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Divided policy community and excluded policy networks:

the case of human genetics regulation

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Abstract

Divided policy community and excluded policy networks: the case of human genetics regulation

The 1999 Review of biotechnology regulation launched a policy designed to deal with the politicisation of GM foods and agriculture and protect human genetics from a similar experience. In implementing this policy, 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 analyses the consequent engagement between a policy community searching for an identity and a broad range of established and emerging policy networks. It reveals a divided policy community characterised by a Whitehall core 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

On 21 May 1999 the UK government announced the results of a Review of the arrangements for the governance of biotechnology. The accompanying report *The advisory and regulatory framework for biotechnology* outlined the structure and functions of the new machinery: the first systematic policy to deal with the governance issues raised by the advent of biotechnology on to the political stage. It was an ambitious statement. Not only were the existing assemblage of 18 scientific advisory committees to be rationalised and brought together under the aegis of three strategic commissions for food, agriculture and environment, and health but they were to operate with an unprecedented degree of transparency, openness and consultation. This approach, it was intended, would bring stability and legitimacy to a promising but sensitive area of scientific endeavour.

Within this policy was positioned human genetics: the most recent example of the potential inherent in the applications of genetic 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 large interest from civil society, the scientific community and industry. 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 reforms would keep things that way. But as a preventive regulatory move it faced a number of significant political obstacles. Although the GM confrontations had demonstrated to the state the importance of citizens' cultural concerns and the consequent limitations of its habitual reliance on technocratic regulation, methods for including this new dimension in the regulatory process were undeveloped (Levidow, 1999). It was likely that the official diagnosis of the political problem to which the reforms were a response was, at best, incomplete. Moreover, the ability of government to construct new policies in human genetics regulation was inhibited by the embryonic nature of the biotechnology policy community, its internal divisions and the diverse range of scientific advice on which it relied. Further complications arose from the fact that 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 therefore decidedly unroutinised.

In analysing the engagement between the policy ambition of the Review and the obstacles which lay in its path of its implementation, this paper draws on findings produced in the course of 'The governance of human genetics project' funded as part of the ESRC's Innovative Health Technologies Programme.[1] The analysis begins with the nature of the political problem to which the 1999 Review was the policy response. What were the major pressures at work in this arena and why was the existing regulatory apparatus considered inadequate? Secondly, and given the relative youth of human genetics science, how developed was the policy community on which these pressures devolved? Policy formation was afterall but one part of the policy community's political task and policy implementation in this sensitive field was likely to test its robustness further. Thirdly, what was the nature of the interaction between the policy community and policy networks of human genetics regulation? Were the policy promises of the Review regarding openness a sure guide to the new politics of human genetics regulation or were some policy networks more favoured than others?

The political and economic pressures

Civil society, science and industry all have a political 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 the state 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 genetic science itself but also in the procedures and institutions which regulate it. If the state 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.

In reflecting on its regulatory task, the state recognises the validity of research findings that the controversy over GM agriculture and GM foods has rendered the creation and application of scientific knowledge in the field of biotechnology problematic and its political negotiation essential (ESRC Global Environmental Change Programme, 1999; Grove-White *et al*, 1997). Public trust, or perhaps more

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accurately, public indifference in the field is no longer a given. What is also apparent is that scientific authority is no longer the dominant force in the negotiation process it once was. As the Office of Science and Technology (OST) observed of the UK's scientific advisory system in the context of an inquiry into genetically modified organisms (GMOs) by the House of Commons Science and Technology Select Committee: 'Government, scientists and medical practitioners are no longer revered as they might have been in the past and the presentation of advice needs to acknowledge this' (OST, 1998: para 4.6). Science can no longer necessarily legitimise science. This view is confirmed by the findings of the 1999 Review of the advisory and regulatory system of biotechnology. Its consultation exercise with representatives of science, academia, medicine, bioethics, interest groups, unions, industry and the government's regulatory bodies found that almost none of those consulted believed that the public had confidence in the system of governance currently in place (Cabinet Office and OST, 1999: diagram 2).

The difficulty of knowing how best to respond to public scepticism about biotechnology is emphasised in Parliamentary inquiries into genetics-related issues. In its report on genetically modified organisms (GMOs) the Select Committee on Science and Technology observed of public opinion that

> in the case of GM foods, indeed any food, attitudes are not only dependent on an analytical assessment of risk and benefit. Other factors, such as ethical and moral considerations, knowledge of the technology and trust in the regulatory system play a part. The Royal Commission on Environmental Pollution stated that "values are an essential element in decisions about environmental policies and standards". This is no less true of decisions over the food we eat and the crops we grow (Select Committee on Science and Technology, 1999a: para 21).

And, it can be added, the health therapies and technologies we consume. Other Parliamentary reports have acknowledged the limitations of the scientific advisory system when dealing with these more subtle aspects of the public mood. The Science and Technology Committee's investigation of climate change concluded that 'public confidence in the efficacy, and even the integrity, of the scientific advisory system has been sadly eroded' and that the government in its use of the scientific advisory

system, has to recognise this social change and respond to it' (Select Committee on Science and Technology, 2001: para 9; see also Select Committee on Science and Technology, 1999b, 2000).

The implication of a decline in the legitimating efficiency of the scientific advisory system is that the state no longer controls the discourse of biotechnology governance. Hence, in the context of the perceived volatility of public opinion, we find the Select Committee on Science and Technology recommending measures to stabilise the science-media relationship and encourage what it termed 'rational debate' without which 'GM technology and its potential benefits may be permanently lost to the UK' (Select Committee on Science and Technology, 1999a: para 31). The feeling in many sectors of the state appears to be that there is a need for 'a more temperate climate in which to build public confidence' and so reduce the disruptive effects of the 'hysteria' of the press regarding biotechnology (Department of the Environment, Transport and the Regions, 1999: paras 21-22).

In pondering the dimensions of civil society's concerns about biotechnology, the state is unavoidably influenced by the economic pressures generated by the UK's leading position in Europe's biotechnology industry. In 2002 the UK was the dominant player in that industry with 43 per cent of total market capitalisation (9.4 billion euros), 37 per cent (2.9 billion euros) of revenues and 45 per cent of public companies in the sector (Ernst and Young, 2003).

As yet, the large scale industrial exploitation of human genetics knowledge on a scale commensurate with agriculture and food is not yet possible and the task of establishing the complex linkages between gene and disease in order to open up the way for new types of drug treatments (where the economic muscle of the pharmaceutical industry would come into play) is only just beginning. Nonetheless, new technologies such as functional genomics, proteomics and bioinformatics are evolving to help identify the steps along the 'gene to drug pathway', as it is called, and new forms of trading relationships are being created between biotech companies and the large pharmaceuticals to enable and organise the exploitation of these technologies (Hosseini *et al*, 2002). The potential, and therefore the pressure, is undoubtedly there. However, with the gene to drug pathway still under construction, much of the actual engagement between human genetics and governance has been in

the realm of relatively esoteric research and development issues such as embryo transfer and fertilisation techniques, cloning, gene therapy and cytogenic screening. Whilst the industrial potential of these fields is small when compared to that of the pharmaceuticals, it is nonetheless growing and the UK is a global leader in cloning and stem cell research and a close second to the United States in gene therapy trials (Martin and Thomas, 1998).

Not surprisingly, therefore, the present government's position was, and remains, that 'as a truly innovative sector which epitomises the dynamism and potential of a knowledge driven economy, [it] is determined that the biotechnological sector should be sustained and enhanced' (Select Committee on Science and Technology, 1998, Annex:1). This is not a new ambition. A dominant theme of the House of Lords Science and Technology Committee's 1993 report on biotechnology and global competitiveness, for example, was that regulation should enable the economic benefits of biotechnology to be fully exploited by the UK (Science and Technology Committee, House of Lords, 1993).

Undoubtedly regulation is a key component of scientific and industrial development. It can, for example, restrict or facilitate scientific research, impact on consumer confidence (the demand for a product), define the parameters of ownership (and hence the potential return on investment), increase R and D costs (safety requirements), influence the time it takes to get a product to market, determine the length of time the product has a profitable place in the market (before the patent expires), and define the costs of continued monitoring in the market. The regulatory options are many. Yet too much regulation can stifle business initiative and, in the state's view as expressed in the 1999 Review, 'it is important that the regulatory system should not place unnecessary burdens on the industry or barriers to its development' (Cabinet Office and OST, 1999: para 2).

The policy task of reconciling the political and economic pressures on the UK's regulatory apparatus is rendered more complex by the demands of multi-level governance. As a Member State of the European Union (EU), the UK's approach to biotechnology is constrained both by the regulatory requirements of the EU's directives and the continuing political contest at the EU level for influence over the EU's regulatory agenda (Salter and Jones, 2002a). Directives on the contained use of

GMOs (Directive 90/219/EEC), their deliberate release into the environment (Directive 2001/18/EC), the protection of individuals with regard to the processing of personal data and on the free movement of such data (Directive 95/46/EC), the legal protection of biotechnological inventions (Directive 98/44/EC) and clinical trials (2001/20/EC) constitute a framework within which the UK's policy making on biotechnology is obliged to work. At the same time, Britain must keep a wary eye on emerging EU regulations since these may override existing UK legislation. (For example, the draft Directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells (COM(2002) 319 - C5-0302/2002 - 2002/0128(COD)) has become a political site for a struggle over therapeutic cloning of human embryos – which the UK permits and wishes to maintain as regulatory support for its lead in stem cell research, but other European countries oppose.)

Given this context, the regulatory question for the policy makers is where to strike the balance between the interests of civil society, science and industry. It was the claim of the Review of the advisory and regulatory system for biotechnology that its proposed measures would reconcile these interests 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 and the Agriculture and Environment Commission, 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 regulatory system is to deal with the pressures it faces, the report argued, then it must be flexible and responsive.

How politically robust has this solution proved to be in terms of its contribution to the operation of both the policy community and policy networks of human genetics? Has it enabled a routinisation of political and economic pressures within a more open system of governance or has the implementation of its regulatory ambition simply stimulated further demands for change and a return to the orthodoxies of closed expert systems of science (Jasanoff, 1997).

Method

Data on the policy community and policy networks of human genetics were 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 purpose of the interviews was to investigate in more detail the operation of political influence in the implementation of the new regulatory apparatus.

The policy community response

Definitions of 'policy community' vary and we needed to be clear about our approach before we could sensibly analyse the data. We took the fairly conventional view that stable policy communities 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). 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). It is able to take responsibility for the delivery of outcomes (Judge, 1993; Marsh and Rhodes, 1992). To maintain its stability, the efficient delivery of policy, and a secure and dominant policy paradigm, a policy community favours some networks over others. As a result those policy networks granted most legitimacy by the policy paradigm become the core civil society actors who participate in the sub-government of actor constellation of the policy community (Coleman, 1999: 6).

Using this approach as our starting point, we explore the nature and operation of the human genetics policy community as it responded to the implementation demands of the 1999 Review. Did it possess the resources necessary for this task or did it find it necessary to reconfigure its own identity in terms of membership and paradigm to deal with the political pressures it faced?

In the case of science, studies have shown that the networks linking government and scientists have traditionally constituted a series of closed and parallel policy communities organised according to a combination of scientific knowledge areas and departmental interests (Frewer and Salter, 2002). When the Ministry of Agriculture, Fisheries and Food (MAFF) was confronted by the issue of bovine spongiform encephalopathy (BSE) in 1996, the impervious nature of these insider policy networks meant that the public health implications of the disease were excluded from consideration until rather late in the day: MAFF and Department of Health policy

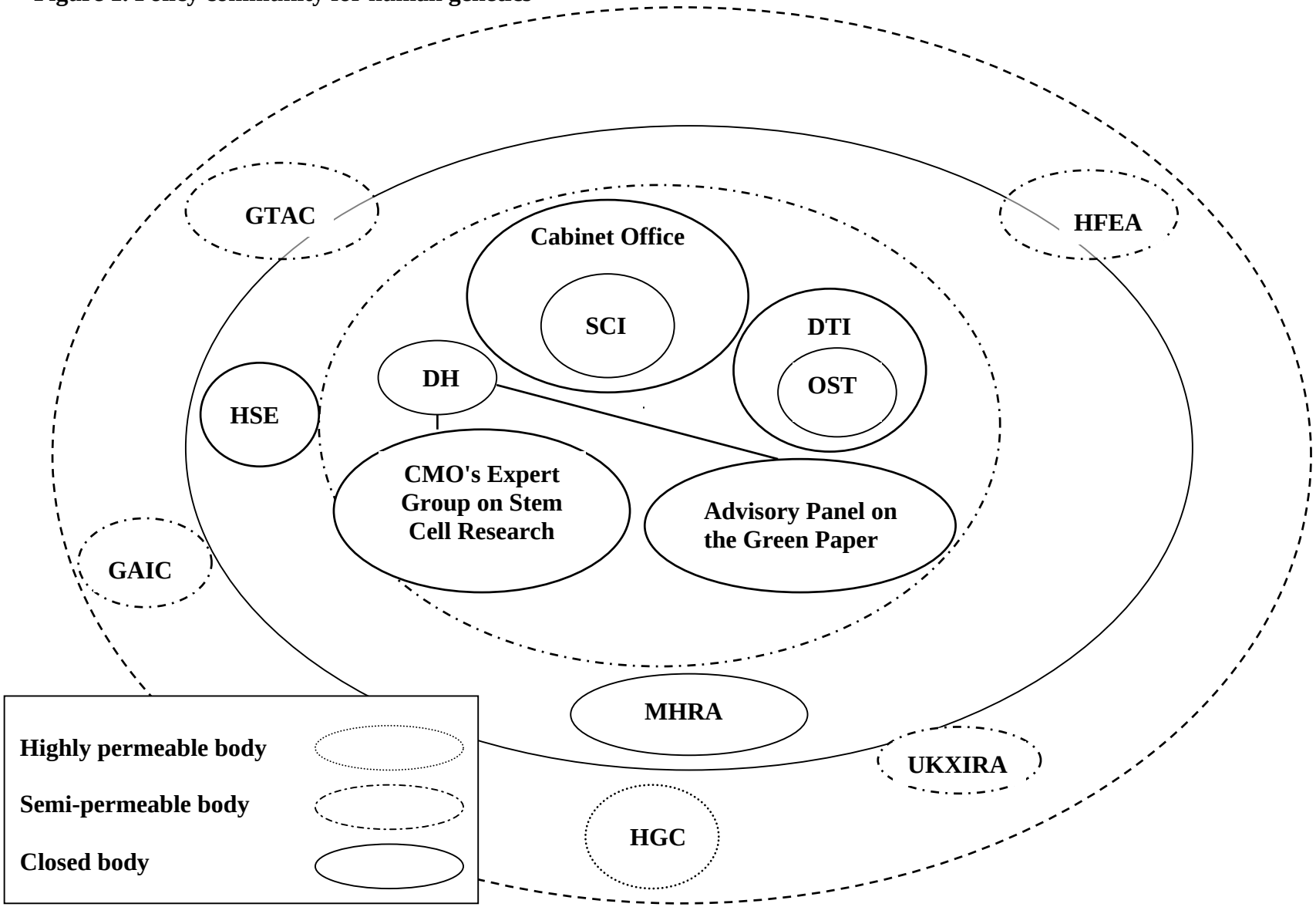
communities did not naturally engage and MAFF's scientific advisory arrangements were heavily influenced by the agricultural industry lobby (Seguin, 2000; Weir and Beetham, 1999). Isolated scientific networks have also bred a consensual, inward looking and essentially private style of operation which resonates readily with the tenets of positivist science with its associated notions of evidence and certainty (Wynne, 1996). In her study of BSE, Jasanoff contrasts this contained British political culture of scientific advice with the American adversarial style based on open disputes between experts (Jasanoff, 1997).

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, 1999c: 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 formal structures involved in the formation and implementation of policy on the regulation of human genetics are those outlined in Figure 1. These structures in turn form 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). What we have 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 our interviews indicate 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.

Figure 1. Policy community for human genetics



However, the dynamic and diverse implications of human genetics knowledge and the variety of political demands it generates makes a tidy definition of its policy community difficult to sustain. An example of this complexity can be found in the approval process for a gene therapy/clinical trial. Any institution wishing to conduct such a trial, in addition to submitting applications through both the MHRA, for methodological approval, and GTAC, for ethical approval, may also have to submit applications either in accordance with the requirements of the Genetically Modified Organisms (Contained Use) Regulations 2000 (for which the Health and Safety Executive has lead responsibility) or the requirements of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (for which the Department for Food and Rural Affairs has lead responsibility). In such cases where several regulatory arenas are involved, the applicant may need to seek advice or information from officials from different authorities who, in turn, may need to confer before making decisions. Making a similar, if more general, point an officer of a patients' organisation noted how human genetics is difficult to contain as an issue: 'For example, provision within the NHS is covered by the Department of Health, genetic research databases by the OST, issues about insurance by the Treasury and employment by Department for Work and Pensions. There are all these different pockets with cross cutting issues like confidentiality, consent and privacy.'(Interview 1)

It is in this context of escalating demands that the relationship between the core policy community, on the one hand, and the periphery of the Human Genetics Commission (HGC) and its associated agencies, on the other, assumes considerable political significance (Figure 1). Afterall, it is 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 lease be built into the consulting process of the core of that community. However, what emerged was a conflict 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, 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 Lady Helena Kennedy.

Ironically, by implementing the policy recommendation on open governance so literally, the HGC thus offended the culture of secrecy so characteristic of the civil service and aroused the suspicions of the core policy community. 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)

Two policy issues reveal the effect of this culture clash: 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.

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 I said 'Well this is just not on'. And even Turnberg, who I met, was embarrassed about this. He's a really nice bloke. And he said 'They should have told you. They should have informed you what was going on and why'. And it's still very unclear. 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 Parkinsons and Altzeimers, 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, 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 (Committee on Science and Technology, 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 completed excluded from the core policy community's deliberation. Its drawbacks for the policy community were that it was open, transparent and composed largely of non-scientists. However, in the second, 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.

Excluded 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 deal with civil society pressures. 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). Whilst the Review suggested that at one level the state had learnt this lesson, its behaviour 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 it did not recognise, as Coleman puts it, the need to change the membership of the central actors within the policy community and thus the range of possible policy outcomes. It 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 context 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).

By rejecting this option and excluding a range of policy networks from the policy process, the state has, the theory implies, merely created a further set of political problems that will have to be confronted at some point. How valid is this view?

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 descriptive 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, 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 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).

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.

The heavy reliance of the core policy community on what one suspects is its established networks of science and industry for its policy agenda setting means that its ability to move towards a new policy paradigm is correspondingly 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? Figure 3 provides some initial insights.

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. In effect, the policy community is allowing some new networks to enter its periphery provided they act to legitimise the existing policy agenda.

This interpretation 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. I am not implying sleaze. You can accuse government of being cowardly and weak and that would be true; and unprincipled, and that would be true. But industry is the one that's pointing the gun at their head, whether it's economic blackmail or legal threats. (Interview 4)

> 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:

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	

> 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:

> With regard to participation in committees or working groups relevant to animal testing, the BUAV takes a view on a case by case basis. In some instances, membership of the Animal Procedures Committee, for example, 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. 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 state where inconvenient. For these policy networks, to be involved in the work of committees which are powerless or in consultations which are ignored is to experience another form of exclusion.

Conclusions

Propelled by the experience of GM foods and agriculture, the 1999 Review of biotechnology regulation enunciated a new vision of an open policy process designed to address the recognised tensions between civil society, science and industry in this new, and valuable, knowledge field. The Review's recommendations appeared to be part of a general recognition that, as the *Science and Society* report by the House of Lords Select Committee on Science and Technology put it, society could no longer be left on the outside of scientific advisory system but instead 'direct dialogue with the public should move from being an optional add-on to science-based policy-making… and should become a normal and integral part of the process' (Science and Technology Committee, House of Lords, 2000: para 19). Without such a shift in the official culture, it was argued, public trust in new technologies and their industrial applications would be fragile and easily undermined.

Policy community and network theory advance a similar view. To survive over time, policy communities should be prepared to change the sources of expertise they consult and the policy networks with which they engage in order 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).

The evidence from human genetics is that, in practice if not in principle, the state remains unimpressed by this view and has adopted an approach to regulatory policy characterised by a divided policy community and the selective exclusion of certain civil society policy networks. Having appointed the HGC as a strategic Commission '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), the core policy community then ignored it, confirmed its position in the periphery of policy making and used a closed, elite model of policy making to deal with two important policy issues: genetics in the NHS and 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.

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, approachable and responsive to public concerns, a legitimating cloak for the policy decisions made elsewhere, capable of absorbing if not deflecting political heat.

Our analysis suggests that for this approach to continue to produce policies which are both legitimate and capable of being implemented, two conditions must be met. Firstly, the excluded policy networks must continue to be as unnecessary for policy implementation as they presently are and have been. As yet they lack political weight 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 excluded 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.

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