum, the Nuffield Council on Bioethics and the UK Vaccines Committee as well as a number at EU level set up by the EU Commission (Interview 6).

Where civil society policy networks clearly did not feel themselves excluded, and where there was general agreement that the Review's principles of openness and transparency have been implemented, was in relation to the activities of the Human Genetics Commission on the periphery of the policy community. Its style was seen by some as a welcome change:

> With the HGC there has been a shift in how things operate. I know I feel better personally because of the transparency in how they work with minutes and documents available on their website and open meetings. Additionally they have demonstrated a commitment to real public engagement through public meetings. One of the criticisms of the Human Genetics Advisory Commission [the HGC's predecessor] was that it was influenced by industry. I don't think the HGC is likely to be charged with such an accusation. (Interview 8)

However, other civil society policy network members remained sceptical of the significance of this shift and, whilst recognising the greater openness of the HGC and other parts of the peripheral policy community, described the attempts at public involvement as 'window dressing' and 'rearranging the deckchairs'. In this context, it was frequently emphasised that the Commission does not 'have teeth' and to that extent its activities are tangential to the operation of power in human genetics regulation and can be ignored by the core policy community where inconvenient. For these policy networks, to be involved in the work of committees which are powerless or in consultations which are ignored is simply to experience another form of exclusion.

Conclusions

The ambition of the 1999 Review was to launch a change in the policy community of human genetics that would render it more open and responsive to a broader range of interests, more able to deal with conflicting pressures from civil society, science and industry and better equipped to resolve contentious issues of public trust in new health

technologies. To this extent it was not an unusual ambition but one that reflected the general need for policy communities to reformulate themselves and their relationship with policy networks in order to adapt to changing pressures in their political environments. In the case of human genetics this was an anticipatory move based on the premise that what could happen to one area of biotechnology in terms of a decline of public trust associated with the GM foods and crops issues could also happen in another.

The experience of the human genetics policy domain shows us that there may be a considerable gap between the awareness of a policy community of the need for change and its ability, or willingness, to implement it. The inertia of the civil service culture and its heavy reliance on an inner circle of policy networks can work against the formal policy intention of policy community reform. Established modes of interaction based on trust and the commonly accepted definitions of expertise that permeate the UK's scientific advisory system are not easily replaced by the modalities of open government. Compromises may be sought between the old and the new but in the case of human genetics the compromise did little to shift the focus of power within the policy community. In part this was because the pressure on the human genetics policy community has come less from the civil society networks and more from the scientific and industrial interests. Public and media interest in the field has remained low key and there has been no sustained mobilisation of issues comparable to the GM experience, no issue networks capable of fragmenting the established consensus regarding the content of policy and the means for its formation.

The policy community has chosen a path of reform characterised by the retention of the closed expert-based approach to policy formation for the inner core of that community and the acceptance of a more open and inclusive style for its periphery of advisory agencies. It is an approach that resonates with the experience in other areas of science policy such as BSE (Frewer and Salter, 2002). Thus policy community change is characterised by a pragmatism that recognises the importance of the open governance imperative but does not disturb the existing balance of power, dominated by scientific and industrial interests, within the policy community. Having appointed the HGC as a strategic Commission, the core policy community of human genetics then confirmed the Commission's position on the periphery of policy making and used a closed, elite model of policy making to deal with two important issues: genetics in the NHS and human embryonic stem cell research. Relying largely on

specialist science networks, the core policy community brought the two policy issues to fruition with little engagement with either the HGC or the wide range of civil society policy networks with a stake in the area.

The ability of the policy community to protect its supportive approach to the development of human genetics science whilst incorporating a degree of greater openness is enhanced by the selective access to committee membership accorded to civil society policy networks. Networks supportive of human genetic research are more likely to gain membership of the advisory and regulatory bodies than are those that are sceptical of or hostile to the new science. The exception to this is the HGC which both incorporates and is seen to incorporate a wide range of interests. It thus serves as an important symbol of policy community change and open government. However, how long it will be able to retain its symbolic strength is questionable.

Thus far, the division between the inner Whitehall core of the policy community and its outer periphery of the HGC and its associated agencies may be deemed to be politically functional. The core can deal with policy issues through the customary routes of departmental and expert consultation undisturbed by political noise from the policy environment. The periphery can be open, accessible and responsive to public concerns, a legitimating cloak for the policy decisions made elsewhere, capable of absorbing if not deflecting political heat. However, the experience of GM food and agriculture and BSE suggests that this approach to policy community change is dependent on two conditions if policies are to be produced that are both legitimate and capable of being implemented. Firstly, the marginalised policy networks which are sceptical of human genetic science must continue to be as unnecessary for policy implementation as they presently are and have been. As yet they lack political weight and negotiating power because regulatory policy can be implemented with or without their cooperation. Secondly, the public profile of human genetics as a constituent of the biotechnology arena must continue to be low, unlike that of food and agriculture. To take one very obvious example, should the issue of the status of the human embryo become as high profile in the UK as it is in European countries such as Germany and Austria then the political significance of the marginalised networks would be much enhanced. However, whether the open governance ambitions of the 1999 Review could then be rapidly and retrospectively implemented is debatable. The inertia of the political culture and its demonstrated preference for technocratic solutions to the challenges of human genetics render such an option unlikely.

References

Borzel, T.A. (1998), 'Organizing Babylon—on the different conceptions of policy networks'. *Public Administration*, 76(2), 253-274.

Cabinet Office and Office of Science and Technology (1999) *The advisory and regulatory framework for biotechnology: report from the government's review* London, Stationery Office.

Coleman, W.D. (1999), 'Internationalized policy environments and policy network analysis', *Political Studies*, 47(4), 691-893.

Department of Health (2000). *Stem cell research: medical progress with responsibility* A report from the Chief Medical Officer's Expert Group reviewing the potential of developments in stem cell research and cell nuclear replacement to benefit human health. London: Department of Health

Department of Health (2001), Alan Milburn speech. Available at : http://www.doh.gov.uk/speeches/apr2001milburngenetics.htm.

Department of Health (2002), Green Paper, Advisory Panel, Membership. Available at: http://www.doh.gov.uk/genetics/greenpaper.htm

Department of Health (2003), *Our inheritance, our future. Realising the potential of genetics in the NHS*. Cm 5791 – II. London: Department of Health.

Department of Trade and Industry (2003), *The biotechnology regulatory atlas,* London: Department of Trade and Industry.

Frewer LJ and Salter B (2002), 'Public attitudes, scientific advice and the politics of regulatory policy: the case of BSE' *Science and Public Policy* 29(2): 137-45.

Hindmoor, A. (1998) 'The importance of being trusted: transaction costs and policy network theory'. *Public Administration*, 76(1), 25-44.

HM Government, (2001). *The interim response to the report of the BSE Inquiry by HM Government in Consultation with the devolved Administrations*. The Stationary Office, London.

Human Genetics Commission (2000a), *Whose hands on your genes?* London, HGC.

Human Genetics Commission (2000b), *Protection of genetic information; an international comparison* London, HGC.

Human Genetics Commission (2001a), *Inside information – balancing interests in the use of personal genetic data* London, HGC.

Human Genetics Commission (2001b), *Outcome of the public consultation on preimplantation genetic diagnosis* London, HGC.

Human Genetics Commission (2002), *Public involvement strategy* London, HGC.

Marsh D and Rhodes RAW (eds) (2002). *Policy networks in British government*. Oxford: Clarendon Press.

Marsh, D. and Smith, M. (2000), 'Understanding policy networks: towards a dialectical approach', *Political Studies*, 48(1), p. 4-22.

Privy Council Office (2004). 'Ministerial Committee on Biotechnology'. Available from: http://www.privycouncil.org.uk/textonly/page67.asp

Salter B. and Jones M. (2002a). 'Regulating human genetics: the changing politics of biotechnology governance in the European Union', *Health, Risk and Society*, 4(3), 325-40.

Salter B and Jones M (2002b), 'Human genetic technologies, European governance and the politics of bioethics', *Nature Reviews Genetics*, 3, 808-14.

Science and Technology Committee, House of Lords (2000) *Science and society* HL38, Session 1999-2000, London, Stationery Office.

Science and Technology Committee, House of Lords (2002). *Stem cell research*. Session 2001-02. London: Stationery Office.

Select Committee on Science and Technology (1999). *Minutes of evidence*. Examination of witness. Rt Hon Dr Jack Cunningham. 28th April.

Smith, M.J., (1991). 'From policy community to issue network: salmonella in eggs and the new politics of food'. *Public Administration* 69, 235-55.

Toke D and Marsh D (2003). Policy networks and the GM crops issue: assessing the utility of a dialectical model of policy networks. *Public Administration*. 81(2): 229-51.

Wright (1988) Policy community, policy network and comparative industrial policies. *Political Studies*. 36, 593-612.

Wynne, B (2001). Creating public alienation: expert cultures of risk and ethics on GMOs. *Science as Culture*. 10(4): 445-81.

Interviews

1. Nicki Ratcliffe, Consumers Association, 22 May 2002.
2. Member of the Human Genetics Commission (HGC), 28 February 2002.
3. Josephine Quintavalle, Comment on Reproductive Ethics (CORE), 13 March 2002.
4. Dan Lyons, Uncaged, 17 July 2002.
5. Charlie Kronick, Greenpeace, 22 July 2002.
6. Wendy Higgins, British Union for the Abolition of Vivisection (BUAV), 17 March 2004.
7. Paul Woolley, Christian Action Research and Education (CARE), 24 February 2002.

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