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**THE TEXTURES OF CONTROVERSY:  
VALUES AND INTERESTS IN DISPUTES AROUND  
GENOMICS**

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A Thesis submitted for the degree of  
Doctor of Philosophy of The Open University  
Design, Environment, Development and Materials  
January 2011

DATE OF SUBMISSION: 25 JANUARY 2011  
DATE OF AWARD: 18 APRIL 2011

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## **Abstract**

This thesis examines values-based and interests-based arguments around potentially disputed developments in genomics and the relevant policy and regulatory responses.

Developments in genomics may result in disputes about the prospects and problems around them, with different stakeholders bringing a range of values and interests to bear on the many actions and decisions concerning this subject. This thesis contends that the relationship between values-based and interests-based arguments and the technical and social contexts reveal unique alignments or textures to different applications of genomics, an understanding of which will contribute to development of appropriate policy responses. Three case studies are examined: genetically modified and cloned animals, population biobanks and stem cell research. For each, a detailed examination is made of the values-based and interests-based arguments advanced and the relevant policy and regulatory responses. From these analyses, it is argued that the superficially simple categorisation into values-based and interests-based arguments conceals a great deal of complexity but also reveals important features about each case studied. The dynamics of each case varies with predominantly interests-based arguments in biobanks, values-based arguments in stem cell research and values-based arguments conflicting with interests-based arguments in the case of cloned animals. These data imply that each application of genomics should be examined in its specific context.

This thesis contributes to a theoretical understanding of disputes by applying a values-interests approach to a range of different contexts, demonstrating that the approach has merit in terms of conceptualising the main features of potentially contested situations. This thesis provides evidence that further examination of arguments identifies three different categories of values-based arguments and three aspects of interests-based arguments. This conclusion points to an increased role for careful examination of arguments with a view to clarifying assumptions about the nature of the issues at stake to enable more discriminating policy responses.



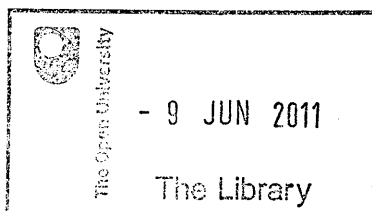
## Acknowledgements

Many thanks go to both my supervisors, Professor David Wield and Professor Joyce Tait who have guided this thesis from its inception to its conclusion. I am immensely grateful to both for their wisdom and their continued commitment and finding time to read drafts despite their very busy schedules.

I acknowledge my debt to the large number of people who contributed interviews to this research and I am very grateful that they were willing to give up time to speak to me. I would like to thank Eileen Mothersole for her extremely efficient and accurate transcribing of the interviews undertaken.

A number of colleagues at Innogen have been unfailingly supportive of the thesis writing process. It seems invidious to pick out only a few, but the moral support provided particularly by Dr Catherine Lyall and Dr Gill Haddow demands a special mention.

The thesis process has inevitably impacted on family life too. I would like to express my thanks to my father who has contributed to this work through his interest, both intellectual and financial. But most of all I would like to thank my husband, Donald Bruce, for his unfailing support, his enthusiasm, and generosity in allowing this thesis the space to develop to fruition.



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## Abbreviations

BBSRC	Biotechnology and Biological Sciences Research Council
BMRB	British Market Research Bureau
BSE	Bovine spongiform encephalopathy
Defra	Department for Environment, Food and Rural Affairs
DG	Directorate General
DNA	Deoxyribonucleic acid
EFFAB	European Forum of Farm Animal Breeders
EFSA	European Food Safety Agency
EGE	European Group on Ethics
EMBO	European Molecular Biology Organisation
EPO	European Patent Office
ES cells	Embryonic Stem cells
ESRC	Economic and Social Research Council
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FAWC	Farm Animal Welfare Council
GM	Genetically Modified
GP	General Practitioner
GS:SFHS	Generation Scotland: Scottish Family Health Study
hESC	Human embryonic stem cells
HFE Act	Human Fertilisation and Embryology Act, 1990
HFEA	Human Fertilization and Embryology Authority
iPS cells	Induced Pluripotent Stem cells
IPTS	Institute for Prospective Technological Studies
IVF	<i>In Vitro</i> Fertilisation
MRC	Medical Research Council
NHS	National Health Service
RAE	Research Assessment Exercise
RNA	Ribonucleic acid
RSPCA	Royal Society for the Prevention of Cruelty to Animals
SC	Stem Cell
SCNT	Somatic Cell Nuclear Transfer
US	United States
USA	United States of America
UK	United Kingdom
UKSCI	UK Stem Cell Initiative
WTO	World Trade Organisation

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# Chapter 1

## A 'values' and 'interests' approach to analysing stakeholder interactions

### 1.1 Introduction

Genetic and genomic technologies are frequently portrayed as sources of innovative new products and future economic growth, as well as providing public goods (e.g. HM Treasury *et al.* 2004). Genetic and genomic technologies, however, have come to signify much more than just the physical manipulation of genetic material. They are raising wider issues such as corporate control over the basic elements for human survival, and appropriate ways of treating the natural world. Innovation in genomics has thus become contested in many cases. Individuals and groups advocating alternative policy and innovation trajectories have the potential to challenge these technological developments on the basis of both different interests and different values. The potential rejection of a genomic technology poses problems for proponents who would like to see the benefits of the technology realised, for industries competing in an international environment and for policy makers who wish to promote economic activity and to maintain legitimacy for decisions in the context of a globalised world. In contrast, for proponents of alternative scenarios some innovation trajectories pose threats to their concepts of a desirable future or breach entrenched barriers. Thus, different stakeholders can have alternative viewpoints of the future that may be at stake in the way in which innovations are adopted.

The history of the failure of adoption of genetically modified (GM) crops in the UK and most of the European Union (EU) demonstrated that technical competence in an area will not inevitably lead to the wide adoption of the products of the technology. This in turn has led to concern among policy makers, research scientists and industry as to whether other new genomic technologies will be similarly rejected. The GM crops debate exemplifies many of these viewpoints. There have been numerous analyses of why the GM crops situation arose (e.g. Levidow *et al.* 2002, Frewer *et al.* 2004, Kearnes *et al.* 2006, Horlick-

Jones *et al.* 2007). In this thesis I will concentrate on one insight emanating from the debate as identified by Tait (2001). Tait suggests that more focus should be given to whether responses are predominantly based on an interest-base or value-base. In the GM crops case, she argues that concerns were treated as a risk issue whereas disputes revolved around different values such as the future direction of agriculture, power of multinational companies over food supply chains etc. The risk regulatory system was therefore required to negotiate a dispute that it was not designed to deal with and important sources of conflict were not discussed. Tait further suggests that different approaches to conflict resolution are needed depending on the extent of the value-based or interest-based responses raised by a specific innovation.

Emphasis on the role of values and interests in disputes around technologies has also been recognised by Nelkin (1992) and the importance of values in policies relying on scientific evidence has been analysed by Pielke (2007). Values and interests also feature heavily in mediation literature e.g. Burton 1990. My initial focus on this research stemmed from a background in mediation, parallels that I perceived in mediation theory to the approach proposed by Tait (2001) and the potential of the values-interests approach.

The issue at the heart of this thesis then is whether a detailed examination of the values- and interests-basis for arguments around developments in genomics and their interaction with the regulatory and governance arrangements whereby these interactions are managed can provide useful information for policy makers to better manage developments in genomics. In this thesis:

- I extend Tait's approach and apply it to three different areas of innovation in genomics: genetically modified and cloned animals, biobanks and stem cell research.
- I examine in detail the arguments put forward in specific situations by different stakeholders and citizens and evaluate the extent to which these are predominantly values-based or interests-based.



- I examine the policy-regulatory responses and consider whether a better understanding of the nature of the issues at stake for different protagonists could make it possible to develop more effective policy responses in disputed areas of genomics within the context of evidence-based policy.

Firstly, a brief note about terminology. In the scientific definition, the term 'genome' refers to the complete set of genetic information of an individual organism (although quite what this means is debatable as is explored by for example Barnes and Dupré, 2008).

Genomics in the scientific sense covers activities such as gene sequencing and genetic mapping as well as the understanding of the function of different genes. Traditional single gene genetics is usually seen to fall outside the term 'genomics', but the term 'genetics' is sometimes understood to include the activities of genomics. Within the social sciences, genomics is usually taken as a broad field including a range of genetic and genomic technologies as well as stem cell science. The inclusion of stem cell science under the category genomics (which would not be the case in natural science) can be justified on the basis that it is concerned with the genetics of how and why cells differentiate.

Accordingly, this thesis will consider applications of quantitative genetics, molecular genetics and genomic technologies as well as stem cell science to humans, animals and plants and include all of these under the term 'genomic technologies'.

This thesis is also about stakeholders. The term is used widely in a range of different contexts from business management to participatory exercises (Friedman and Miles, 2006). The term is sometimes used to describe identifiable groups advocating particular courses of action, that is, those actively engaged with an issue. However, I am taking the term 'stakeholder' in its widest sense, and returning to its roots in business management I am defining it following Mitroff (1983) as all those entities, parties, actors, organizations, groups, individuals that affect and are affected by the innovation. This definition extends the term 'stakeholder' to include citizens or wider publics likely to be affected by the innovation (and impact on it), even if they are not directly engaged as actors in the innovation process or actively participating as advocates for a specific trajectory.

In this introductory chapter I will firstly give a brief outline of Tait's insights. I will then consider other applications of genomic technologies where there is either an existing dispute or the potential for such disputes to develop and where the Tait approach could be potentially helpful. I will conclude the chapter with a description of the outline of the thesis which includes the thesis research questions.

## **1.2 Values-based and interests-based motivations in the GM crops debate**

Tait's work has followed the trajectory of public attitudes to GM crops from the late 1980s to the early 2000s and examined these in the context of industry strategy and regulatory policy and practice (Tait 1988, Martin & Tait 1993, Tait 2001). A prescient quote can be found in Martin and Tait (1993) where they predicted the potential for public hostility to GM crops if certain industry strategies were continued.

*"Based on the results of this survey, we believe that public attitudes to biotechnology may now be in a fairly finely-balanced state. They have not yet become negatively polarised, but a single high-profile incident could trigger such a process. Many of industry's current strategies...seem likely to generate such incidents." (Martin & Tait 1993, p133)*

This hostility in due course erupted in the UK, following a number of events in 1998 (e.g. Horlick-Jones *et al.* 2007). For Tait, a key component providing indications of how future attitudes will be formed is whether and under what circumstances the focus of stakeholders is on the grounds of pragmatic interests or on fundamental values (Martin & Tait, 1993). Tait outlined this approach in 1988 but the ideas are more developed in her subsequent 2001 paper (Tait, 2001) which forms the basis of the remainder of this section.

Tait identified as one of the contributory factors in the GM crops trajectory an understanding that arguments framed using value-based opinion could not be expressed in the risk regulatory system.

*"People whose objections are based on ethics or values, or on an alternative conception of what is in the public interest, had no way of being heard within a*

*reactive/preventative regulatory system other than to dress up their concerns in the guise of rationality. This has often, as in the case of GM crops, exacerbated risk-related conflicts where a wrong or simplistic identification of the underlying human motivations has made it difficult for government bodies and policy makers to engage in a meaningful dialogue about the issue with other stakeholders” (p179)*

Thus, Tait's analysis is strongly linked to the way in which specifically risk-related regulation is conducted in European contexts. Having considered the risk regulatory system as a whole, Tait turned to consider how different stakeholders acted in the case of GM crops and in particular how the values and interests of different groups influenced the trajectory of GM crop development. Tait categorised motivations of different stakeholder groups involved in the GM crops debate on notional interest-based and value-based dimensions. From her analysis, she ascribed the following:

- Environmental groups were strongly negative on both value-base and interest-base. *“biotechnology was perceived to be inimical to their fundamental values which were opposed to intensive farming and favourable to organic.” (p 180)*
- Scientists were mostly positive to GM crops both from a value-base and interest-base. *“it was in their interests for their research to lead to marketable products” (p 180)* and *“they also had strongly pro-GM values, seeing the crops mainly as a benefit to humanity with less risk attached to them than current chemical-based technology” (p 180).*
- Organic farmers were antagonistic to GM crops both from a value- and from an interest-base.
- Intensive arable farmers were positive toward GM crops from a value-base but negative from an interest-base. *“they were concerned about the impact on their business interest from negative public opinion” (p 180)*
- Multinational chemical companies were strongly positive both from a value and an interest base.

- Smaller companies were closer to intensive arable farmers in that they were concerned about negative public opinion.

Tait explains how in 1998 the views of UK consumer organisations moved from being neutral about GM crops to being strongly negative both from a value and from an interest perspective. This shift in motivation was triggered by a series of complex events, including the development of an advocacy coalition of environmental and consumer groups against GM foods and resulted in a major change in public opinion.

Tait's approach is particularly attractive as it lends itself to considering the wider innovation system, including regulation, and provides sufficiently general principles that it can be used in a cross-cutting analysis of different applications.

### **1.3 Values and interests in different genomics developments**

The GM crops context was of a risk-regulatory regime and a technology that raised questions primarily about risks to the environment and to humans, as well as wider-questions such as the interaction between technology and industry structure and the relationship of humans to nature. Developments in genomics are more generally raising questions about fundamental values such as the relationships between humans and nature, between humans and non-human animals as well as the essential nature of humans and their relationships with each other. In this thesis therefore, I have taken Tait's approach and applied it in contexts that bring in a range of different relationships. I have selected three case study examples; population biobanks, GM and cloned animals and stem cell research. These, together with Tait's original paper demonstrate a range of different social relationships associated with genomic technologies:

- human relationships with the environment (GM crops and GM & cloned animals)
- human relationships with non-human animals (GM & cloned animals)
- human relationships with other humans (stem cell research and biobanks)
- risks related to food (GM crops and GM & cloned animals)

Each of these innovations is still in the relatively early stages of development. There are currently few products on the market from these innovations (except GM crops outwith EU and arguably cloned animals with a few early stem cell therapies emerging). Even with GM crops, products on the market are mainly first generation developments with more sophisticated versions still in laboratories. Developments in genomics can be expected to continue to raise new complex issues as the ability to understand and manipulate life processes continues. Therefore, this study involves observing current and changing circumstances rather than considering past and established events. Both the new technologies being considered here and society's attitudes to them are evolving, sometimes rather rapidly, for example recent increasing concerns about food security. These technologies are thus still unfolding stories and this thesis is only able to provide a snapshot in time.

This thesis adopts an explicitly interdisciplinary and problem-focussed approach to the research questions (e.g. Bruce *et al.* 2004, Lyall *et al.* 2011). This research is informed by concepts used in ethics but it is not using methods of ethical inquiry. Similarly this research is informed by insights from social psychology but it is not a piece of psychological research. This thesis is not an exploration of behaviour nor does it examine the role of different institutions in influencing actions and beliefs. Although the above may be important in disputes, the focus of this thesis is on expressed values and interests and the role these play in genomic developments.

This thesis will examine three case studies of technological developments in genomics and will demonstrate that both values-based and interests-based arguments are advanced by stakeholders in each of the cases but that there is no one single pattern of argument that holds across the case studies. Furthermore, the analysis will reveal considerable complexity in both values-based and interests-based arguments and will suggest a more nuanced framework consisting of three different types of values-based argument and three-different ways of arguing from an interests-basis, that provide a more discriminating framework.

## 1.4 Thesis outline

This thesis examines whether values-based and interests-based arguments are found in genetic technologies other than GM crops and how these arguments are aligned between the relevant stakeholders. In the case of GM crops, the dispute became focussed at the point where commercial release of GM crops was contemplated and the potential risks of these releases to the environment (and human health) were being evaluated. The genomic developments studied here are at different stages in terms of availability for public consumption ranging from very early research phases to early products becoming available on the market. This thesis will also consider the nature of the policy-regulatory framework applicable to specific genomic technologies and the main location of the negotiation of any dispute. Finally, the usefulness of the values-interests framework as a tool of analysis will be considered.

This thesis therefore examines the following questions:

1. To what extent are values-based and interests-based arguments found in areas of genomic technologies other than GM crops?
2. How are these values-based and interests-based approaches aligned between stakeholders in potentially disputed areas?
3. Where are values- and interests-based arguments negotiated and how does the policy-regulatory framework relate to the main values and interests being expressed?
4. Is the values-interests approach an appropriate and useful way of distinguishing between arguments around innovation in genomics?

This thesis is unique in that it combines case studies in a range of genomics applications with an approach derived from considering the motivations of a range of stakeholders and examines the values and interests at stake in great detail. Numerous studies have been conducted into specific aspects of biobanks (many of which are referred to in Chapter five) and human stem cell research (many of which are referred to in Chapter six) although GM and cloned animals (Chapter four) remain a relatively under-researched subject. However,

I am not aware of any qualitative study that considers this range of applications using such an interdisciplinary approach. This thesis avoids treating all future genomics developments as a case of 'another GM crops' yet gains from the insights from detailed, long-term study of the development of GM crops.

The subject is important because the public acceptability of genomic technologies continues to exercise policy makers and scientists, witness the emphasis that the UK Treasury's Ten Year Investment Framework gives to increasing public confidence in science and technology innovation (HM Treasury *et al.* 2004). The main focus of social science research, however, has been on science in society and public engagement activities (e.g. Wilsdon & Willis, 2004). The early engagement of citizens in science innovation, while important, may not be a panacea to resolve all potential conflict (Tait, 2009). The values-interests framework provides a complementary approach to that of public engagement in understanding the dynamics around disputed areas of genomic technologies that is worthy of investigation.

The following six chapters of this thesis address the research questions from several different perspectives.

Chapter two examines the relevant literature from a range of disciplines and in particular focuses on the role of values and interests in disputed areas of policy. I engage with the question of whether a values-interests distinction is merely a re-run of previous debates regarding fact-value distinctions and constitutes an attempt to dismiss values-based arguments as emotional and irrational. I conclude that this is not a necessary inference. I identify some of the critical influences on decision-making, including cognition, affect, the views of others, and institutions as well as personal and local experiences. I further note that research scientists are not immune to these influences. Given that the context for this thesis is disputes around genomic developments, I reflect on the use of the concepts of values and interests in the mediation literature. I also give specific consideration to the role of values in a risk context and note that among the factors that appear to influence risk perception are the extent to which there is agreement on values. Thus, where there is agreement on values, there is likely to be a higher level of trust and hence less dispute

about risk calculations. I reflect on the use of values-considerations as evidence, together with scientific evidence, in the context of evidence-based policy

Having laid out the theoretical context for a consideration of values and interests, Chapter three describes my research design. I argue for the multiple case-study method that I have adopted and explain how I operationalised the conceptual tools of values and interests. Operationalising the concepts of 'values' and 'interests' proved challenging and I resolved this by dealing with the concepts on a grounded basis, not predefining the values and interests to be paid attention to but allowing each case to reveal the key values and interest involved. I then present the empirical data for this thesis in the form of three different case studies. Within each case study, the strategy is first to describe the case and then to analyse the data using the values-interests framework and finally to consider the policy and regulatory responses.

Chapter four describes and analyses the first case study and examines GM and cloned animals. Cloned and GM animals are currently not commonly found in European agriculture but the first calves from a cloned bull have been born in the UK, imported as embryos. The contexts in this case are how non-human animals should be valued and their welfare regarded, and the safety of products from these biotechnology-derived animals. This case particularly examines how policy makers have attempted to engage with the contentious area of animal cloning where there appears to be little demand for the products by European industry, expected antagonistic public attitudes and no scientific basis for distinguishing cloned animals and products derived from them that could be used as a discriminating factor in international trade. This is a case where policy-makers are expecting resistance to developments from citizens but where there is currently little public awareness and not much conflict apparent in the public arena.

Chapter five provides a case study of biobanks. More specifically, the cases of UK Biobank and Generation Scotland are examined as two of UK's major biobanking projects, both promising to create resources for health related research that will enable genetic, lifestyle and environmental effects of common diseases to be understood better. The focus of attention around biobank developments has been on maintaining the confidence



of human participants contributing to creating the biobank, a case where negotiating between different human interests has been key. Nevertheless, the benefit of biobanks has been promoted on a promise of future, wider health benefits. This case also highlights how bioethics advisory groups have become an important agent of governance. This is a case where there is currently no public conflict in the UK, although biobanks in other jurisdictions, such as Iceland, have become contentious.

Chapter six considers the case of research on human stem cells and in particular human embryonic stem cells. This is a case with a recognised conflict, between upholding the integrity and sanctity of human embryos against the needs of people diagnosed with specific diseases. This dimension of the conflict has so dominated the debate that other important issues, such as inequalities of access to health care are hardly addressed at all. The justification for research is largely based on visions of cell therapies: however, the likely early applications such as use of human embryonic stem cells for toxicity screening of potential pharmaceutical drugs are hardly mentioned in ethical discussions. This case also covers a situation where policy makers are deemed to have dealt with a contentious issue in a successful way so that whilst embryonic stem cell research is contested, there has been no widespread protest in the UK to undermine the technology.

Chapter seven pulls together these different case studies, synthesises the findings and draws conclusions regarding the thesis questions. While it may be tempting to perceive all genomic developments as instances of the same dispute, a closer examination reveals that each case consists of a different structure of interwoven elements, giving each case a distinctive quality or texture. For example, GM animals are not just another case of GM crops. Furthermore, a close examination of arguments made by stakeholders reveals a degree of complexity, where arguments are not always what they appear at first to be. Arguments purporting to be about animal welfare, for example, may be about deeper issues of animal integrity. The values-interests dichotomy can furthermore be dissected into three different types of values-based argument and three different types of interests-based argument.

Chapter eight provides a final coda, reprising the textures of the case studies, the implications for policy and theory and the limits of the research. The chapter argues that this thesis presents an original application of the values-interests approach to empirical data on three different applications of genomic technologies that reveal important features about the nature of the issues at stake.

### **1.5 Chapter summary**

Innovation in the area of genetics and genomics may become contested for a range of different reasons. Widespread resistance in Europe to the commercial release of GM crops highlighted the impact of such resistance. Tait's (2001) analysis of the GM crops case demonstrated a mismatch between the risk-based regulatory regime and the many predominantly value-based concerns which exacerbated the dispute. The risk regulatory system simply had no mechanism for dealing with these value-based concerns. There is continuing concern among policy makers and others to ensure that other technological innovations do not follow the GM crops trajectory. This thesis seeks to apply Tait's values-interests approach to a range of different applications of genomic science and examine the extent to which discussions and debates raise interests-based and values-based issues and how the policy community has responded to these concerns.

In this chapter, I have set out the basic outline of the thesis. In the next I will review relevant literature and demonstrate that values and interests have been widely recognised as important factors both in disputes and in risk evaluation.

## **Chapter 2**

### **Values and interests in disputes and evidence-based policy**

#### **2.1 Introduction**

Reflection on values and interests has a long, multi-disciplinary and sometimes controversial history. This thesis is therefore inherently and explicitly interdisciplinary. It draws on aspects of moral philosophy, sociology, science and technology studies, anthropology, psychology, risk analysis, policy studies and dispute resolution. The aim in this chapter is to elucidate common themes that have arisen from various disciplinary perspectives on the subject. I will firstly examine literature on what are values and interests, then on what has been identified as their role in disputes, the role of values and interests in rational decision making, leading to the use of interests- and values- based considerations in evidence-based policy and finally reviewing methods that have been used to measure values and interests.

This chapter will cover broad areas that are relevant to each of the following chapters. Literature relevant to specific applications of genomic technologies are reviewed in the relevant case study chapters.

#### **2.2 What are values and interests?**

The values-interests framework presupposes firstly that such things as values and interests exist and secondly that it is possible to identify and differentiate between them. These presuppositions underlie the first of the thesis questions, the extent to which values-based and interests-based arguments are found in domains other than GM crops. The first supposition seems self-evident. The language of values and interests is used in common parlance and it is in widespread use in social science literature without necessarily warranting a definition. Stirling (2008) for example argues that social appraisal of technology enables actors to learn about the key differences between their own values and interests and those of others, without clarifying what he means by values and interests.

The language of 'values' resonates with the discipline of ethics. Within ethical theory there is disagreement as to whether values are purely subjective, reflecting a person's reaction or whether there exists some objective value that can be identified. For the purposes of this thesis, I will consider values and interests as concepts or attitudes rather than artefacts. There may or may not exist an objective value that is being sought but this is immaterial for understanding the deployment of arguments in practical situations. Even if there are no objective values that can be identified, people generally behave as though they can not only be identified but are also shared.

Defining what is an interest and what is a value has proved a little more difficult. As my starting point, I have taken a definition of values and interests that is found in one of the key authors in mediation literature, John Burton. I have consulted mediation literature on the basis that the subject of this thesis is potentially disputed areas of genomics and hence mediation literature contains relevant insights.

Burton (1990) defines interests as:

*"The occupational, social, political and economic aspirations of the individual, and of identity groups of individuals within a social system. Interests are held in common within groups in a society but are less likely to be held in common nationally. Interests are transitory, altering with circumstances. They are not in any way an inherent part of the individuals as are needs and as values might be. They typically relate to material goods or role occupancy."* (p38)

He also notes that interests are negotiable. In this definition, interests are understood as extending beyond merely individual self-interest to include group interests.

Burton defines values as:

*"Ideas, habits, customs and beliefs that are a characteristic of particular social communities. They are features that lead to separate cultures and identity groups."* (p38)

Burton explicitly links values to different cultures and social communities. He also notes that values are not easily changed and they are not traded. Gregory (2002) goes so far as

to argue that there are circumstances where it would be unethical to ask people to undertake specific value trade-offs because to do so would be to ask them to violate their own absolute standards.

I do not wish to suggest that values and interests are completely separate categories. Tait (2001) already noted that arguments are unlikely to be purely values-based or interests-based. There are clearly situations where they overlap and interact with each other. Neal (1965) for example, suggests that values can be perceived as setting limits to the interests that can be expressed, or that the interests of specific groups can be perceived as generating values or manipulating existing values as a means to legitimating group-member behaviour.

There may be specific difficulties in identifying values because they may be hidden and unarticulated for strategic purposes, because they are not deemed acceptable or because they are so deeply entrenched that they appear to require no articulation with the presumption that they are commonly shared and acknowledged (Bruce & Tait, 2003).

Myrdal (1958) argues that expressed values may reflect primarily what we believe are other people's conceptions of the good, that expressed values are those that are deemed socially virtuous.

Some researchers stress the social construction of values rather than their basis in ethical theory. For example Macnaghten (2004) argues that "*specific embodied social practices, rather than abstract ethical principles,...are most likely to shape and transform our relationships to animals*" (p537). Macnaghten's research was specifically structured to identify different social constructions (it involved running focus groups with groups that had different experiences of animals e.g. pet owners, farmers, wildlife observers and country sports enthusiasts), so it is perhaps not surprising that these were found.

However, the research does not explain what were the grounds for these respondents to be involved in the different activities in the first place and does not preclude the presence of values-based orientations. Indeed, Macnaghten appears to conclude that ethical concern towards animals includes both a historical, cultural component and a component embedded in social reality (p548). Macnaghten's main criticism appears to be that specific

utilitarian and deontological ethical frameworks are inadequate to accommodate the range of ethical concerns raised by animal biotechnology. In other words, values may not be based on overt reliance on ethical theory but be developed in a specific context. This tension between the influence of the social circumstances and ethical principles has been recognised elsewhere (e.g. Haimes 2002, Hoeyer, 2006) and will not be resolved here.

For research purposes these rather general definitions of values and interests need to be converted into concrete categories. In section 2.6, I will return to consider how different researchers have approached this task. I will consider aspects of operationalising values and interests for this thesis in detail in Chapter three and will return to reflect further on a definition of values and interests in Chapter seven.

## **2.3 The role of values and interests in disputes**

### **2.3.1 What is the evidence that values and interests considerations are important in genomic developments?**

There is ample evidence that decisions on GM crops raise values and interests issues. In Chapter one, the approach of Tait (2001) based on empirical evidence identifying values and interests components in disputes around GM crops was outlined. This approach has been subsequently adopted for example by Levitt (2003). But to what extent does it matter that values and interests issues are found in genomic developments? This section examines the evidence that values and interests in genomic developments are worth investigating.

Staying in the sphere of GM crops, Wynne (2001) argues not only that values are important considerations but also advocates that they should be made explicit:

*“the policy discourses about risk and ethics of GMOs [Genetically Modified Organisms] embody prior unacknowledged and thus unaccountable yet arbitrary human values and ethical commitments. These should be recognized as contingent human commitments, not imposed as truths which any rational person should respect. These human commitments are not deliberately concealed, but are culturally embodied, taken-for-granted habits and routines of thought and*

*practice...They need to be rendered more explicit, and more open to public deliberation."* (p472)

Thus, Wynne argues that values are important in a policy context as they represent commitments that may not be acknowledged but are none the less present.

Moving beyond the GM crops sphere, Nelkin (1992) considered a wide-range of applications of contested science and technology. From these, she identified four different categories of controversy based on:

- i) Infringement of values (e.g. with respect to embryos or animals)
- ii) Different political priorities (e.g. environment or economy)
- iii) Fear of risks (e.g. health hazards) and
- iv) Threat to individual rights (individuals vs. community)

She constructed these categories to have a general validity and to be applicable across a range of applications of technology, focussing on the critical elements of the controversy. Disputes in category one explicitly include values considerations, whereas categories two and four in particular consider balancing different interests (rights and priorities). Category three is more complex and I will specifically consider risk as an issue in section 2.4.2. Nelkin thus recognises the importance of both interests and values in disputes around technology. There is evidence, therefore, that both interests and values-based considerations have a role in disputes and are concepts and categories worthy of investigation. Mediation literature deals with dispute resolution and if values and interests are important in disputes then they would be expected to appear in that literature. The next section will examine how mediation literature can inform an understanding of the role of values and interests in disputes.

### **2.3.2 Defining the sources of controversy**

It is a basic tenet of mediation that it is important to understand the roots of a dispute in seeking to facilitate mutually satisfactory resolutions. Tait (2001) identified the distinction between values and interests-based motivations as particularly salient for resolving

conflicts. Nelkin's (1992) analysis agrees with Tait, that the means to resolve a dispute may depend on the underlying reasons for the dispute and these in turn may be linked to values and interests.

*"If the issue is one of competing interests, compensation measures can reduce conflict. But where more basic moral premises or ideological principles are at stake, direct solutions will not satisfy the protagonists." (Nelkin, 1992 pxxi)*

Burton (1990) critiques the tendency to address the apparent symptoms of disputes without understanding the underlying causes. He suggests that an understanding of interests and needs of protagonists is required. He argues that even though people differ in their interests (acknowledging some interests may be shared), there is more likely to be overlap among needs and it is these that must be identified and which form the basis of mediating disputes. Needs in his case refer to fundamental human requirements such as those outlined in Maslow's hierarchy of needs (Maslow, 1943): physiological, safety, belonging, esteem and self-actualisation.

The Harvard Negotiation Project style of negotiation is a classic of its kind. In the book *Getting to Yes*, Fisher and Ury (1987) describe what they term 'principled negotiation' as an effective means of dispute resolution. Similar to Burton (1990), Fisher and Ury suggest that underlying opposed positions are elements that are shared (although the terminology used by Fisher and Ury is rather different). It is these shared elements that provide the room to negotiate. Fisher and Ury also note that a position is likely to be concrete and explicit but the elements underlying it may well be unexpressed, intangible and perhaps inconsistent (p45). Furthermore, information is likely to be used selectively in this type of situation.

*"How you see the world depends on where you sit. People tend to see what they want to see. Out of a mass of detailed information, they tend to pick out and focus on those facts that confirm prior perceptions and to disregard or misinterpret those that call their perceptions into question" (p23)*



Thus there is a body of evidence to suggest that understanding the underlying causes of disputes rather than merely taking the stated positions as the source of negotiation can help build consensus and resolve conflicts.

The role of values is also recognised as an important factor in disputes. Acland (1995) suggests that while values are not negotiable, it is rare that only one value is at stake, and that the relative priority given to different values can be negotiable given sufficient evidence (p 51). Furthermore, it is possible to identify values that are shared. However, practitioners Acland and Hickling (1998) also point out that conflicts are particularly difficult to negotiate where one party considers an issue to be a negotiable interest and the other a non-negotiable value, as also identified by Nelkin (1992) and Tait (2001). One of the key impediments to effective resolution is articulating a rationale for resolution (Tidwell, 2001 p175). Another important question is, when is a conflict constructive and when is it destructive? If parties do not wish to engage in resolution, then it seems likely that there is little that can be done to promote such a resolution. Equally, it may not always be in the interests of protagonists to arrive at a resolution. Unequal power relations may impact on the desirability of resolution of conflicts for different parties.

Lukes (2005) notes that there are different ways in which power may be exhibited

*“A may exercise power over B by getting him to do what he does not want to do, but he also exercises power over him by influencing, shaping and determining his very wants” (p27)*

This suggests that power does not only show up in cases of conflict but that power can be exhibited in preventing conflicts taking part in the first place. Lukes' observation suggests that dispute resolution may not always be in the best interest of all the parties. It may be in the interests of more powerful actors to prevent conflict and preserve their position in this way.

From a slightly different perspective on power, Nelkin (1992) notes that a dispute may be less about the implications of science and technology than with the power relationships associated with them; less against specific technological decisions than against the

declining capacity of citizens to influence policies that affect their interests; and less against science than against the use of scientific rhetoric to mask political or moral choices (p xii-xiii).

Other researchers have highlighted the importance of institutions in shaping values and interests and it is to this aspect that I turn next.

### **2.3.3 Values, interests and institutions**

Although the focus of this study is values and interests, it is worthwhile noting that a body of literature identifies institutions also as important factors to be considered. Values and interests do not exist in isolation but are formed and expressed in the context of institutions. Weiss (1995) developed an analytical model similar to that of Tait (2001) which has subsequently been used in policy analysis (e.g. Nutley *et al.* 2007, Levitt 2003). This model includes not only interests and values ('ideology' in Weiss' terminology) but also information (or knowledge) and importantly, institutions. Weiss' theory suggests "*that people bring different interests, different ideologies, and different information to the decision making task.*" (p. 574). She suggests that the institutional environment is important in shaping the way in which participants interpret their interests, values and information as well as affecting the decision making process in terms of who is empowered to make decisions. Her approach recognises continual interplay between information, ideology, interests and institution (the '4Is' in her terminology).

Institutions have also been recognised as important in cultural theories of risk (Douglas and Wildavsky, 1983). Institutions here are understood as key in stopping what is deemed inappropriate behaviour and the concepts of 'pollution' and 'taboo' are deployed to do this (Tansey, 2004 reviewing the work of Mary Douglas). Thus, values and beliefs are products of the organisations that sustain them, allowing the development of organisations capable of collective action. In terms of risk perception, the implication is that the hazard may be real but powerful entities decide how big the risk is and who is responsible for it, and construe the real danger to be the behaviour that is collectively disapproved of (Tansey, 2004). Thus, cultural theory aims to explain different opinions

about who should manage risk and how this should be done (Marris *et al.* 1998). For Douglas & Wildavsky (1983) attitudes to risk are not merely the products of psychology but reflect the institutions that provide the context in which they arise.

A detailed examination of values and interests in a single organisation however reveals that differences in values-interests orientation can exist and serve a useful purpose within the organisation. Neal (1965) used a values-interests framework to analyse the response of Catholic clergy in Boston to change (they were then facing major doctrinal adjustments). She assumed that both values and interests operated in every case but that individuals differed in the extent to which their views were guided by each one (p46-47). Neal's aim was to unravel whether values or interests were primary in encouraging social change. So she categorised people's responses to change as dividing into change and non-change oriented and value-interest oriented. That is, she defined four categories

- change – value
- change – interest
- non-change – value
- non-change – interest

She concluded that: Boston priests would co-operate with reform, not because of special interest factors but for realisation of the basic values of a Christian commitment; but

- change - value men tended to be in staff positions that limited them to consultant roles in specialized areas and they were not in the direct line of command.
- Pastors of local churches tended to be interests, non-change oriented.

In this way, the church was able to articulate its value commitments to change and yet be resistant to its day-to-day effects. While there was a basic value commitment within the institution, different roles exhibited different degrees of orientation to values and interests. Line and staff pulled in different directions.

Both the '4 Is' approach and cultural theory attest to the importance of the location of decision-making. Neal (1965) links primarily values-based orientation or interests-based

orientation to individuals in different roles within one organisation. Weiss (1995) emphasises the way in which institutional location influences what is identified as important. Disputed situations are most explicit in the work of Douglas & Wildavsky (1983), with its emphasis on the role of power relationships and the way in which beliefs and values are deployed to maintain those relationships within social organisations. In this understanding, conflict around risk is part of a political struggle to influence society. Having argued that values and interests are commonly recognised and that they are important in dispute situations, it is evident that institutions form an important part of the context shaping disputes, however, they are too specific to be taken account of in the data analysed for this thesis. I now turn to consider two critiques of a values-interests approach.

## **2.4 The role of values and interests in rational decision-making**

Two main criticisms have been made of the values-interests approach. The first argues that values and interests are in reality a distinction between facts and values, a distinction that has been discredited in social science theory (as exemplified later in this section). The second, pursuing a more natural science approach, argues that values are irrational and therefore they have no place in evidence-based policy making that should be restricted to rational 'facts'. Both of these criticisms are important to address in pursuit of answering the fourth of the thesis questions, namely is the values-interests approach an appropriate and useful way of distinguishing between arguments around innovation in genomics?

### **2.4.1 Facts are firm and values are irrational?**

Resonance is often seen between the interests-values distinction and that between facts and values (e.g. Horlick-Jones, 2005). However, I will argue in section 3.3 that interests cover a range of considerations that go beyond the concept of 'facts'. Interests-based arguments may be supporting the interests of marginalised or vulnerable groups as well as self-interest. Burton (1990) linked interests to individual aspirations. Facts do not therefore necessarily equate to interests.

The ability to distinguish between facts and values, particularly in the context of policy decisions, has been questioned (e.g. Jasanoff, 1990). Nelkin (1992) similarly argues that the technical and political domains cannot always be clearly delineated:

*"Efforts to resolve conflicts over science and technology are confounded by intrinsic difficulties in assessing technical matters. The specialized knowledge involved in such assessments creates problems for the concerned citizen, especially in a climate of mistrust. The vagueness of the boundaries between the technical and political dimensions of policy decisions, and the problems of technical feasibility and political acceptability enhance the difficulty of finding appropriate means to expand public choice. There are also problems in determining who should be involved in a decision, who really represents the public interest."* (pxxiii)

Pielke (2007) suggests that there are relatively few circumstances where scientific facts are sufficient to address a policy question, he argues that these are likely to be circumstances where values are shared and uncertainty is minimal or fully describable (p75).

I conclude that whilst it may be difficult to distinguish between facts and values particularly in a policy context, the fact-value distinction is not the same as a distinction between values-based arguments and interests-based arguments.

Turning secondly to consider the critique that 'values' are too subjective to be included within policy decisions. In technical scientific understandings, values are viewed as subjective and matters of individual choice, in contrast to facts that are viewed as definitive and universally applicable. Wynne describes this as a: *"divide between factual, objective and real knowledge on the one hand, and cognitively empty emotion or values on the other"* (Wynne, 2001 p445).

If this analysis is accurate, there is an inevitable tension between decisions which only accept scientific evidence as the basis for negotiating interests, and those people expressing values-based commitments which are ignored on the basis of being purely emotional. Thus, the effect of this fact-value distinction is to focus on the 'facts'

component and relegate 'value' commitments to matters of individual choice. For Wynne the result is that any ethical dimension "*can either be scientifically defined – by defining (and weighing) consequences – or else they are solely matters of private, individual choice which can be resolved by market mechanisms*" (p446). Levitt (2003) notes that the effective result is that the values reflected are those of the policy-makers. Thus, values either have to be expressed in scientific or risk terms or they are relegated to matters of consumer choice. The GM crops study (Tait, 2001) is a good example of how advocacy groups critical of GM crops were left with the option of using the risk regulatory system to express their concerns, in the absence of any mechanism for dealing with their values-based objections.

Part of the justification for ignoring values-based critiques is the concept that they are irrational and therefore cannot be defended as objective factors to be taken into account. An evaluation of the 'rationality' of a choice based on values considerations, however, depends on an understanding of what is meant by rationality. Weber (1968) identified four different types of rationality: (p24)

- *Instrumentally rational*. Determined by the expectations as to the behaviour of objects in the environment and of other human beings; the expectations are used as 'conditions' or 'means' for the attainment of the actors' own rationally pursued and calculated ends. This is closest to the way in which 'rationality' is seen to be exhibited by considering 'facts' or 'real knowledge'.
- *Value-rational*. Determined by a conscious belief in the value for its own sake based on some ethical, aesthetic, religious or other form of behaviour, independent of its prospects of success.
- *Affectual* (especially emotional), determined by the actor's specific affects and feeling states, such as need for revenge, sensual gratification, contemplative bliss or working off emotional tensions.
- *Traditional*. Determined by ingrained habituation.

In both the value-rational and affectual motivations for action, the emphasis is not on the achievement of a result, but in carrying out the specific type of action for its own sake. Thus a viewpoint or action is rational if it is consistent with meeting particular values or beliefs or an affectual need.

Weber argued that from the point of view of instrumental rationality, value-rationality is always irrational. The more the value to which the action is oriented is elevated to the status of an absolute value, the more 'irrational' is the corresponding action. The more a person is oriented to the value, the less they are influenced by consideration of the consequences of the action. Weber however cautions that it is very unusual to find cases of action which are oriented only in one of these ways. Nor does he claim that this is an exhaustive list of all modes of rational orientation.

Barnes (1988) argues cogently from a sociological perspective that people do not usually take a fully-worked out calculative 'rational' orientation to a particular situation; rather people act out of two behaviours: self-interest and habit. This means that *"the best that can be done is to calculate a few things, some of the time, taking account of some contingencies"* (pxiii). Thus in practice it is common to take short-cuts in making rational decisions, an insight that is echoed in psychology literature.

A psychological approach divides human mental life into affective (feeling), cognitive (thinking) and conative (willing) aspects. Often studied as separate, distinct entities, Forgas (2001a) for example, suggests they are inseparable and interwoven. Furthermore, rather than viewing affect as a source of disruption on 'proper' (i.e. affect-less) thinking, affect is viewed as an important means of dealing with the social environment (Forgas, 2001b).

*"There is now strong evidence that evaluative, affective responses can often be produced in a fast, automatic, and highly adaptive manner even in the absence of inferential cognitive deliberations"* (p 389)

However, affect and cognition interact with each other. Forgas (2001b) suggests that:

*“the affect/cognition relationship is fundamentally [an] interactive one...Cognitive appraisal processes do, for instance, seem to make a critical difference to mediating even visceral reactions to subtly different challenge and threat situations.” (p392)*

And further that affect is particularly important in decision-making in uncertain environments:

*“affect is most likely to serve as a useful source of adaptive information when people need to engage in open, constructive processing to solve an inherently uncertain, complex, and demanding social cognitive tasks...One of the most common instances when we need to draw on affectively coloured information is when we anticipate our reaction to future events” (p392)*

Judgements about issues such as GM crops, stem cells or biobanks are made in just the sort of environment described i.e. complex, uncertain and in the future. So it would be reasonable to hypothesise that affect would be expected to be a strong component in decision-making in these situations.

Some research has been undertaken on the role of affect in decision-making around GM food by Townsend and Campbell (2004) and Townsend *et al.* (2004). In the latter study, using ‘dread’ as a measure of affect they found that in comparison to other issues facing a groups of (primarily) students, affect was not an important component of risk perception for GM crops. Affect was found to be much more important for risks of biological, chemical and nuclear warfare. In the former study, in an experimental situation involving eating (or not) apples purporting to be genetically modified, and indicated willingness (or not) to purchase genetically modified food, Townsend and Campbell found that affect was a factor influencing intention to purchase. Non-purchasers viewed GM food as significantly more dreaded and risky than those indicating willingness to purchase. These data therefore give some support to the importance of affect in decision making about genomic technologies, although the importance is likely to vary depending on context.

One of the implications of the importance of affect in developing attitudes is that issues are linked together in ways which may not be immediately expected



*"The representational categories people formed of their social encounters had little to do with the actual features of these situations and were almost entirely based on the similarities of affective reactions they produced...To the extent that affect is a significant source of cognitive categorization, we may predict close associative links between all kinds of affectively loaded representations"* Forgas, p397.

I have seen just this type of situation arising during focus group discussions around contentious issues in genomics with the cloned sheep Dolly, Bovine spongiform encephalopathy (BSE) and tasteless tomatoes in supermarkets all discussed at the same time as GM crops.

Psychology also emphasises the role of social relationships in developing attitudes and views. Forgas (2001) argues that social relations are important in forming reactions (p394): *"affective reactions arise in a social context, and actual or anticipated reactions by others are a major source of appraisals and affective responses."*

The anticipated reactions of others are also emphasised in other psychological approaches, as can be seen in research around attitudes to risk (see section 2.4.2) and models of understanding behaviour such as the Theory of Reasoned Action (and the associated Theory of Planned Behaviour, Ajzen 1991). The Theory of Reasoned Action (Ajzen and Fishbein 1980) is a semi-quantitative approach to identifying expected behaviour based on detailed analysis of attitudes and norms. This theory provided an inspiration for Tait's concept of interest-based and value-based motivations (Tait, personal communication). In the Theory of Reasoned Action *attitudes* are determined by belief that the behaviour leads to various outcomes and the evaluation of the desirability of these outcomes. *Norms* are beliefs about what significant others think about the behaviour. Attitudes and norms determine intentions and intentions to act usually lead to action (although various events can intervene between intention and action). For some intentions, attitudinal considerations are more important than normative considerations. For others normative considerations may predominate. This approach is widely used in some policy spheres as it is attractive in providing a quantitative basis for analysis. The main issue of note here is that the Theory of Reasoned Action acknowledges the

importance of beliefs about what significant others think about the behaviour in question in determining action.

These psychological insights are also upheld by sociological arguments. For example, Berger (1971), in the context of religious beliefs, refers to the concept and importance of plausibility structures. He argues that different world views are maintained by social processes *"Most of what we 'know' we have taken on the authority of others, and it is only as others continue to confirm this 'knowledge' that it continues to be plausible to us."* (p19). The theme of plausibility has been followed in social studies of scientific knowledge. Harvey (1981) conducted interviews with scientists in the field of Quantum Mechanics and demonstrated that an evaluation of knowledge-claims from two competing theories was strongly influenced by the plausibility of that knowledge-claim in the scientific cultures concerned. Similar studies have demonstrated that the scientific research is not completely divorced from value commitments. Barnes and MacKenzie (1979) studied how two competing ideas in the development of statistics gained legitimacy and concluded that the competing scientific theories were linked to evaluations of what could be done with the theories. In the case of one theory, the scientist (Pearson) was interested in providing a scientific basis for eugenic policy, an activity which could better be addressed by his theory. In the case of the second theory, the scientist (Yule) was more concerned with the problems of alleviating poverty which was more amenable to his statistical approach. Judgements on the rightness of statistical methods were thus being made in the context of a commitment to a specific outcome.

In summary, the critique that values are irrational and therefore have no place in policy is refuted by exploring differing concepts of rationality (Weber, 1968) and by a range of insights about decision-making (Barnes 1988, Forgas 2001a & b). The importance of plausibility of scenarios to significant social groups is also stressed (Berger 1971 and Ajzen & Fishbein 1980, Forgas 2001a & b) including evaluation by scientists (Barnes & MacKenzie 1979, Harvey 1981). Psychological insights (Forgas 2001a & b) suggest that decision-making is influenced by both cognition and affect, with the two modes interacting with each other. Furthermore, affect is particularly important in complex and uncertain

decision-making environments. Therefore, the literature suggests that a values-orientation does not necessarily imply irrationality and cognitively empty emotion and may be an effective way of making decisions regarding complex and uncertain future scenarios.

#### **2.4.2 Values and interests in a risk context**

Many of the applications of genomic technologies involve some aspect of hazard, and risk regulation has become a key policy consideration. GM crops are an excellent example of this. The contentious nature of risk regulation and evaluating the appropriate extent of precaution has exercised the European Union for some years. Tait (2001) explicitly links into these tensions when she identifies the risk regulatory regime as becoming the locus of negotiation of many, not apparently risk-related issues. In her analysis it was the values-based concerns that the risk-regulatory regime most struggled with. Policy around several genomic developments is inextricably linked with regulation of risk, particularly where food, human health or the environment are potentially impacted. It is this link with risk that explains why an analysis of the extent to which values and interests are found in debates (thesis question one) has such big implications. If there is a strong values component but the issue is being treated in policy as though it was a risk regulatory issue, then there is a mismatch between issue and regulation (thesis question three). In this section, I examine literature related to understandings of risk and in particular any evidence pertaining to interactions between risk and values. Understandings of risk are linked with concepts of trust, and I also examine the evidence relating to trust in risk-related issues and values.

Perceptions of risk are an important part of disputes around technological developments and formed an important part of the GM crops debates. Psychometric approaches suggest risk perception by lay citizens is different from technical calculations of probabilities of hazard. Salient factors that influence perceptions of risk include the extent to which the hazard invokes feelings of dread, the extent to which the risk is voluntary, the apparent controllability of the hazard, the equity of distribution of risk and threat to future generations (Slovic, 2000). Low probability, high consequence events pose particular challenges as lay people have a tendency to focus just on the high consequences of the

event (Sunstein, 2005). There is evidence to suggest that many people find probabilistic data difficult to deal with in decision-making (Tidwell, 2001) and hence use heuristics or short-cuts to simplify decision-making. These processes take into account for example the similarity to other events (Kahneman & Tversky, 1982) as well as the type of information and the way in which it is presented (Tidwell, 2001).

Sunstein (2005) suggests that people are averse to risks from specific sources, rather than being generally risk-averse. In his view someone concerned about the risks from pesticides is unlikely to be similarly concerned about the risks associated with organic foods. He also points out the importance of group in terms of risk evaluation, referring to 'social cascades' where people are influenced by the fear of specific risks expressed by others in society, thus echoing the important influence that social relationships have on an individual's evaluative processes as already outlined in section 2.4.1.

There is a large and rich literature on risk perception but the intention here is to focus more specifically on the links between risk perception, values and interests. There is evidence for a link between risk perceptions and value orientations, such that activities that are consistent with a particular value stance are seen to be less risky than ones that are in conflict with this value stance. Sjöberg and Wählberg (2002), for example found moderately strong relationships between indicators of New Age beliefs and risk perception.

Kahan *et al.* (2006) argue that cultural worldviews (characterised as hierarchical, egalitarian, individualistic or solidaristic) and disputes over what constitutes the 'good life' are really at the core of risk disputes. They cite evidence that individuals conform in their beliefs about risk to their visions of an ideal society (p1072). Hence, for Kahan *et al.* the challenge for policy/regulation is how to accommodate diverse visions of the good.

Kahan *et al.* also argue that we trust those who share our cultural worldviews (p1085). This link between trust and values is echoed by Earle (2004) who found from experimental evidence that agreement on values (inferred from policy statements) influenced participants' judgements on trustworthiness of the source of the statements. Poortinga

and Pidgeon (2004) found pre-existing beliefs to be important in determining trust in the specific context of GM crops. They studied the stated responses of people to events in the context of GM crops on levels of trust. People identified as positive towards GM crops (defined as believing GM food has high benefit and low risk) on the basis of their prior beliefs tended to view events in this light, those who were negative (defined as low benefit, high risk) viewed events in that light. Trust in the ambivalent group (defined as high benefit, high risk) tended to be impacted more by negative events than positive events. Indifferent groups (defined as low benefit, low risk) were unpredictable. Some events, however, increased the trust of the negative group but decreased the trust of the other three groups (e.g. a hypothetical situation where the Government stops the introduction of new GM food on the market). Other events had a similar impact on all groups – whether increasing or decreasing trust. Therefore, the evidence suggests value-consonance is one component of determining whom we trust where risk issues are concerned.

Horlick-Jones (2005), however, emphasises the contextual and situated nature of risk evaluations in contrast to value-based concerns. He studied attitudes to risk from local industry using focus group discussions and noted how personal experiences and commitments are brought to bear on the issue. Hence, Horlick-Jones concludes:

*“Exchanges of this nature reveal the difficulty in drawing a clear distinction between interest-based and value-based attitudes towards risk issues. The processes of reasoning are rather more complicated, emerging, as I suggested from a wider framing of topics, considerations and agendas than that typically used by technical experts, personal experiences and circumstances, local knowledge, and, during, and through, interactions with others.” (p262)*

Thus, for Horlick-Jones, there are four key aspects to how lay people make sense of risk issues:

- Involves a wider-framing of topics than usual with technical experts
- Reflects personal experiences and circumstances

- Reflects local contextual issues and local knowledge
- Arises from interaction with others.

None of these preclude the influence of values-based and interests-based considerations in sense-making. And indeed his recognition of evaluation of risk based on individual commitments suggests a degree of values-based analysis. It is also worthwhile to consider whether technological developments situated in specific locations (such as in this case and in many instances of land-use dispute) or more widely in society (such as whether human embryonic stem cell research is acceptable or not) or specific individuals (such as the safety of new pharmaceuticals) differ in their nature. In the case of developments in specific locations for example, both protagonists and antagonists in any dispute will be impacted by the consequences of decisions. This may be less directly so in other contexts.

Many of the suggested applications of genomic science have within them an element of hazard that needs to be evaluated. From the above evidence it is not sufficient to derive technical risk calculations (probability of harm and their likely consequences) but also to take into account the perceptions of risk by different people. These risk perceptions appear to be influenced by value-based judgements. Some have even gone so far as to suggest that controversies ostensibly about risk are essentially political contestations about the form of ideal societies (Douglas & Wildavsky, 1983).

## **2.5 The role of values and interests in evidence-based policy**

This section sets the scene linking values, interests and policy related to scientific issues. While recognising that there is an extensive literature on evidence-based policy, only a few salient issues are raised here. The UK government has adopted an approach to policy that emphasises evidence-based policy, where 'what matters is what works' (Solebury, 2001) and evidence has a key role in discovering what works (Nutley and Webb, 2000). Policy-makers are required to make rational decisions that protect citizens from harm, respect their ethical values and are legitimate. As Levitt (2003) notes:

*"Policy making and implementation require two fundamental starting conditions: the government must be able to construct or acquire interpretations of what society wants and needs in that area, and it must know how to use its power legitimately to deliver it." (p24)*

Levitt posits that in obtaining evidence to inform policy making, the views of publics may conflict with the aim of producing technological competitive advantage. Brownsword (2008) addresses the challenges of legitimation in plural cultures and suggests that legitimation can be based on appealing to public or national interest but may also result in appeal specifically to moral and ethical reasons.

Policy-making around scientific developments depends on scientific evidence but to what extent does this evidence alone compel action? In the area of contested scientific and technological developments, 'evidence' itself becomes contested, as in the case of GM crops (Tait, 2001). Studies of controversies suggest that where the dispute has a strong values-basis more evidence does not lead to resolution, as identified by Nelkin (1992).

*"In the creation controversy, the animal rights dispute, and the opposition to fetal research, efforts to compromise have largely failed to sway those morally committed to a cause. Nor is there much evidence that technical arguments change anyone's mind. No amount of data could resolve the premises underlying the conflict over animal experimentation. Both animal rights advocates and scientists use technical information to legitimate their arguments. And both positions are based on existing priorities and well-entrenched beliefs." (pxxi)*

Tansey (2004) comes to a similar conclusion using the cultural theory approach and states that

*"for issues such as genetically modified organisms, research that seeks to demonstrate the safety of the technology will not dissipate political opposition since protest is in defence of a moral boundary" (p29)*

Pielke (2007) goes so far as to suggest that science has come to be viewed as a resource used by groups to lobby for their particular interests (he gives climate change debates as

an example of this). Nelkin (1992) goes even further and refers to expertise as “*a weapon in the political arsenal of competing groups*” (pxix). Jasanoff (1990) and Schön & Rein (1994) similarly concluded from studies of policy-making that scientific evidence alone will not resolve all policy disputes.

Pielke (2007) suggests a taxonomy of science-related policy issues depending on their value content and also points out the uncertainty that is inherent in much science. He argues that scientific evidence can only compel action in specific circumstances where values are shared and there is low uncertainty in the relationship between the desired outcome and alternative ways of getting there.

A number of potential solutions to introducing public values into the innovation system have been offered including a better understanding of public values by scientists (e.g. House of Lords, 2000), developing new forms of governance of science (Irwin, 2006), and upstream engagement (e.g. Wilsdon & Willis, 2004), each broadly emphasising the role of citizens in technological developments. However there have been a number of critiques of upstream engagement in innovation (e.g. Williams 2009, Pidgeon & Rogers-Hayden 2007, Tait 2009) on the basis of the inherent unpredictability of future developments and the potential to fuel excessive concerns over issues to which genuine uncertainties still attach. Tait's (2001) approach, however, suggests that paying more attention to the nature of arguments can better enable an appropriate response to disputes. It is this proposition that will be investigated in this thesis. Levitt (2003) agrees that interests and values are important factors in the policy process.

*“Interests and values are powerful determinants of evidence, policy and practice, even when they are partly hidden from view. Each person and organisation uses them all the time, sometimes unconsciously, to shape their perceptions of the world, to select their area of attention, to choose what they care about and what they want to promote or prevent, and to decide how to obtain legitimisation, satisfaction and other rewards from what they do and can get others to do. No amount of regulations, procedures or ‘objective’ evidence can prevent these beliefs and*



*motivations from affecting individual and group attitudes and perceptions (in a so-called free society, at least).” (Levitt, 2003: p3-4).*

Policy-making in genomics issues has a high reliance on scientific evidence both for understanding the potential of the science and also to undertake technical risk evaluations. This does not of course mean that policy-making in the scientific realm is immune from strategic and political considerations (e.g. Millstone & van Zwanenberg 2001, Nutley *et al.* 2002). Science therefore opens up new possibilities but they may have the potential for hazards to arise and may have profound social consequences. Disputes may arise as to what is the appropriate policy response. Calls to include public values to mediate or at least to provide legitimacy to decisions have resulted in increasing use of ethics committees and public engagement.

The intention of this thesis is to provide empirical evidence to investigate how values and interests are being negotiated in practice (thesis question three) but in order to do so, a method of operationalising the concepts needs to be developed. It is to this aspect that I turn to next.

## **2.6 Measuring values and interests**

Broadly, three different ways of approaching the issue of operationalising values and interests can be found in the literature.

1. Defining specific values by which people are categorised (e.g. Douglas & Wildavsky 1983, Inglehart 1990, Neal 1965)
2. Defining the sources of controversy which in turn highlights the value/interest basis of the dispute (e.g. Nelkin, 1992)
3. Identifying specific characteristics of an argument with a value or interest base (Evans 2002)

I will now consider each of these in turn.

### 2.6.1 Defining specific values by which people are categorised

Douglas and Wildavsky (1983) in their widely cited cultural theory of risk posit four clusters of values that form competing cultural worldviews: namely hierarchical, egalitarian, individualistic and solidaristic. This approach has been widely referenced, however, as Adams (1995) points out, whilst the cultural theory typology is useful, there has been limited success in validating it statistically (p66). Furthermore, the typology restricts values to two dimensions which may not be the most salient ones to be considered in disputes around genomic technologies.

As noted earlier, Neal (1965) used a values-interests framework. She applied this framework by using a questionnaire based on 120 cliché statements<sup>1</sup> that she had identified as habitually used by her respondents. She allocated these statements to different orientations by first administering the questions to a group of clergy whose views were known. Neal argued that *"By writing cliché-type items and asking subjects if they accept or reject them, one can get measures of orientation to the content"* (p47). However, this approach might be criticised on the basis that it depends heavily on allocating specific questions to specific orientations in ways that accurately reflect values and interests. A group of people whose values and interests orientations are known is necessary for this method in order to provide the 'calibration' necessary and that knowledge is not available for developments in genomic technologies.

Inglehart (1990) infers values by a consistent emphasis given to particular types of goals, and in particular he defines goals that suggest either materialist or post-materialist values. For Inglehart materialist values are reflected in goals such as maintaining order in the nation, maintaining a high rate of economic growth and fighting against crime. Post-materialist values are reflected in goals such as giving people more say in the decisions of the government, protecting freedom of speech, moving towards a society where ideas count more than money and which is friendlier and less impersonal and trying to make our

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<sup>1</sup> Example of statements are: for values 'Concerns about caution have little place when the issue is one of social justice' & 'When I think of social reform, I think of things I believe in so deeply I could dedicate all my efforts to them; for interests 'The best way to improve world conditions is for each man to take care of his own corner of the vineyard' & 'In the last analysis, it's having the power that makes the difference' (pp169-170).

cities and countryside more beautiful. Inglehart used these orientations in questionnaires to elicit motivations underlying the failure to adopt environmental behaviours. However this questionnaire makes assumptions about the importance of materialist and post-materialist values which may not be critically important beyond the environmental sphere.

### **2.6.2 Identifying the characteristics of an argument**

Weber's concepts of value rationality and instrumental rationality have been developed by Evans (2002) and used to analyse changes in the bioethical debates in USA. Evans refers to value rationality and instrumental rationality as substantive and formal rationality, respectively. Evans notes the difficulty of operationalising these concepts (p14)

*"unfortunately, this literature offers little help in parsing arguments in a particular debate into substantive and formal"*. Evans' solution is to link these two types of rationality to the ends and means of research and use this as a way of distinguishing between the two.

Broadly speaking:

Value rationality is characterised by:

- Means need to be consistent with ultimate value system
- Ends are defined and defended. A number of different ends can be discussed and need not be universally held

Instrumental rationality is characterised by:

- Any means that maximises ends is ethical.
- Ends are implicit or considered outside the decision-making process
- Ends can be translated into a commensurable metric and are considered universal.

Evans concludes that instrumental rational considerations have increasingly come to dominate over value rationality in the ethical debate in the USA around human genetics. I have attempted to use this type of analysis but I found the approach was not able to discriminate finely enough between different types of argument made in the examples that I studied. Many arguments contained elements of both value and instrumental rationality.

Thus, a range of different approaches have been adopted to operationalise values and interests. Each has something to offer but each has been developed within a specific context and answers specific questions. None of these methods is immediately adoptable for a different application but a context specific application is required and will be outlined in Chapter three.

## **2.7 Conclusions**

There is ample evidence from a range of different disciplines that both values and interests are important in decision-making around technology. A number of common themes have also emerged. That we trust those who appear to share our values, we reflect our values-preferences in our attitudes to risk and consider actions that further our concepts of the good society as being inherently less risky than those that seem to produce societies that do not conform to this ideal image. We may prefer certain technological trajectories due to a commitment to a particular form of political control in society or reject others as infringing some fundamental values. Whilst scientific evidence is a factor in lay assessment of technologies, it is only one factor, particularly when evidence is unclear, uncertain and consequences are in the future and therefore contestable. Individual decision-making involves affect, the influence of significant others, and the use of intellectual short-cuts such as identifying similarities with other familiar situations. Local context and personal experiences are also important in forming attitudes. Policy makers and regulators face particular challenges in negotiating contested genomic developments with a high values-content. Policy must be accountable to be legitimate and a clear evidence-base provides that legitimacy. Disagreement on values is unlikely to be resolved by scientific evidence and therefore requires some other way of negotiation. Therefore, the literature suggests that values and interests are important considerations in attitudes to technological developments and in disputes. A detailed analysis of specific applications of genomic technologies that involve varying proportions of values-based arguments and the way in which policy communities have negotiated these issues

appears to offer a fruitful way of understanding and potentially contributing to resolving disputes around genomic technologies.

## **Chapter 3**

### **Method**

#### **3.1 Introduction**

The previous chapter analysed the broader theoretical and empirical context on which my research draws. Chapter two demonstrated from a range of different disciplines that values as well as interests are important in disputes in technology. Disputes with a strong values-component are likely to be more difficult to resolve than those with interests-based issues predominating. Therefore, understanding the extent to which genomic developments are prone to engender values-based or interests-based considerations is likely to be important. Contested genomic developments are expected to provide particular challenges to policy-makers when there is a strong values-based element and the way in which policy-makers have dealt with different genomic technologies is worthy of examination.

In this chapter I describe the methods used to address my research questions. I explain the research approach that I have adopted, data sources that I have used and how I have selected specific interviewees. I describe how I have operationalised the concepts of 'values' and 'interests' in order to conduct the research. Finally, I explain the approach I have taken to analyse the data including the use of software to produce visual representations or 'cognitive maps' of interview data.

#### **3.2 Research design**

The aim of this thesis is to understand better the different types of argument deployed by various stakeholders in debates around genomic technologies and how these are managed by policy makers. The specific research questions, stated in Chapter one, are re-stated here.

- To what extent are values-based and interests-based arguments found in areas of genomic technologies other than GM crops?

- How are these values-based and interests-based approaches aligned between stakeholders in potentially disputed areas?
- Where are values- and interests-based arguments negotiated and how does the policy-regulatory framework relate to the main values and interests being expressed?
- Is the values-interests approach an appropriate and useful way of distinguishing between arguments around innovation in genomics?

From these questions it follows that the research will need to identify appropriate areas of genomic technologies to examine and devise a method of operationalising the categorisation into interests-based and values-based arguments and to consider the innovation, regulation and citizens' perspectives in the genomic technologies examined.

Quantitative data in the form of opinion surveys have been used successfully to investigate genomics developments (e.g. Poortinga & Pidgeon 2003, Eurobarometer surveys<sup>2</sup>). However, a weakness of public attitude surveys, particularly given the relative newness of genomic technologies, is the low level of knowledge about the realisable outputs from the research. Questions may be formed in the abstract but if there are few or no products on the ground (as is often the situation with respect to genomic developments) it may be difficult for people to engage meaningfully with the developments. Furthermore, public views may well be relatively unformed at the early stages of technological development. Public surveys may measure what people think but are less helpful in obtaining an in-depth understanding of why they think the way they think. The problem of identifying meaningful questions for survey work is exacerbated for this research due to the difficulty of operationalising values and interests across a range of different genomic applications. I have therefore adopted a primarily qualitative approach for these research questions as they are exploratory in nature, dealing with operational links rather than measures of frequency or incidence. Existing survey data is referred to

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<sup>2</sup> Available from [http://ec.europa.eu/public\\_opinion/index\\_en.htm](http://ec.europa.eu/public_opinion/index_en.htm) [accessed 06/01/11]

in the case studies on cloned animals (Chapter four) and biobanks (Chapter five) providing additional material to support the qualitative data analysis.

The research questions invite consideration of specific contexts. GM crops were introduced at a time and in conditions where trust in scientific evidence and the institutions regulating them was particularly low, due to experiences such as BSE (Horlick-Jones *et al.* 2007). There was also considerable questioning of globalisation and the power of international corporations at a time when crop seed companies were being bought up by multinational agrochemical companies. Additionally, there was also an increasing awareness of the negative impact that human populations were having on the environment (Horlick-Jones *et al.* 2007). All of these features provided an important background for the introduction of GM crops. This suggests the contexts of stakeholder interactions around genomic technologies are important for understanding the nature of the interaction. It is thus desirable to consider other innovations in genomics also in their contexts.

In this research I have therefore adopted a case study approach that will allow the subject matter to be examined in depth in a particular place, time and specific circumstance in a way that recognised interactions and complexity (Yin 1994, Thomas 1998, Punch 2009 ).

The first research question asks whether values-based and interests-based arguments are found in areas of genomic technologies other than GM crops? It is therefore inappropriate to conduct the research on a single case study that may be atypical.

Similarly, it has not been possible to readily identify a 'critical' case (Thomas, 1998), i.e. a single case that tests all the aspects of values-based and interests-based arguments as outlined in the research questions. Each of the research questions will benefit from considering more than one configuration of actors and stakeholders. I have therefore chosen a multiple case study route where each case explores and extends the ideas presented by Tait (2001) in different ways.

In considering the most appropriate cases, the decision was made to examine applications of genomic technologies rather than attempting to expand the use of the



values-interests framework to other areas of science, such as nuclear power. In this way the cases could also examine for any consistent arguments that applied across the cases of genomic applications. Cases were selected to examine several areas of innovation in genomics and applications of genomic technologies that could illustrate different configurations of the value-interest dimension. Although the intention of the research was to explore the value-interests dimension in detail, there was already some *a priori* information available in various applications of genomic technologies, for example suggestions of the importance of the value attributed to the status of the embryo in stem cell research. However, in the absence of such information in every application of genomic technology, the approach taken was to identify case studies that interrogate a range of different key relationships, the expectation being that this method of selecting cases would illuminate different aspects of values and interests.

Three cases were selected: genetically modified (GM) and cloned animals, biobanks (population genetic databases) and human stem cell research. GM animals were an obvious extension of the GM crops case, and allowed investigation of whether extension of genetic modification to animals engenders the same disputes as applications to crop plants. This is the simplest level of extension of the values-interests framework but the animal context also introduces new aspects involving human relationships with animals, different industry configurations and different biological considerations. As developments in GM animals have been integral to animal cloning it is appropriate to consider these two genomic technologies together. There is no overt public dispute currently around GM animals but there are likely to be strong values-based views, given the controversies over animal experimentation, and hence the potential for dispute.

At the time at which this research was started, biobanks were being initiated and were engendering some controversy. Since biobanks were being promoted on the basis of use of genomic technologies to increase health, based on biobank collections, they provided a further situation where the values-interests framework could be tested across a range of different circumstances. Biobanks were also chosen as a case of growing importance in terms of application of genomic technologies to humans and one which is concerned with

human relationships. The timing of access to stakeholder reflections on biobanks was opportune as national biobanks were in the process of being discussed, negotiated and initiated in the UK and in Scotland. The case involves aspects of health and wellbeing in populations, as well as individuals, and the prospect of considering future health for those currently well. There is currently no public dispute around the development of biobanks in the UK.

Stem cell research was identified as a third case study which was already recognised as having a strong values component regarding use of human embryos. There was a theoretical possibility that GM animals and biobanks cases could be similar in terms of the values-interests characteristics and hence a further case study which appeared to be at the extreme values end of the values-interests distinction seemed desirable. Access to stakeholder reflections was also opportune as there was ongoing debate as to the acceptability or not of embryonic stem cell research. The stem cell context is one of health of individuals particularly those already with disease diagnoses that are currently degenerative or incurable. The stem cell research case allowed the exploration of applications of genomic technologies to be extended to a situation that was already contentious and which afforded consideration of how contentious issues are being negotiated.

Further cases of emerging technologies, such as synthetic biology could also have been examined. However, these were rejected largely on practical grounds. There were insufficient resources to consider a fourth case study, developments in synthetic biology were hardly apparent when the research was instigated and access to stakeholders in the areas of GM and cloned animals, biobanks and stem cell research were much more readily available.

Each of the cases considered consists of a study of the emergence of an application of genomic technology. By bounding the case studies in this broad way, they allow developments over a period of time to be examined and permit the examination of an increasing engagement of stakeholders with the technology. Each of the cases reflects a

mainstream application of genomics that was under discussion during the research period.

The relational attributes of the three case studies are summarised in table 3.1, with GM crops given as a comparison. Ticks in parentheses indicate that whilst the relationship may not be immediately obvious, there may well be 'second order' effects on relationships. At some level, all human activity can be expected to have an impact on relationships between other humans but the intention here is to only identify major factors. So for example, GM crops affect human relationships because of the North-South, Rich country-Poor country divide that is the context of a globalised agriculture. Adoption (or not) of GM crops by some countries will have an effect on these relationships and indeed one of the major critiques of GM crops is their potential negative impact on poorer countries given the dominance of large multinational companies in supplying seeds (e.g. Horlick-Jones *et al.* 2007). With respect to stem cell research, a range of human relationships are important (more recently human-animal relationships have recently come into play regarding stem cell research with discussions about the potential use of animal eggs combined with human DNA – so called hybrid or cybrid embryos - in research but these debates emerged after the completion of the field work).

The intention of the cases is to provide context-based and detailed understandings of specific situation rather than to provide statistically valid samples (Thomas 1998). Case studies can be critiqued for only applying to the specific circumstances pertaining to the case. However, it may also be possible to discern patterns and principles that are applicable more widely. The prospects of doing so are increased by using a multiple case study method and providing a rich description of each of the cases. A rich description provides sufficient information to allow an evaluation of whether the contexts are sufficiently similar for the transfer to be appropriate from case studies to other situations (Seale, 2000).

**Table 3.1 Characteristics of case studies in genomics**

	Key attributes			
Case study	Human-human relationships	Human-nature relationships	Human-animal relationships	Extent of dispute in the area
GM & cloned animals		√	√	Potential for dispute recognised
Biobanks	√			Currently little or no dispute
Stem cell research	√		(√)	Existing dispute regarding aspects of stem cell research
GM crops	(√)	√		Dispute entrenched

Punch (2009) identifies two main ways of generalising from case studies. One is to focus on developing concepts from case studies, the second is to develop propositions or hypotheses. The research questions in this thesis lend themselves to the former approach; that is, developing concepts of how values-based and interests-based arguments are used in the development of genomic technologies in order to understand key features that may be exhibited more generally. Therefore, the intention is to examine the detailed case studies with a view to identifying broader principles that could be more broadly applicable, as well as furthering understanding of the applications of genomic technologies in specific cases.

The second research question asks how these values-based and interests-based approaches align between stakeholders in potentially disputed applications? The

development of genomic technologies involves complex relationships between research scientists, innovation networks and companies; consumers, citizens and advocacy groups; and policy makers and regulators. Innovation involves not only the innovator, producer and the user in a linear relationship but a complex range of relationships, linking the innovator and producer (Walsh, 1984) or requiring users in turn to innovate in order to appropriate new technologies (Geels, 2004). Within these complex relationships, the influence of policy makers and regulators can be very important. Regulatory systems may have complex interactions with innovation and produce unexpected effects (Tait, 2007). Thus, examining the way in which values and interests-based arguments deployed by these diverse groups interact is expected to provide richer insights on the issues at stake than focussing purely on one stakeholder perspective.

For simplicity my reporting framework consists of three broad communities: innovation; citizens and advocacy groups; and policy makers and regulators. This framework is represented in figure 3.1 and is described in more detail below. This approach has been adopted widely in the research conducted at the Economic and Social Research Council (ESRC) Innogen Research Centre.

#### Innovation communities

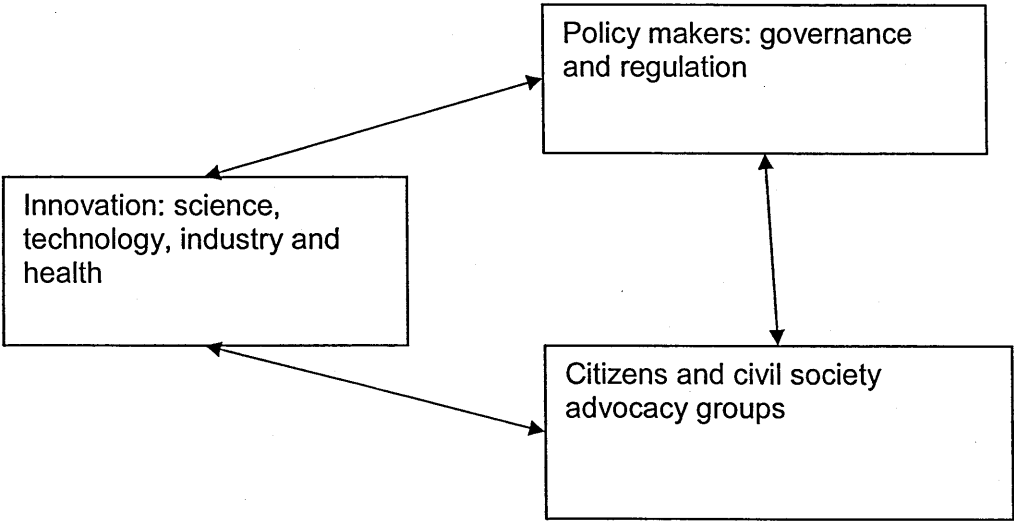
This category includes a wide-range of actors including research scientists, other necessary specialist with expertise such as data security, industry, medical researchers and clinicians. Food producers, processors and retailers are also important innovators as well as the myriad intermediary organisations that exist, such as health care workers.

Innovation communities generate new ideas, processes and products; satisfy customers; generate profits and generate risks and costs both to themselves and to others.

Innovation communities have a strong stake in the development of genomic technologies. The development of new possibilities that arise from scientific knowledge is influenced by funding bodies and industry strategies. Innovators are not, however, a single, distinct community neither are they necessarily constant with time. This thesis deals with new technologies whose adoption may be in the future. Therefore there may be future

innovation communities that will develop and adopt genomic technologies in new and unforeseen ways. Furthermore, the nature of the innovation community is very different in each of the case studies examined here. In the case of GM animals, for example, there is a complex relationship with farmers as innovators (in selecting their own replacement animals), as producers (selling products to processors and retailers) and as customers (buying the products of genomic technologies). In the case of biobanks, the 'product' is a research resource that will enable innovation. And in the case of stem cell research there are clear research scientist innovation communities but the nature of any commercialisation and the community this would entail is not yet clear.

**Figure 3.1 Showing the three constituencies that will be used as the reporting framework of case studies.**



Civil society advocacy groups and citizens

This category aims to capture two main groups; citizens at large and self-identified civil society groups that are advocates of specific viewpoints. These groups are the beneficiaries of new products and processes and bearers of some of the risks of these products and processes. These groups may exert considerable political influence.

Civil society advocacy groups include those promoting a particular interest or viewpoint, such as patient advocacy groups, animal welfare advocacy groups or advocates for early, pre-implantation embryos. They may equally be advocating different approaches based around alternative views of the world such as resisting what they perceive to be excessive emphasis on genetic solutions to problems while down playing environmental and social causes. Advocacy groups will by definition wish to make their viewpoint known and may purport to represent wider constituencies.

This category aims to capture the views of groups of citizens who are in the broadest sense activists in the particular area of application of genomics. These groups may be promoting the application or may be active against its application. These groups are likely to form communities (in the same sense that I refer to innovation communities) but as with innovators, they may form several different communities, or may not form a community at all (as may be the case with some patient groups). I refer to these as civil society advocacy groups in order to distinguish them from for example, trade associations or other advocacy groups for innovators.

There is also the wider public. Given that there is no-one single public that can be identified (the 'general public') but myriad groups whose membership is likely to be complex and blurred, I refer to these people as citizens and do not infer that they exist in particular communities or groups (the term 'publics' is sometimes used to describe this constituency but I find it clumsy). In several cases the people will be acting as consumers or receivers of health care or givers of health care as well as citizens. All stakeholders are also citizens, therefore the term 'citizens' could be seen to encompass all other stakeholders. In the context of the empirical data presented in this thesis by and large the way in which citizen views have been ascertained (e.g. deliberate recruitment to focus groups) has allowed people with a special engagement with the subject to be screened out. The same is unlikely to be true of the survey data quoted.

In many cases, citizens have views on genomic technologies. There are likely to be a multiplicity of different values and interests represented. Attempts to measure citizens' viewpoints (and in doing so often also evaluating the extent of support for advocacy group

position) generally involve questionnaire surveys involving representative samples, or focus groups that are recruited using a range of different methods. Governments may also use open consultation to ascertain support for particular policy positions.

#### Policy makers and regulators

Policy makers and regulators can have major influences on innovation processes. Policy makers are confronted with a range of competing values, interests and ability to lobby, which they are required to negotiate. Regulation may be in place to protect citizens or consumers (e.g. by regulating risk), negotiate a level playing field between innovators (e.g. trade regulation and patenting) or to determine acceptable practices (e.g. licensing of embryo research or animal research). Policy makers and regulators respond to new products and processes from industry; licence and regulate products and processes as well as set standards and penalties; respond to public interests and concerns and importantly for this thesis balance industry and public interests. The policy making community thus encompasses parliamentarians, as well as committees set up to advise them (such as various ethics committees or committees advising on stimulating commercial development). Regulators include bodies charged with licensing (such as the Human Fertilisation and Embryology Authority) and safety (such as the Food Standards Agency) and bodies charged with protecting the environment (such as those tasked with determining releases of genetically modified organisms into the environment).

#### Interactions between communities

Combining the three different constituencies allows the case studies to interrogate the relationships between the different perspectives and the methods used by policy makers to attempt to negotiate between different viewpoints. This is particularly important as this analysis is dealing with areas of science and technology which are either already disputed or may be disputed in the future, and therefore the views of protagonists with different perspectives need to be considered. It thus allows the third of the research questions to be addressed: namely, where are values- and interests-based arguments negotiated and



how does the policy-regulatory framework relate to the main values and interests being expressed?

The next step in the research process is to determine a systematic way of identifying values-based and interests-based arguments.

### **3.3 Operationalising the concepts of values and interests**

Operationalising the concepts of values and interests proved to be one of the most challenging aspects of this research. In Chapter two I concluded that 'values' and 'interests' have been operationalised by different researchers in different ways. The approach I have adopted is to consider the values and interests as presented in each case and in their own context. This case-by-case approach to the concept of values has theoretical support, for example, Smith (1986) suggests that rather than values having generic meanings they can be situation specific. This approach to values involves recognising values in their own, differing domains (e.g. religious, aesthetic, legal, economic and political) as concepts of the good with the special features associated with these specific contexts (e.g. the intrinsic worth of persons or the values of commodities in exchange). By adopting this understanding of values, it is reasonable to consider a set of pertinent values within the context of the situation and case study being considered rather than adopt some set of values that transcends the particular situations.

The approach I have adopted is contextual reflecting the focus of this research on the role of values and interests in disputes rather than treating them as philosophical concepts. Thus, the focus is on identifying two types of argument that have different characteristics in ways that are salient to disputes. The operationalisation of the concepts of values and interests is informed by ethics but is not bound by any particular theoretical ethical framework (such as deontological, utilitarian, rights, dignitarian, communitarian, virtue etc.).

In Chapter two, we saw that Burton (1990) defined values in the context of specific communities and included their ideas, habits, customs and beliefs in his definition. I have conceptualised values in the common-sense understanding of something having worth.

'Worth' or value can be expressed in many different units and not just a purely monetary one. Values may have a moral attribution such as the intrinsic value of humans or animals or desirable relationships, such as ones based on justice. Values may be expressed as a desirable quality, such as freedom. Values may express a desirable outcome, such as increasing knowledge or economic growth.

For the purposes of this research, values-based arguments are inferred from explicit reference to values or normative judgements or appeals to any underlying principles. The intention here is not to engage with normative arguments around values but to accept them as authentic accounts of people's perspectives. Thus, values expressed by individuals do not need to be widely shared in order to be identifiable as values-based arguments made by these individuals. Values-based arguments are here accepted as social phenomena and I do not seek to explain them by consideration of, for example, institutional cultures. Values-based arguments are however closely associated with ethical concepts of deontology and with cultural ideas about the rightness of specific actions. Values may be underpinned by concepts of barriers that should not be broken or absolute goods that should be sought.

In Chapter two we saw that Burton (1990) defined interests to include occupational, social, political and economic aspirations. Therefore, I have conceptualised interests-based arguments as involving balancing between the 'good' of different groups or protecting the interests of specific groups. They ask questions about who wins and who loses? Interests-based arguments are inferred from reference to risk:benefit or cost:benefit implying some degree of calculability. Instrumental approaches to issues convey the use of interests-based arguments. Interests are not here restricted to self-interest or to purely economic interests. They may be supporting the interests of others (e.g. marginalised or vulnerable groups) or may reflect the interests of animals. The critical element is the way in which arguments are made. If they could in principle be satisfied by adjusting the context then I consider them to be amenable to negotiation and thus categorised as an interests-based argument.

Interests may be underpinned by broader values such as justice, forming the basis on which to evaluate an appropriate balance of interests. Where interests-based arguments were made but implied an underlying value-basis, both were included in the analysis.

Two or more values may be in opposition to each other. In arguing for the primacy of one value over another, different interests will also be preferred. Again, in this circumstance both the values and the interests were included in the analysis.

As already noted in Chapter two, a number of different explanations have been advanced for the development of a disputed situation in the context of technological developments. A dispute may be more about the power relationships associated with technological developments than with the characteristics of the technology (e.g. Nelkin 1992). Similarly, institutions have been viewed as critical in terms of imposing structures that 'disapprove' of the behaviour collectively disapproved of (Tansey, 2004) or in terms of how disputes can be expressed and who is empowered to express them (Weiss, 1995). Furthermore, historical aspects can be important as recognised in the GM crops dispute where the experience of BSE has engendered a lack of trust in authorities (e.g. Horlick-Jones *et al.* 2007). Controversies are complex and multi-faceted and it seems unlikely that any one of the explanations advanced (including the values-interests approach) will be able to explain fully the causes of a dispute in specific circumstances for all possible stakeholders.

In this research, institutional aspects, whilst recognised as important, have not been investigated specifically as the study of institutions would only be possible when studying a smaller number of institutions in detail. An alternative approach to this research would have been to consider smaller cases where one instance of interactions between stakeholders was studied in more detail. I have rejected this as being inappropriate to answer the research questions which require an examination of a whole range of stakeholder views over a period of time that might not be apparent in a single incidence. As noted in section 3.4.7, I included a research question in my in-depth interviews in the stem cells case study seeking to elicit whether the case could be considered one of powerful groups imposing their views on society. Although one question is inadequate to

elucidate power structures fully, the confusing nature of responses suggests that there was no general awareness of a power struggle taking place. Although from responses to other questions, it seemed apparent that some stakeholders viewed the arguments around embryonic stem cell research as beginning to embody wider arguments around scientific freedom and the influence of religion on society. These aspects may come to the fore in the future, but at the time of the field work there did appear to be genuine differences in values among stakeholders. Finally, the historical context of disputes was taken into account in this research where this was identified as respondents as being important, for example in the GM and cloned animals case study, the history of criticism of animal breeding and husbandry practices provide some of the wider context to the values-interests dimensions of the dispute which were more examined in more detail. I conclude that whilst alternative explanations as to why controversies arise are plausible, they are complementary to the values-interests approach.

The approach taken for this thesis is one of critical realism. Even if the premise that values are merely social constructions is accepted, values still appear to serve a function in societal debates. No attempt has been made in this research to identify how people construct values and resolve tensions between them nor is data presented on how people's values and interests are influenced by how they perceive the values and interests of protagonists. Nor have I attempted to examine how 'values' are used strategically in specific circumstances. Examples are given in the stem cell research case study (section 6.4.2) where respondents' values appear to act against their own physical interests such that individual patients indicate their opposition to embryonic stem cell research. Instead I seek to understand how the disputed situation is constructed by participants and to identify patterns in those constructions. I treat values and interests as heuristic devices that represent something about reality. Since societies behave as though these concepts exist, and indeed develop whole disciplinary, research and policy areas including ethical frameworks based on such an understanding, I find it plausible to work on this basis.

My approach therefore has been to examine each case, to look at what arguments are being made and derive values and interests inductively from examining the arguments made in the case in hand, considering a range of issues that include but also move beyond risk.

### **3.4 Data collection**

Within each Case Study I have used multiple sources of evidence including wide-ranging documentary analysis, observations in meetings and workshops as well as in two of the cases (biobanks and stem cell research), specific in-depth interviews. I have also conducted secondary analysis of focus group and survey data. Rigour in the case studies is now further examined by considering data collection. I will consider the types of data collected in some detail, firstly looking at documentary analysis and observation of meetings and then interviews. I will then turn to consider in detail the particular data sources used for each case study.

#### **3.4.1 Documentary analysis and non-interview meetings**

Surveys of literature included both academic peer-reviewed publications and 'grey' literature including key policy reports. Additional web information was collated, particularly with respect to advocacy group responses. Relevant meetings were attended (e.g. open meetings for stakeholders, specific meetings to consider for example patenting issues etc.) and observed.

Political-level arguments have been obtained from records of parliamentary debates (UK and EU) and reports from parliamentary committees. Formal published opinions e.g. on the safety of food from cloned animals by the European Food Safety Agency - EFSA (EFSA, 2008) have also been examined. Documents chosen included key or seminal policy documents, such as the report of the first review of whether embryonic stem cell research should be allowed (Department of Health, 2000). Additional information outlining the way in which decision-making bodies are expected to work has also been considered (e.g. the UK Biobank Ethics and Governance Framework – UK Biobank 2007). These documents were chosen as setting out the policy (often with some background

information) as stated and aspired to. It may be that these policy positions are not always realised but for the purposes of this research, the intention of the policy is at least as important as whether and how the policy aspiration has been realised.

Documents were particularly chosen as a tool for understanding policy and regulatory stances as these represent a permanent repository of information. Whilst some supplementary interviews were conducted, these tended to be somewhat limited in usefulness as civil servants move around frequently and therefore change the area of their responsibility and furthermore tend to be focussed on their immediate needs (in the case of stem cell research for example, the focus was on a United Nations debate proposing a ban on cloning). This tends to restrict the breadth of reflection that is easy for civil servants to undertake. Key regulatory instruments were also identified. Documents have been analysed for their 'surface' or 'literal' meaning (Punch, 2009) to understand the main messages that the documents intend to convey.

Factual information such as company size and public policy positions were obtained from company web sites. Advocacy group literature (newsletter etc.) was also used (in addition to web information and interviews) to understand the arguments made by them.

Secondary sources have been used for ascertaining citizens' viewpoints. Given resource constraints, this research has not attempted to generate new data on citizens' viewpoints. I have used published reports of research on both reconvened focus group and survey data for this purpose. Survey data provided some 'triangulation' (Seale, 2000) for focus group data.

Meetings attended provided additional understanding of context, a potential source of contacts and occasionally, but importantly also as a method of 'triangulation' (Seale, 2000). Arguments advanced in relevant meetings (such as a stakeholder meeting regarding regulation of cloned animals) allowed an opportunity to check whether these varied from those advanced in interview settings. In general, the interview data were more nuanced and brought in a wider-range of issues but were otherwise consistent with stakeholder meetings. The meetings attended (listed in Annex 1) provided opportunities

for understanding progress in research as well as legal, ethical, business and social scientific analyses. Other meetings attended were those whose aims were to engage with a range of stakeholders (e.g. a meeting to examine farm animal cloning in 2005 as part of a European research project) and those aimed at opening up regulatory processes to wider view (e.g. Human Fertilisation and Embryology Authority open meeting in 2008).

### **3.4.2 In-depth interviews**

Qualitative interviews were undertaken to explore individual, informed viewpoints in depth. The interviews were used to tease out why individuals held particular positions on specific applications of genomic technologies and to uncover reasons for expressing particular viewpoints. A semi-structured interview framework was adopted to combine structure with flexibility. An interview guide that set themes to follow was developed specific to each case study (and can be found in Annex 3). The semi-structured format allowed questions to be asked in a different order, the questions to be probed and explored and allowed issues raised spontaneously to be followed. The interview guides were developed on the basis of literature review and were peer reviewed with colleagues prior to use. Most of the interviews were tape recorded and the interviews then transcribed allowing "*The emphasis on depth, nuance and the interviewee's own language*" to be maintained "*as a way of understanding meaning*" (Legard, Keegan and Ward, 2003 p142).

Interviewees were purposively sampled within case studies to cover appropriate diversity and in order to avoid bias as far as possible (Ritchie, Lewis & Elam, 2003). Because this research sought to understand the full-range of arguments around technological developments, I have looked for well-developed views and hence the community interviewed was that of informed stakeholders, rather than citizens. Details of recruitment for interviews are given in the method for each case study that follows.

Although the interviewees were chosen to have thought-through positions, I did not approach the interviews as a data mining exercise, treating respondents as "*repositories of knowledge – treasuries of information awaiting excavation*" (Holstein & Gubrium, 2002 p113). The paradigm of a neutral interviewer eliciting knowledge and information held by

the interviewees does not resonate with the reality of complex social interactions (e.g. Holstein and Gubrium, 2002). I viewed the interview situation rather as a site of co-producing knowledge. Meaning was not merely elicited by questioning but created in the interview encounter. This understanding is endorsed in the interviews conducted. Despite the interviewees constituting a well-informed sample, on numerous occasions interviewees would pause to reflect on the questions being posed. One interviewee noted that these are “difficult” questions that he had not thought about before.

Respondents were offered the opportunity for the interview encounter to be unattributable. In one case the interviewee stated that this meant they felt free to express opinions that they would not offer in a situation where quotes would be attributable. In a very few cases relating to stem cell research the interviews were not recorded, at the interviewees request, reflecting the perceived sensitivity of the subject. In one case the recorder was switched off at one point in the interview to allow exploration of a particular area that had media coverage at the time.

Given the highly political content of the research, I felt it was inappropriate to seek user validation of the case studies to avoid the tendency for informants to further a particular political stance in their validation (Seale, 2000). Furthermore the extended time between interviews and case study development in this part-time PhD meant that this review process would have proved impractical (many of the key respondents had already moved to new posts which in several cases were in other jurisdictions).

A series of in-depth interviews therefore contribute to the case studies by giving authentic accounts of the views of a range of protagonists regarding the genomic technologies being studied. Quotes in this thesis have been selected to give illustrative examples of more widely held views.

I will now turn to consider data collection within the case studies in more detail.

### **3.4.3 GM & cloned animals**

This case study was informed by my decade of employment in the research department of an international pig breeding company followed by part-time employment as scientific



administrator at a major animal breeding research institute (Roslin Institute, 2000-2008). The main data collection phase consisted of documentary analysis (including grey and web site information as well as newsletters and factsheets), attending relevant meetings and informal interactions during and outwith these meetings (see Annex 1 for a summary of formal meetings attended). Information on public attitudes was obtained from published opinion poll and focus group information. A major resource base for this case study was a series of reports prepared by a team led by myself, for the European Commission Joint Research Centre, Institute for Prospective Technological Studies (IPTS) (Whitelaw *et al.* 2005, Bruce *et al.* 2005, Braun *et al.* 2005) based on web searches, documentary analysis, questionnaire and interview data. Parts of the research have been published in Nature Biotechnology (Suk *et al.* 2007) and Genomics, Society and Policy (Bruce, 2007). A concurrent European Commission Framework 6 project 'Cloning in Public'<sup>3</sup> with which the IPTS project collaborated, provided additional in-depth information. Background data on the adoption of non-GM biotechnology in the pig breeding industry in Europe in 2006 was obtained from my further research for IPTS based on published data, company reports and interviews with 18 company representatives from a range of European countries (a summary is reported in Zika *et al.* 2007).

During this PhD study, cloned and GM animals shifted from existing only in research organisations to the real prospect of products from cloned animals (and their progeny) coming onto the EU food market. The licensing of the first pharmaceutical product derived from GM goats for medicinal use in the EU during this time has also provided context. These developments have meant that the regulatory aspects have come to the fore. The focus of data collection on regulation for this case study included attending and observing relevant stakeholder meetings (e.g. stakeholder meeting with the European Group on Ethics (EGE) on 24-25 Sept. 2007), documentary study of the formal opinion of the EGE (and the US Food and Drugs Administration), documentary study of the advice from the EFSA, transcripts of debates in the European Parliament, decisions by the

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<sup>3</sup> <http://www.sl.kvl.dk/cloninginpublic/index-filer/Page361.htm> [accessed 4/1/11]

Council of the European Union as well as informal discussion with industry representatives and staff at the European Commission DG Sanco and EFSA.

### **3.4.5 Biobanks**

Data for this case study consist of documentary analysis (including grey and web site information as well as newsletters and factsheets) and attending relevant meetings and conferences (see Annex 1 for a summary of formal meetings attended). These data were supplemented by interview and focus group information relating to the development of Generation Scotland carried out as part of the Generation Scotland preparatory work. This work consisted of 17 in-depth interviews with specialists in key areas (e.g. clinical geneticists, lawyers, ethicists, specialists in information and insurance, public health officials) conducted between April and July 2003 and ten focus groups with diverse groups of citizens across Scotland conducted between January and March 2004. Groups were chosen to reflect a range of demographics (gender, ethnicity and age) and localities (rural and city) and to include patient and other groups who would normally meet together (e.g. a choir). Patient support groups included cystic fibrosis, multiple sclerosis, dementia carers and breast cancer. The aim was to sample a range of citizens but they were not viewed as representatives of any specific constituency nor as statistically valid samples.

Individual interviews were conducted among specialists who were identified by brainstorming the range of relevant expertise and the availability of that expertise in Scotland within the research team for the Generation Scotland project. The in-depth interviews were conducted face-to-face and each was approximately one hour long. Interviews were semi-structured around a set of themes and the interview guidelines are reproduced in Annex 3. Of the 17 in-depth interviews, six interviewees gave specific consent for the detailed interviews to be used for this thesis. Other information is based on published results from this work (Haddow *et al.* 2006, Haddow *et al.* 2007, Haddow & Cunningham-Burley 2008). This work will be referred to as the 'Generation Scotland project'. Parts of the research presented for this case study have previously been published in Bruce and Tait (2004) and Laurie *et al.* (2009). Additional material on ethics committees has been provided from collaboration with Professor Graeme Laurie, chair of

the UK Biobank Ethics and Governance Committee and member of the Generation Scotland Advisory Board in the production of an article examining the governance arrangements of UK Biobank (Laurie *et al.* 2009).

#### **3.4.6 Stem cell research**

This case study is developed from documentary analysis including grey literature and web sites, as well as attending conferences and workshops. A summary of conferences and workshops attended can be found in Annex 1. Additional context was provided by my part-time employment at Roslin Institute (2000-2008), which at the time was undertaking commercially-funded research on human embryonic stem cells. Data were also provided by 26 semi-structured interviews (each approximately 1 hour long) with stakeholders in stem cell research. Interviews were conducted from October 2004 to December 2005 as part of an ESRC-funded research project. These interviews were with specialists who had already reflected on the issues around stem cell research, rather than with members of the public. This approach allowed investigation of well-considered positions that could throw light on how debates are shaped and how values and interests are deployed in framing an issue, particularly in a case such as this where values often clash. Interviewees included research scientists, physicians, patient advocacy groups and advocates of adult stem cell research. Table 3.2 summarises the specialists interviewed.

**Table 3.2: Summary of interviews conducted with stakeholders in stem cell research**

	Total interviewees
Research scientist	10 <sup>4</sup>
(of which involved in human embryonic stem cell researcher)	(6)
(of which also consultant physicians)	(3)
Research technician (stem cell research)	2
Industry	4
Policy/research funding community	4
Consultant physician (non-stem cell)	2
Patient advocacy group	1
Adult-stem cell advocacy group <sup>5</sup>	3
<b>Total</b>	<b>26</b>

The intention had been to interview a number of patients and patient advocacy groups. However, the sampling of necessity took into account the exigencies of the research process and thus modifications were required. Two of the interviews planned did not in the end take place (one due to serious illness the other due to the respondent changing their mind about being interviewed). Arguments advanced by patient advocacy groups (including patients) have therefore been analysed from a video representation on DVD of a meeting held in Brussels 15-16 December 2005 which had the specific aim of engaging patients. Additional material is provided from an interview with a patient advocacy group representative conducted as part of the main interviews for this case study.

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<sup>4</sup> Including one IVF clinician

<sup>5</sup> This terminology has been adopted to avoid connotations with anti-abortion campaigns that would be implied by the term pro-life advocates. These interviewees advocated research using adult stem cell rather than human embryonic stem cells but were not directly involved in research themselves.

The two-day conference was entitled 'Patients and Stem cells: stem cell research in Europe, the patients' perspective'. It was organised by the European Federation of Neurological Associations and funded by the European Union 6<sup>th</sup> Framework Programme (with the production of the DVD funded by the industry association, EuropaBio). Audience votes suggested that around 100 patients, carers or patient advocacy groups attended (the total number of attendees is not clear). The conference consisted of a series of sessions with panels of experts (including patients) who were interviewed by a central presenter/facilitator (a well-known news presenter from the UK) followed by questions and comments from the audience, some of which had been pre-determined to represent particular viewpoints. At various stages the attendees were invited to take part in electronic voting on various issues. The context was partly discussion within the European Union as to whether the framework research programmes should be able to support research on embryonic stem cells or not. The contention being that countries such as Germany were large funders of the framework programme but due to German legislation would be unable to conduct research on embryonic stem cells and hence benefit from these research funds. This data source is likely to be more constrained than a focus group for example, but was an effective way of gathering information from a large group of people. The views expressed were consistent with views that I have heard elsewhere in conferences and other events.

Wider public attitudes were obtained from an MRC/BBSRC-sponsored engagement exercise conducted by the consultancy company British Market Research Bureau (BMRB). I was on the oversight group for this exercise. The data consisted of stakeholder interviews, five deliberative workshops each reconvened three times with a total of 200 people recruited to them. Focus groups were held around the UK, in London, Cardiff, Newcastle, Edinburgh and Bristol. Each of the three reconvened workshops considered a specific aspect of stem cells; introduction and general aspirations, in-depth consideration of social and ethical issues and finally therapies and clinical trials. Data on policy and regulation are primarily from policy documents and parliamentary debates with some additional data from interviews with policy makers.

Interviewees were selected to include a range of geographical areas in the UK, and of positions with regard to embryonic stem cell research and technical expertise. They included senior and junior research scientists and technicians, medical consultants, representatives from advocacy groups (for and against embryonic stem cell research), policy makers and people involved in industry. In so far as was possible, people strongly influenced by a US perspective were excluded e.g. people who had moved from the US to the UK (on the basis that the debate in the USA is rather different from the UK) but it was not entirely possible to do this, reflecting the influence that the US debate has on the UK. An initial target list of interviewees was developed and peer reviewed with colleagues. The response rate to requests for interviews was very high (with only three refusals).

These interviews are not intended to be representative of any particular group but to map out a range of different views and arguments. Research scientists were targeted in order to include understandings of those who are involved in human embryonic stem cell research and those who are not.

Interviews were conducted on the premise that all sources of stem cells should be considered, but in practice interviewees focussed on embryonic stem cells and 'adult' stem cells with very little reference to cord blood cells and the almost total absence of reference to foetal stem cells. The interviews pre-dated the development of induced pluripotent stem cells.

Interviews were semi-structured and sufficient interviews were carried out to reach thematic saturation (Punch, 2009) (i.e. new interviews were not providing new insights). Open-ended questioning was used to enable interviewees to frame some of the contours of the debate. All apart from one interview were face-to-face (the remaining interview was conducted over the phone for logistical reasons). A copy of the interview guideline is given in Annex 3. Interviews were taped by permission of the interviewees (in three cases where this permission was not granted, notes were taken) and the interviews subsequently transcribed. All identifying information has been removed from the following analysis and illustrative quotes.

Triangulation (Seale, 2000) was used where possible to ensure internal consistency. This was conducted by use of multiple data sources as much as possible. For example in-depth interviews with research scientists in the stem cell area was supplemented by written reviews in appropriate journals (in this case EMBO Journal) and listening to opinions expressed in meetings, seminars and conferences

### **3.4.7 Potential sources of researcher bias**

A technique suggested for avoiding bias is to be careful to consider alternative explanations of the data. As noted in Chapter two, Nelkin (1992) suggests that protests about technologies may be less against the implications of science and technology than against the power relationships associated with them. Much of the GM crops debate reinforces the importance of power relations in disputes. The dispute was focussed as much on the power of multinational companies as on any ecological or health impact. It would therefore seem prudent to consider attributions of power as part of this research. Barnes (1988) suggests there are two ways of knowing where power lies i) asking people to name the most powerful people ii) looking at instances of successful use of power. Therefore in the interviews around stem cell research, I included questions about the nature of the power relationships as perceived by the respondents. The answers to this question were confusing, contradictory and difficult to interpret and did not contribute meaningfully to a discussion about perceived power relationships. Therefore they are not reported in this thesis.

I was aware that interviewees may respond to me based on who I am, and the perspectives that I might be presumed to have, and someone else might be given a different narrative.

*"Interviewees may not trust us, they may not understand our questions, or they may purposely mislead us in their responses. Likewise, given a lack of membership in their primary groups, we may not know enough about the phenomenon under study to ask the right questions" (Miller and Glassner, 2004, p128).*

These interviews may not have reflected the interviewees 'true' views but a representation that they felt was most appropriate for the circumstances of the interview encounter.

However, given the research topic, my main aim was to understand how interviewees seek to influence the debate. Values and interests are likely to be multitudinous and complex. My experience of interviews was that most interviewees engaged willingly and in detail in thinking about the issues and revealed many things that suggested they were being very open and not conforming to anticipated stereotypes (for example someone in a senior position in industry involved in stem cell research suggesting that it was too early for industry to be involved in stem cell research, a research scientists indicated they were disillusioned with research).

At the time of collecting data for this research I was a colleague of researchers in GM and cloned animals. This gave me a good understanding of viewpoints but it also resulted in a potential confusion of roles had I attempted to interview them more formally. As I was also working closely with senior management, there was a danger that this could be seen as an initiative that was intended as management information within the organisation, particularly during the periods of organisational change being experienced at that time. However, as one of the major institutions in the world working in the area of GM and cloned animals, I could not justifiably restrict interviews to researchers in other organisations. There are relatively few institutions in Europe undertaking research in GM and cloned animals, institutions in France, Germany and Hungary being the prime examples. It also seemed inappropriate to ignore the Roslin Institute, one of the main institutions involved in this work. Similarly I felt there would be a confusion of roles had I attempted to interview people in advocacy groups opposed to research on GM and cloned animals. With respect to both the above constituencies, inappropriate motivations may have been imputed to attempts at formal in-depth interviews in ways that were likely to skew the resulting discussions. I have therefore chosen to rely on published information, informal discussion and attending meetings for this particular case study.

Interviewees for the stem cell research case study were briefed with information about my links to both Roslin Institute and the Church of Scotland. The Roslin Institute was the



publicly known for its positive stance on human embryonic stem cell research. Whilst the views of the Church of Scotland are nuanced in this area, it is unlikely that all interviewees would be aware of this and would be more likely to attribute negative views to the whole church. It is possible that these links affected the nature of the subsequent discussions although there was little evidence of reluctance to express views during the interviews. I was never asked about my own views on the subject and it may be that the apparent mixture of positive and negative affiliations resulted in an acceptance of research without a specific agenda and lack of defensiveness.

The mixture of methods used reflects some of the practical realities of research that is conducted over a period of years and where experimental approaches require adaptation to deal with changing circumstances. It is the nature of social research that few factors can be controlled, unlike the experimental conditions that can often be applied to natural science research. The result was, however, that slightly different approaches were used for each of the case studies. The lack of individual interview data in the GM and cloned animals case study was effectively replaced by participant observation. It is possible, however, that as a result these data gave a somewhat different perspective than would have been the case if individual in-depth interviews were conducted by an external observer. Which approach would give the more 'accurate' description of the case remains debatable. However, the 'participant observation' approach was complemented by information from meetings and reports. The question remains did the different methods of collecting data produce different data? No strict comparison is possible but if different data collection methods were to produce very different results in terms of the values-interests framework then the framework itself would be suspect. If a dispute is present, one would expect it to be reflected in all of the aspects being examined.

#### **3.4.8 Ethical considerations**

The research for this thesis was reviewed by myself and my two supervisors and considered not to require submission to an ethics committee. The research did not present any specific issues of consent, coercion or confidentiality which are not adequately handled under the normal standards of academic research. There were no

foreseeable risks to the researcher or the researched and there were no identifiable vulnerable groups researched, such as children. Patients could have been identified as particularly vulnerable but the research interviews were sought with patient advocacy groups rather than individual patients themselves.

Prior to each interview (and focus groups) participants were informed about the nature and purpose of the research and invited to consent to take part. Written invitations to take part are reproduced in Annex 2. Written consent to digitally record interviews for the stem cell case study was also sought and a consent form is reproduced in Annex 4. Where digital recording was not consented to, notes were kept of the interview. In all the interviews conducted, participants were offered anonymity but were asked to consent to having their specialism identified. Because this research was funded by the ESRC, respondents were also given an opportunity to agree to data sharing. This did cause some problems. Only 14 out of 25 stem cell interviewees consented to data sharing and in the stem cell case one prospective interviewee felt so strongly that this was a wrong approach that they very nearly pulled out of the interview. Recordings and anonymised transcripts are stored securely and access limited to me and the person undertaking the transcription.

### **3.5 Data analysis**

Individual interview transcripts were coded into themes relating to arguments around genomic technologies and cognitive maps were produced. This framework allows complex data to be displayed and is rigorous and inclusive in that it does not discard contradictory evidence and it preserves the relationships between concepts and arguments. An example of a complete map of an interview is reproduced in Annex 5. Complete maps are difficult to view due to their size and so relevant extracts from maps are used in preference in the report of the research.

Cognitive maps provide a pictorial method of representing some of the cognitive activity involved in a specific situation. Huff (1990) describes how cognitive mapping techniques are used for understanding how people think and understand their world: "*The basic idea*

*is that, in a world of incomplete data, individuals nonetheless make causal inferences that allow interpretation” (p28).*

Farsides (2004) points out that at the theoretical level, cognitive mapping involves “*the mental ‘concepts and relations among concepts’ implied by people’s verbal accounts of any aspect of their experience or their understanding of the world and their place in it*” (p258) and at the practical level, the way of identifying and representing these concepts and the relationships between them. I used Banxia Decision® Explorer<sup>6</sup> software to produce the cognitive maps. Here concepts are represented by nodes and causal connections between them are indicated by lines. An example of an extract from a cognitive map is given in figure 3.2.

The cognitive maps are based on the following conventions:

- i. Cognitive maps - consist of ‘nodes’ or ‘concepts’, joined by ‘links’.
- ii. Concepts - are expressed as short statements, each covering a single idea or notion.  
In figure 3.2 these are represented by boxes containing statements.
- iii. Links - concepts are linked by arrows indicating a causal link, i.e. A ‘leads to’ B. Links act in the direction of the arrow and are positive except where a negative sign is attached to the causal link, in which case the link is negative (i.e. A leads to ‘not B’).

The numbers in the top left hand corner refer to a concept number. The number in parenthesis in the bottom right hand corner refers to a paragraph of the transcript. Where no such number is given, the concept has been inferred from other statements.

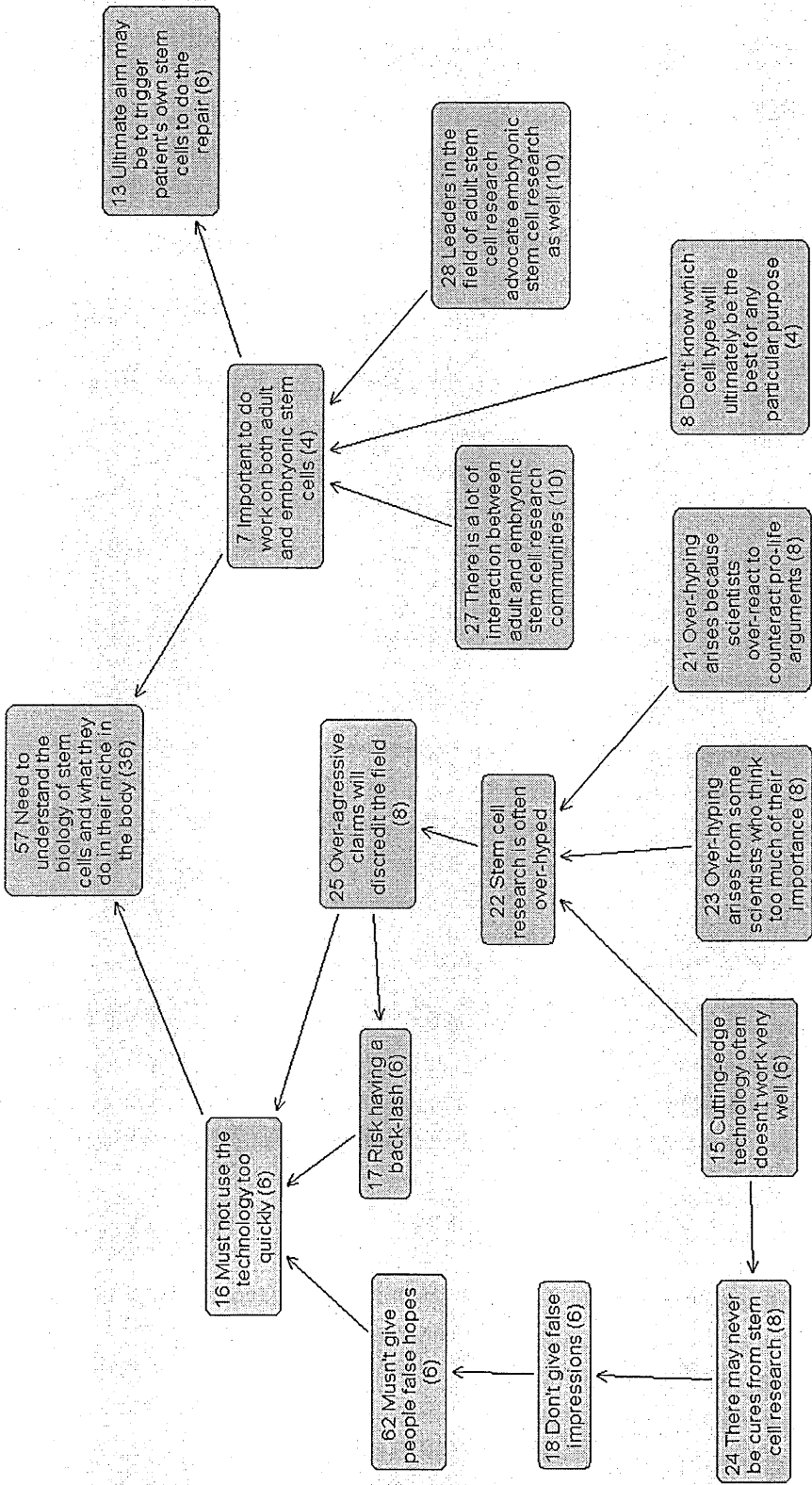
For the research scientist represented by this map, the aim is to understand biology better and how stem cells behave in different niches in the body (57). Because of this, it is important to research both adult and embryonic stem cells (7) with the ultimate aim of being able to trigger the patient’s own stem cells to repair the damaged tissue (13). At the moment it is not clear whether adult stem cells or embryonic stem cells will work the best in specific circumstances (8), researchers in the field of adult stem cells advocate

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<sup>6</sup> <http://www.banxia.com/dexplore/> [accessed 4/11/10]

research also in embryonic stem cells (28) and research in adult and embryonic stem cells inform each other (27). This researcher was also aware of the possibility of the research being hyped (22) and suggested this was partly by over-confident researchers (23), the reaction to negative comments from pro-life activists (21) and also that cutting-edge technology may not work very well (15). As a result there may never be 'cures' from stem cell research (24) and researchers should not give false impressions (18). Over-hyping will give patients false hopes (62) and potentially discredit the research (25), risking a backlash (17). The technology should therefore not be adopted too quickly (16).

Figure 3.2 An example of a cognitive map of views on stem cell research (interview 18)



I read through the transcripts of interviews and identified concepts. I summarised these concepts into short phrases that reflected the language being used in the interview. I then identified connections between the concepts, reflecting causal relationships in the arguments. Farsides (2004) suggests that "*Causal connections reveal beliefs that certain concepts have some form of influence on other concepts*" (p260). Farsides further argues that "*the concepts and connections represented in our cognitive maps are to some degree 'grounded' in the psychological structure and processes that 'actually exist' within our participants' minds*" (p261). Cognitive mapping therefore:

*"attempts to identify (and represent for the purposes of communication) enduring and causally efficacious beliefs, values and attitudes that research participants have. Because researchers cannot have direct access to such things, their nature has to be inferred from certain of their products, in this case the accounts produced during semi-structured interviews."* (Farsides p262).

Further reflection of the whole interview identified key aspects of the argument and these were placed at the 'pyramid apex' of the cognitive map. Only after the coding and mapping was completed was any interpretation into values-based and interests-based arguments attempted. Concepts were numerically identified with paragraphs in the interview transcript allowing the exact wording and context of the concept to be easily checked. In this way, the analysis was grounded in the interview transcript while allowing iteration with the values-interests framework (Punch, 2009).

One of the key decisions was whether to use only maps that reflect individual cognition or the shared perception of a group. Grouping maps may be useful when contrasting the views of one group against another but the research design I have adopted does not allow this (representative viewpoints for comparison were specifically not sought). My approach was rather to explore the full range of views and hence I have mapped views on an individual basis.

One of the distinctive features of cognitive mapping is that it focuses on the relationship between concepts that are being studied (Huff & Fletcher, 1990) thus allowing analysis to

move between a holistic synthesis and analysis by parts. Cognitive maps are a way of displaying data in ways that keeps arguments within their context and avoids the oversimplification that may easily result from normal coding practice. Whilst the concepts of values and interests that are of concern to this thesis are at one level very simple, social contexts and the logics of argumentation may not be and it is particularly important to capture this complexity.

### **3.6 Conclusions**

Qualitative research methodology is particularly suited to the type of research question being investigated in this thesis. A multiple case study approach allows different cases to interrogate the research question in different ways. In-depth, semi-structured interviews provide an authentic 'voice' to a range of different protagonists to add to data gathered from academic and grey literature and relevant meetings. Causality in interview transcripts has been interrogated using cognitive mapping methods. Operationalising the concepts of 'values' and 'interests' has proved challenging and I have resolved this by dealing with the concepts on a grounded basis, not predefining the values and interests to be paid attention to but allowing each case to reveal the key values and interest involved.

The individual case studies are now reported moving from a case that extends the application of genetic modification from plants to animals (GM and cloned animals) via a case that introduces human health in a group context (biobanks) to one involving individual health concerns (stem cell research).

## Chapter 4

### Cloned and GM farm animals: a case of policy nervousness

#### 4.1 Introduction

In the previous chapter I argued for the multi-case study method used for this thesis. The choice of method has its origins in seeking to understand the reasoning underlying different stakeholder positions within their specific contexts. The approach begins by examining the arguments made by various protagonists. It is discursive and empirical in character and allows each individual case study to address the issues raised by the thesis questions.

In this first case study I examine cloned and genetically modified (GM) farm livestock. This case was selected to extend the values-interests approach from GM crops to a situation where issues associated with animals come to the fore. It is a case where there has been little public debate to date and almost no products available in the market place and yet an expectation in policy and other spheres that the likely public reaction will be one of strong rejection (e.g. Gaskell *et al.* 2007). EU policy makers are confronted with a need to make decisions about food products from cloned animals and their progeny, likely to be developed in third countries and traded internationally but, particularly given the experience of GM crops, expected to be strongly rejected by EU citizens. I shall argue from evidence in this chapter that nervousness about public attitudes is a major contributor to the very precautionary approach that is being adopted by the EU and that values-based arguments are predominant.

This case study is restricted to applications to food animals of genetic modification and cloning in the UK and EU contexts, although given the international nature of the technology, developments world-wide have been taken into consideration where relevant. Regulation is similarly largely considered on an EU basis although again in the context of global trade in food products. The case study is primarily restricted to farmed animals (mammals, birds and fish) although other applications relevant to human medicine, companion animals or the maintenance of rare species have been developed and are



referred to when appropriate. Most applications of cloning to date have been in mammals (i.e. in the farm context; cattle, pigs, sheep and horses) although genetic modification has also been applied to chicken and fish. Genetically modified mice, laboratory animals and experimental animals produced to model human diseases are excluded. The term 'cloning' as used in this chapter refers to Somatic Cell Nuclear Transfer (SCNT) rather than any other form of cloning such as embryo splitting.

In this chapter I firstly provide a brief overview of the technology followed by a review of the literature in which I briefly examine the normative issues around GM animals, the tensions identified in animal production (production vs. welfare, scientific knowledge vs. farmer knowledge, local vs. global production), the complex and sometimes ambiguous relationships between humans and animals and the many different ways in which animal welfare is understood. I then consider the stakeholder communities most closely involved (innovators and citizens/civil society advocacy groups) and the responses by policy-makers and regulators. I examine the arguments made by stakeholder groups about the acceptability or otherwise of the technology and the extent to which these can be seen to be primarily values or interests-based. Finally, I bring together the values and interests of the various stakeholder groups and address the question whether and how an 'interests' and 'values' framework can inform an understanding of what is expected to be a disputed area of an application of genomics and how this contributes to policy nervousness.

## **4.2 The application of genomics to food animals**

Genomics has a long history of being applied to food animals in the form of selective breeding. However, for the purpose of this case study I will only consider more recent developments in cloned and GM animals. From a purely technological point of view, cloning and genetically modifying animals are considered different techniques. However, they may be applied together so that cloning technology is used as a way of achieving genetic modification as well as potentially a way of multiplying GM animals. In general usage they are also frequently considered together under the general theme of the application of biotechnology to animals. In this section I will give a brief overview of the

technology behind both cloning and genetic modification, outline the current range of applications being considered and summarise the relevant social science literature.

#### **4.2.1 Genetically modified animals**

The first GM animals (mice) were developed in 1982 in the USA (Palmiter *et al.* 1982), exemplified most dramatically by a photograph on the front cover of the journal *Nature* of two mice, one substantially larger than the other, due to the presence of a rat growth hormone gene. In the rush of initial optimism all kinds of applications of this new technology were envisaged, from increased productivity of farm livestock to the production of therapeutic proteins in the milk and eggs of various species. This optimism was not, however, followed by a plethora of applications; rather the limitations of the technology quickly became apparent.

The method used to produce these first GM animals and many subsequent ones relied on using a technique which involved injecting DNA into a fertilized egg, where the DNA became integrated into the embryo in a random fashion, with varying location and copy number. The results using this method were therefore very variable and very inefficient at providing desirable and stable modifications. Only around 1% of treated embryos resulted in a live, genetically modified animal (Whitelaw *et al.* 2005).

A variety of different methods have been used subsequently to increase this efficiency. In mice it has been possible to derive embryonic stem cells, modify these cells and generate modified animals, having first produced chimeras (animals with cells with different genotypes – some genetically modified, some not). The use of embryonic stem cells has provided the technical basis for producing large numbers of genetically modified mice used as disease models for humans but the inability to produce embryonic stem cells from most other species (except humans) has meant the use of the technique has been restricted to mice.

More recent scientific developments have included dramatically increasing the efficiency of genetic modification by the use of a group of viruses known as lentiviruses to deliver the introduced gene into a cell (rather than injection). Using lentiviruses produces around

30% live transgenic animals (Whitelaw, 2004) as compared to the 1% by injection. Methods have also been developed to improve the ability to target the gene into a specific place in the genome (McCreath *et al.* 2000). These major developments theoretically provide the basis for new opportunities to apply genetic modification to animals and open up new avenues of application. It appears therefore that scientific innovation is continuing with respect to GM animals. Animal cloning is one of these areas of innovation.

#### **4.2.2 Cloned animals**

Cloned animals came into public consciousness with the cloning of 'Dolly' the sheep in 1997 (Wilmut *et al.* 1997), although the media focus quickly moved to the more exciting prospect of cloning humans. In reality Dolly was not the first cloned animal; two sheep (Megan and Morag) had been cloned the previous year by the same scientific team using a similar technique (Campbell *et al.* 1996) but the media focus on Megan and Morag was quickly overtaken by other dramatic events (the shooting of young children in a school in Dunblane, Scotland). Megan, Morag and Dolly were all cloned using a novel technique which involved transfer of the nucleus from a cell of the animal to be cloned to an egg which had its nucleus removed (nuclear transfer). In theory, this would allow a limitless number of clones to be produced from an individual. In the case of Dolly, the cell producing the clone was derived from an adult, non-reproductive (or somatic) cell - hence the technique became known as Somatic Cell Nuclear Transfer. However, in the case of Megan and Morag the donor cells were from fetuses. It was the possibility of cloning from an adult and the prospects of cloning humans from an adult cell that particularly captured the public imagination.

Since 1997, cloning using nuclear transfer has been rapidly achieved in a number of different mammalian species, as outlined in table 4.1 (adapted from Suk *et al.* 2007). A number of rare and wild species have also been cloned but these are not included in this table.

**Table 4.1 Timeline for animal cloning**

<b>Species</b>			Mouse				Rabbit	Horse				
<b>Cloned</b>	Sheep		Cow	Goat	Pig		Rat	Mule	Cat	Dog	Ferret	Came
<b>Year</b>												
<b>first cloned</b>	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2010

The original purpose for developing cloning, however, was not to produce multiple copies of selected animals but to develop more effective techniques for genetically modifying animals. The specific aim was to develop animals that could produce therapeutic proteins for human use in their milk. This was done by inserting a gene for the production of the therapeutic protein in the animal so that the gene would be active in their mammary gland and thus the therapeutic protein would be produced in the milk.

The process involved genetic modification of individual animal cells in the laboratory, selecting the modified cells that proved desirable and growing these cells back into adult animals, using the nuclear transfer technique. The first step was to prove that nuclear transfer would work (as exemplified by Dolly) and genetic modification quickly followed once the cloning technique had been achieved (Schnieke *et al.* 1997). The combination of genetic modification of cells and nuclear transfer has meant not only that genes can be added but they can also be removed (which is not possible using injection methods), thus opening up further theoretical applications of genetic modification with cloning.

**4.2.3 Potential applications of cloned and genetically modified animals**

Potential applications of cloned and genetically modified animals are summarised in table 4.2. based on a survey in 2005 (Whitelaw *et al.* 2005) conducted by a team led by the author for the European Commission Joint Research Centre Institute for Prospective Technological Studies. Inevitably more distant applications are increasingly speculative

and it remains to be seen whether these become practical, economic or publicly acceptable.

Although a large range of applications has been suggested, the number of scientific groups working in each area of application is small. Commercial involvement in the area is also currently small and there has been considerable turbulence with many companies either not surviving or merging with other companies. The survey in 2005 (Whitelaw *et al.*) identified only six companies worldwide that were developing either cloned or GM livestock for agricultural purposes, four of which were based in North America and none in the EU. The survey also identified five companies working on cloned or GM pets (four in North America, none in the EU), 15 companies developing applications to produce pharmaceutical compounds in milk or eggs, so called pharming (nine in North America, four in the EU), four companies developing pigs for transplanting cells and organs to humans, so called xenotransplants (three in North America, none in the EU), two companies producing cloned sporting animals (one in USA and one in the EU) and four companies working on cloning endangered species (one in the USA, one in the EU).

There is no single register where all the cloned and GM animals in the world are recorded but indications are that the numbers of such animals are small. EFSA attempted to collect information on numbers of cloned animals (EFSA, 2008) and concluded that in the EU in 2007 there were around 100 cattle clones and fewer pig clones. In the USA, they estimated around 570 cattle clones and 10 pig clones. Cloned farm animals also exist in Argentina, Australia, China, Japan and New Zealand giving an estimate, according to EFSA, of less than 4,000 cattle clones and 500 pig clones in existence worldwide. These animals can of course reproduce using normal methods and the number of progeny of these clones could rapidly increase.

**Table 4.2 Potential applications of GM and cloning technology in farm livestock**

(adapted from Whitelaw *et al.* 2005)

	Currently available	Expected in the near to medium term	Expected in the medium to long term
<b>Applications to agriculture</b>	Cloned sires of beef cattle	Faster growing GM salmon and trout  Cloned sires of pigs	GM pigs which produce less phosphorus pollution  GM dairy cows with altered milk composition  GM disease resistant livestock
<b>Applications to human medicine</b>	Anti-coagulant produced in the milk of GM goats	Wider range of therapeutic proteins in the milk of GM rabbits, sheep, goats and cows and in the eggs of chickens	Cells and organs for transplantation produced in GM pigs (xenotransplants)
<b>Other applications</b>	GM fish with unusual colours  Cloned pet cats & dogs  Cloned horses, rodeo bulls and deer for sports shooting  Cloning rare breeds and rare species of animals		GM fish to detect environmental pollutants  Sterile males for control of feral populations

In summary, there are currently few food animals derived using cloning and even fewer applications of GM technology to food animals commercially available anywhere in the world. Several potential applications are being developed but it is by no means clear which, if any, will become widely adopted. Speculation about the potential uses of genetic technologies has been ongoing since the days of rather naive optimism immediately following the production of the first genetically modified animal in 1982. Yet, in common with many other applications of biotechnology, the realisation of these visions is taking several decades to materialise. Cloning technology appears to have been adopted much faster, although again the extent of adoption of this technology is not clear at the time of writing.

#### 4.2.4 Literature review

Most of the social science literature engaging with the application of biotechnology to food animals relates to GM animals with much less exploration of cloned animal associated issues, although the considerations relevant to GM animals are likely also to apply to cloned animals in most cases. Much of the literature has tended to focus on contrasting polar opposites rather than exploring the complexity around issues.

##### i) Genetic modification

The normative question concerning the morality of genetic modification of animals either on the basis of rightness or wrongness of the activity itself or due to the consequences of the modification has been extensively addressed (e.g. Bruce & Bruce 1998, Rollin 1995, Reiss & Straughan 1996). A number of philosophical approaches have been used to evaluate the application of genetic modification to animals (e.g. Ryder 1990, Holland 1990, Fox 1990). Consideration has been given to objections on the basis of need to respect the intrinsic nature of animals (e.g. Fox 1990, Rollin 1995, Bruce & Bruce 1998, Verhoog 2003), the crossing of species boundaries (e.g. Rollin 1995, Bruce & Bruce 1998) or unnaturalness (e.g. Bruce & Bruce 1998, Verhoog 2003). Different ways by which genetic modification can be understood to violate animal integrity have been explored. For example, the UK government sponsored Banner report on the ethics of emerging technologies in animal breeding (Banner, 1995) considered the theoretical possibility of reducing the sentience of animals using GM technology, an application which is widely held to be a violation of integrity (and as far as I am aware not advocated by anyone). Whether GM technology *per se* can be viewed as violating animal integrity is a more contentious issue.

The expected consequences of modification, and in particular the impact on animal welfare, were variously evaluated by specialists nearly 20 years ago. Some thought GM animals had potential but with some problems still to be resolved (e.g. Bulfield 1990). Others thought the application of GM to animals was hyped by both protagonists and antagonists whereas the realistic scope for genetic change would be much less than

might initially be thought (e.g. Webster 1990). And yet others thought the impact would be purely negative (e.g. Fox 1990). Wider questions included the potential loss of family farms and the desire to reflect values other than just efficiency in food production (e.g. Rollin 1995).

Twenty years later, with the benefit of hindsight, the most accurate expectation has proved to be that of Webster who called for a more realistic evaluation of the scope of possibilities from applications of GM to animals. The early hopes and fears have either not been realised or have proved very slow in coming to reality.

The stress on values other than merely efficiency in food production has become more widely accepted as reflected for example in the reduction in funding for agricultural research into productivity over the last 20 years (the recent high profile of food security as an issue to be addressed may be reversing this trend). Verhoog (2003) brings together several of the strands of argument to describe what is for him a desirable future, one which is currently represented by organic farmers and a more 'natural' way of living and producing food. He contrasts this 'natural' approach to the step by step fracturing of the relationship between the animal and its reproductive processes and the fracturing of the farmer's relationships with the animal represented by biotechnological applications. In his argument biotechnology encourages an exploitative relationship with animals to replace one of partnership and the use of artificial insemination, embryo transfer, genetic modification and cloning represent increasing disaggregation of reproductive processes. For Verhoog, cloning and genetic modification demonstrate an increasing undesirable trend.

## **ii) Animal breeding**

Genetic modification is sometimes considered in the context of earlier forms of genetic selection using statistical techniques that have formed the history of animal breeding and animal genomics. Twine (2007) reprises the above reductive bifurcation for considering GM animals in contrasting the views of scientists involved in animal breeding and genomics with the views of welfare scientists. Genomic scientists (in his interpretation)



have a narrow, reductionist view that considers the 'animal' as abstract genetic code within a global productivist system. In contrast many welfare scientists (in his analysis) go beyond welfare to reflect on the ethical aspects of animal breeding technologies and tend to be more respectful of non-human life. This seems an excessively simplistic analysis. It is no surprise that specialists tend to focus on their area of expertise, whether this is welfare or genomics, and consequently tend to frame any issue within their own terms.

Moving from the research to the applied level, Holloway and Morris (2006) examined the evaluation of cattle breeding merit by genetic scientists and pedigree breeder farmers. The technical and expert-led evaluation by genetic scientists was contrasted with the intuitive judgement and connoisseurship that formed the basis of evaluation by pedigree farmers, although the authors recognised that these two models of knowledge are to some extent intertwined. Thus, pedigree breeders will often take into account not only the physical appearance but also the estimated breeding value obtained from genetic scientists.

Farmer knowledge is also identified as being 'locally situated' (Morris & Evans, 2004) due to a long-term relationship with a particular piece of land. The contrast between a 'productivist' and 'post-productivist' mindset in agricultural production has also been highlighted (e.g. Winter, 2005), the post-productivist mindset leading to an increasing focus on aspects of agriculture other than production.

Animal agriculture is seen by these authors as taking place in a local context (although arguably some 'industrial-type' farming is undertaken in a similar manner, irrespective of geography). Biotechnological developments on the other hand take place at a global level. Michael (2001) contrasts the local situatedness of animal knowledge with the globalised nature of biotechnology and points out the dilemma of attempting to combine the two. Any commitment to user and lay engagement with biotechnological developments will have a multitude of different communities to engage with in different locations. Yet the application of biotechnology is likely to be global in nature, despite any local commitment to competing values.

Schakel & van Broekhuizen (2003) studied animal breeding in USA, Thailand, France, Italy, Norway and Netherlands noting the way in which the breeding organisations in each country were shaped by attempts to balance the local with the global. They highlighted the extent to which motivations of the national breeding organisations reflected different national concerns and values in terms of the quality of food produced, the food culture, rural development and the future of agriculture and the countryside. So, for example, they highlight the priority given in Norway to maintaining rural populations and supporting farmers, in contrast to Italy where farmers appear less important than the quality of the food produced. These differences in aspirations were reflected in how each country was mobilising local culture to maintain their own distinctive production systems in the face of a globalised industry.

### **iii) Attitudes to animals**

Views on animal cloning and genetic modification are likely to be strongly influenced by different understandings of the relationship between humans and animals. In 2005, The Nuffield Council on Bioethics (2005, p24) identified three different positions taken by people with respect to human-animal relationships.

- i) There is something special about a human that is present in all humans but not in non-human animals.
- ii) There is a hierarchy of moral importance with humans at the apex and invertebrates near the bottom.
- iii) There is no categorical distinction between human and non-human animals.

These types of attitudes can be seen in much of the literature, for example the UK Farm Animal Welfare Council (Farm Animal Welfare Council, 1998) stated that *"It is not clear that a radical distinction between human and non-human is now defensible, either biologically or ethically, nor that any such disjunction is sufficient to warrant the treatment of other living creatures merely as means"*. (p4). It is therefore not surprising that FAWC conclude that there should be a moratorium on the use of cloning by nuclear transfer (I will return to this in 4.5.3).

However, at the level of individuals, tensions and ambivalence with respect to attitudes to animals have also been identified (e.g. Michael, 2001). Macnaghten (2004) provides empirical evidence for this, highlighting how individual attitudes to animals (in the context of focus group studies on attitudes to GM animals) reflected tensions in terms of eating animals and yet acknowledging their intrinsic value. He argues that these tensions may not be resolved by individuals but allowed to co-exist. This complexity and ambiguity makes people's responses to the application of GM and cloning to animals particularly complicated to understand. Thus, we may conclude that the evidence suggests human relationships with animals are complex, varied and probably in flux. It is therefore likely to be difficult to achieve consensus on whether applications of biotechnology to animals are intrinsically acceptable or not.

#### **iv) Animal welfare**

Good 'welfare' is often raised as a criterion in the context of biotechnological applications to animals. The term 'welfare', however, can be understood in several different ways.

Fraser (2003) identifies three main ways in which animal welfare scientists have understood welfare. The first is concerned with the biological functioning of the animal, the second emphasises pain and other forms of affective suffering, including for example frustration due to confinement and the third the extent to which an animal is allowed to live a natural life.

These different approaches are not just academic distinctions as they may have real regulatory consequences. Fraser notes that EU animal welfare scientists argued for, and successfully achieved, a ban on the use of sow stalls in pig production whereas Australian welfare scientists concluded on the basis of the same evidence that both sow stalls and other systems can be adequate for welfare. This evidence from Australian scientists was used in the US to provide scientific evidence that sow stalls did not cause welfare problems and therefore should not be banned. Thus, the same scientific evidence was used both to ban and not ban a specific production system. Fraser argues that these differences in assessment were based on the Australian scientists' focus on the first (and to a lesser extent second) definition of welfare, whereas the EU scientists stressed the

second and third definitions. The Australian scientists' focus was on biological functioning and alleviating suffering whereas EU scientists' focus was on allowing animals to live a natural life and alleviating suffering. Thus we should exercise caution when reference is made to 'good welfare' and recognise that there may be many different interpretations of what constitutes 'good welfare'.

The concept of animal welfare may also vary between lay and expert groups. Lassen *et al.* (2006) conducted focus groups in Denmark to ascertain views on pig welfare and found that as well as issues around rejecting suffering, lay publics emphasised a range of factors related to the extent to which animals were seen to be 'living a natural life', so that for example death of piglets due to accidental overlying by their mother was preferable to controlling the ability of the mother to move. In another example, 'dirt' on pigs was seen as an indicator that the pigs were able to exercise their natural behaviour. This could be interpreted to mean that this group of lay persons understood welfare in the third sense that Fraser outlined (living a natural life) or that expert evaluations may not be fully reflected in lay perceptions of good animal welfare (dirt is unlikely to form a major part for a scientific evidence-base of welfare).

#### **v) Conclusions from existing literature**

The evidence to date therefore suggests that applications of GM and cloning to agricultural animals have primarily been considered in a normative way – is it right or wrong? There appears to be little consensus on the conclusion of these normative reflections. Once applied to the on-farm situation, the complex relationship between the 'local' of agriculture and the 'global' of technology and international trade come into play and are negotiated. For individuals, attitudes towards animals are complex and may not be resolved. Understanding one of the key determinants of attitude, namely the welfare of animals, is not straightforward and can cover a range of different aspirations. Within this context there are a number of values and interests that are being expressed and which act as motivations for developments that appear to contain the seeds of an incipient dispute. The task of the remainder of this chapter will be to understand better these values

and interests dimensions and in particular how regulators and policy makers negotiate these dimensions.

In the next section I will provide a brief portrait of the different stakeholder communities involved around GM and cloned animals and the main values-based and interests-based arguments advanced by them. I will use the structure outlined in Chapter three and consider innovation communities and citizens/civil society advocacy groups in turn and then examine the policy and regulatory responses.

### **4.3 Innovation Communities**

The first group of stakeholders I will consider are the innovation communities. These communities are defined by their involvement in creating the ideas and developing the technologies and products that form the basis of the subject being studied. I will firstly seek to describe these communities and secondly to examine the arguments which they make in support of specific developments.

#### **4.3.1 Innovation communities described**

Despite restricting this case study to agricultural applications, there is still no single innovation community. Research may be undertaken in universities and research institutes or within breeding companies and other breeding organisations. The food production chain involves farmers but also food manufacturers and retailers as well as a number of intermediary organisations such as auction marts, meat processors and abattoirs. There is therefore a range of types of organisation and community involved within a broader understanding of innovation communities.

These organisations and communities do not necessarily share the same views or motivations concerning the innovation process for GM and cloned animals. A relatively small number of organisations however appear to have become involved in the debates around cloned animals in particular. For example a call for evidence by the European Food Safety Authority in April 2009 elicited responses from two industry associations (Biotechnology Industry Organisation and the European Forum of Farm Animal Breeders),

one specialist society (International Embryo Transfer Society), one company (ViaGen Inc., USA) and the remainder from research institutes or individual research scientists.

Given the current early stage of commercialisation of development of cloned and GM animals, it is not surprising that the major innovator stakeholders tend to cluster around the organisation and conduct of scientific research. Commercial development has been restricted to a small number of companies many of them originating as spin-out companies from university research. For example, one of the best known, ViaGen Inc., was founded in 2002 in Texas, in part using technology developed by Texas A&M University. The small size of the company is indicated by the fact that in 2008 it was reported to have only 50 employees<sup>7</sup>. This is in contrast to the commercial environment for the production of GM crops where large multinational companies such as Monsanto predominated.

That said, the animal breeding industry (particularly for poultry, pigs and dairy cattle) has a number of companies that dominate and that could rapidly take up GM and cloning technologies should they wish to do so (Bruce, 2007). It has been estimated, for example, that three animal breeding companies provide chickens that produce 80-95% of Europe's eggs and 75% of the world's eggs, and four companies produce chickens that produce 35-60% of the world's poultry meat.<sup>8</sup> Chicken breeding appears to be the most concentrated in a few companies and pig, dairy cattle and beef cattle less so. Despite the presence of these large breeding organisations, in the context of UK cattle breeding for example, these companies coexist side by side with small traditional pedigree breeders who may only have a few tens of animals. The livestock breeding industry, particularly with respect to chickens, pigs and dairy cattle, is extremely well organised and has companies that are well able to adopt (and even develop) advances in 'traditional' breeding techniques. These may include use of increasingly sophisticated statistical analysis tools and genetic marker-assisted selection (including genome-wide selection) which will allow effective selection amongst existing genetic variation. Indeed, some

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<sup>7</sup> <http://www.viagen.com/about-us/history/> [accessed 18/10/09]

<sup>8</sup> <http://eadgene.info/animalbreeding.html> [accessed 18/10/05]

individual genetic markers such as susceptibility to stress in pigs (the presence of which predisposes the animal to sudden death) are in wide use within the industry to identify animals without this trait (Zika *et al.* 2007). Thus any genetically modified animal would need a clear advantage over relatively rapid ongoing incremental change (Bruce, 2007).

Technical expertise is allied to a world-wide distribution network that allows any genetic change made in one place to be multiplied and distributed to a larger network. It has been estimated for example that one highly selected male pig (great grandparent) will influence the genetics of 570,000 slaughter pigs, equivalent to around nearly 43,000 tonnes of pig meat<sup>9</sup>.

It takes time to introduce a new gene into a population of animals. In farm animal production, only a percentage of the herd is replaced at any one time and furthermore there are well established 'pyramids of multiplication' that mean it takes several generations for any genetic change to arrive at commercial farms. This is in contrast to crops where a whole field can be sown with a new (GM if desired) variety within one season (Bruce, 2007). Similarly, in many species (particularly sheep and cattle) individual farmers are active in the innovation process in many ways, including selecting some of their replacement animals from their own animals rather than purchasing animals produced elsewhere.

The absence of suitable single genes to transfer also acts as a restriction on the use of GM in farm animals (Bruce, 2007). It is not clear what new traits based on single genes it would be possible and desirable to introduce. Currently the application of genetic modification to farm animals seems unlikely to be attractive, with the possible exception of salmon genetically modified for faster growth, pigs genetically modified for reduced environmental impact and novel ways of using genetic modification in control of infectious diseases.

Whilst the 'vision' created for cloned and genetically modified animals in agriculture has tended to focus on food production, in one case at least a link was made to extend the

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<sup>9</sup> Mark Wilson, BPEX, personal communication

use of farm animals to produce pharmaceuticals. An image for the future of agriculture presented to the public in a communication exercise ('Elonkierto') by the agricultural research institute at Jokioinen (Finland) was of herds of 'medicine cows' grazing in the fields. The company producing the cows however subsequently went into liquidation and the GM cows producing pharmaceuticals in their milk were destroyed, so this vision has not been realised. However, the first therapeutic protein from GM animals has been approved for use in the EU. The first therapeutic protein (ATryn – an anticoagulant) derived from genetically modified goats produced by the company GTC Biotherapeutics was approved by the European Medicines Agency in August 2006.<sup>10</sup>

Applications of cloning technology may be more immediately attractive as they offer advantages over current practices yet fit into the existing socio-technical systems. Cloned elite pigs and beef cattle, for example, are envisaged as the sires or grand-sires of slaughter animals. In this way, only the very top performing animals are used and their (usually small) advantage in performance can then be spread over a large number of slaughter animals. Cloning technology means that the most extreme animals can be multiplied so that they can be used to supply enough semen to produce a larger number of offspring. This is calculated to be of a particular advantage in pigs (Whitelaw *et al.* 2005) where reproductive biology currently limits the number of offspring from one animal (pigs require a large volume of semen to achieve conception).

In the longer term other applications of cloning to agriculture have also been envisaged, for example identifying the best carcasses and cloning the original animal from the carcass and using this animal in breeding to improve carcass quality, or cloning herds of dairy cattle in order to be able to optimise management for that particular genotype. Cloning technology may also be used in securing a 'spare' of an elite animal as 'insurance' in case of accidents. Cloning has also been suggested as a way of moving breeding animals internationally in some circumstances. Finally, cloning has also been suggested as a way in which breeds that are under threat of extinction can be preserved and recovered in case of loss or disaster (such as a disease epidemic).

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<sup>10</sup> <http://www.transgenics.com/news.html> [accessed 3/3/07]



For this research, motivations for GM and cloning for these innovators have been inferred primarily from public statements by company representatives and research scientists. In the next section, I will give an account of these arguments based on the extent to which they can be categorised as values-based or interests-based. As noted in Chapter three, the basis I have used for discriminating between these two is essentially pragmatic. Values involve explicit reference to values or normative judgements or any underlying principles that can be inferred. Interests refer to balancing between different groups or protecting the interests of specific groups or reference to risk:benefit or cost:benefit implying some degree of calculability. Interests may be underpinned by broader values. For example calculations of economic benefit imply an underlying value-judgement that using animals for economic benefit is not intrinsically wrong. This value-judgement may be contested by others who do not so judge.

#### **4.3.2 Interests-based arguments of innovation communities**

Considering firstly arguments based on interests. Interests refer to balancing between different groups or protecting the interests of specific groups or reference to risk:benefit or cost:benefit implying some degree of negotiability. Interests-based arguments have been made on the basis of:

- Economics
- Freedom to compete on an equitable basis
- Using scientific knowledge to meet human need
- Some interpretations of animal welfare.

Each of these will now be considered in turn.

##### **i) Economics**

Many of the proposed agricultural applications of cloning appear to be primarily economics driven. The rhetoric surrounding the benefits of cloned animals is mainly one of improved production efficiency and profit. This is stated as a motivator for the adoption of cloning in food production. It is also used as an argument by industry bodies within the

EU to prevent the outright banning of cloning techniques in order to ensure a level competitive playing field should cloning techniques become widely adopted elsewhere in the world (e.g. as evidenced by statements made publicly by the European Forum of Farm Animal Breeders - EFFAB and Copa-Cogeca the European farmers' organisation). These arguments are calculable in nature and thus both the discourse and the motivation behind the discourse appear to be based primarily on 'interests'.

## **ii) Freedom to compete on an equitable basis**

Commercial companies are keen not to prematurely close off avenues that competitors may be able to use, as noted above. On the other hand, commercial organisations are also aware of public attitudes. The stated position of EFFAB (effectively a trade association) for example is

*"Cloning (somatic cells) is a new technology that is currently not being used by European Breeding Organisations. This is partly for technological and economic reasons, and partly because there is no public approval of such developments at present"*<sup>11</sup>

Commercial freedom does not necessarily mean that individual organisations see it in their best interest to adopt cloning. Based on the limited data available, food retailers also appear to be cautious about cloning. A number of food companies (e.g. Nestle, Kraft) are reportedly unwilling to sell products from clones<sup>12</sup>. Smithfield Foods is similarly reported to have no plans to produce meat from cloned animals despite holding a stake in the cloning licensing company, Start Licensing.<sup>13</sup> Informal discussion with representatives of a large supermarket in the UK also suggested this is a likely stance for food retailers in the UK. In effect, these supermarkets are acting as regulators of last resort and they are currently one of the major determinants of whether products from cloned animals (or their progeny) appear in their stores. Thus, while arguments are advanced by innovators (particularly the

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<sup>11</sup> Statement from the Code of Good Practice for Animal Breeding and Reproduction Organisation in Europe, available from <http://www.code-efabar.org/content/view/14/83/1/8> [accessed 07/03/07]

<sup>12</sup> New Scientists (2008) *Food companies reject clones over consumer fears*, 17<sup>th</sup> September NewScientists.com news service

<sup>13</sup> *Nature Biotechnology* news item, (2008) Volume 26, No 10, pp1058

animal breeding communities) that their interests should be protected by ensuring freedom to compete on an equitable basis and the possibility of utilising cloning technology should it become a competitive requirement to do so, this does not necessarily equate to widespread use of cloning.

### **iii) Use of scientific knowledge to meet human needs**

Cloning has also been mooted as contributing towards a solution to some of the problems facing societies, such as the impacts of climate change and epidemics of animal diseases.

The impact of livestock agriculture on the environment is beginning to receive increasing attention. In 2007 the United Nations Food and Agriculture Organisation (FAO) issued a report (FAO, 2007b) on the world-wide environmental impact of livestock agriculture. Among its conclusions were that livestock, particularly ruminants (e.g. cattle, sheep and goats) are major sources of greenhouse gases. It would seem, therefore, that reducing this environmental impact should be a key concern for animal breeders. Indeed, calculations undertaken for UK's Department of Food, Environment and Rural Affairs (Genesis Faraday Partnership, 2008) suggest that one of the biggest effects on reducing the environmental impact of agriculture has been breeding for improved efficiency of feed use and faster growth achieved by 'traditional' breeding methods. The use of cloning could potentially speed up these changes.

One GM application has been developed as a direct method of reducing environmental impact of pig farming. Researchers in Canada have produced GM pigs that produce an enzyme in their saliva that allows them to digest phosphorus from cereals thus, it is claimed, reducing phosphorus content of manure by up to 60% (Golovan *et al.*, 2001). However, the pigs have not yet been approved for commercial release. Both the GM pigs and the argument for the use of cloning to reduce environmental impact appear to provide potential technical solutions to existing problems. As such, innovators argue for these developments on the basis of furthering wider social aspirations. Nevertheless, they may also be furthering the innovators own aspirations at the same time. There is little evidence of wider social acceptance of the arguments, mainly due to the absence of any evidence.

Conservation of farm animal biodiversity has achieved an increasingly high profile, witness for example the publication of the FAO State of the World's animal genetic resources for food and agriculture report (FAO, 2007a) which found that 20% of the 7,000 livestock breeds identified in the world are at risk of extinction. Cloning could offer a method of biobanking individuals of these threatened breeds. Cells could be taken and frozen with the aim of using these cells to clone the animal to recover it as necessary in the future. This technique would complement existing conservation methods which rely heavily on maintaining the breeds in their existing physical locations, a potentially risky strategy in the face of climate change and outbreaks of infectious diseases. The cloning approach here is analogous to the use of 'seed banks' for plant varieties. The use of cloning for this purpose is pragmatic to achieve socially desirable goals, and does not appear to reflect an entrenched values-basis but rather as one of a range of tools for endangered breed conservation.

Epidemics of animal diseases in the UK and Europe, including Foot and Mouth disease, Bluetongue and bovine TB have brought concerns about controlling infectious animal diseases to the fore in recent years. Additionally, zoonotic diseases such as BSE, *E.Coli* O157 and avian influenza have highlighted the vulnerability of humans to diseases propagated by livestock. GM technologies have been suggested (at least in theory) as having potential in reducing susceptibility of livestock to BSE and potentially in increasing resistance to viral diseases such as avian influenza (Clark & Whitelaw, 2003). Some experimental work has been undertaken in this area. GM animals with increased resistance to BSE have been produced in the research context by deleting a key gene. The use of GM technologies to control viral diseases such as avian influenza (using RNA interference methods to 'knock-out' the messenger that causes viral particles to replicate) is currently at the experimental level and their value in disease control is yet to be ascertained. These applications are still speculative and their widespread adoption will depend partly on their effectiveness in achieving the desired aim. This area of application currently appears primarily to reflect the interests of research scientists in furthering knowledge although future practical uses cannot be ruled out. Arguments advanced for

research into GM disease resistant animals may therefore be made on a values-basis, that of the intrinsic worth of disease resistant animals, although this aspiration appears to be some way off.

Predictions regarding livestock production are that there will be a 50% increase in production by 2020 (Delgado *et al.* 1999) with the majority of this increase expected in developing countries. Thus, livestock production would be expected to be an important component of food security. However, unlike GM crops, the key motivator for genetically modifying or cloning animals is not usually stated as 'feeding the world'; indeed this is hardly ever mentioned, except in the case of GM fish. The main applications of GM to livestock are to expand characteristics other than improved productivity. It may be that this reflects the ability of 'traditional' genetic techniques to be competitive with GM technology in changing most usual production traits or it may reflect a move away from focus on production traits. Whatever is the case, the argument for GM animals is not generally made on the basis of increased production. In the context of cloning, the ability to increase production is given as a justification but the link to 'feeding the world' is not made and if it were made, might be criticised for being rhetoric rather than reality in the absence of applications specifically for use in poorer countries.

#### **iv) Animal welfare**

As well as interests-based arguments and motivations supporting the development of cloned and GM animals, there are also interest-based arguments that are advanced by innovators to overcome criticisms. Perhaps the most serious of the criticisms is the negative impact that cloning and genetic modification currently has on animal welfare.

Cloned animals are known to be vulnerable to a range of problems such as the development of abnormally large offspring that may not survive to the conclusion of pregnancy or die soon after birth. A wide-range of other developmental abnormalities has also been seen. The suggested cause is that the 'resetting' of an adult cell into an embryo is sometimes faulty (known as inadequate reprogramming and thought to be caused by

epigenetic effects, that is heritable factors not associated with changes in DNA, but rather the ways in which DNA functions). However, these effects are not well understood.

The extent of any welfare concerns is contested with some commercial companies quoting 'success' rates comparable with the use of other reproductive technologies. It is suggested that improvements in embryo culture techniques and selection of individuals less prone to these problems can to a large extent alleviate the problems, although these assertions remain undemonstrated in public.

The welfare of GM animals is a more complex area than the welfare of cloned animals and usually requires case-by-case evaluation, reflecting the specific nature of particular modifications. Relatively few data are however available on welfare evaluation of GM animals, and such that exist are usually on only a few individuals possibly because only a few genetically modified farm animals exist at the moment. Additionally, there are unresolved issues as to what constitutes good welfare, for example should any subtle behaviour changes be included? What is the appropriate period of time over which the animals should be evaluated? How many generations should be examined? Evaluation of welfare is thus potentially a more complex process than just evaluating any gross effect presented at birth or soon after. Furthermore, as described earlier (4.2.4 iv) the concept of good 'welfare' can be understood in many different ways.

Concerns about adverse animal welfare in the applications of both GM and cloning technologies are widespread and by no means all research scientists who are expert in the area of cloning would currently advocate the use of the technology routinely in agriculture. Risks to animal welfare are acknowledged by innovation communities but here they are often presented as a technical issue that can be resolved rather than an intrinsic and necessary defect of the technology.

#### **4.3.3 Values-based arguments of innovation communities**

Turning now to consider arguments that involve explicit reference to values or normative judgements or underlying principles that can be inferred that reflect the ideas and beliefs of innovation communities. Values-based arguments have been advanced on the basis of:

- Use of scientific knowledge to meet human needs
- Attachment to individual animals.

#### **i) Use of scientific knowledge to meet human needs**

Underlying the promotion of cloning and GM is the principle that it is right (or even a human duty) to use scientific knowledge and apply this to animals for human benefit. This ethos or principle is not strongly articulated but is apparent in statements of some scientists and industry commentators in particular. Given this is a principle that is being expressed, the type of motivation here is one of 'values'. The strength with which this principle is held in the particular case of cloned and GM animals is not clear. There is little evidence of a strong, broadly-supported campaign advocating cloning (in contrast to for example stem cell research, where there is evidence for such a campaign). The lack of such a campaign suggests that the broader scientific enterprise is not strongly threatened by any rejection of cloning animals for food production. It may be, however, that arguments advocating freedom of scientific research or 'proportionate' responses to risks may be easier to apply in the context of other genetic applications.

#### **ii) Attachment to individual animals**

It is also noticeable that many of the media articles describing cloned animals are based around individual farmers who have wanted to clone individual animals with the animals specifically named in the articles e.g.

*"Karyn Schauf sets a frosty glass of milk...in front of me...I swirl the glass: a thick lather coats the sides. I sniff: it has a rich, almost buttery aroma. I hate the idea of milk over ice, but the drink is on the rocks because it was squeezed in a steamy, unpasteurized froth just half an hour ago from Mandy2" (Paynter, 2007).*

Similarly, the Financial Times refers to a cow named Peggy Sue (Grant, 2008). This may just be a journalistic device but it does suggest that there is a degree to which cattle cloning in particular is being driven by individual attachment to particular animals. Given the influence of individual pedigree breeders within cattle production and the cultural import of pedigree animal evaluation this is not surprising. With other species, such as

pigs, where individual animals have less importance, the expectation might be that economic benefit would act as a stronger driver of cloning technology. The attachment to individual animals as a driver for cloning seems to be contextual in nature rather than reflecting any interest-based or values-based motivation regarding the technology itself.

#### **4.3.4 Conclusion on innovation communities**

The food chain consists of a complex range of interacting stakeholders who may have different motivations with regard to cloned (and GM) animals. Nevertheless, the main driver for adoption of cloned animals in the UK is largely based on the visions of small companies primarily in the USA, allied with individual livestock breeders, rather than any expressed unmet human need. There are underlying principles about the rightness of applying science for human purposes and the expectation (in some quarters) that the technique of cloning may become useful for example for rare breed conservation. However, the competitive nature of the animal breeding industry (in which the EU is a major player) means that breeders do not wish to find themselves competing with companies in third countries who are able to use techniques like cloning that they cannot use. As such, the response of the innovation community to cloning has been largely pragmatic reflecting their interests, although these interests are underpinned by an understanding that the use of biological techniques to modify animals for human purposes is a desirable goal.

Among innovators, the use of cloning in animal breeding is seen as an extension of existing techniques such as artificial insemination, embryo transfer and quantitative genetic techniques used in selective breeding. Cloned animals are viewed as 'copies' of existing animals not as something 'other'. Welfare problems resulting from cloning are viewed as resolvable. Less has been said here of GM animals, largely because there are few if any developments in GM that are close to market and therefore they remain largely speculative at the time of writing. Thus I conclude that the trajectory for cloned farm animals is currently being driven primarily by the values and self-interest of a number of small companies based outside the EU.



## **4.4 Citizens/civil society advocacy groups**

There has been relatively little public debate about farm animal cloning or GM animals and to date, little research into public attitudes. Civil society advocacy groups, while arguing their perspective, have not made GM and cloned animals a high profile issue. This may be partly because the products of these applications of genomics have not reached the market to any great extent. In this section I will review the public attitude research that is available as well as review public statements made by various civil society groups about the subject.

### **4.4.1 Citizens**

Data on public attitudes to cloned and GM animals suggest that attitudes are generally negative (Lassen, 2007). A Eurobarometer report in 2008 (The Gallup Organization, 2008) on attitudes of EU citizens to cloning found that 84% of the 25,607 respondents felt that there is insufficient knowledge about the long-term health and safety effects of using cloned animals for food. Over half (61%) felt that animal cloning is morally wrong and a smaller proportion (41%) that animal cloning will cause animals unnecessary pain, suffering and stress. Not surprisingly therefore, 58% said cloning for food production purposes could never be justified and 63% said they were unlikely to buy meat or milk from cloned animals (a similar response was obtained for products from the progeny of cloned animals). However, 44% would accept cloning for specific circumstances such as preserving endangered species. Over three quarters (77%) felt that animal cloning might lead to human cloning. An overwhelming majority, 83% wanted labelling of food products from the offspring of cloned animals. The survey found that 20% of respondents were fundamentally opposed to cloning, 17% accepted cloning and the majority (59%) gave a mixed response being willing to accept one or more reasons for animal cloning under certain circumstances. The main criterion that would justify cloning was helping solve worldwide food problems (53%) with the respondents not convinced by other arguments (36% agreed with justification by nutritional/health benefits, 32% by price/economic benefits and 15% by improved quality/taste/variety).

Opinion polls will test current attitudes but do not give any indication of the stability of opinions nor what respondents understood by the questions and what might influence their views in the future (for example the impact of increasing concerns around food security and cost of food). Given the relatively small amount of public discussion around GM and cloned animals the attitudes recorded are likely to be rather unreflexive and potentially unformed. Focus group data, while dealing with smaller numbers of participants, have the potential to elucidate factors underlying attitudes.

Seventy participants in four deliberative reconvened workshops to elucidate attitudes to food from cloned animals in the UK, run for the Food Standards Agency (Creative Research, 2008), struggled to identify any convincing benefits to cloning for food production. Participants were again concerned about the safety of food from cloned animals and were fearful that the process may somehow create new diseases e.g. a respondent is quoted as saying (p48)

*"The thing that would worry me is [something] like BSE. I mean they're saying that it can sit dormant in you for years, stuff you could have had five or maybe ten years ago. And then how do they know this isn't going to affect you the same way? How are they going to test it to see if it's going to happen? Ten to fifteen years down the line you could be talking about something coming from these things affecting humans".*

They were also concerned about the morality of cloning animals and whether it may lead to human cloning. As with the Eurobarometer survey, there was a demand for labelling of food derived from cloned animals and their progeny.

Unlike the Eurobarometer attitude survey, the participants here were able to learn more about the technology and as they did so, they became increasingly concerned about animal welfare and this became important in their reluctance to accept food derived from cloned animals and their offspring. It is not clear, however, what sources of information were accessed by participants. Given the apparent lack of proponents of cloning in easil

accessible web-based information and the preponderance of negative material, the increasing negativity towards food from cloned animals is perhaps not surprising.

The beneficiaries and reasons for undertaking cloning were identified as important e.g. one respondent is reported as saying (p31)

*“Who benefits? How do we benefit as the consumer? I mean, do we get better tasting meat or cheaper meat? Meat is already cheap enough in my view, in fact it’s too cheap in many ways. The only people who are benefitting are the biotech companies, genetic pioneering companies and the big corporate farmers with the prize bulls. How do we benefit as consumers? Why should we take a chance on this for no seen benefit to us?”*

Negative connotations were drawn from Dolly, e.g. her alleged premature ageing. Parallels were also drawn with inbreeding leading to problems (p35)

*“To me, it’s a little bit like inbreeding that they used to have like in the royal family. It ended up that some went mad or whatever.”*

This quote seems to capture a sense of disgust about cloning but concerns were also expressed that the use of cloning could allow the overuse of a limited number of breeding animals and hence increase susceptibility of the farm livestock population to a specific disease.

Concerns that animal cloning will lead to cloning of humans were expressed, for example, (p41)

*“What is the reason for cloning in the first place? Why do they want to clone animals and if they clone the animals perfectly as they say, will they then be starting on humans and that’s what I’d be worried about.”*

Attitudes to the application of GM to farm animals and food production have been less well researched. Such evidence as exists, suggests that attitudes are influenced by both the purpose of the application and the species being modified (Gaskell *et al.* 2007). Thus, applications to humans appear to be the most controversial, followed by plants and micro-

organisms. Attitudes are also affected by the aims of the modification, with medical applications more acceptable than applications to food (e.g. Gaskell *et al.* 2007). These findings are consistent with the work conducted by Macnaghten (2004) for the *Animals and Biotechnology* report for the Agriculture and Environment Biotechnology Commission (AEBC, 2002) which concluded that there needs to be a demonstrable and authentic benefit in order for GM animal biotechnology to be acceptable. Furthermore applications need to take into account the intrinsic character of animals as well as animal welfare.

#### **4.4.2 Civil society advocacy groups**

Of the civil society groups the campaign group Compassion In World Farming has been one of the most vocal and has been extensively involved in debates around GM and cloned animals and will likely be found represented at any meeting relating to the subject. The organisation GeneWatch has also been involved and more recently the Soil Association has also indicated some interest e.g. with a contribution to a stakeholder presentation by the EGE on ethics of cloning animals in December 2007. Other organisations such as the Royal Society for the Prevention of Cruelty to Animals (RSPCA) are also expected to hold views but in the absence of detailed documentary evidence of views of the Soil Association and RSPCA, this section focuses on the first two organisations only.

Joyce D'Silva, representing Compassion in World Farming, argued the case against cloning at a stakeholder meeting of the EGE in September 2007 (prior to the EGE issuing its opinion - EGE, 2007). She based her arguments largely on the animal welfare issues raised by cloning, not just the birth of malformed animals but also the fact that the technique requires invasive procedures such as surgery. Additional concerns were the level of control over the lives of animals and as an enabling technology for genetic engineering (in her terminology) "*another technology which has a devastating record regarding animal welfare*" (p16).

The initial impression given by published material from Compassion in World Farming (e.g. CIWF, 2002) and listening to presentations by Joyce D'Silva is that their concern is

mainly interests-based under the definitions used for this research. The driver is to ensure good animal welfare at the level of physical harm to the animal and once that level of welfare is achieved, the interests of the animal are deemed to be met and cloning becomes acceptable. The argument therefore appears to be negotiable rather than reflecting a non-negotiable, principled position and is therefore categorised as an interests-based argument. However, many of their statements are very strongly against the application of biotechnology to farm animals, for example,

*"Compassion in World Farming Trust believes that all the evidence shows that genetic engineering and cloning can have no place in the future of sustainable animal husbandry. Up to now these technologies have cost the suffering and the lives of countless farm animals with no benefit to either farmers or consumers. This waste of animals' lives and society's resources is a strong argument for a moratorium on all such experiments and a redirection of scientific resources towards research into animal health and welfare in sustainable agriculture"* (CIWF, 2002 p9)

It is therefore difficult to envisage a scenario where CIWF's concerns about cloned and GM animals would be met in full. The underlying ethos of how animals would fit into a 'sustainable agriculture' suggests that there is an element of values driven motivations in the arguments put forward by CIWF.

Statements by GeneWatch (2002) suggest stronger concern on values-based principles. Concerns are expressed about *"the profit driven manner in which the technology is being applied"* (p8) and expectation that profits *"will drive development rather than medical or social need"* (p8). GeneWatch strongly advocate the use of alternatives to applying biotechnology to animals wherever possible. It is also worth noting that they refer to how the use of GM and cloning will change the relationship between humans and animals e.g. *"Cloning normalises a technology which could at some point be extended to humans"* (p70). However, their official position with respect to GM animals is:

*"fundamental alteration of the genetic code of other species should not be undertaken lightly and that there should be a presumption against such modification unless there are*

*compelling arguments to do so*" (p11). This suggests that there is some room for negotiation and the argument is not completely reliant on a values basis. A 'compelling argument' could justify use of these techniques.

Some additional information on attitudes of civil society advocacy groups can be found in the academic literature, although it is quite limited. Pivetti (2007) conducted five focus groups with Italian animal welfare and pro-animal activist groups and found the basis for arguments against application of biotechnology to vary. On the one hand activists took into consideration the usefulness of the application (interests-based argument) but on the other they used 'vivisection' as their paradigm. Vivisection, in their view, has been misleading and unreliable and they expect animal biotechnology to be the same. Values-based considerations were also important. Genetic modification of animals was considered unnatural and lacking respect for animals.

Religious groups have mainly been absent from these debates (unlike, say, debates around human embryonic stem cell research). One of the few to have given an official pronouncement is the Church of Scotland who agreed at its General Assembly on 22 May 1997 that "*The General Assembly of the Church of Scotland: Commend the principle of proteins of therapeutic value in the milk of genetically modified sheep and other farm animals, but oppose, and urge Her Majesty's Government to take necessary steps to prevent, the application of animal cloning as a routine procedure in meat and milk production, as an unacceptable commodification of animals.*" (Church of Scotland, 1997). Again this stance suggests a mixture of values-based motivations (the use of the concept of commodification that implies an undesirable relationship) and interests-based motivations: applications of biotechnology to farm animals may be acceptable under certain circumstances and for real human benefits.

#### **4.4.3 Conclusions on citizens/civil society advocacy groups**

In summary, a range of values-based and interests-based arguments are advanced both by citizens and civil society advocacy groups and are generally antagonistic towards cloning animals for food. Interests-based fears about food safety are more dominant in

public discourses than in those of specialist groups and citizens draw on a range of other negative connotations. For a proportion of citizens, moral concerns would mitigate against cloning animals. Links are made with the cloning of humans as a result of cloning animals both by citizens and civil society advocacy groups. Citizens are concerned about the reason why cloning is being undertaken and whether this is being driven mainly for profit and the benefit of corporations rather than to meet real human needs, thus indicating a strong strand of interests-based argument. Cloning might be acceptable given there was a sufficiently good reason for doing so. Some of the civil society groups are actively campaigning for improved animal welfare so it is not surprising that this aspect is a major determinant of whether they would find cloning acceptable or not. Whilst their arguments are generally couched as interests-based (animal welfare concerns could in theory be satisfied), it is difficult to distinguish the welfare argument from broader ones made about a different approach to agriculture. Thus, theoretically cloning would be acceptable if a good level of animal welfare was achieved but it is difficult to envisage a scenario where such a level would be attained.

I conclude that a range of values and interests-based motivations and arguments are apparent in citizens' and civil society groups' attitudes to use of cloning technology for food production. There is less evidence related to genetic modification but indications are that attitudes would be even more strongly against GM food animals with a stronger values-basis driving the arguments.

#### **4.5 Policy and regulation**

In December 2007, the Daily Mail announced that a calf, the offspring of a clone, had been born in the UK, apparently without the knowledge or approval of the regulatory authorities, thus opening up the spectre (in the view of the Daily Mail reporter) of meat and milk from cloned farm animals flooding the EU supermarkets. Parallels were drawn with GM crops and references were made to 'Frankenstein Farming' (Poulter, 2007). EFSA was asked by the European Commission to express an opinion on the safety implications and the EGE on the ethical implications of food products from cloned farm animals. What

should, and moreover what *could* policy makers do about this apparently troubling development? To a very large extent, the values and interests around cloned animals are currently in the process of being negotiated within the policy-making and regulatory processes of the EU.

Suk *et al.* (2007) highlight the regulatory uncertainty that has existed with respect to cloned animals and important issues that arise from this uncertainty. For example, how might EU regulation on animal welfare (particularly Directive 98/58/EC) be applied to cloned animals and their progeny? How is it possible to enforce any labelling regime that may be demanded given there is currently no mechanism for identifying cloned animals nor any apparent technical basis for doing so? How is it possible for any jurisdiction working in an international trade system to prevent the introduction of cloned animals if it wished to do so?

UK regulation regarding GM and cloned animals is primarily conducted at the EU level, although there is some regulation in specific areas, notably animal welfare, within the UK.

The main areas under regulation are:

- Safety of food
- Releases into the environment
- Animal welfare
- Ethical aspects
- International trade.

Each of these areas will now be briefly considered in turn.

#### **4.5.1 Safety of foods**

The risks of consuming products from cloned animals (or from their progeny) have been evaluated by EFSA (EFSA, 2008) who concluded that *“there is no indication that differences exist in terms of food safety between food products from healthy cattle and pig clones and their progeny, compared with those from healthy conventionally-bred animals”* (p2). This opinion was upheld in an update of EFSA’s advice adopted 23 June 2009



(EFSA, 2009). However, EFSA also concluded that the health and welfare of a significant proportion of clones is adversely affected. Insufficient data were available on species other than cattle and pigs to reach a conclusion on food safety. The evaluation by EFSA included consideration of genetic and epigenetic effects of SCNT, impact on animal health and animal welfare, composition of meat and milk from cloned animals as compared to non-cloned animals, checking for toxicity by feeding to rats, testing for genotoxicity, testing for allergenicity and evaluating potential impact on the environment and genetic diversity. In their opinion, EFSA recommended additional investigations regarding food products from cloned animals, including investigating the extent to which somatic cell nuclear transfer may induce DNA mutations, collecting additional data on health of clones and routine monitoring of chemical contaminants, particularly veterinary product residues, in the meat and milk of cloned animals.

Information on the safety of food from any GM animals would need case-by-case evaluation but to my knowledge no such evaluation has taken place to date in the EU.

EFSA as a regulatory body has an explicit remit to conduct risk assessment and to advise (but only advise) the European Commission and member states. EFSA was set up partly in response to the dispute between UK and France with respect to risks from BSE (Demortain, 2008) and as such provides an explicit disengagement of risk assessment (conducted by specialist scientific panels in EFSA) from political decision making (conducted by the member states). Thus the members of the scientific committees in EFSA do not act as representatives of member states (Demortain, 2008) and the scientists composing the committees are limited in their role to risk assessment rather than risk management.

In EU, the relevant regulation with respect to food safety is the regulation of novel foods and ingredients (EC regulation 258/97). Initially, there was some uncertainty as to whether products from cloned animals would be included in the novel foods regulation but following an ongoing review of the novel foods regulation, it is expected to apply to products of cloned animals and products from their progeny, as well as food from GM

animals, and is likely to require labelling of products from both. The regulation regarding cloned animals remains unresolved at the time of writing.

At the political level, there is antipathy towards cloned farmed animals as expressed by the European Parliament. In September 2008 the European Parliament (partly instigated by the UK MEP Neil Parish) called for a ban on the agricultural applications of cloning which was achieved by an overwhelming majority of 622 votes to 32<sup>14</sup>. The debate was largely dominated by concerns around animal welfare<sup>15</sup> although ethical and reputational concerns were also mentioned. There was also a nebulous sense of unidentified risks with a clear distinction being made by some between research applications of cloning and applications to food.

Dolly the sheep provides a large part of the context. Dolly is portrayed in the public eye as ageing prematurely, dying young and being ill and malformed as a result of the process of cloning (although this view is not aligned with scientific opinion). These images are reflected in the parliamentary debates e.g. MEP David Hammerstein said<sup>16</sup> *"Dolly the Sheep died ill and malformed. The Dolly the Sheep experiment was a failure."* Ethical and unspecific risk concerns were expressed for example by Agnes Schierhube who hoped that *"we shall not find ourselves in the same dilemma as Goethe's sorcerer's apprentice, who could not rid himself of the spirits he had conjured up"*. Similarly MEP Wojciechowski considered cloning animals for economic purposes as an ethical abuse and argued that *"We should reject it on moral grounds in the name of respect for animals, but also in the name of our own humanity. It is only one step from treating animals as objects to treating human beings as objects. It is already only a short step from cloning animals to cloning people."* Even those who had a generally positive view of reproductive technologies found cloning wrong. The MEP Jim Allister although supportive of artificial insemination and

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<sup>14</sup> European Parliament RSP/2008/2598 Resolution on the cloning of animals for food supply. Available from: <http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=en&procnum=RSP/2008/2598> [accessed 6/1/11]

<sup>15</sup> European Parliament debates PV 02/09/2008-17 Available from: <http://www.europarl.europa.eu/> [accessed 06/05/09]

<sup>16</sup> European Parliament debates PV 02/09/2008-17 Available from: <http://www.europarl.europa.eu/> [accessed 06/05/09]

embryo transfer stated that *"whichever way I look at this subject, I can find nothing to convince me that animal cloning is right, necessary nor in the public interest."* Following the resolution to ban animal cloning, the European Parliament subsequently debated the subject again in the context of the draft revised novel foods legislation.

The draft revised novel foods legislation was debated by the European Parliament on 24<sup>th</sup> March 2009 (debate PV 24/03/2009-16<sup>17</sup>). Again, even MEPs who advocated measures that would support innovation were against cloning of food animals. For example, MEP Magor Imre Csibi stated that *"we should not fall into the trap of safety hysteria and kill innovation"* and again *"we cannot demand that a novel food has no negative impact on the environment"* and yet he also stated *"I strongly support the exclusion of foods from cloned animals and their descendants from the scope of the Regulation, and call on the Commission to ban cloned animals in the food chain"*. The reasons given for advocating this ban were related to ethical implications and potential human health and animal welfare concerns.

The draft legislation was subsequently considered by the Council of the European Union who agreed on a revised draft Novel Foods Regulation on 16<sup>th</sup> June 2009<sup>18</sup> that explicitly includes the products from cloned animals and the products from their progeny. Two countries (the UK and Greece) abstained from the vote.

One of the key issues appeared to be whether products from cloned animals should be included in the Novel Foods regulation or whether specific regulation would be required. The Council invited the Commission *"to report on all aspects of food from cloned animals and their offspring within one year after the entry into force of the regulation and to submit, if appropriate, a proposal for a specific legislation on this topic"*. In an addendum<sup>19</sup> the Presidency made a statement clarifying that new legislation will be required to cover food

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<sup>17</sup> A transcript of the parliamentary debate is available from <http://www.europarl.eu/> [accessed 06/05/09]

<sup>18</sup> Council of the European Union press release 11218/09 (Presse 188) 22<sup>nd</sup> June 2009. Available from: [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/misc/108678.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/misc/108678.pdf) [accessed 6/1/11]

<sup>19</sup> Council of the European Union, Addendum to the 'A' item note. Interinstitutional file 2008/0002 (COD), 17<sup>th</sup> June 2009. Available from: <http://register.consilium.europa.eu/pdf/en/09/st10/st10754-ad01.en09.pdf> [accessed 6/1/11]

products from cloned animals and the Novel Foods Regulation is only intended as a temporary measure to avoid any legislative gaps. The addendum also indicated that the UK and Netherlands did not support the statement on the basis that legislation should be evidence-based. Greece on the other hand did not support the statement on the basis that Greece would prefer an outright ban on food from cloned animals.

*“This position is dictated by, among others, the need to apply the precautionary principle since, based on scientific evidence to date, potential future dangers arising from the application of animal cloning techniques for food production cannot be ruled out. We would further emphasise that our position reflects the great sensitivity and negative attitude of Greek public opinion as a whole with regard to the issue of food from cloned animals”.*

It seems clear, therefore, that the political climate for foods derived from cloned animals in Europe is rather negative and that this antipathy is motivated by a range of values-based and interests based arguments and motivations. From a purely food risk (interests) perspective however, regulators seem to have no real issues of concern with respect to food from cloned animals or their progeny although from a welfare point of view there appear to be grounds for concern. Policy makers appear motivated both by the sensitivity and uncertainty around food from cloned animals but also by the expected negative public attitudes.

#### **4.5.2 Releases into the environment**

In conducting an environmental risk evaluation with respect to cloned animals EFSA (2008) concluded that:

*“There is no indication suggesting that clones or their progeny would pose any new or additional environmental risks compared to conventionally produced animals”*  
(p31)

With respect to GM animals the EU regulation on safety, labelling and deliberate release as developed for GM crops will apply (e.g. Directive 2001/18/EC). The prospect of GM animals for food is however further in the future than clones and evaluation on a case-by-

case basis will be required, so until a definite case can be considered it is difficult to understand the issues except in the generality.

Risk of spread of GM to wild populations of relatives and 'volunteer' crops was (and is) a major concern with respect to the adoption of GM crops. With GM and cloned mammals and birds, the potential for 'escapes' is thought to be minimal due to the small number of individuals involved (in comparison to the potential for spread of pollen, for example) and there are few, if any, wild mammal and bird populations to interbreed with. Unlike GM crops, risks to the environment are therefore unlikely to be central concerns with respect to GM and cloned mammals and birds.

In contrast, the risks to the environment are expected to be considerable with respect to GM fish. Unless fish are kept in tanks on land, the prevention of escapes into the wild appears impossible. Methods of inducing sterility to prevent breeding are unlikely to be 100% effective. Experiences from farmed fish suggest that escapees can have a significant impact on indigenous fish populations. Thus, potential environmental impact of GM fish could be substantial.

In the context of use of cloned animals and their progeny in food production, the risk evaluation on an interests-basis suggests that there is little or no concern with releases of cloned mammals to the environment. The impacts of any potential GM animals have yet to be evaluated fully.

#### **4.5.3 Animal welfare**

The Treaty of Rome recognises animals as sentient beings and the main European-wide legislation relating to farm animal welfare is Directive 98/58/EC which states that '*natural or artificial breeding procedures which cause, or are likely to cause, suffering or injury to any of the animals concerned shall not be practiced*' and that '*no animal shall be kept for farming purposes unless it can reasonably be expected, on the basis of their genotype or phenotype, that they can be kept without detrimental effect on their health and welfare*'. As MacArthur Clark *et al.* (2006) note, it is not clear how this legislation is applied and

whether it has been used successfully to restrict any breeding procedure. Some practices that might be prohibited by this legislation are in widespread commercial use.

The farm animal welfare context within which cloned and GM animals are being introduced is not a neutral one. Welfare of farmed livestock and the impact of 'conventional' breeding technologies have already attracted attention from some bodies, including from the UK Farm Animal Welfare Council (FAWC) an independent advisory committee set up by the UK government to advise on farm animal welfare. FAWC's concerns include issues such as excessive selection pressure on some characteristics at the expense of others e.g. selection of broiler chickens for faster growth such that the level of leg problems has increased as a consequence of this selection pressure (although subsequent corrective selection may have been effective in mitigating this difficulty in some cases) (MacArthur Clark *et al.* 2006). Other concerns relate to keeping farmed livestock in more extensive conditions than those under which they were selected and subsequent unsuitability of the high performance animals to a rougher environment. An example of this is the growth in outdoor pig keeping in the UK where some of the animals kept outdoors may have been selected for keeping in indoor intensive conditions and may not be robust enough to thrive in an outdoor environment (although some breeding companies have produced more robust genotypes specifically suited to outdoor conditions). These concerns, expressed by FAWC are interpreted here as interests-based because they rely on evaluating the physical welfare of animals.

FAWC however extend their critique to more values-based concerns (MacArthur Clark *et al.* 2006). They suggest that conventional breeding techniques have also produced animals considered by FAWC to have had their integrity violated to an unacceptable degree. Examples given include two natural mutations; featherless broiler chickens produced in Israel and blind chickens produced in Canada (although it is not clear that either is in widespread commercial use). In each case, from a purely physical perspective, these birds may even have improved welfare over their conventional counterparts but these changes are considered intrinsically objectionable. A final concern for FAWC is that breeding techniques should not be used to change behavioural traits to the point that

animals lose behavioural flexibility and sentience. However, others might argue (as recognised by FAWC) that some changing behaviour may be advantageous in the context of changing production environments e.g. to reduce chickens pecking each other in free-range systems. Breeding for behavioural change is thus a contested area.

In terms of the commercial applications of cloning, FAWC have made a very clear recommendation (Farm Animal Welfare Council, 1998) that until the welfare problems associated with cloning are resolved there should be no commercial use of cloning in agriculture. However, they found no basis for intrinsic objections to cloning, thus FAWC's objection appears to be primarily on an interests basis.

In England, the Council Directive 98/58/EC has been implemented by the Welfare of Farmed Animals (England) Regulations 2000 (S.I. 2000 No 1870) which bans the use of breeding procedures that are likely to cause suffering or injury to animals and in paragraph 29 states that '*No animals shall be kept for farming purposes unless it can reasonably be expected, on the basis of their genotype or phenotype, that they can be kept without detrimental effect on their health or welfare.*' Again, it is not clear how this regulation will be enforced in practice.

FAWC proposed that a Standing Committee on the welfare implications of animal breeding should be established (MacArthur Clark *et. al.* 2006) to provide ongoing advice on animal welfare issues. The Banner committee called for a similar committee to have ethical oversight of developments in reproductive biology (Banner, 2005). Such a Committee exists in, for example, Norway (Mejdell, 2006) where a mixed lay and expert Committee has reportedly been influential in, for example, bringing about changes in fur farming practices.

The approach adopted at the time of writing in the England and Wales by the Department for Environment, Food and Rural Affairs (Defra), however, is to rely on a 'governance' model that encourages appropriate behaviour rather than a 'government' model that legislates for behaviour. 'Government' is here defined as '*top down legislative approach which attempts to regulate the behaviour of people and institutions*' and 'governance' as

*'attempting to set the parameters of the system within which people and institutions behave so that self-regulation achieves the desired outcomes'* (Lyal and Tait, 2005, p3-17). This development is rather recent and its impacts remain to be seen. The UK approach then has rejected the advice of its animal welfare advisors to use a standing welfare committee in the process of implementing animal welfare legislation. The reliance on a governance model suggests that a range of values and interests could come into play but that the main aim is a pragmatic one.

At the EU level, however, there is a standing committee on ethics and this committee has also addressed the welfare aspects of cloned and GM animals. Their deliberations will be considered next.

#### **4.5.4 Ethics**

Ethics advice is provided to the European Commission by The European Group on Ethics in Science and Technologies to the European Commission - EGE - (formerly the Group of Advisers on the Ethical Implications of Biotechnology) which concluded in 1997 regarding GM animals that *'genetic modification may contribute to human wellbeing and welfare, but is acceptable only when the aims are ethically justified and when it is carried out under ethical conditions'* (Group of Ethical Advisers, 1996). In January 2008 the committee considered cloning and concluded (with one dissenting voice) that

*"Considering the current level of suffering and health problems of surrogate dams and animal clones, the Group has doubts as to whether cloning for food is justified. Whether this applies also to the offspring is open to further scientific research."*  
(EGE, 2007 p45 section 5.10).

The EGE goes on to list requirements that need to be fulfilled should products from cloned animals to be introduced to European markets relating to food safety, animal welfare and health, traceability and global trade. The EGE also expressed concern about cloning increasing meat and milk consumption globally and hence the environmental impact of these extra animals.



Within Europe, three countries have specific legislation relating to animal cloning in place. In the Netherlands, the Animal Health and Welfare Act of 1992 (Bruce *et al.* 2005) prohibits applications of biotechnology to animals without a special licence. Criteria for being given a licence include that the goal of the research is of substantial importance to society, there are no alternatives and the benefits outweigh the risks to health, welfare and the integrity of the animal. This requirement for a special licence is ostensibly the reason why the Dutch company Pharming (developing pharmaceutical products from GM animals) relocated its animal facilities to Belgium and USA<sup>20</sup> although some have questioned the nature of their original licence applications. Denmark has enacted legislation to ban the use of animal cloning and genetic modification except for experimental purposes (Bruce *et al.* 2005, Cloning in Public 2005) citing concerns of animal welfare and animal integrity. In Norway animal cloning has also been banned (Bruce *et al.* 2005) although concerns about human cloning appear to be implicated in that decision (Cloning in Public, 2005). Intrinsic value is therefore not just of theoretical interest since both Danish and Dutch legislation to control the use of farm animal cloning and genetically modified animals appears to have been driven, at least in part, by concerns around animal integrity. This move from 'consequential' concerns for the impact of the technology on the welfare of the animal to 'in principle' concerns around the integrity of the animals reflects the involvement of both interests-based and values-based arguments in the ethical arena.

#### **4.5.5 International trade**

Food products are traded globally and a complex web of regulations forms the basis for this trade. The main relevant regulatory instruments are embedded in the World Trade Organisation (WTO) and the Cartagena Biosafety Protocol.

The Cartagena Biosafety Protocol is part of the international agreements intended to protect biodiversity but the protocol applies to Living Modified Organisms and it is not clear if this definition would include cloned animals (although GM animals would be

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<sup>20</sup> Frank Pieper, Pharming Group N.V. personal communication

included). The Protocol includes a wide definition of the precautionary principle in risk assessment and more scope for including socio-economic factors in decisions on movements of organisms.

The WTO generally promotes free trade under the General Agreement on Tariffs and Trade of 1994. However, restrictions are allowed under the Sanitary and Phytosanitary Measures Agreement and the Technical Barriers to Trade Agreement. These allow restrictions to protect human, animal or plant health (based on scientific risk assessment) and control requirements for labelling and consumer information. Thus restricting import of animal products would need to be on the basis of human or animal health. Given the risk evaluations of products from cloned animals by both EFSA and the US Food and Drugs Administration this hazard evidence-base to prevent imports does not currently appear to exist.

The European Union has a number of zootechnical regulations that control the entry of breeding animals into herd books hence regulating free trade in breeding animals. For example Directive 94/28/EC lays down the principles relating to the conditions applicable to imports from third countries of animals, their semen, ova and embryos. This regulation includes the requirement for information on the parents and grand-parents of the imported animal (semen, ova or embryos). However, there is currently no restriction on entry of cloned animals into herd books (unlike some horse stud books).

#### **4.5.6 Conclusions from policy and regulation**

The policy responses to the prospect of cloned farm animals have been extremely precautionary. There are a number of negative connotations associated with discussion around cloning. Dolly the sheep has formed part of the context and in parliamentary debates Dolly has been portrayed as a monster, rather than a scientific achievement or a fat pet sheep, both which could be alternative framings. The call for a ban on cloning farm animals was made strongly by the European Parliament with a whole range of interests and values-based arguments being deployed, although with values-based arguments having a very strong presence. Arguments against farm animal cloning were made even

by those parliamentarians who would normally seem to advocate biotechnological developments. This appears to be less a case of regulating a hazardous technology but rather more of one that causes nebulous anxiety on a variety of different levels (for example the idea of unleashing uncontrollable technology, or unease about prospects of human cloning) as well as the real and visually powerful issue of harm to animal welfare. The nervousness with respect to cloning technology was reflected in the political debates in the Council of Ministers.

The EU has a regulatory system that considers the human, environmental and animal welfare risk as well as ethical concerns. However, arguably EFSA is experienced in assessing risks from food but the extent of its expertise with respect to assessing animal welfare and environmental risk or the risks from reduced biodiversity is not clear. The EGE is an advisory body only, although it may be very influential, and is likely to reflect the views of its current membership which may or may not be indicative of wider ethical perspectives.

The regulatory instruments available to policy makers are limited. EU zootechnical legislation may be used to prevent the entry of cloned animals into herd books but these will only be effective in circumstances where the pedigree animal or its progeny reside in the EU. Similarly, people could be required to have a licence to conduct cloning (even after the technique progresses beyond experimental techniques which already require a licence) which could provide some control over animal welfare concerns. The current indications are that products from both cloned animals and their progeny will require labelling within the EU. However, there appears to be no scientific basis for monitoring the accuracy of any labelling system since there appears to be no method of testing for cloned origin. It is therefore difficult to envisage any method of control by governments to prevent food products from cloned animals appearing in the food chain. Finally, animal products are traded on an international basis where evidence of hazard is required in order to prevent trade in products from cloned animals and such a basis seems unlikely at present. Ethical concerns are not generally accepted as reasons to prevent trade within the WTO. It seems possible, therefore, that consumers who strongly object to these

products may need to resort to organic production, branded products, or specific supermarkets or avoiding animal products altogether. Despite the best intentions of policy makers and their nervousness about cloned animals, there seem few reliable regulatory instruments available that can be enforced to prevent products from cloned animals entering the food chain.

## **4.6 The role of values and interests in debates around cloned and GM animals**

### **4.6.1 A summary of arguments**

In this section I summarise the main values-based and interests-based arguments in the area of cloned and GM animals based on the evidence presented (table 4.3) and relate these data to the thesis questions.

The first question of this thesis asks the extent to which values-based and interests-based arguments are found in areas of genomic technologies other than GM crops?

There is sufficient evidence to suggest that a range of values-based and interests-based arguments are being advanced both in support of and against the development of cloned (and GM) animals. I have categorised interests-based arguments as those that appear to promote the 'good' of or prevent 'harm' to a particular group, have desirable or undesirable consequences or imply some degree of weighing-up activity, for example of economic benefits or risks, as defined earlier in section 3.3. Arguments that appear to refer to normative judgements, such as appeal to the intrinsic value of an animal, are categorised as predominantly values-based. From this starting point, a rich mixture of both interests-based and values-based arguments are advanced within the context of cloned and GM animals.

**Table 4.3 Main values-based and interests-based arguments with respect to use of cloned and GM animals for food.**

	Stakeholder groups		
	Innovators <sup>21</sup>	Civil Society groups	Citizens
<b>Arguments favouring cloned/GM animals</b>			
<b>Values-based arguments</b>	Scientific knowledge		
<b>Interests-based arguments</b>	Economic and other benefits		Some acceptance of specific benefits
	Equity of competition		
<b>Arguments against cloned/GM animals, or in response to concerns</b>			
<b>Values-based arguments</b>		Morally wrong	Morally wrong
		Not consistent with sustainable agriculture	
		Driven by profit rather than need	Driven by profit rather than need
<b>Hybrid of values &amp; interests</b>	Potential harms to animals acknowledged, but seen as resolvable (primarily interests)	Harm to animals expressed both as a value and an interest	Harm to animals, values-interests basis not established
	All knowledge required for human cloning already exists	Could lead to human cloning	Could lead to human cloning
<b>Interests-based arguments</b>	Concerns about inbreeding acknowledged but can be managed		Concerns about inbreeding
			Risk to safety of food
	Consumer antagonism could mean the technology is not in the interests of food retailers		

Some caution is needed in interpreting these data. Presenting the results of the analysis in this tabular form can seem to imply that each argument is autonomous. This seems unlikely to be true. Views are more likely to be held as a whole series of inter-linked factors. Whilst the data analysis gives some idea of strength of feeling, there is no indication of numbers of people holding specific views. Also, there is little indication of the strength of evidence base e.g. little evidence is available regarding attitudes of

<sup>21</sup> Innovators by definition are unlikely to argue against a technology but may be responding to criticisms

supermarkets. Additional quantitative research would be needed to obtain this type of information.

The main arguments advanced by proponents of cloning in the EU relate to the interests of breeding organisations for fair competition at a global level. These arguments are closely linked to production advantages including facilitating the production of animals with reduced environmental impact or increased disease resistance. Negative aspects of cloning, such as adverse impacts on animal welfare, are recognised by innovators and are balanced against benefits to be accrued, and viewed as resolvable. From a values-based perspective, cloning and genetic modification can be viewed as applications of scientific knowledge for human benefit. From this standpoint many applications of the technology are viewed positively.

Opposition is expressed both on a values-basis and an interests-basis. Values-based opposition to GM and cloned animals cluster around two main factors: the intrinsic value of animals and the value of different approaches to agriculture. From the perspective of antagonists of the technology arguments are often made regarding failing to respect the 'intrinsic value of an animal'. Of course there is no guarantee that the 'intrinsic value' attributed to an animal by one person is the same as that attributed by another person as there is no single agreed definition of what constitutes 'intrinsic value'. This can make adjudication on the potential failure to respect the intrinsic value of an animal difficult. As already indicated, intrinsic value has been used to argue against genetic modification to reduce animal sentience (Banner, 1995) and producing genetically blind chickens (MacArthur Clark *et al.* 2006). The second value-based argument advanced is on the basis of whether this technology is associated with appropriate forms of agriculture, linked to whether the driver is human need or corporate profit. These arguments have been well expounded for example by Verhoog (2003).

The major objection to cloned animals is on the basis of harm to animal welfare. Animal welfare can be considered an interests-based as well as a values-based issue if it is granted that animals can have interests (I will return to this in Chapter seven). The argument that cloning is harmful to animal welfare and therefore should not be allowed

suggests that if there were no adverse consequences to welfare then the technology would become acceptable. In practice, arguing from an animal welfare basis may or may not be undergirded by concerns about animal integrity, invoking values-based concerns that may be much less easy to resolve. In any case, determining an agreed measure of satisfactory animal welfare may be difficult. Avoiding gross abnormalities due to the use of the technologies is one measure that can be adopted (and appears to have been adopted by both the European Parliament and EGE). However, others argue that ascertaining animal welfare requires evaluation over a number of generations which is a much more stringent condition to meet. Yet others suggest that not only must the technology produce 'normal' animals but the technique itself should not cause harm. Given the requirements for surgery for these techniques (which by definition causes harm) it is only if non-surgical procedures are developed that cloned and GM animals may become accepted. Finally, the concept of 'good welfare' can encompass a range of factors that involve the concept of 'naturalness' as noted in the literature review in section 4.2.4 iv), which move towards the realm of values-based argument. The extent to which animal welfare arguments have an underlying values-based orientation may not always be clear. There may be very different visions for the desirable end point of the animal welfare argument that are not distinguished in normal discussion.

The evidence therefore suggests there is a great deal of confusion as to what are the issues at stake with respect to cloned (and GM) animals. For some, fundamental values are threatened by technologies such as cloning but much of the debate has been framed around animal welfare which is itself a complex concept that means different things to different people.

#### **4.6.2 Configuring stakeholders**

The second thesis question asks how these values-based and interests-based arguments are aligned between different stakeholders?

From the evidence gathered for this chapter the main driver for cloning is the desire for fair competition by the animal breeding industry allied to the prospects for broadly

production-related benefits. If the technology proves not to be economic, there is likely to be little drive for its adoption by innovation communities. Proponents of cloning in the EU emphasise protecting the interests of an industry sector from international competition rather than advocating cloning itself. Within breeding organisations there appear to be a mixture of different orientations. In so far as can be ascertained, many companies are neutral with respect to value positions but negative with respect to their current interests, due to concerns about public acceptability of cloning. However, they do not wish to be put at an economic disadvantage should the technology be available to competitors. It seems surprising that cattle breeding associations or companies have apparently not addressed issues around the potential impact of cloning on genetic diversity. While failure to address issues of inbreeding is unlikely to result in exacerbating any potential dispute, it could have a negative impact longer-term on the industry should cloning become widely adopted. The apparent failure to address this issue could be taken as an indication of lack of enthusiasm for widespread adoption of the technology.

Companies producing cloned animals have a positive value and interest position with respect to developing cloned animals. Research scientists in this specialist area are likely to also have positive value and interest positions with respect to cloned animals. However, from a research perspective, understanding the processes, safety issues and use of cloning for research are all likely to satisfy the value and interest positions without the necessity for commercial production. Some individual cattle farmers in the UK have utilised progeny from clones and are therefore inferred to have both positive values and interests. Organic farmers are likely to find these technologies as inimical to their values, given the links made by civil society groups between cloning and non-sustainable agriculture as well as animal welfare concerns. Organic farmers are also likely to find these technologies contrary to their interests, given the image of organic food as safe and the public concerns about safety of food from cloned animals. The innovator picture therefore suggests a great deal of heterogeneity with respect to support and advocacy for cloning technology to be adopted.



Opposition to these developments, particularly from civil society advocacy groups, is currently on the basis of concern around animal welfare and animal integrity, and for them there is likely to be a strong values-basis to the arguments. Animal welfare advocacy groups have a negative interests-based view of cloned animals and they are also likely to have values-based concerns about these developments. The evidence suggests that consumers are concerned that their interests will not be furthered by food from cloned animals and for many this technology is also contrary to their values. Food companies, responding to these concerns have not been enthusiastic about food from cloned animals, possibly because they perceive it is not in their interests to be so.

This analysis suggests that there are opposing forces pulling the technology in different directions. Scientific research continues to develop new techniques, new approaches and lead to new ideas on how animal biotechnology might be used. In the other direction, animal welfare concerns, a desire to maintain the integrity of animals and uncertainty as to the acceptability of applications of genomic technologies animals to the public act as restraints on developments. Until some paradigm breaking application for GM is developed it is hard to see this technology being widely adopted in agriculture in the EU. With respect to cloning, if the technology were to be widely adopted elsewhere, then there would be economic pressure on EU breeders and producers to do likewise. At present, however, there appears to be no strong advocate in the EU for cloned animals in the food chain.

In summary, the use of cloned animals in food is in the EU being driven by individual companies largely based in the USA, allied with individual choices made by pedigree breeder farmers in the EU. Consumers are wary of the desirability of cloning and particularly the safety of products from cloned animals (and their progeny). Strong objections to cloned and GM animals are expressed by animal welfare groups and by advocates of alternative forms of agriculture.

#### 4.6.3 Policy-regulatory responses

The third thesis question relates to where are the values and interests-based arguments being negotiated and how does the policy-regulatory framework relate to these arguments?

Within the EU, the main negotiations are taking place within EFSA, EGE, the European Parliament and the Council of the European Union. As noted earlier, EU mechanisms provide advice about food safety, animal welfare, environmental impact and ethics for consideration by policy makers (the Parliament and Council). The substantive arguments made within the European Parliament, however, appear to be strongly influenced by values-based considerations both of the parliamentarians themselves and also by what they consider will be the views of their constituents. This response is congruent with civil society advocacy groups concerned with animal welfare.

Risks to the environment and to humans of cloned animals and products from them have been evaluated by EFSA and no major concerns have been raised, although some gaps in knowledge have been acknowledged. The findings of EFSA have not been challenged by advocacy groups critical of cloning. However, the data on citizens' responses to food from cloned animals (although there are only limited data) suggest a much greater concern about long-term health risks. It is not apparent how these concerns are currently being taken into account as what seem to be demanded are long-term feeding trials to assuage fears based partly on the experiences of BSE, which may be impossible to conduct. Evaluation of the risks to the environment and humans of the use of any GM animals in the EU has yet to take place.

Animal welfare arguments have featured strongly in this case. The ways in which animal welfare arguments are used by different stakeholders within the regulatory policy agenda are salient when focussing on potentially disputed territory. Where animal welfare is part of an interests-based set of overall concerns, proponents will be willing to engage in negotiations to improve overall welfare or safety, and there will be a point at which agreement can be reached on a level that satisfies all parties. However, where one party

comes to a dialogue from a values-based perspective, such accommodation is unlikely and mechanisms to improve welfare will instead be met by raising the barrier from the value-based side of the dialogue. As previously noted, a European Directive exists to regulate animal welfare but it is not clear how this will be applied in any circumstance, let alone that of cloned animals.

The potential benefits of cloned farm animals, whether in terms of improved food security or reduced environmental impact have not had high profile. The fact that the European Parliament is considering requiring labelling the food products derived from progeny of clones as well as clones themselves suggests that at heart there is a moral concern (animal welfare concerns are not a direct issue with the progeny of clones).

This is a situation where policy makers in the EU have anticipated a controversy and have begun to legislate on that basis. Whilst there is debate and discussion among the well-informed stakeholders, this debate has not percolated widely to the general public consciousness. In their attempt to anticipate responses, policy makers have taken a very precautionary approach. Innovator stakeholders have been left fighting a rearguard action to ensure that should the technologies become important and widespread in their use in the future, European industry will not be at a disadvantage.

These considerations suggest there is a mismatch between policy/regulation and concerns about the risks of consuming food from cloned animals, allied to uncertainty as to how regulations on animal welfare will be applied. Thus, what might have been a risk issue is defined by policy makers as a moral issue. However, if the intention by the European Parliament is at minimum to ensure labelling of food products from cloned animals and their progeny and potentially to ban products from cloned animals and their progeny altogether then these mismatches may not have any practical relevance. Similarly, values-based objections to cloned animals on the basis that they reflect the ethos of commerce and profit rather than sustainable agriculture have not been fully addressed in the policy sphere, but again this seems not to have much practical relevance due to the strongly precautionary approach that seems likely to be adopted. Finally, an aspect of the debate that has not been fully explored is that of food security. Both

innovators and the policy-community appear to have downgraded food security to an issue not worthy of consideration in the context of cloned animals.

#### **4.7 Conclusions on cloned and GM animals**

The birth of a calf, the progeny of a cloned bull, on a UK farm in 2007 signalled the beginning of the commercial application of biotechnology to farm livestock and with it raised a number of questions on whether and how this contested technology should be used and governed. The numbers of animals involved at the moment are small and it seems unlikely that there will be an immediate flood of cloned and genetically modified animals appearing on EU farms and products from them on supermarket shelves. It is by no means clear which, if any, of the applications will become widely adopted. There appear to be no companies in the EU developing cloned or GM animals for agricultural uses, although some such applications are being developed elsewhere in the world.

The main driver for adoption of cloned animals in the UK is largely based on the visions of small companies primarily in the USA, allied with individual livestock breeders and an international trading system for agricultural products. The response of EU breeders to cloning has been largely pragmatic, reflecting their interests. Welfare problems resulting from cloning are viewed as resolvable by them.

A range of values-based and interests-based arguments are advanced both by citizens and civil society advocacy groups and are generally antagonistic towards cloning animals for food. Citizens are concerned about animal welfare and food safety. Interests-based fears about food safety are more dominant in public discourses than in those of specialist groups and citizens draw on a range of other negative connotations. For a proportion of citizens, moral concerns would mitigate against cloning animals. Citizens are also concerned about the reason why cloning is being undertaken and the extent to which this pursues company interests rather than public interests. Most of the relevant civil society advocacy groups are actively campaigning for improved animal welfare and animal welfare is a major determinant of whether they would find cloning acceptable or not.

Animal welfare may often be expressed in ways that suggest that is in the nature of a values-based argument but it can also be argued on an interests-basis.

Policy makers in the EU have begun to engage with the issue of appropriate regulation of cloned animals and food products derived from them with both EFSA and the EGE having been invited to advise respectively on the safety and ethics of cloned animals. Whilst there is little direct evidence on public attitudes to cloned animals and products derived from them, the expectation is that the overwhelming attitude will be negative. This is borne out by the evidence that is available. The advice from EFSA is that food derived from cloned cattle and pigs is as safe as food derived from non-cloned animals. The EGE has concluded that it is currently unethical to use cloning commercially, given the welfare problems which occur during the cloning process. The European Parliament has called for a ban on the use of cloning for agricultural applications and the Council of the European Union has responded by proposing (at least temporarily) that Novel Foods Legislation should apply to both the products from cloned animals and the products from their progeny. This would require specific approval and labelling of any food derived from cloned animals and their progeny. This legislation is not yet enshrined in law and may of course change. Nevertheless, it suggests that European politicians are influenced most strongly by the arguments of value-oriented protagonists in developing early-stage legislation. However, given that it is difficult to conceive how the regulation will be implemented, this can also be viewed as politicians furthering their own interests in that they expect their constituents to resist food products from cloned animals and their offspring.

This situation cannot be easily understood as consisting of a purely values-based or interests-based dispute. The strong history of concern not just on animal welfare but on the relationship between humans and animals and what this implies to how humans should treat animals, suggests that there is a strong values-basis to any consideration of genomics applied to animals. However, there is a lack of consensus on what is appropriate treatment of animals.

In terms of protecting food animals from physical harm, there is more consensus but the evidence that welfare concerns have been resolved in the cloning process has not been convincing to date. This has given a strong interests basis for legislating against cloned animals themselves, although not their progeny who do not have the same welfare problems.

There is currently lack of evidence of risks from consuming products from cloned animals and their progeny and yet given the history of BSE, concerns are expressed by citizens. Here the 'interests' dimension as perceived by regulators may not be in accord with the 'interests' dimension as perceived by citizens. The degree of evidence on food safety required by citizens seems so extreme that it is difficult to see how these demands can be met. Labelling can be used as a device that enables policy makers to fulfil their international trade requirements and yet allow individual choice but enforcing such labelling may be very difficult. This case study therefore demonstrates a large degree of policy nervousness in the area of cloned and GM animals.

This case study of GM and cloned animals has demonstrated the existence of values-based and interests-based arguments in a situation analogous to GM crops but applied to the animal kingdom rather than the plant kingdom. In the case of cloned animals, the policy-regulatory response has been very precautionary and strongly influenced by perceptions of normative judgements expected to be made by citizens. There has been far less emphasis and contention around any risks to human health or the environment despite the prominence of these considerations in an application that involves food and presence of biotechnically-derived organisms in the environment.

In the next two chapters I will consider two further applications of genomic technologies to humans and examine how these different contexts influence policy-regulatory responses to the values-interests dimensions expressed in these circumstances. The first human case-study will consider population genetic databases or biobanks.

## Chapter 5

### Biobanks: a case of maintaining participants' confidence

#### 5.1 Introduction

In the previous chapter I considered cloned and GM animals. I found evidence of a very precautionary stance being taken by EU policy makers, reflecting values-based concerns around the inappropriateness of the use of cloning as an agricultural technology and particularly animal welfare concerns. Allied to this, European citizens are expected to be antagonistic to cloning. For some it will represent a threat to their fundamental values, many will be concerned about the welfare aspects and the evidence suggests there is likely to be anxiety about health risks associated with consuming products from cloned animals. Scientific assessments, however, suggest there is little basis for concerns about food-borne risks. The technology appears to be driven by small companies in the USA and there is little evidence of advocacy for cloning as a technique in the EU. Industry concerns instead revolve around ensuring competition on an equitable basis in global markets.

In this second of three case studies I extend the values-interests approach to human genetics and examine large-scale collections of human genetic and biological information in biobanks. This case was selected to extend the GM crops case to one where human genetics comes to the fore but where the major concern is with populations rather than individuals. The sequencing of the human genome forms an important context for biobanks, promising "*revolutionary new ways to diagnose, treat, and someday prevent the thousands of disorders that affect us*" (HGP, 2008). Biobanks are described as one of the key mechanisms linking disease diagnosis and genetic information to achieve these aims. In order to obtain data linking disease diagnosis and genetic information, participation by large numbers of people is required and they in turn, have to have confidence in the biobanking projects. I shall argue in this chapter that based on the evidence analysed, maintaining the long-term confidence of participants has been a major driver in the

governance arrangements for biobanks and that as a result interests-based arguments have become predominant in determining how biobanks are managed.

Biobanks or population genetic databases are collections of human tissue (usually associated with DNA) linked to health records and sometimes also including family genealogy information. For decades medical researchers have been collecting information and biological samples relating to specific diseases in small, individual databases. This has taken place not only in the context of the National Health Service (NHS) but also in the pharmaceutical industry. As early as 2001, Martin identified six private sector biobanks (Martin, 2001) and in a submission to The House of Lords Science & Technology Select Committee inquiry into Genomic Medicine in 2008, AstraZeneca<sup>22</sup> indicated that they had collected samples from 70,000 individuals with a disease diagnosis from their clinical studies.

Recently, interest in collecting information on a much larger scale has increased, to the level of regional or national populations. This change has focused ethical, legal and social scientific interest in a way that the smaller collections have not. This interest was partly generated by the controversial features of the first proposed population biobank in Iceland where an exclusive licence was given to one commercial organisation (deCODE Genetics) for commercial exploitation of a database of a whole population of DNA and health information (e.g. Merz *et al.* 2004) and the assumption of consent to be included in the database. However, there is currently little public debate surrounding biobanks in the UK, providing a less polarised context than GM crops for this case study.

There are numerous examples of biobanks around the world, including Estonia, Quebec Canada (CARTaGENE), Singapore, Latvia, Australia, and Marshfield Medical Research Foundation, Mayo Clinic and First Genetic Trust Inc. in USA. Review articles comparing biobanks have been published (e.g. Cambon-Thomsen, 2004 and Salter and Jones, 2005). In a UK context, the UK Biobank and Generation Scotland are the biobanks most closely associated with population-based collections and will be the focus of attention of

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<sup>22</sup> Available from: <http://www.parliament.uk/documents/lords-committees/science-technology/stgmastrazeneca.pdf> [accessed 21/8/10]



this chapter. The main differences between the two biobanks are the huge scale of UK Biobank and the focus on family information collection in Generation Scotland.

In this chapter, I firstly consider some of the scientific aspects of biobanks. I will then provide a brief survey of relevant literature considering relationships between biobanks and participants, questions raised about the legitimacy of the biobank concept, and the drivers or visions for biobanks. I then map out the main stakeholder communities involved (innovators and citizens/civil society advocacy groups). Using empirical data, I examine the arguments made either supporting or opposing the development of biobanks and evaluate the extent to which these are primarily values-based or interests-based and what has been the response of policy makers/regulators. Finally, I examine the current configuration around values and interest-based arguments and based on this analysis, address the question of how an 'interests' and 'values' framework can inform an understanding of the governance of biobanks and how the need to maintain participant confidence has led to a predominance of interests-based considerations.

## **5.2 UK Biobank and Generation Scotland**

### **5.2.1 UK Biobank**

UK Biobank, a £61M project funded by UK research councils, the Wellcome Trust (a medical charity), health departments, regional governments and regional development agencies<sup>23</sup>, aims to build a major research resource containing lifestyle and environmental information, medical history, physical measurements and biological samples from 500,000 people in the UK, aged between 40 and 69 (UK Biobank, 2007). The stated purpose of UK Biobank is to support a diverse range of health-related research to improve the prevention, diagnosis, and treatment of illness, as well as to promote health both in the United Kingdom and internationally<sup>24</sup>. Participation in UK Biobank is voluntary and contact is made with potential participants by UK Biobank based on contact details in NHS

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<sup>23</sup> As of September 2008, UK Biobank is funded by the Wellcome Trust, the Medical Research Council, the Department of Health, the Scottish Government, the Welsh Assembly Government and the Northwest Regional Development Agency

<sup>24</sup> Available from [www.ukbiobank.ac.uk](http://www.ukbiobank.ac.uk) [accessed 21/8/10]

records and other registers. The intention is to recruit a generalisable population sample. Participants will be followed for many years through accessing medical and other health-related records. The aim is to study gene-environment interactions in complex diseases. No individual results will be provided to participants from the results of this research although feedback on aspects such as height, weight, blood pressure, lung function and bone density are given at the end of the recruitment process. Participants retain the right to withdraw from the project at any time without giving a reason. Recruitment began in April 2007 based in 13 regional centres around the UK.

UK Biobank is set up as a not-for-profit company and its governance arrangements consist of:

- A Board of Directors, with representatives of the funders.
- A Steering Committee, led by a Chief Executive Officer.
- An Ethics and Governance Council, appointed by an open process in keeping with the Nolan Principles.
- An International Scientific Advisory Board that meets three times per year

By July 2010 the recruitment phase was completed with the target of 500,000 participants achieved.

### **5.2.2 Generation Scotland**

UK Biobank and Generation Scotland are presented as two complementary population databases. UK Biobank is UK wide (including a Scottish arm) and collects lifestyle, health and genetic data on an age cohort that it plans to follow as they age, develop diseases and die. Generation Scotland is specific to Scotland and consists of a number of projects primarily designed to identify families and to collect DNA from them. The two data banks reflect different scientific approaches to issues around health and disease, the different health systems and practicalities of collecting information from a smaller population in Scotland.

Generation Scotland refers to a group of three related projects.

- The Scottish family health study (GS:SFHS), collecting medical and genetic information on 50,000 individuals from family groups and following their health records for up to 30 years. As of 14/12/10 the Generation Scotland web site<sup>25</sup> indicated that over 28,000 volunteers had come forward. The stated intention is to identify which lifestyle and inherited factors are connected with higher and lower risk of illness.
- Genetic Health in the 21<sup>st</sup> Century (GS:21CGH) gathering genetic information on 2,500 individual inhabitants of different areas of Scotland (500 from each of five different regions). The stated intention is to look for genetic factors for illness and obtain a better picture of the genetic make-up of Scotland.
- Donor database (GS:3D) which is a collection of human DNA to act as a 'control' across a range of different studies. Samples have been collected from blood donors and the collection is recorded as being completed.

Generation Scotland is funded by the Scottish Government Chief Scientist's Office and the Scottish Funding Council. It is a collaborative project between the Universities of Aberdeen, Dundee, Edinburgh, Glasgow and St Andrews, the Medical Research Council Human Genetics Unit, the National eScience Centre, the Scottish School of Primary Care and the National Health Service (NHS) Scotland.

The governance arrangements for Generation Scotland include four components.<sup>26</sup>

- A Scientific Committee responsible for the strategic direction of the study and ultimately accountable to the public for the performance of Generation Scotland.
- Generation Scotland Advisory Board. An independent body to oversee Generation Scotland which reports to the Scottish Ministers.
- Generation Scotland Executive Group to report to the Scientific Committee on operational matters of the study.

<sup>25</sup> Available from <http://www.generationscotland.co.uk/> [accessed 14/12/10]

<sup>26</sup> Generation Scotland Management, Access and Publications Policy version 4.2 Dated 08.03.10 Available from: [http://www.generationscotland.co.uk/Documents/GSMAPP\\_Access\\_Policy\\_v4-2\\_080310.pdf](http://www.generationscotland.co.uk/Documents/GSMAPP_Access_Policy_v4-2_080310.pdf) [accessed 7/1/11]

- Resource Management and Development Committee.

Generation Scotland (GS:SFHS) “*aims to identify genetic variants accounting for variation in levels of quantitative traits underlying the major common complex diseases (such as cardiovascular disease, cognitive decline, mental illness) in Scotland.*” (Smith *et al.* 2006b). Participants and their family members are mainly recruited through primary care and names of all potential participants are screened by their GP and invitations to participate are signed by the GP. The initial person recruited (‘proband’) is then expected to recruit a further two or more siblings. Participants are invited to attend a research clinic where data are collected. These data include aspects such as cognitive function, personality traits, psychological distress and screening for major mental illness. These traits require considerable expertise and time to measure. Participants will be able to withdraw from the project at any time at which point any data and samples that have not been analysed will be removed and destroyed. As with UK Biobank, Generation Scotland (GS:SFHS) will follow its participants through health records.

UK Biobank and Generation Scotland stress the complementarity of the two biobanks using the concept of ‘Two studies: one vision’. For example, the UK Biobank website notes that “*Generation Scotland will identify the key genes that contribute to good or poor health...UK Biobank will find out how these genes combine with lifestyle factors to cause disease*”.<sup>27</sup>

It is clear from the above descriptions that both UK Biobank and Generation Scotland are ‘works in progress’. Funding has been obtained to initiate the collections, initial management and governance frameworks have been developed and data collection is in progress. There is undoubtedly a multitude of issues yet to be addressed in practice by both biobanks, such as negotiating terms of access for commercial organisations, determining links to any additional databases of information and ascertaining resilience of the frameworks to challenges from hitherto unknown and therefore not yet considered

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<sup>27</sup> Available from <http://www.ukbiobank.ac.uk/> [accessed 17/9/08]

issues. Commercialisation of products or development of treatments derived from data or samples either in UK Biobank or Generation Scotland is still in the future.

### **5.2.3 Scientific basis for biobanks**

Early genetic studies tended to be based on small, highly selected groups of people and were used to identify single genes with large effects that were easily identifiable (Smith *et al.* 2006a). With the move to biobanks, the focus has shifted to identifying more commonly occurring genes with smaller effects, the involvement of multiple genes and their interactions with each other and with environmental effects. Thus, identifying genetic effects becomes a more complex process.

This distinction between single genes with large effect and many genes with small effect is not only important because it has an impact on how people understand genetic information but also on how different health communities are being brought together, providing the background for some of the scientific disputes around the construction of biobanks. Traditionally, clinical genetics dealt with single gene diseases and public health with societal, environmental and behavioural issues (Halliday *et al.* 2004), thus the two worked independently. As geneticists have become more interested in diseases affected by genes with smaller effect, the two communities of clinical genetics and public health have begun to converge on the same health areas.

Opinions differ in scientific circles over the scientific merit of different ways of constructing biobanks. Differences exist over whether family or only individual information should be collected, what size of genetic effect the biobank should seek to detect and hence how many people it would need to enrol, and what traits should be measured. These differences are reflected in the different ways in which Generation Scotland and UK Biobank have been constructed.

UK Biobank has taken the approach of seeking to uncover associations between disease diagnosis, environment and underlying genetic predispositions, which require large numbers of participants. This tactic is particularly suitable to address genetic predispositions to diseases that are common but is less likely to discover rare

associations, even when the genetic component has a medium impact on the disease (Foster and Sharp, 2005). Therefore, it is argued, biobanks which are smaller but also include family information would be more efficient in those circumstances. Generation Scotland, in contrast, is a smaller collection but does include family information. Thus as explained by Smith *et al.* (2006a) "*GS: SFHS does not focus on gene:environment interactions, and is not powered for this*" (p7/9). The authors note that the focus in Generation Scotland is therefore "*to identify genetic variants of moderate rather than large (likely to be already discovered) or small (unlikely to be detectable by this approach) effect sizes.*" (p 7/9) (authors' emphasis).

The smaller size and familial nature of GS:SFHS are accompanied by some other features. The focus on cognitive function and mental illness is complementary to UK Biobank. The smaller sample size in GS:SFHS allows time to be taken to collect complex information such as cognitive function which is more difficult to carry out in the 'production line' approach adopted by UK Biobank requiring rapid collection of information from a large number of people. The availability of family data allows not only the ability to carry out statistical calculations based on family information but also to obtain information on larger areas of the genome that tend to be inherited as 'chunks' (haplotypes) and to provide information on imprinted genes (e.g. where the effect of a gene will depend on whether it is inherited from the mother or the father).

A second strand of opinion difference relates to whether a biobank could be constructed from combining several existing longitudinal collections (e.g. Willett *et al.* 2007) or whether it requires a *de novo* collection (e.g. Collins and Manolio, 2007) with the expense and time lag that this entails. The reasons suggested for needing a new collection include the difficulty of combining data collected in a variety of different ways in existing collections. Whilst this remains an area of scientific dispute, both UK Biobank and Generation Scotland involve developing new collections.

The potential for developing pharmacogenomics ('personalised medicine') forms an important context for the development of biobanks. The prospects of individual treatment however appear to have been de-emphasised in favour of treatments of similar groups (

individuals. Stratification of disease treatment on the basis of genetic information is already taking place, for example use of the drug Herceptin to treat breast cancer depending on the presence of specific markers on the tumour that indicate it will be susceptible to the treatment. Thus, treatments are being targeted to specific groups of individuals according to genetic markers rather than being targeted to specific individuals.

#### **5.2.4 Literature review**

The early development of population biobanks in the late 1990s and early 2000s took place during a time of controversy over the Icelandic Health Sector Database (the Health Sector Database Act was passed in 1998, Gertz 2004), as well as the very public debate over GM crops, which came to a head with the UK in the '*GM Nation?*' public debate in 2003. The nature of biobank development in the UK is to some extent a product of this background of caution over developments in genetics. In 2000, the House of Lords produced its seminal report *Science and Society* (House of Lords, 2000) advocating public engagement in areas of contentious science. Combining this call for increased engagement with the existing emphasis on consent within medicine, it is therefore not surprising that the relationship with participants (and public engagement to guide the terms of this participation) has been a major focus in the literature. A second theme has also emerged that questions the legitimacy of the biobank concept. Finally, a third theme explores the 'drivers' and visions for biobanks.

##### **i) Relationship with participants**

The issue of 'consent' to participate in biobanks has become central to debates. One of the main contentious issues was the 'presumed consent' of the Icelandic Health Sector Database (one part of the Icelandic biobank) and the assumption that the whole population was automatically included unless they specifically 'opted out'. The presumed consent raised a number of difficult issues, not least whether it was possible to 'opt out' on behalf of dead relatives (Gertz, 2004). The controversy raised by the original presumed consent in Iceland has meant that the requirement to opt-in to the projects has become standard (e.g. Sweden, Estonia and UK). Although in these countries a model of individual

consent is appropriate, this may not be so in other cultures e.g. a proposed biobank in Tonga in collaboration with an Australian company Autogen failed, reportedly partly because the consent procedures did not involve the extended family in decision making as would be the norm in that culture (e.g. Maschke, 2005). Similarly, Scott *et al.* (2005) suggest that in the context of Maori culture, biobanks raise specific issues around ancestors and relationships with them.

Hoeyer (2005) from his detailed examination of the Swedish UmanGenomics biobank, suggests that ethics became reduced to a contractual relationship reliant on individual consent and relating to the use and ownership of data. Ethical issues became construed as a conflict between individual and societal benefits and so the solution became the provision of information to the individual in the context of consent procedures. An individual could choose to participate or not and so all potential conflicts were resolved by that individuals' decision. From the perspective of this thesis the discussion became one of balancing interests based on individual decisions.

The importance of also taking into account innovators' viewpoints has been highlighted in the accounts by Rose (2003) and Hoeyer (2004) of the failure of UmanGenomics. Marketed as an ethical database, the enterprise failed largely due to disputes over allocation of intellectual property (IP) rights (particularly relating to University staff), difficulties matching its ethical ownership model with IP requirements of a successful venture, disputes over the role that the people who established the biobank should have in the new venture and failure of the marketing plan with subsequent expensive re-directing of scientific activity. Whilst the causes of failure of this enterprise were complex (and explored in more detail by Hoeyer, 2004) nevertheless, the example highlights the potential consequences of failing to take all relevant stakeholders into account, including the innovators.

The future outputs from biobanks are uncertain. Thus, consent to contribute to a biobank is essentially consent to participate in the research rather than being 'informed' about the research, the direction of which is as yet unclear. Thus the focus of social science research has shifted to understanding participant views and attitudes on different aspects



of control of data and in particular trust. Levitt and Weldon (2005) found deep cynicism around trust in institutions in a series of focus groups in the UK. Focus group participants felt (based on their previous experiences with other types of personal information) that information given to one body would inevitably travel elsewhere. The cynicism was not restricted to specific institutions but was more wide-spread "*Genetic information will not be used to benefit individuals because no-one will have an interest in doing so*" (p316). Levitt and Weldon make a link between trusted institutions and individual values, suggesting that individuals tend to trust organisations that appear to promote their values by the actions the organisations take. This is consistent with the evidence from risk-related issues referred to in Chapter two (Earle, 2004). In the case of biobanks, however, the information will be of interest to numerous organisations which are likely to have different motivations for action and are thus likely to promote a range of values. Since prospective participants cannot evaluate their agreement with the motivations of these organisations, the focus of trust is likely to be on the biobank organisation and the management and governance arrangements around access to data and the values that these are seen to promote.

Participant concerns about the loss of control implied by commercial access to biobanks have been identified by Hoeyer (2005) and Haddow *et al.* (2007). Haddow & Cunningham-Burley (2010) used discrete choice experiments to determine the strength of opinion of likely participants to commercial access (and other aspects of biobanking). They found that whilst commercial access was a concern and needed careful handling, the main barriers to participation were linked to the participant's interest, motivation or time available to take part.

The term 'participant' used to describe those contributing material to biobanks has been critiqued by some (e.g. Tutton 2007, Winickoff, 2007) who advocate a direct and ongoing input into governance, for example through a participant panel. Thus their role could move from passive participants who merely give consent, to active participants who take part in shaping the future uses of the biobanks. However, Haddow & Cunningham-Burley's findings (2010) indicating lack of time and motivation as key barriers to participation

suggest that it may be unrealistic to expect many participants to be engaged at deeper levels with the governance of biobanks.

## **ii) Legitimacy of the biobank concept**

Some researchers have queried whether the whole basis of the biobank concept has ever been subject to rigorous debate. Levitt (2005) argues that the public have never been asked fundamental questions such as the priorities given to commercial research versus the public interest, the likelihood of benefits versus other possible uses of the resources and the content of regulations and who should be enforcing the regulation. Similarly, Hoeyer and Tutton (2005) suggest public consultation exercises have sought to legitimate decisions that have already been made rather than engage citizens and enable them to shape the biobank. Wallace from GeneWatch (a UK advocacy group critical of genetic technologies) notes (2005) there were no extensive debates in parliament over the setting up of UK Biobank, a critique shared by Busby and Martin (2006).

The work of ethical committees associated with biobanks has also come under examination. Hoeyer and Tutton (2005) are critical of the debates by ethics committees associated with the biobanks for failing to ask wider questions about the purpose of the biobanks *"ethics is not used to initiate debate about the purposes of UK Biobank...What is it about the language of ethics that makes it difficult to ask whose health, prosperity and benefit?"* (p393). Salter and Jones (2005) make similar points suggesting that ethics committees of biobanks are dominated by people from the medical, science and legal professions:

*"rather than being informed by human values orientation that could respond to citizen concerns about biotechnology, the medical, science and legal professions are more likely to map their orientation directly on the regulatory process and resist the precautionary values that characterize citizen discourses oppositional to biotechnology"* (p728).

Thus, Salter and Jones argue that those people currently charged with the ethical oversight of biobanks are not the appropriate people to conduct these evaluations.

Ashcroft (2003) highlights the complexity of the task given to Research Ethics Committees more generally within the governance of medicine in the UK:

*“Far from the classical sense of regulation which defines a commonly agreed goal, and draws up a regime and authority to ensure that private activity tends in that direction, here the regulators are not sure what the goal is.” (p56)*

Ashcroft further highlights the ambiguity that exists in Research Ethics Committees in having to balance ethical reflection with acting as a gatekeeper to research and the concomitant need for justice for researchers (who need a rapid, fair and consistent approach to ethics) and furthermore some questions will be outwith their competence. Ashcroft notes that as a consequence

*“What may be overlooked is the way any research constructs worlds, re-orders societies, reinforces or disrupts systems of power and influence, and does all this in ways that can be hard to foresee or predict”. (p45)*

Addressing the issue of whether biobanks should be established or not, is unlikely once the decision has been made to go ahead with a project and the funding has been promised. There is then a commitment to that project, and it is no surprise at that stage if public engagement activities and ethical reflection focus on the best way of realising that ambition rather than asking whether it should proceed or not. There does seem to be an ongoing commitment to public engagement and ethical reflection in UK Biobank, for example the Ethics and Governance Council has initiated research on public attitudes to UK Biobank's access policy, in particular relating to commercial access. It remains to be seen how responsive the biobanks will be to challenges from any such future research. Commitments to public engagement will also be influenced by the availability of funding for this purpose

### **iii) 'Visions' for biobanks**

Rather than critique the basis on which biobanks have been set up, another strand of research has analysed the 'visions' of those developing biobanks. Biobanks are linked to

specific visions, particularly the promise of better health for citizens and the promise of commercial benefits from the research resource (Haddow *et al.* 2007).

As noted earlier, one 'vision' for biobanks has been personalised medicine (section 5.2.3). Mitchell and Waldby (2009) focus on the potential outputs from biobank research and link these to the potential from pharmacogenomics. They suggest that biobanks will expand the market for diagnostics but also for preventative drugs, by identifying a new societal category, 'the future ill'. Mitchell and Waldby's analysis repeats the tension that runs through discussion on biobanks; the importance of the genetic component vis-a-vis the environmental impact. The 'vision' analysed by Mitchell and Waldby is relatively unformed; diagnostics, risk calculations and preventative drugs are not a major component of health care as yet and their future adoption remains to be seen.

Another vision concerns the concept of nationhood. The association of a biobank with nationhood is a point of departure when moving from a small, single disease biobank to one with national coverage. The link between national identity and biobanks has been made clearly in the case of the Estonian and Icelandic biobanks. The proponents of the Iceland project emphasised the composition of the gene pool of Icelandic people and linked it to the self-understanding of Icelandic people as a nation. However, emphasis on the purity and uniformity of Icelanders has resulted in their genetic uniformity becoming contested, with different geneticists coming up with somewhat different data. (Thorgeirsdottir, 2004)

The Estonian national identity (according to Tammpuu, 2004) appears to be strongly affected by Estonia's post-Soviet transition. Initiators and proponents of the Estonian Genome Project have referred to it as the 'Estonian Nokia' to draw a comparison with Estonia's Finnish neighbour (a country with which Estonia shares linguistic and cultural links) and home of Nokia, a leading telecommunications company that has been regarded (according to Tammpuu) as a national symbol of Finland, recognised worldwide. The Estonian Genome Project is also seen as part of Estonia's 'Return to the West' and evidence of a post-communist success story.

*“Such a framing and contextualisation ...has attributed to the genome project a meaning of a national venture that calls for joint efforts and provides a common point of reference for identification” (Tammpuu 2004, p205).*

Busby and Martin (2006) develop this theme of national identity and suggest that in many cases of genetic research, the notion of belonging to a particular group or imagined community (region or nation) is invoked as part of the process of creating a vision for the project. This group may be a nation or a region within a nation or an institution (such as the UK's NHS) that in some ways symbolises national identity.

Thus, whilst there has been some examination of ‘visions’ for biobanks, the literature has mainly engaged with consent procedures, access to data from biobanks and a general unease about whether emphasis on genetics research has been fully, publicly legitimated. The literature suggests use of a range of values-based and interests-based arguments. I will now turn to a more detailed analysis of these arguments based on empirical data collected for this case study, as outlined in Chapter three.

In the next section I will provide a brief portrait of the different stakeholder communities involved around biobanks and the main values-based and interests-based arguments advanced by them. I will use the structure and data collection and analysis methods outlined in Chapter 3 and consider innovation communities and citizens/civil society advocacy groups in turn before considering the responses of policy makers/regulators.

### **5.3 Innovation communities**

The first group of stakeholders I will consider are the innovation communities. These communities are defined by their involvement in creating the ideas and developing the technologies and products that form the basis of the subject being studied. I will firstly seek to describe these communities and secondly to examine the arguments which they make in support of specific developments.

### 5.3.1 Innovation communities described

Relevant members of the scientific community, such as medical and biological research scientists and epidemiologists have an interest in pursuing biobank projects. Biobanks have been publicly framed by innovation communities as research tools to understand the genetics underlying disease processes better, for health monitoring purposes and potentially for the development of improved drugs. A quote from one of the interviewees in the Generation Scotland project captures this common framing of biobanks by researchers *"we are not certain about exactly what the outcomes will be...But it's an experiment that needs to be done because we don't know the answer"* (interview C, geneticist). Research scientists have therefore been at the forefront of developing the biobank concept and both UK Biobank and Generation Scotland are being funded (at least in part) by traditional funders of scientific research (such as the Medical Research Council, the Wellcome Trust and the Scottish Funding Council).

Research scientists have been instrumental in developing the 'vision' for biobanks. The origins of UK Biobank can be traced to 1998 when the Medical Research Council (MRC) provided £12m funding to support the development of DNA collections (Martin, 2001). One of the first impetuses for UK Biobank appears to have been from an industrial research scientist Dr George Poste, then Chief Science and Technology Officer of Smith Kline Beecham, who in a memorandum to the House of Lords Select Committee on Science and Technology in 1999<sup>28</sup> highlighted the potential for NHS records to be used as a research resource.

Both UK Biobank and Generation Scotland were the result of research groups developing competitive bids to obtain funding to set up biobanks. The scientific basis of UK Biobank was initially critiqued e.g. because of concerns that the project may be unable to identify subtle genetic links (Finkelstein *et al.* 2004, Watts 2006). The initial disquiet in the scientific community may have been exacerbated by the timing of funding of UK Biobank.

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<sup>28</sup> Available from: <http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/11/1112.htm> [accessed 7/1/11]

Concurrently the MRC was severely reducing the number of responsive mode grants it could fund. Some in the research community suspected that funds were being committed to UK Biobank rather than responsive mode grants. This was strongly refuted by the MRC who argued that the funds for UK Biobank were specifically ring-fenced for the project. In the words of Professor Sir George Radda (then Chief Executive of the Medical Research Council) to the House of Commons Select Committee on Science and Technology *"That was an earmarked fund from Government to do that programme...So, actually, Biobank money has not come in competition with grants."* Nevertheless, the Select Committee was not convinced and concluded that *"It is not clear to us that Biobank was peer-reviewed and funded on the same basis as any other grant proposal. Our impression is that a scientific case for Biobank has been put together by the funders to support a politically driven project"* (House of Commons Select Committee on Science and Technology, Third Report, 2002, para 58)<sup>29</sup>

As well as promising health benefits, biobanks also create expectations of economic benefit. The pharmaceutical and biotechnology industries have however remained relatively low profile in the development of biobanks so far. The MRC held discussions with the pharmaceutical industry when setting up UK Biobank<sup>30</sup>, and the Generation Scotland project received early support from Scottish Enterprise and commissioned a report from Deloitte Touche on commercialisation prospects (this report, whilst mentioned on the project web site, is not publicly available). There are indications that the low profile of the pharmaceutical industry was a deliberate policy e.g. George Radda when giving evidence to the House of Commons Select Committee on Science and Technology in 2003 is reported as indicating that *"he had had expressions of interest from the*

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<sup>29</sup> Available from <http://www.publications.parliament.uk/pa/cm200203/cmselect/cmsctech/132/13206.htm> [accessed 16/09/08]

<sup>30</sup> Select Committee on Science and Technology. Minutes of Evidence, Examination of witnesses (questions 140-155), Wednesday 4 December 2002, Available from: <http://www.publications.parliament.uk/pa/cmselect/cmsctech/132/2120409> [accessed 16/9/08]

*pharmaceutical industry but that they were holding back because 'too early an involvement from them might jeopardise the programme'*<sup>31</sup>

It is noteworthy that the environmental influences on disease development as well as the genetic aspects have been stressed from early on in the development of UK Biobank. George Radda said in giving evidence to the Select Committee on Science and Technology in 2002 *"Maybe it is heresy to say it, but the study might well show that actually environment is the critical thing"*<sup>32</sup>. This appears to refute the criticisms by advocacy groups such as GeneWatch that biobanks represent an excessive focus on genetic rather than environmental causes of illness (Wallace, 2005).

The wider innovation communities involved in the development of biobanks also include academic and health care researchers. Communities often have multiple roles, however. For example, the pharmaceutical industry is both innovator and also users of the research conducted by the academic research community. The academic research community includes clinicians who have both a healthcare role and a research role. Other health care workers (such as General Practitioners - GPs) are considered users and as such will have an important role in translating any medical advance into a realisable health care benefit but they may also be involved in recruiting participants for the biobanks (as in the case of Generation Scotland). As well as academic scientific researchers, the innovation community includes expertise in data management and security, law and ethics.

Primary health care providers have been engaged in the development of biobanks to some extent, for example health care workers were consulted over the data collection aspects of UK Biobank (Hapgood *et al.* 2001). An article written by scientists closely involved with planning Generation Scotland and the Scottish arm of UK Biobank explores the impact of genetic epidemiological data on primary care (Smith *et al.* 2006a). Both biobanks make direct links to, and stress the value of, data from the NHS.

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<sup>31</sup> House of Commons Select Committee on Science and Technology, Third Report (2003) para 66 <http://www.publications.parliament.uk/pa/cm2002203/cmselect/cmsctech/132/13206.htm> [accessed 16/9/08]

<sup>32</sup> Select Committee on Science and Technology. Minutes of Evidence, Examination of witnesses (questions 140-155), Wednesday 4 December 2002, Available from: <http://www.publications.parliament.uk/pa/cmselect/cmsctech/132/2120409> [accessed 16/9/08]



Generation Scotland gives greater stress to partnership aspects of the project than UK Biobank. Thus, GS:SFHS involves GPs intimately in recruitment unlike UK Biobank. This is described by Smith *et al.* (2006a) p 217 *"There is an important difference between doing research on a population, and doing research with a population"* (authors' emphasis). GPs are described as key links between researchers and participants. The author is a Professor of General Practice and also part of the management team for Generation Scotland. The support of GPs is seen as important not just for ensuring appropriate recruitment but also for consent for use of routinely held data and to maintain trust in Generation Scotland. This is not to imply that UK Biobank is not a partnership but merely to note the difference in emphasis. It is obviously easier for Generation Scotland to work more closely as a partnership due to its smaller scale and more limited geographical spread.

Several interviewees for the Generation Scotland project stressed that genetics is one component to be examined, but only one component. Equally important was the quality of the phenotype information and the biological measurements taken. The importance of working with clinicians as well as geneticists (and the need for due recognition to the whole team) to collect phenotypic information was expressed in the interviews e.g.

*"...there would be a genius in [sic] a molecular biologist and a genius as a statistician first and last also, and in the middle there'd be these clinicians. And the comment would always be 'well all they did was give the tumour sample' or whatever. I think we have to a certain extent get away from that...and value each with the authorship equivalently."* (interview A, geneticist).

Thus, the innovation community consists of a complex network of academic scientific researchers, clinicians, geneticists and specialists in other pertinent areas. GPs and healthcare workers are sometimes viewed as being part of the 'innovation community' but their particular contribution appears to be restricted in the context of the biobanks considered largely to that of users. The pharmaceutical industry is seen as a key source of innovation in the future but is not immediately visible during the current development phase of the biobanks, although it may have a more subtle influence on developments.

The complex range of innovation communities is an indicator of the changing nature of the production of scientific knowledge, with tighter integration of different specialisms and therefore bigger and multiple communities. In the next section I will restrict consideration of values and interests based motivations primarily to the scientific and medical research communities as the main current drivers of innovation in this area. Innovation communities are only one of the dimensions to be considered and in later sections I will turn to considering civil society advocacy groups and citizens views.

### **5.3.2 Interests-based and values-based arguments by innovation communities**

Having described the communities, I will now examine the arguments made for and against biobanks by innovation communities, based on the extent to which they are values-based or interests-based. As detailed in Chapter three, the basis I have used for discriminating between these two is essentially pragmatic. Values involve explicit reference to values or normative judgements or any underlying principles that can be inferred. Interests refer to balancing between different groups or protecting the interests of specific groups or reference to risk:benefit or cost:benefit implying some degree of negotiability. Interests may be underpinned by broader values. For example expectations of health benefits rely on an underlying value-judgement about the health benefits from genetic knowledge.

Before disaggregating interview data into component arguments, it is useful to consider the interviews as a whole. Two examples from the Generation Scotland project are given, one using a preponderance of interests-based arguments (Figure 5.1) and the other a preponderance of a single value argument, the appeal to Scottish national identity (Figure 5.2). Interview transcripts in each case have been summarised in a cognitive map, as described in detail in Chapter three. To recapitulate, maps are based on the following conventions:

- Cognitive maps - consist of 'nodes' or 'concepts', joined by 'links'.
- Concepts - are expressed as short statements, each covering a single idea or notion. These concepts are numbered for ready identification. The numbers do not imply any sequence.
- Links - concepts are linked by arrows indicating a causal link, i.e. A is seen as leading to B. Links act in the direction of the arrow and are positive except where a negative sign is attached to the causal link, in which case the link is negative.

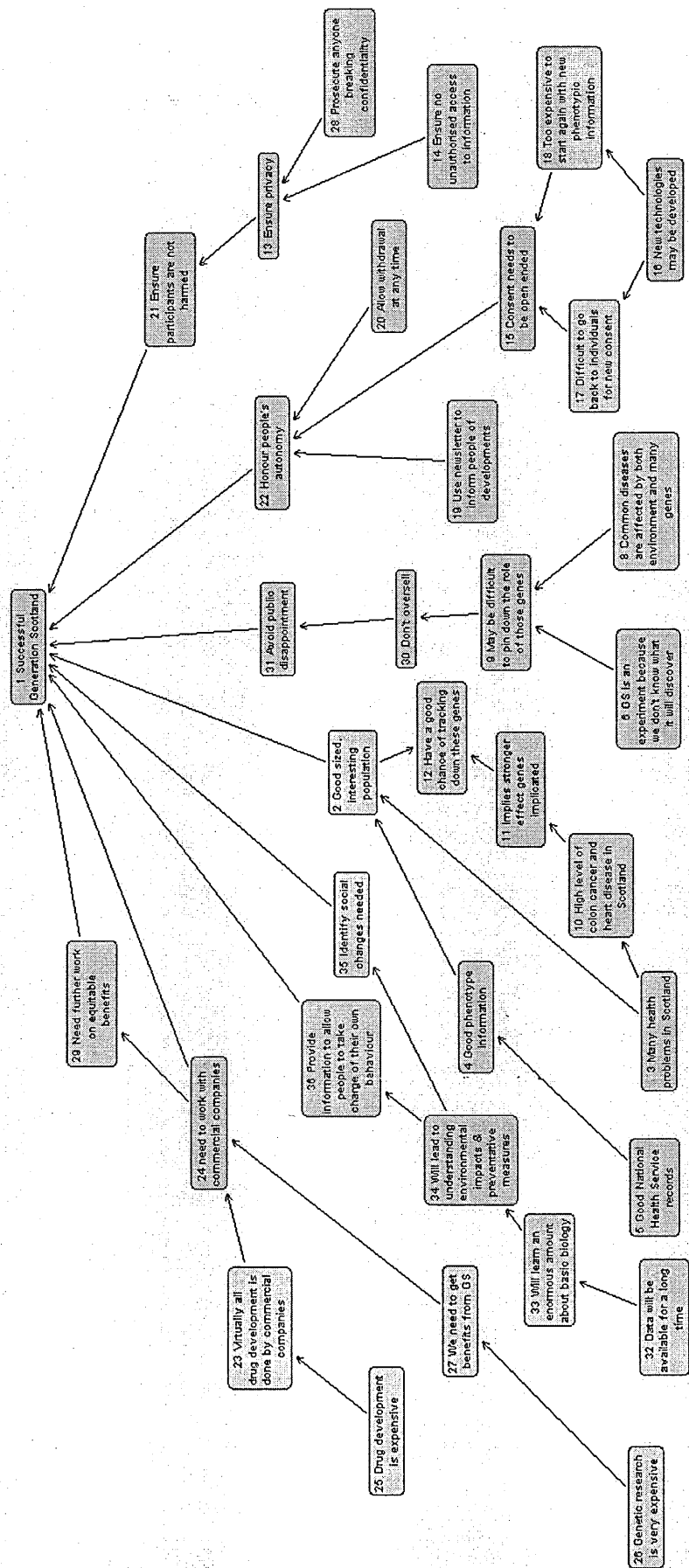
In each case the main aim is to achieve a successful Generation Scotland (GS) project. In Figure 5.1 the context is an interviewee (interviewee C, a geneticist) who frames Generation Scotland as a valuable research tool which has the potential to provide population benefits in the longer-term and in which it is critical to protect the interests of the participants. Concepts 23-27 indicate commercial benefits are a significant driver (although with equity and justice – concept 29). There is an important element of protecting participants from harm (non-maleficence) as indicated in concepts 13, 14, 21 and 28. Individual autonomy is to be respected (concepts 15-20 & 22). Non-genetic benefits which may arise from biobanks are identified in concepts 32-36 including both individual behavioural changes and wider social changes needed. Concepts 2-5 cover arguments as to why Scotland is a good place in which to develop a biobank and the remainder of the concepts identify benefits of biobanks (supporting the value of beneficence) such as increased understanding of biology (concept 33) but also recognising that these benefits should not be oversold (concept 30). Whilst the arguments are predominantly interests-based, stressing commercial benefits and protecting participants from harm, there are underpinning values which are also expressed. The interviewee, as a clinical geneticist, would be expected to be well versed in the medical ethical principles of autonomy, justice, beneficence and non-maleficence, (Beauchamp & Childress, 1979) so it is perhaps not surprising that these values feature as underpinning arguments.

Figure 5.2 reproduces a cognitive map of an interview where the Scottish dimensions were stressed. This Interviewee (interviewee A, a geneticist) views the success of Generation Scotland as dependent on two factors; the ability to obtain good phenotypes (concept 6) and maintaining a positive public image (concept 7). Again, although this example is given as a predominantly values-based argument, there are also elements of interests-based arguments incorporated within it, such as the desire for the uptake of research results for industrial benefit. It is noteworthy that for both these interviewees examined here, industrial benefits are considered important, even though industry has not been explicitly involved in the development of Generation Scotland.

The positive public image of Generation Scotland benefits from involving local people who are known and trusted (concepts 12, 13 & 18). The biobank is for the benefit of Scottish health (concepts 11 & 22) and used to drive Scottish industry (concepts 19 & 34). Furthermore, Scottish academics are viewed positively by the public (concept 10). Local people could be recruited as partners to raise funding for the biobank (20 & 21).

From this perspective, good phenotypes are important and can be obtained because of good NHS records in Scotland that allow family historical data to be obtained (concepts 5, 14, 15 & 8). The perspective goes on to emphasise that clinicians need to be fully involved in collecting phenotypes (concept 16), this means their contribution has to be valued (concept 16) being aware that the Research Assessment Exercise (RAE) inhibits this (concept 30) and it may be difficult for small teams to give up their time to contribute to Generation Scotland (concept 32). However, clinicians across Scotland are networked (concept 17) which will counteract these difficulties. From this interviewee's perspective, Scottishness becomes important not only because there is a sense of national identity but also the value of localness and the high store that people place on personal contacts: these are the people you trust.

Figure 5.1 Cognitive map of interview C (geneticist) highlighting preponderance of interests-based arguments





### **5.3.3 Interests-based arguments of innovation communities**

Although it is instructive to examine the whole argument advanced by stakeholders, the intention of this thesis is primarily to examine arguments advanced by innovation communities and to ascertain the extent to which they can be perceived as interests-based or values-based. Innovation communities are found to articulate a number of interests-based arguments related to the running of the biobanks. These are broadly grouped under the following headings:

- Who should have access to data and materials in the biobanks?
- How should the issue of participant consent be addressed?
- How are benefits to be shared?

Each will now be considered in turn.

#### **i) Who should have access to the data and materials?**

Biobanks are predicated on the understanding that the information (data and potentially biological materials) should be made available to innovators who have an interest in making use of them. However, access issues raise questions about protecting the individual participants from harm (maintaining confidentiality, avoiding research that could amplify prejudice). One of the most problematic issues arising from biobanks is whether it is in the interests of individual participants to receive pertinent information about their propensity to develop a disease, uncovered by research based on the biobanks. The general principles applied have been that people have the right to know genetic information about themselves but also have a right not to know. UK Biobank and Generation Scotland have come up with slightly different strategies for feeding back information. UK Biobank will provide participants basic physical measurements (such as blood pressure and body mass index), in Generation Scotland: SFHS participants are also provided with basic physical information and given the option of feedback being sent to their GP. In neither case, however, is genetic information given to participants.

An associated question is which other groups should be allowed access to biobank data and under what conditions. As one Generation Scotland project interviewee put it:

*“there are real concerns about things like privacy and ensuring that there’s no unauthorised access to the information...we do feel that there are almost bound to be some mistakes or misuses and that what we have to try to do before we set out on anything like this is to ensure that people can’t suffer from any disclosures which are not really permitted”* (interview C, geneticist).

Key issues revolve around access by research groups that could potentially produce new knowledge from the analysis of biobank data, including from overseas and commercial companies. Increasingly there will be issues around linking a specific biobank to other databases, including those not directly associated with health, such as information from use of supermarket loyalty cards. There are also examples of international initiatives to link biobanks across the world more closely together. For example, the European Commission is funding a project to collate biomedical data collected in the EU (Biobanking and Biomolecular Resources Research Infrastructure)<sup>33</sup>. An international project, P<sup>3</sup>G, has also been established<sup>34</sup> to develop research tools for collaboration between biobanks. This initiative started in 2007 and includes a number of actions that increase the possibility of sharing data internationally between biobanks in ways that will increase the statistical power to identify important causal links (Knoppers *et al.* 2008). These developments could potentially increase the possibilities for using data collected in ways that could serve societal interests but also again highlights the requirement for managing biobanks in ways that continue to have the support of the original participants.

Other issues revolve around groups such as insurance companies whose interests could be served by access to the information, but potentially to the detriment of the interests of participants. As one interviewee put it:

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<sup>33</sup> Available from <http://www.bmri.eu/about.htm> [accessed 19/09/08]

<sup>34</sup> Available from <http://www.p3consortium.org/about.cfm> [accessed 17/09/08]



*"This is a balancing exercise...there's an interest in not having facts about oneself put into the public domain. At the same time there's a very strong community interest, public good interest as you might put it, in the sort of research which requires that we give up that information, obviously preferably in an anonymised form and I think that you balance those two, in my view you can make a strong case, and a defensible case, a case which the public ultimately understand, for the public good, justifying the surrender of personal information, as long as that surrender is protected by an adequate regime of confidentiality."* (interview I, lawyer/bioethicist).

In a similar vein, another interviewee (interview B, specialist in public health) described donations to a biobank in the context of viewing the NHS as a social contract where treatment is provided for individuals who in turn provide the information to improve treatments, although the interviewee also acknowledged that this relationship was beginning to break down because in their view people are starting to feel exploited by commercial companies.

The fear of potential genetic stigmatisation affecting participants' interests was rejected by some of the interviewees. For example, one specialist (interview D, specialist in insurance) was clear that insurance companies would not seek this type of information as it would not add much to risk estimates based on family phenotypic information. Another suggested that the concern was unnecessary and related to an understanding of monogenic diseases rather than multifactorial ones and failing to appreciate the difference between biobanks and pre-symptomatic genetic testing.

*"we're talking databases here, we're not talking pre-symptomatic testing, but most of the fear comes from being labelled as being 'you're from the north of Scotland, you must have that weirdo disease...because before monogenic meant those weird families with those weird diseases, now that we find out that everybody is at risk of something...I think we're in a time warp here and that this idea of stigmatisation is a fear that that we have but that might not really come to life, it's a precautionary kind of concern."* (interview E, lawyer/bioethicist).

Arguments around access to biobank data thus have a strong element of balancing between different interests - balancing the interests of individuals in retaining control of personal genetic information against community interest in research that involves giving up this interest. A value underpinning this balancing of interests is the principle of justice.

As suggested by Haddow *et al.* (2007) potential participants did trust bodies to look after the data but this trust was conditional. Technology may also open up new threats, such as the recent discovery that individuals can be identified from pooled data (Homer *et al.* 2008). Holders of current publicly available health-related databases have acted swiftly to stop access to this type of data (Couzin, 2008) but the implications of this development are not clear. The risk to individuals is said to be small because information on the person you are looking for is needed before the person could be found. However, this incident demonstrates how new challenges to the security of biobanks may come about. Commercial access is also yet to be tested and the way in which this is negotiated is likely to have a big impact both on the public acceptability of biobanks but also the ability of commercial companies to benefit appropriately from them.

## **ii) How should issues of consent be dealt with?**

Consent procedures were originally developed to protect participants in medical research from physical harm, as outlined by an interviewee for the Generation Scotland project:

*“the right to withdraw historically developed under the Nuremberg principles after the second world war where it was clear that there was coercive participation in many cases quite appalling research and so that has always been a cornerstone of the ethical regulation of research. Of course it’s been developed through in the context of physical participation of people who participate in drug trials and other procedures and it’s tended not to focus on the processing of information beyond this physical process. So the whole right to withdraw, the strength of the right to withdraw has emerged from the fact that it’s a right to say physically don’t touch me. It’s more complicated when it’s information about you which is being crunched by computers or whatever” (interview I, lawyer/bioethicist).*

The principle of 'informed consent' has become a basic tenet of medical research.

However, there remain a number of difficult issues around informed consent to participate in biobanks. Because biobanks are a long-term resource for a range of different (undefined) research projects consent cannot be for a specific type of research at the start of the project. Renewing consent for each specific research project would be logistically extremely difficult as well as potentially annoying to participants. This is exemplified by the following quote from a specialist:

*"We have an idea about what we can do with DNA and possibly establish cell lines from individuals at the moment but that might change and there might be very different technologies developed and it would be very, very difficult to go back and say to every individual, can we have your consent again to carry out a slightly different protocol on your material"* (interview C, geneticist).

This means that any consent obtained at the start of the project, to protect the interests of participants, cannot be 'informed', by the nature of research in biobanks. The quote above also highlights the possibility of new developments affecting the running of the biobanks, so that, for example cell lines could be established from the biological material placed in the biobanks, for legitimate research purposes. However, the prospect of being able to establish clones from cell lines makes this potentially more problematic, particularly as citizens are generally very concerned about any prospect of human reproductive cloning (which is illegal in the UK), an aspect that was already highlighted in section 4.5.1.

Because defining all research in advance is impossible, there has been a pragmatic need to reconceptualise 'consent' as consent to participate in the project rather than consent for a specific piece of research into a particular disease. Once information based on data provided by participants has been used in analyses, it may be too late to withdraw consent. Measures have been taken to try and honour the consent that has been given and to ensure continued confidence and support for the biobanks. Both UK Biobank and Generation Scotland allow participants to withdraw from the project at any time but (in the words of one interviewee) the right to withdraw

*“from a project which is using information which is fairly far down the line is difficult...Because there you see you’ve got another set of interests which come into existence, in other words the work done by the researchers”.* (interview I, lawyer/bioethicist).

In the case of UK Biobank for example, the right to withdraw is linked to a ‘no further use’ clause i.e. that UK Biobank undertakes not to make any further use of the data. However, due to the structure of the biobank and the need for audit and archiving there is no undertaking given to participants that all the data pertinent to them will be removed from the biobank (Laurie *et al.* 2009).

Further measures suggested by the Generation Scotland interviewees included more openness about biobank activities so that citizens can ensure their interests are being protected, that the project is being kept accountable and that there are publicly identifiable persons who are held responsible for the conduct of the biobank. Both biobanks appear to have made some response to comments about the need for openness. Early participants in both of the biobanks have been given questionnaires on completing their assessment visit. Whilst the main objective has been to smooth the data collection process, it has provided an opportunity for participants to comment on their specific experience. There has therefore been some limited opportunity for participants to contribute to shaping of the biobanks as well as to improve ‘customer satisfaction’. Additional periodic open meetings have also been held by both projects to allow people to hear more about the project and to ask questions about them. Finally, both projects have material publicly available on web sites, including minutes of the ‘ethics committees’ meetings (Ethics and Governance Council for UK Biobank and Advisory Board for Generation Scotland).

As well as avoiding coercion by directly consenting to participate in the biobank, other more subtle forms of coercion may exist. For example one of the interviewees suggested *“When people receive a request from their GP they sometimes feel obliged to participate in order to stay in the good graces. It’s not direct coercion but it’s indirect”* (interview E, lawyer/bioethicist). In UK biobank, contacts are made through the biobank itself rather

than through a request from a GP which may redress this issue to some extent. This criticism might however apply to Generation Scotland recruitment.

The analysis so far suggests that balancing the interests of participants and researchers is inherently negotiable, although different people may arrive at a different acceptable balance. The underlying value basis here is the principle of autonomy, allowing people to make their own decisions.

### **iii) How are benefits to be shared?**

Biobanks are publicly funded initiatives relying on voluntary public donations of biological material and data in the expectation of benefits. One of the 'balancing' acts required is therefore the balance between enabling development of therapies by allowing access to commercial companies but avoiding exploitation by the same companies or development of therapies which will not be to the benefit of the participants, wider society nor funders (e.g. therapies which are too expensive to be made available by the NHS). This balancing act is made more difficult because it may well be future generations that will benefit from this work.

One conceptualisation is to view participants as owning some of the intellectual content of their genetic data but generally this view has been rejected or balanced out by the view that genetic data should contribute to the common good and that therefore the ownership of the genetic data should be under some form of public control. The need for intellectual property protection in order to ensure involvement of commerce has been generally accepted (even if intellectual property raised problematic issues for some) and the involvement of commerce is accepted as 'a necessary evil' for the development of drugs.

The proposal that a share of any income generated should accrue to either to the NHS or a health-related charity is strongly supported (Haddow *et al.* 2007). But as one of the interviewees for the Generation Scotland project noted this is not straightforward because of the difficulty of determining the

*"precise role of the contribution of knowledge attained from this database and assess its input to the final value of the product when held against other bits of*

*knowledge which go into the creation of the value of that product...I don't think one can necessarily make glib statement about benefit sharing without appreciating the difficulty of translating that into formulae" (interview I, lawyer/bioethicist).*

An alternative method suggested for balancing these interests is charging differentially for access but again a fine balancing of interests is advocated

*"You would want also to have a system which didn't inhibit people unduly from using it. Clearly this is meant to be used and it's meant to be accessible and you wouldn't want to put people off from using it." (interview I, lawyer/bioethicist).*

As the biobanks are (at the time of writing) still in their data collection phases the problematic issues of benefit sharing and just distribution of any benefits are still somewhat theoretical but they are likely to become increasingly important in the future.

The above summary identified the arguments that were negotiable and therefore were categorised as interests-based. However there were also a number of more fundamental values that were expressed and it is to these that I now turn.

#### **5.3.4 Values based arguments of innovation communities**

Values were identified as likely to underlie several of the interest-based arguments described in the previous section. Hence values such as autonomy, justice and doing good to others (beneficence) were found to be important factors in stakeholder interactions around biobanks. There are a number of other values-based arguments that can also be empirically identified. My data emphasise the following values-based arguments:

- The inherent value of conducting research and increasing knowledge
- The value of health-related research
- The appeal to national identity.

All of these are supportive to the development of biobanks and will be considered further in the next section.

### **iii) Inherent value of research**

For many scientists there is an inherent value in undertaking research e.g.

*"I think any research that leads us to understand clinical disease better, to be able to diagnose it, prognosticate with it and eventually treat it, is useful...I think we have to continue to underpin the future of applied research with good basic research"*  
(interview A, geneticist).

This is part of what scientists do and the view was reflected in several of the interviews in the Generation Scotland project. Research scientists may of course also have a self-interest in their pursuit of research but many appear genuinely to be driven by the value of gaining knowledge.

### **iv) Inherent value of health-related research**

Health research is widely held to be a benefit and valued as such by interviewees. However, a number of issues have been raised concerning the direction and balance of the research, for example expressed in the following quote (from a lawyer)

*"I think I'd be concerned about the obvious issues of establishing satisfactory ethical and legal framework, in order to avoid any substantial public disquiet, in order to avoid public misunderstandings...But I'm also concerned that ethical niceties should not stop people using this sort of database in a productive fashion."*  
(interview I, lawyer/bioethicist).

Specific issues raised during the Generation Scotland project interviews included the following.

- The need for health research to also include lower profile, high impact research and not just high profile work such as the biobanks.
- Excessive focus in medical research on diseases of affluence from which profits can be made.

- Concern with how much society can afford to spend on health care “*Because there seem to be limitless possibilities in terms of pursuing the problem*” (interview C, geneticist).

A number of specific areas of research were also identified as being potentially of concern. Research on behavioural genetics in areas such as homosexuality, aggression and genetics of personality disorders was thought to be particularly sensitive. Research on genetics of mental illness was held to be acceptable by some although others noted that there is a general denial of mental health problems so that information on genetic predisposition may provide unwelcome information. Thus, while the value of medical research was upheld, the interviewees recognised that not all research would be in the interests of wider society.

The inherent value of research is often linked with valuing economic progress, so that research is seen as the first step to economic growth. Again this may be held as an underpinning value but it can also reflect interests that protagonists may have in ensuring continuing economic growth or it may be primarily a device for attracting a positive funding response from policy makers.

There was also some tension reported within the innovation communities for example between geneticists and public health specialists (Halliday *et al.* 2004) in part due to the ‘hype’ that has been perceived to be part of the genetics discourse and the resultant over-optimistic claims for what genetics can contribute to intervening in these common, complex diseases. However, this tension did not negate the positive value of health research but rather indicates a dispute over the most useful forms of research. UK Biobank with its emphasis on environmental factors appears to be less challenged by this criticism of excessive focus on genetics than Generation Scotland with its greater emphasis on genetic information might be.

#### **v) National identity**

The value of nationhood has not been invoked by UK Biobank, except in so far as it is perceived to be associated with the NHS. As noted earlier, Busby and Martin (2006)



suggest that the NHS invokes a sense of national identity. However, national identity has been reflected in some of the discussions around Generation Scotland. It is argued that Generation Scotland will be good for Scottish health, for the Scottish biotechnology industry and for providing high value jobs. Smith *et al.* 2006b argue for conducting GS: SFHS in Scotland due to:

- High prevalence of diseases in Scotland
- High prevalence of lifestyle risk factors
- Relatively stable population, facilitating follow-up of participants.

### **5.3.6 Conclusions on innovation communities**

These data illustrate that innovation communities articulate strong interests-based arguments in favour of the development of biobanks, although there are different views about the best way of using resources for health research, particularly over the degree of emphasis on genetics. There are arguments advanced for the best way of balancing the interests of the various stakeholders, participants, patients, citizens and innovators. There has been less overt discussion of how biobanks can be used to meet specific policy objectives, but it is likely that these will be defined by the funding of specific research projects that rely on the biobank information. As provision of a valuable research resource, biobanks are congruent with both the values and interests of the relevant research community. I will now turn to consider civil society stakeholders.

## **5.4 Citizens/ civil society advocacy groups**

Data on values and interests of civil society groups and citizens were obtained from published consultations, survey data, attending public meetings and ten focus groups conducted as part of the Generation Scotland project. Information on civil society groups was obtained from their published literature and statements. There is a blurred distinction between public consultations conducted by specialist organisations and public engagement as part of research projects. Because of the considerable overlap between

research and consultation, many of the results from consultations that were framed in the context of research, have already been considered in the literature review in section 5.2.4.

Both UK Biobank and Generation Scotland conducted targeted consultations with public groups in advance of data collection (e.g. table 5.1) and appear to indicate their intention to continue to consult as and when appropriate. Table 5.1 summarises the main public consultations conducted with respect to UK Biobank and Generation Scotland.

**Table 5.1 Public consultations conducted with respect to UK Biobank and Generation Scotland**

Consultation	Reference	Date	Sample
Human sample collection	Cragg Ross Dawson, 2000 (for The Wellcome Trust & MRC)	2000	16 focus groups and individual in-depth interviews
UK Biobank: A Question of Trust	People, Science & Policy Ltd, 2002 (for MRC & The Wellcome Trust)	March 2002	60 people in 3 reconvened groups
The UK Biobank Ethics Consultation Workshop	The Wellcome Trust, MRC & Department of Health (2002)	April 2002	Workshop with 60 invited individuals from a range of stakeholder groups
UK Biobank consultation on the ethical and governance framework	People, Science & Policy Ltd. (2003) for the Wellcome Trust and MRC	June 2003	Panel of 64 lay people aged 45-69
UK Biobank: Consultation on the Ethics & Governance Framework	Opinion Leader Research Consultation (2003) for UK Biobank	August 2003	Workshop with 39 public and practitioners, and workshop with 14 other stakeholders plus 25 questionnaires plus 4 interviews with MPs
ELSAGEN project	Levitt & Weldon (2005)	Not specified – 2004?	Six focus groups – lay
Transformations in Genetic Subjecthood project	Tutton (2007)	Not specified – 2006?	19 focus groups – lay & professional, two groups mixed
Generation Scotland	Haddow <i>et al.</i> (2006)	2003-2004	17 interviews with specialists, 10 lay focus groups

Table 5.1 demonstrates that a considerable amount of consultation has taken place on the UK Biobank and Generation Scotland.

Patient advocacy groups have been specifically targeted by some of the public consultations and open meetings but otherwise they have not had a high profile during the development of these projects, although they may have had a deeper and less obvious role e.g. one of the interviewees from the Generation Scotland project noted that *"individual organisations which have a very clear stake in scientific work proceeding...sometimes are very impressive and very vocal."* (interview 1, lawyer/bioethicist). In the next section I will examine separately the data relating to citizens, patient advocacy groups and other civil society advocacy groups.

#### **5.4.1 Citizens**

As part of the Generation Scotland project, ten focus groups were undertaken. The views expressed in the focus groups were broadly similar to those expressed by specialists in individual interviews, although varying in degree (Haddow *et al.* 2006). Initial reactions to the proposed Generation Scotland project, with its emphasis on common diseases and families, were positive (Haddow *et al.* 2006). This is consistent with the high ranking that health and relationships have consistently in surveys. For example a UEA/MORI risk survey (Poortinga and Pidgeon, 2003) found health and family scored highest in importance among a range of issues, and furthermore health issues were important to a broad range of individuals as compared to issues such as GM food that were particularly important only to a sub-set of people. We can therefore conclude that the value of medical research is accepted by citizens.

This positive affirmation of medical research could potentially be undermined by use of biobanks for research that was not in the interests of the participants, something that was recognised in the focus groups, for example one respondent raised the potential for use of the biobank for research into chemical warfare *"Who's to say that the database couldn't also be used for chemical warfare?"* (FG5) (Haddow & Cunningham Burley, 2008). Similarly, focus group participants expressed strong, value-based opposition to cloning,

even though this was not part of the proposal for Generation Scotland and would be illegal (Haddow & Cunningham Burley, 2008). Thus, citizens identified a number of potential applications of biobanks that they considered inimical to their values and hence against their interest to be pursued.

Considerable trust was placed in the medical research community by citizens in the Generation Scotland focus groups *"if they are clever enough to be doing this, they should be trusted because who else will be able to help"* (Haddow *et al.* 2006). This importance of continued trust in the researchers was emphasised in a number of the consultations listed in table 5.1. As indicated in the literature review (section 5.2.4), wide-spread cynicism was found in some consultations (Levitt and Weldon, 2005), in stark contrast to the degree of trust expressed in the above focus group quote. These differences may relate to the specific context in which discussion is being undertaken; general cynicism may be consistent with trust in a particular circumstance.

The Generation Scotland focus groups indicated that they thought the Generation Scotland biobank was a good use of resources although recognising that benefits were some time in the future and accrue to other people (Haddow *et al.* 2006). In this sense, the biobank was viewed as supporting a general public interest rather than specific individual interests. Consultation around UK Biobank also suggests that despite their initial curiosity in gaining information about themselves, people are able to accept the concept of altruism or wider interests as a motivation for proceeding with the biobank project (People, Science and Policy Ltd, 2002).

Interests-based arguments also focused around access to biobank data by different organisations. In particular, some anxiety was shown about potential stigma if taking part, and access by insurance and pharmaceutical companies. The uncertainty as to what the samples would be used for and who would have access to them caused some concern (Haddow *et al.* 2006): *"I would hate to think that the small amount could be taken and circulated around Britain and various people taking out a dollop here and there. That I would worry about"* (FG9 R2).

The example of sperm donors was given as an example where donations were given in the expectation of anonymity only for donors to be confronted by their offspring years later (FG2) (Haddow *et al.* 2006). Thus an altruistic donation made for the benefit of others turned out not to be in the perceived interests of the donor in the longer-term.

There was an acceptance that the donor would lose control, nevertheless there was an expectation by citizens that the samples would be used for good purposes (Haddow *et al.* 2007)

*"I can see how once you've given up the blood it would be difficult to keep control of what happens to it and so on. But I would hope that there would be ethical safeguards built into you dealing with it and companies would have to meet a certain standard and so on"* (FG4 R1)

Haddow *et al.* (2007) suggest that underlying the concern about access by pharmaceutical companies is not just concern about someone making a profit but also what is done with the profit. So most people in the focus groups felt the benefits from Generation Scotland should go to the community. The privileging of wealth-related interests of a few might impact negatively on some participant's willingness to contribute to biobanks. Haddow *et al.* (2007) conclude *"publics generally accept the commercial realities of research. The underlying unease seems to be the sense that these are pursued at the expense of publics' interests"* (p278). Thus, on the basis of focus groups, the authors deduce that whilst motivations to participate in biobanks are driven by expectations of broader health benefits, these must be realised in ways that are just and reflect the interests of citizens who are expected to contribute materially to the enterprise. Thus, underlying the negotiation of different interests is a strong sense of justice.

Information on general public attitudes to biobanks is also available from survey work. Surveys may be more representative of the population as a whole than focus groups, but may be less able to contextualise attitudes or explain their source or invite people to reflect more on their views. The results from one UK survey involving 3272 interviewees (Sturgis *et al.* 2004) suggested that nearly nine out of ten (86%) people are in favour of

biobanks to better understand human disease but fewer than two out of ten support the use of biobanks to judge suitability for insurance (19%) or getting a job (14%). Thus, this survey re-iterates the findings of focus groups that highlight the importance of the purpose for which the biobank has been established and the control of access to the data. There is little evidence to suggest widespread 'in principle' objections to biobanks. On the contrary there is strong support for medical research and potential for future health benefits.

#### **5.4.2 Patient advocacy groups**

As expected, patient groups exhibit strong interest-based arguments in favour of biobanks. Focus groups consisting of patient support groups recognised that they had additional reasons for contributing to Generation Scotland because of the potential direct benefit (Haddow *et al.* 2007):

*"People have obviously got, when you've got somebody that's got a condition in the family then they're more inclined to help" (FG1, R3).*

Patient groups were also more willing to accept the involvement of pharmaceutical companies (Haddow *et al.* 2007):

*"Let's face it, drugs companies have got to make a profit. They don't make a profit the money's not going to come back round again and back into research. So it's just a big wheel, it's got to be done, you can't turn round and say 'stop making any money'" (FG1 R2).*

Haddow *et al.* 2007 concluded that for patient groups to participate in a biobank such as Generation Scotland (that is explicitly recruiting individuals and siblings) the motivations are largely self interest and health benefits.

#### **5.4.3 Civil society advocacy groups**

The organisation GeneWatch has been particularly vocal in opposing biobanks. Helen Wallace from GeneWatch argues that there are big issues missing from the debate about UK Biobank (Wallace, 2005). She identifies the following missing issues.

- The disputed nature of health benefits from a genetic approach to the prevention and treatment of common diseases (as opposed to non-genetic approaches).
- Scientific challenges to the validity of associations between genes, environmental factors and disease.
- Role of commercial companies, including their role in setting research priorities.
- Ignoring the role of social and economic factors in disease.
- Creating a market for unnecessary pharmaceuticals by geneticisation of health and illness.
- Information is produced that is of wider interest for surveillance and control and potentially of interest to industries such as nuclear and tobacco which some might see as unwelcome.
- Current research priorities are far from optimal and give too little weight to public health intervention activities.

Whilst this list gives a mixture of potentially values-based and interests-based arguments the biggest issue for Wallace seems to be the excessive focus on genetics. This might be an interests-based argument in that she may envisage some appropriate level of genetic research in the context of much more focus on social and environmental factors. However, no attempt is made to define any such level. Her opposition to the creation of biobanks is very strong e.g. her critique of biobank ethics committees in failing to ask fundamental questions about why the biobanks exist in the first place (Wallace 2005). Arguably, then, her criticisms are driven primarily by strong value-based arguments that would be difficult to satisfy except by drastic reduction in research into genetics.

David King from the campaign group Human Genetics Alert has also been sceptical of genetic research (not specific to biobanks) noting for example that "*it is very uncertain whether it [genetic research] can live up to the hype which currently surrounds it.*"<sup>35</sup> He

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<sup>35</sup> Available from <http://www.hgalert.org/topics/geneticshealth/geneticsnhs.html> [accessed 19/11/03]

stresses the complexity of diseases and is critical of the over-emphasis frequently given to genetic causes.

Both of these responses suggest concern by civil society groups that the wider aspects of health should not be ignored by simply focussing on genetics. There is however little evidence of any organized opposition to biobanks in the UK at present.

#### **5.4.4 Conclusions on citizens/civil society advocacy groups**

Citizens emphasise the value of the health benefits expected from the creation of biobanks. Citizens may wish to participate from altruistic motivations, taking part voluntarily, without reward and emphasising other-regarding interests. Altruism is a strong value held by society. Participants do however seek protection from harm or exploitation when participating in biobanks and look for just allocation of future benefits. Patients groups are supportive of biobanks on both an interests basis and on the basis of value of health research. Civil society groups in opposition to biobanks seek to de-emphasise the focus on genetic information in ways that suggest at least some degree of values-based argument.

Having identified the main stakeholder groups and examined the range of values and interests-based arguments used by them, I will now turn to considering the responses of the policy communities.

### **5.5 Policy and regulation**

Biobanks have policy implications partly because of government support for the use of genetic information in both medicine and biotechnology. The UK government indicated its support for the increased use of genetic information in the NHS in the 2003 report '*Our Inheritance, Our Future. Realising the potential of genetics in the NHS*' (Department of Health, 2003). It also promotes the practical outputs from science research in its ten year scientific investment framework for the period 2004-2014 (HM Treasury *et al.* 2004). Moreover, both the Scottish and UK governments are directly (through the Department of Health and Scottish Government) and indirectly (through MRC, Scottish Funding Council and the Northwest Development Agency) involved in funding the biobanks. Furthermore,



the body charged with ensuring public value from Generation Scotland (the Advisory Board) reports to the Scottish Government. We can therefore conclude that policy makers are clearly engaged with both biobanks.

Policy makers and regulators are engaged at a variety of different levels:

- Parliamentary
- Regulatory
- Ethical.

I will consider each of these in turn.

#### **5.5.1 Parliamentary engagement**

Both the Lords and Commons Science and Technology Select Committees have discussed aspects of the UK Biobank (House of Lords 2001, House of Commons 2003). Parliamentarians have engaged with the project, sometimes critically e.g. Dr Ian Gibson MP, who indicated he is an advocate of biobanks, critiqued the design of UK Biobank in 2002 particularly with respect to collection of environmental information (Hansard<sup>36</sup>). He was also concerned that genetic factors should not be over-emphasised noting that *“The data that flow from Biobank need to be balanced with a clear commitment to population-based public health approaches and a strong emphasis on tackling health inequalities”* (Hansard, 3 July 2002 , 367). In a later article in the British Medical Journal (Watts, 2006), Ian Gibson is reported to have changed his views and to now be confident about the design of UK Biobank.

It is difficult to identify whether Parliament has engaged on a values or interests-basis as much of the debate has focused on whether funding UK Biobank has reduced the availability of funding for other research from the Medical Research Council. Some discussion concerns whether UK Biobank should have been funded or not, which suggests a value-based argument (the ‘rightness’ of the project). On the other hand, some arguments proposed alternative emphases (such as Ian Gibson’s above about avoiding

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<sup>36</sup> Available from <http://hansard.millbanksystems.com/commons/2002/jul/03/biobank> [accessed 09/09/08]

excessive focus on genetics) and as such imply negotiable issues around balance of interests.

### **5.5.2 Regulatory engagement**

In contrast to Iceland and Estonia, there is no new regulation relating specifically to either UK Biobank or Generation Scotland as existing legislation has been deemed to be adequate.

The main legal instruments pertinent to biobanks have been outlined by Laurie and Gibson (2003). They identify a number of relevant instruments the most important of which they consider to be the Data Protection Act 1998 and the common law duties of confidentiality, both concerned with protecting personal information. Subsequent to Laurie and Gibson's report, the Human Tissue Act 2004 was introduced in the UK to control the storage and use of human materials. This Act seeks to protect the interests of participants. There are also a number of instruments concerning intellectual property rights, material transfer agreements and data control contracts which seek to protect the interests of researchers and innovators. Thus the evidence suggests regulatory focus is firmly on balancing interests.

### **5.5.3 Engagement with ethical oversight**

Ethics committees, both national and project specific, have provided a further layer of governance to UK Biobank and Generation Scotland.

#### **i) National ethics committees**

The Human Genetics Commission (HGC) – a strategic level advisory body to UK Government – considered biobanks in its report '*Inside Information*' (Human Genetics Commission, 2002). In the report the HGC expounded the basic values-related principles upon which they based their report "*These are the principles of genetic solidarity and altruism and that of respect for persons...we develop other, secondary principles, such as those of confidentiality and non-discrimination*" (p10). At a more detailed level, the report focuses on balancing interests within the context of these fundamental values and indeed the sub-title for their report is '*Balancing interests in the use of personal genetic data*'. So,

for example, the report advocates methods of protecting individual genetic privacy in ways that allow the interests of others to be also taken into account.

## **ii) Research ethics committees**

Since they are research projects, both UK Biobank and Generation Scotland have had to obtain ethical approval from relevant Research Ethics Committees. As part of their governance frameworks both have added a further level of scrutiny. In the case of UK Biobank this is the Ethics and Governance Council. In the case of Generation Scotland, it is the Advisory Board. The Generation Scotland Advisory Board<sup>37</sup> is appointed by the Scottish Health Minister following open competition according to Nolan principles. Members (accountable to the Scottish Government) advise the Generation Scotland Scientific Committee with the aim of ensuring that Generation Scotland resources are used to the best advantage of participants. Current members<sup>38</sup> include representation from higher education, media, clinical cytogenetics, medical jurisprudence and a patient group. Again the stress is on the interests of the participants (in this case family groups).

The Medical Research Council and the Wellcome Trust have appointed an independent Ethics and Governance Council for UK Biobank, using the Nolan principles, and the governance protocol has been made publicly available (UK Biobank, 2007). The ten members of the Council<sup>39</sup> represent expertise in medical jurisprudence, sociology, family research, ethics, consumer affairs, NHS, general practice, pharmacology, clinical genetics and molecular epidemiology although recent adverts indicate the desire to recruit members with expertise in e.g. information security. The remit of the Council includes *“acting as an independent guardian of the Ethics and Governance Framework and*

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<sup>37</sup> Available from: <http://129.215.140.49/gs/GSAB.htm> [accessed 08/09/08]

<sup>38</sup> Members on 17<sup>th</sup> September 2008 were Lord Sutherland of Houndwood (with a broadly higher education background), Ms Valerie Atkinson (with a media background), Dr Mair Crouch (clinical cytogeneticist with an interest in law, ethics and extending the understanding of genetics to wider society), Professor Graeme Laurie (medical jurisprudence) and Mr Jim Jackson (Alzheimer Scotland)

<sup>39</sup> Members on 17<sup>th</sup> September 2008 were Professor Graeme Laurie (medical jurisprudence), Ms Andrea Cook (Consumer Council), Professor Erica Haimes (sociology), Professor Roger Higgs (general practice and medical ethics), Professor Ian Hughes (pharmacology), Professor Anneke Lucassen (clinical genetics and ethics), Dr Roger Moore (former Chief Executive of NHS Appointments Commission), Professor Martin Richards (family research), Dr Heather Widdows (global ethics), Professor Christopher Wild (molecular epidemiology).

*advising the Board on its revision*" (UK Biobank, 2007 p15). The implication is that the Ethics and Governance Council plays an important role in calling UK Biobank to account and in effectively providing an ongoing ethics review committee. This is unusual in that for most research projects ethical review is only conducted once, at the start of the project, whereas in this case review is ongoing thus recognising the open-ended nature of the UK Biobank project.

The Ethics and Governance Council has developed a publicly available Ethics and Governance Framework (UK Biobank, 2007) that outlines the biobank's commitments to its stakeholders: participants, researchers and society at large. The framework also details how the biobank is to be managed, for example recruitment and consent procedures. The framework engages with both values-based aspects (such as a commitment to manage the resource for the public good) and interests-based aspects regarding issues such as access (Laurie *et al.* 2009).

#### **5.5.4 Conclusion on policy and regulatory communities**

I conclude from the evidence gathered that in the policy making and regulatory area, there is a strong preponderance of interests-based arguments. Parliamentary oversight appears to have been primarily about achieving an appropriate balance of research funding (interest-based arguments) although there may be values-based arguments underlying these. The advice from the national strategic ethics committee (Human Genetics Commission) is almost entirely on the basis of balancing competing interests (although again with underlying values) and the work of biobank-specific ethics committees has been largely around interest-based issues such as consent and access, although UK Biobank Ethics and Governance Council has also indicated the principles and values that have informed its decision-making processes. The lack of perceived conflict of values may have resulted in values-based considerations receiving less attention from policy and regulation.

## 5.6 The role of values and interests in debates around biobanks

### 5.6.1 A summary of arguments

The main results concerning values-based and interests-based arguments with respect to biobanks are summarised in table 5.2. Conditional arguments are those conditions identified that should be met for the technology to be acceptable.

**Table 5.2 Main values-based and interests-based arguments with respect to biobanks**

	Stakeholder groups			
	Innovators <sup>40</sup>	Civic Society groups	Patient advocacy	Citizens
<b>Arguments favouring biobanks</b>				
<b>Values-based arguments</b>	Scientific knowledge			Altruism
	Health benefits		Health benefits	Health benefits
<b>Interests-based arguments</b>	Research resource		Relieves suffering	Relieves suffering
	Wealth and job creation			
<b>Arguments against biobanks, or in response to concerns</b>				
<b>Values-based arguments</b>		Ignoring the real causes of disease.		
<b>Conditional arguments</b>	The principle of justice underlies the conditionality of preventing harm to participants			
	The principle of respect for autonomy underlies the conditionality of protecting individual autonomy			
	A requirement for efficiency underlies the argument for ease of access to biobank data			
<b>Interests-based arguments</b>	Avoid conduct of non-desirable research	Potential for conduct of non-desirable research		Potential for conduct of non-desirable research
	Control inappropriate access	Access by organisations with a different agenda		Access by organisations with a different agenda
	Ensure pharmaceutical companies have sufficient access to realise benefits	Exploitation by pharmaceutical companies	Ensure pharmaceutical companies have sufficient access to realise benefits	Exploitation by pharmaceutical companies

<sup>40</sup> Innovators by definition are unlikely to argue against a technology but may be responding to criticism

The first question of this thesis asks the extent to which values-based and interests-based arguments are found in areas of genomic technologies other than GM crops? The evidence presented in this chapter indicates the presence of both values-based and interests-based arguments in debates around biobanks. The main arguments advanced by proponents of biobanks relate to their potential as a research resource with the aim of understanding diseases and improving their treatment. Biobanks not only provide the means by which scientific knowledge can be furthered but are potentially the means by which health benefits can be created. Whilst this is an interests-based argument, in that providing health benefits is in the interests of people generally and the provision of a research resource serves the interests of the scientific research community more specifically, there is also a values-based element to these arguments. Both increasing knowledge and improving health can be seen as absolute goods having the status of moral imperatives. In a values-based understanding, the worth of increased knowledge would not be curtailed by whether the knowledge is expected to be beneficial or not. Instead the taken for granted expectation would be that benefits will flow from knowledge.

A values-based understanding of improving health would not be concerned about factors such as resource limitations determining who benefits and who does not and whether the emphasis of health-related research is appropriate or not. It is, however, difficult to evaluate the degree to which arguments around health benefits and benefits of knowledge are values-based or interests-based in specific instances.

A more subtle values-based argument was evident in the appeal to nationhood in the context of Generation Scotland which appeared to be an appeal to common societal origins for the biobank as well as to common societal benefits. This appeal to commonality could be viewed as a way of engendering a deeper commitment to the biobank project by participants by appealing to values-based considerations. Values-based critiques of excessive focus on genetics at the expense of environmental and social causes of disease have also been made of biobanks but I have seen little evidence of strong engagement with this issue.

A number of interests-based arguments were also identified such as concerns that the resource could be used for undesirable purposes. The data also suggest a series of conditional arguments, conditions specified in order for the biobanks to be acceptable. These are often founded on appeals to basic principles such as justice and respect for autonomy. The data suggest that these have been the main focus for those involved in the governance of biobanks. For example extensive consideration has been given to appropriate consent procedures (respecting individual autonomy) and securing confidentiality of information about individual participants (preventing harm to participants) whilst ensuring that there is sufficient access to the biobank to realise the potential benefits from data within it.

By and large, the evidence clarifies that biobanks do not threaten fundamental values held by the population of the UK: although potentially some of the research undertaken could be in conflict with some basic values (e.g. research of eugenic nature, research on aspects of behaviour, research for cosmetic or military purposes or cloning). Quite the contrary, the expectation of health benefits to self and others upholds citizens' values. Much of the debate around biobanks has been about protecting participants from harm, which are interests-based considerations ensuring that the interests of participants are protected. However, underlying these interests considerations are the applications of underlying values such as justice.

### **5.6.2 Configuring stakeholders**

The second thesis question asks how are these values-based and interests-based arguments aligned between different stakeholders?

The evidence illustrates that the development of biobanks has been strongly influenced by an alliance between the interests and values of research scientists with government funding bodies. But they are dependent in the long term on maintaining the support of participants and interest from the commercial sector. Public health and primary care interests have been influential to some extent (arguably more so in Generation Scotland

because of its stronger partnership ethos) but it is difficult to view them as the main drivers of the biobank projects.

Research scientists have been at the forefront of the development of biobanks which are congruent with their values regarding greater knowledge and understanding and their interests in terms of new areas of research opening up. Biobanks can be viewed as large pieces of research equipment, rather analogous to the proton colliders of physicists. Many research scientists also genuinely see this area as providing potential health benefits.

Antagonism to biobanks has been primarily on the basis of excessive focus of genetics at the expense of social and environmental causes of disease. The advocacy group GeneWatch has been particularly vocal in articulating strong reservations about the value of genetics research, and hence biobanks, in producing human benefits. The debate around the appropriate emphasis to be given to genetics is to some extent replicated within the medical community between geneticists and epidemiologists, although here more common ground appears to have been found.

The nature of engagement of citizens in biobanks as participants rather than consumers or beneficiaries means the relationship between citizens and research scientists is different than in the other cases studied in this thesis. However others question whether the participants are truly being engaged as participants or whether the concern with their interests is more cynically intended merely to maintain confidence and serve the interests of the research scientists.

Finally, biobanks are being developed on the basis of future provision of public goods and thus serving the public interest. If biobanks do not produce the promised health benefits or particularly if they produce information that is not helpful to public health (e.g. promoting discrimination/producing therapies too expensive for the NHS, producing 'trivial' therapies/cosmetic products or venturing into controversial areas) then value-based public opposition to biobanks could emerge.

The role of companies is somewhat ambivalent in that their interests are served by opportunities arising for therapies from new genetic information contributing to improved



business models. There may be conflicts of interest in this respect with the public accountability and benefit that is demanded of biobanks but also within the strategies that pharmaceutical companies themselves have with respect to for example pharmacogenomic information. Both biobanks envisage some form of commercial involvement. However, the way in which they will interact with commercial interests is still in the future and therefore untested.

### **5.6.3 Policy-regulatory responses**

The third thesis question relates to where are the values and interests-based arguments being negotiated and how does the policy-regulatory framework relate to these arguments?

Policy makers have been evident primarily in holding research funding bodies to account although in both biobanks there has been funding commitment (and hence presumably perceived future health and/or economic benefits) from regional development agencies and Scottish Enterprise. Government appears to be a stakeholder that finds the development positive from a values perspective and also furthers its interests in incorporating genetic information in the health service and in stimulating the commercialisation of science particularly in the biotechnology area.

Ethics has become an important tool for governance of biobanks. Different biobanks have been set up with somewhat different ethical guidelines but the main debate within them appears to have been with respect to balancing interests. Ashcroft's (2003) concerns noted earlier in section 5.2.4(ii) about the lack of consistency in decisions made by ethics committees may well not be reflected in decisions regarding access and use of an individual biobank because a single ethics committee should be able to ensure that successive decisions are consistent with each other, even though the membership of the committee will vary with time. However, ethics committees of specific biobanks are restricted in what issues they can and cannot address. They are unlikely for example, to have the remit to ask whether the establishment of the biobank represents good value for

money or not. Such decisions are for the wider policy community to make, whether by default based on a series of independent decisions or more explicitly.

A set of regulations, more broadly relevant to health care, exists to ensure protection of participants in medical research. However, the biobanks have gone beyond these requirements in seeking to ascertain what kind of practices and governance arrangements are likely to garner public (and participant) support in the longer-term. Thus, consideration of the interests of the participants can also be in the interests of biobank management and research scientists.

## **5.7 Conclusions on biobanks**

In this chapter I have investigated a case study of biobanks, using data from the UK Biobank and Generation Scotland, two of the UK's major biobank projects. Both are still in their data collection phase but they promise to create resources for health related research to enable better understanding of genetic, lifestyle and environmental effects of common diseases. They also offer prospects for new therapies, improved treatments, new jobs and the potential for economic growth. Research scientists have been at the forefront of the development of biobanks but with the support of policy makers and furthermore these projects fundamentally rely on the participation of large numbers of people. The activities of biobanks are not currently a cause for wide public comment although civil society advocacy groups do exist which oppose their development mainly from a values basis.

The evidence demonstrates the presence of both values-based and interests-based arguments in debates around biobanks. Innovation communities articulate strong interests-based arguments in favour of the development of biobanks underlaid by a values-based commitment to medical research. Interests-based arguments are advanced for the best way of balancing the interests of the various stakeholders; participants, patients, citizens and innovators. Patients groups are supportive of biobanks as both furthering their interests and also due to the inherent value of health research. Civil society groups in opposition to biobanks seek to de-emphasise the focus on genetic

information in favour of social and environmental aspects in ways that suggest at least some degree of values-based argument. Citizens emphasise the value of the health benefits expected from the creation of biobanks as well as seeking protection from exploitation when participating in biobanks.

Regulation exists to protect the interests of participants and commercial partners using a variety of mechanisms. Most of the 'regulatory' oversight of biobanks has been through ethics committees. Advice from the HGC is primarily on the basis of balancing competing interests. The work of biobank-specific ethics committees has been largely around interest-based issues such as consent and access, although UK Biobank Ethics and Governance Council has also stated the principles and values that have informed its decision-making processes. These project-specific ethics committees have become the sites where contested approaches to future development of the biobanks and the values and interests involved are being negotiated, although the final responsibility for decisions lies with the respective Governing bodies of the biobanks.

Commercial access to biobanks is a particularly sensitive issue and focus of unclear understanding of an appropriate balance of interests. On the one hand commercial access is required for developing therapies and commercial companies will require a viable business model. On the other hand access that results in participants feeling they are being exploited or that inappropriate research is being conducted will compromise trust in the biobank projects. Given that both projects allow withdrawal of consent, the result on the future of the projects of a loss of confidence could be very serious. The questions raised by access by commercial companies are resulting in innovative approaches to benefit sharing being discussed but the success (or otherwise) of enabling appropriate commercial access remains in the future

Mostly the development of biobanks does not threaten fundamental values held by the population of the UK, although potentially some of the research undertaken could be in conflict with basic values. Quite the contrary, the expectation of health benefits to self and others upholds citizens' values. Much of the debate around biobanks has been about maintaining the confidence of participants in the longer-term, ensuring their interests are

protected and they are not being exploited whilst at the same time allowing the benefits of the biobanks to be realised by enabling access to the data stored in them by a range of researchers.

Participation in biobanks has been on the basis of a promise of future health benefits.

Failure to deliver these benefits, or worse still the delivery of 'benefits' that may be questionable (e.g. in areas that could be deemed to be cosmetic) have the potential to undermine the 'value' basis on which the biobanks have been constructed.

The 'values and interests approach' was developed in a context of agricultural applications where environmental and human health risks were important (GM crops) and in Chapter four I extended the approach to cloned and GM animals. In this chapter I have applied the approach to a situation primarily involving human concerns and have demonstrated how the values and interests approach can be used to clarify the types of argument being made – in this case, predominantly interests-based. I will next turn to consider the case of stem cell research, an application of genomic technologies to humans where individuals are of higher profile than populations and where the research is known to challenge the fundamental values of some people.

## **Chapter 6**

### **Stem cell research: a case of over-simplifying arguments**

#### **6.1 Introduction**

In chapters four and five I have considered cloned and genetically modified animals and biobanks. The policy community has responded to cloned animals in precautionary ways suggesting particular concerns about values-based arguments opposing animal cloning. Biobanks, however, do not seem to threaten fundamental values held by the population of the UK. The development of biobanks has been much influenced by an alliance between the interests and values of research scientists with government funding bodies, with policy makers evident primarily in holding research funding bodies to account. Ethics committees have become important tools for the ongoing governance of biobanks but biobanks are dependent in the long term on maintaining the interest from the commercial sector and ongoing support of participants who donated material to establish the biobanks.

In this third case study I explore research on human stem cells, with particular focus on use of embryonic stem cells. This case was chosen as one where strong, values-based arguments are advanced and where questions around appropriate ways of treating humans predominate. There have been extensive debates in the public realm, leading to new legislation being crafted, but with few products on the market as yet. This case represents a situation that is frequently referred to as an example in which policy-makers in the UK have dealt well with a contentious issue. The UK's approach to dealing with stem research is often highlighted as a model for other jurisdictions. I shall argue in this chapter, with evidence, that the UK emphasis on one values-based argument has led to other important arguments being disregarded and oversimplification of complexity.

This case study is restricted to the UK context (while recognising the influence of the USA on European legislation). The main arguments considered relate to the relative merits of 'adult' stem cell research and human embryonic stem cell (hESC) research, which were the focus of attention during the data collection phase. Subsequent developments (such

as the use of 'cybrid' embryos which include animal material and induced pluripotent - iPS - cells) are not considered.

In this chapter I will firstly briefly consider scientific aspects of stem cell research followed by a review of the relevant literature where I examine evidence on how stem cell research has been allied to the promises of therapies, the values that have been identified as important in hESC research and the ways in which conflicting values are negotiated. I will then map out the broad stakeholder communities most closely involved in debates around research on, and potential use of, stem cells, namely innovators and citizens/civil society advocacy groups and the responses by policy makers/regulators. I examine the types of argument made by each of the stakeholder communities and in particular how the arguments made might map onto values-based and interests-based categories. Finally, I will examine the overall configuration of the debates and examine whether and how an 'interests' and 'values' framework can elucidate the nature of the disputed area.

## **6.2 Introducing stem cell research**

### **6.2.1 Scientific aspects**

Stem cells are unspecialised cells which under specific conditions may develop to form a range of different cell types (liver, heart, pancreas, nerves etc.). Stem cells in adult humans have been found to exist in small numbers, for example in bone marrow, and have the ability to develop into a narrow range of tissue types, forming the basis of bone marrow transplants, for example. Stem cells have also been found in umbilical cord blood and have been obtained from human fetuses (aborted or still-born). The first public announcements that stem cells had been isolated from human embryos (Thomson *et al.* 1998) caused little public attention, but gradually, this development, particularly when associated with the prospects of human cloning, became very high profile. Sourcing stem cells from fetuses has been much less discussed (e.g. Pfeffer & Kent, 2007), a situation that is replicated in this research.

Until the time that human embryonic stem (ES) cells were isolated, the main species from which embryonic stem cells could be isolated was mice (as already mentioned in Chapter

four). Numerous attempts were made to isolate embryonic stem cells from farm animals but these had not been successful, although the derivation of human embryonic stem cells was preceded by the isolation of primate embryonic stem cells in 1995 (Rubin, 2008). The scientific breakthrough demonstrated by deriving human embryonic stem cells should therefore not be underestimated. Furthermore, human embryonic stem cells were isolated at a time when the ability of cells to differentiate into different types of cells, and to be reprogrammed back into an embryonic state, had been given new impetus from research on somatic cell nuclear transfer (see Chapter four).

A brief summary of the various sources of human stem cells, their strengths and ethical considerations associated with them is given in table 6.1.

Stem cells are of interest particularly due to their potential to develop cell therapies to treat and repair serious disease and injury for which there are currently few or no cures.

Examples of potential targets for treatments include diabetes, spinal cord injuries, heart disease and neurodegenerative diseases. However, embryonic stem cells can also cause tumours so have to be handled with care. A recent development has been the discovery that it is possible to induce 'normal' adult cells to become stem cells by manipulation in the lab (Takahashi *et al.* 2007, Yu *et al.* 2007). The process involves genetic manipulation of the cell by inserting three or four genes that cause the cell to become like a stem cell in its behaviour. These iPS cells have changed the landscape of stem cell research considerably, although as yet their full potential is not known. The empirical research conducted for this case study predates the development of iPS cells and therefore iPS cells are not considered further.

**Table 6.1 Sources of human stem cells**

Source	Isolation	Flexibility	Ethical considerations of derivation
Adult tissue	Few such cells. Difficult to multiply in culture but forming the basis of existing treatments for individual patients.	Contested but probably less than embryonic stem cells	Few
Cord blood	Restricted quantities available	Flexible	Balancing interests of mother/child and yield of stem cells
Foetuses	Sourcing foetuses is an issue	Moderately flexible	Ethically contentious
Embryos	Requires destruction of human embryo but then, can be multiplied readily apparently indefinitely	Highly flexible	Ethically contentious
Induced pluripotent	Normal adult cell that is genetically modified to become like a stem cell	Moderately flexible but currently variable and unstable	Few, but some applications, such as derivation of sperm cells, could be contentious

In the UK, a stem cell bank has been established to ensure widespread availability of cell lines that have been isolated from a variety of different sources. As of 15<sup>th</sup> November 2010, 16 stem cell lines were reported as available for distribution from UK stem cell bank.<sup>41</sup> Eight of these are registered as UK in origin, four from Sweden, three from the USA and one from Australia. However, most of these cell lines are of research origin and not of a suitable quality for use in therapeutic treatments.

Some stem cell therapies based on 'adult' cells are beginning to be realised. As early as 2005, Wilan *et al.* (2005) listed 37 companies world-wide with preclinical and clinical trials in therapies based on 'adult' (including cord blood-derived) and foetal stem cells. In terms of therapies based on non-adult stem cells, the lead products are probably a therapy for spinal cord injury based on human embryonic stem cells, produced by Geron Corporation

<sup>41</sup> Available from <http://www.ukstemcellbank.org.uk/> [accessed 15/11/10]



in the USA which was given regulatory approval from the Food and Drugs Administration to begin Phase 1 clinical trials and recruited its first patient in October 2010<sup>42</sup> and a potential treatment for stroke based on foetal stem cells produced by the company ReNeuron that was granted approval in February 2010 for Phase 1 clinical trial in the UK.<sup>43</sup>

There are other indications that industry activity in this area is increasing, for example Pfizer announced in November 2008 that they were investing in a stem cell research unit<sup>44</sup> and GlaxoSmithKline announced a collaboration with the Harvard Stem Cell Institute also in 2008<sup>45</sup>. Products from stem cell research are expected to be applied within the health care sector and there is also some experimental clinical activity (e.g. skin grafts, the transplant of a cadaveric trachea impregnated with a patient's own stem cells). However, it is too early in the development of therapies to determine which, if any, prove to be widely adopted.

### 6.2.2 Literature review

The main themes relevant to this thesis are the values expressed in the 'promise' of stem cells and how this has shaped subsequent discussion and regulation (e.g. Martin *et al.* 2008, Rubin 2008), views on values associated with embryos, and the negotiation of the values and interests related to the status of the embryo and the interests of patients.

#### i) The promise of stem cells

The promise of therapies has been a key feature of arguments advocating stem cell research. Parry (2003, p23) for example found that in the context of Parliamentary debates "*Potential users were constructed as not only demanding but also **needing** stem cell therapies; without them they would continue to suffer*" (p24). The strength of the expression of need suggests that not only is the research in the interests of patients but it

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<sup>42</sup> Available from <http://www.geron.com/> [accessed 15/11/10]

<sup>43</sup> Available from <http://www.reneuron.com/> [accessed 15/11/10]

<sup>44</sup> Available from <http://www.inpharm.com/news/pfizer-makes-major-stem-cell-investment> [accessed 17/03/10]

<sup>45</sup> Available from <http://www.gsk.com/responsibility/research-practices/cloning-technology-and-stem-cell-research.htm> [accessed 17/03/10]

is a right of the patients to have these therapies and obtaining these therapies is an absolute good that should be sought, in other words in the definitions used in this thesis, a values-based argument is being advanced.

The tendency of innovators to overstate their claim is often highlighted and is frequently referred to in the context of stem cell research (e.g. Martin *et al.* 2008). However, as Solbakk (2003) points out that there is the possibility of over-stating the opposition case resulting in “*over-killing of therapeutic arguments*” (p389).

Bonnicksen (2002) suggests that as research has moved from fertility treatments to stem cell treatments there has been an associated change in emphasis of research benefits for potential future embryos to benefits for people with debilitating diseases. This change in emphasis, she argues, has subtly shifted the politics of embryo research.

*“Traditionally, the potential beneficiaries of embryo research were a compact segment of the population interested in fertility treatment...The potential harms fell on human embryos and on society if embryos were treated as commodities and as means to other ends. In addition, the harm of not proceeding (lost knowledge) would be largely contained in populations with a stake in fertility treatment and reproductive research... The debates [now] highlighted a growing group of potential beneficiaries of embryo research, namely, persons with debilitating diseases. The harm of not proceeding (lost knowledge) took on sharper form with the possibility that this would prolong the suffering of people with chronic diseases.”* (p67)

Thus, the promise that stem cell therapies offer to suffering humanity forms an important part of the context within which embryonic stem cells are considered. The presence of a carer or a patient within a debate provides a stark reminder of who might be the losers if embryonic stem cells research is discontinued. Nevertheless, as Parry (2003) points out, this does not mean that there is always a rigorous examination of alternative approaches to therapies.

## **ii) Values relevant to embryos**

Research into how stem cell research scientists understand embryos, provides a varied picture. Parry (2009) emphasises how research scientists portray (and also presumably understand) the material they are working on as 'a bunch of cells' which lack sentience. Wainwright *et al.* (2006), on the other hand identified a more discriminating approach. They found embryonic stem cell researchers in two specific UK laboratories were comfortable with researching spare IVF embryos or embryos discarded in Pre-implantation Genetic Diagnosis procedures but were opposed to creating embryos solely for research. Furthermore, they found that some research scientists working with embryonic stem cells held strong Christian beliefs but nevertheless were able to reconcile their beliefs with their work.

In terms of citizens, Ho *et al.* (2008) studied public attitudes to embryonic stem cell research in the USA explicitly taking into account values-predispositions, by which they meant religiosity, political ideology and degree of deference to scientific authority. Their conclusion was that public opinion about embryonic stem cell research was strongly shaped by a values-based predisposition. In comparison, the amount of scientific knowledge had negligible impact on attitudes towards hESC research. This echoes the more general findings in Chapter two that, where values-based considerations are important, scientific evidence is unlikely to change opinions. Ho *et al.* also found that respondents who believed that scientists would make decisions that would be in the public interest were more likely to rely on scientific evidence in forming their views. Again this echoes the more general findings presented in Chapter two that people are more likely to trust information from sources that appear to share their value-predisposition.

## **iii) Negotiation of hESC research**

Central to many analyses of debates around hESC research is the worth attributed to early human embryos, either valued the same as adult humans, of no more worth than a laboratory reagent or something in-between. Several analyses have highlighted how UK

regulation on hESC research has been influenced by earlier debates relating to embryo research in the context of *In-Vitro* Fertilisation (IVF) treatment. This established the principle of research being allowed on embryos up to 14 days old, given sufficiently good reason and under a licence from the Human Fertilisation and Embryology Authority (HFEA). Interpretations of the influence of earlier debates have, however, varied.

Parry's analysis (2003) suggests a re-run of old debates:

*"The 1990 HFE [Human Fertilisation and Embryology] Act debates were a rich source of rhetoric and tactics for the stem cell debates. Put simply, those against [stem cell research] seized upon the opportunity for redressing the embryo question and those in favour drew upon the successes of the 1990 debates by arguing that the pro-research lobby had already 'won'." (p10).*

Because of this re-run of old debates she also notes that several issues remained unaddressed in the parliamentary debates, for example (p11) *"What is surprising is the absence of discussions about the sociocultural implications of cloning technologies for kinship relations and health inequalities"*

Hauskeller (2004) perceives regulatory drift to have taken place. For Hauskeller (p 517):

*"This refusal [by the Donaldson committee] to review former decisions and instead debate new issues strictly on the grounds of the currently existing regulation – regulation that passed [sic] under circumstances in which cloning, for example, was not possible - is an example of the tendency to a policy via stepwise watering down of prohibitive regulations".*

Hauskeller thus suggests an inexorable process of regulatory relaxation that has allowed hESC research to take place in the UK.

Whilst Parry and Hauskeller are critical of the policy communities for not re-evaluating existing regulation, Banchoff (2004) in contrast, stresses the importance of institutional legacies in development of norms and values that strongly influence the subsequent debate. The previous Warnock debates (around the acceptability of research on embryos for fertility treatment) and 1990 Human Fertilisation and Embryology Act are given as

examples of “*how institutions created at critical junctures shape constellations of actors and interests around subsequent controversies.*” (p3). Thus, earlier regulation (on IVF research) forms a path-dependency that is followed by later regulation (on hESC research).

Banchoff (2004) analyses the dispute as one where two competing values require balancing and notes that in terms of the policy-making process:

*“In no case, however, did the balance of interests determine the policy outcome. Cloning and stem cell breakthroughs generated a broad public debate that escaped the confines of interest-driven politics...political controversy and coalition building took place mainly around two clashing values, embryonic life and solidarity with the sick. Public opinion was, for the most part, ambivalent and uninformed... [a survey] found comparable levels of support for both values” (p7).*

The literature therefore suggests that the main tension is between solidarity with the sick and the worth of embryos, the latter having been already negotiated during the 1990 HFE Act where the principle of permissibility of research on human embryos was established.

The task of the remainder of this chapter will be to understand better the values and interests of a range of stakeholders in the context of stem cell research and in particular how these relate to prospects of therapies. In the next section I will provide a brief portrait of the different stakeholder communities involved around stem cell research and the main values-based and interests-based arguments advanced by them. I will use the structure outlined in Chapter three and consider innovation communities, citizens/civil society advocacy groups and policy makers/regulators in turn.

## **6.3 Innovation communities**

### **6.3.1 The communities described**

The innovation communities considered here are research scientists and technicians as well as early-stage industry and clinicians. They may be based in basic science research labs, universities, medical research institutes or clinics and industry. Where human

embryos are required, IVF clinics will be involved. Given the early stage of developments there is less involvement by intermediaries and a less varied range of actors involved than in the case of cloned animals.

In the next section I will consider the arguments made by innovation communities, in particular the extent to which arguments can be identified as interests-based and values-based. Given that an understanding of the worth of a human embryo is a critical element of discussions, I will specifically examine arguments made around this aspect, followed by considering how each argument-type is advanced by individuals when evaluating the relative merits of embryonic- and adult-stem cell research. Finally, I will consider arguments made by industry stakeholders more specifically.

### **6.3.2 Interest based arguments**

The following broad categories of arguments that are classified as interests-based were made by the innovator interviewees. All the arguments listed below rely on fulfilling specific interests or achieving a balance between competing claims.

- Providing therapies for people with serious degenerative diseases.
- Protecting the interests of embryo and egg donors.
- Reducing the number of animals used in toxicity testing of drugs.
- Protecting the interests of the resource poor, whether within countries or across richer and poorer nations.

Each of these will now be considered in more detail.

#### **i) Providing therapies for people with serious degenerative diseases**

The potential treatments that could arise from stem cell research were repeatedly emphasised by interviewees. Treatments would clearly be in the interests of current patients with conditions that could potentially benefit from therapies based on stem cell research. Innovators could then be viewed as acting in ways that further the interests of others or altruistically. An argument could be made that these motivations contain an element of self-interest as innovators working in providing therapies will also be serving

their own interests in terms of furthering their careers (and this link was explicitly made by some interviewees). In arguing for the interests of people with a disease diagnosis, innovators are also appealing to a broadly held value that altruistic behaviour is a social 'good'. It is therefore particularly complex to evaluate whether arguing in the interests of others is an interests-based argument or a values-based argument as both could be true at the same time.

In the definitions used for this thesis, the characteristic of negotiability is a key determinant as to whether an argument is categorised as values-based or interests-based. I suggest that arguing in the interests of others can be considered an interests-based argument as it is negotiable. There are several different ways of potentially satisfying it. Debates about the relative merits of research on different types of cell-source may reflect genuine differences of opinion as to which holds out the greatest benefit for patients. Advocating one source of cell over another is potentially amenable to changes in opinion with increasing scientific knowledge. But health benefits may be expressed also as a values-based argument. I will return to this in section 6.3.3.

## **ii) Protecting the interests of embryo and egg donors**

Research on hES cells depends on the availability of embryos for deriving stem cell lines (at least initially). Several interviewees stressed the need for appropriate consent procedures for embryo donors to ensure their interests are protected. The need to recognise the important role of donors of embryos was particularly stressed by one interviewee.

*"I would like to see the role that the infertile couple play in making this technology work be better recognised. I think they are at the moment the unsung heroes in this because none of this would happen if they didn't give their embryos... There are parts of the country where the NHS doesn't provide any treatment for infertility and yet it is expecting the infertile couple to cough up their surplus embryos to provide these cures for everybody else and somehow that's got to be, that's got to come over."* (interview 11, IVF clinician).

This interviewee makes a strong appeal not just for protecting embryo donors from exploitation by ensuring appropriate consent but for their contribution to stem cell research to be more deserving of praise. The underlying value to these appeals is that of justice to embryo donors.

However, in terms of adoption of stem cell therapies, this argument is less about whether this avenue of research should be advocated but rather specifying conditions under which the therapies may be developed; conditions where all parties are treated with justice.

### **iii) Reducing the number of animals used for toxicity testing of drugs**

A number of other non-therapeutic benefits from hESC research were identified e.g. the potential to reduce the number of animals used in experiments by the use of human stem cells to produce cell cultures for testing for toxicity of drugs. This testing is expected to be more accurate than using animals and will therefore provide safer drugs (see figure 6.6). In the views of some, non-therapeutic applications (and improving understanding of basic biology) may well prove to be the greatest benefits from ES cell research in the long-term. Thus, the research can be seen to be justifiable on these bases irrespective of whether cell therapies will be realised. Here, the interest to be served is primarily the desirable end of reducing the use of animals in research.

### **iv) Protecting the interests of the resource poor**

Some of the interviewees felt that there was a danger that hESC research would result in developing expensive therapies that would not be available to poorer people and in poorer countries (e.g. see figure 6.2). The technology would be harnessed to serve the interests merely of the rich rather than the poor. Interviewees, however, felt unable to mitigate this tendency. In contrast, one interviewee suggested hESC research would be in the interests of poor people in providing stem cells as an alternative to sourcing organs for transplant where poor people might otherwise be pressured into selling their organs (see figure 6.4). Whilst emphasising the interest of resource poor people, both of these perspectives draw on the underlying value of justice. Scientists in both research and industry were aware of and reflected on the questions raised by their research with respect to whether stem cell



research is an appropriate use of money in terms of best serving the interests of resource poor people.

*“This is a very profound question in a way because, if we look at it from a global context, we could save a lot more people by putting the same money into just clean water... We might be getting too sophisticated nowadays. Stem cell therapies you might think are one step too far, we could use the monies for many other worthy health sort of extending things but I don’t know if that’s true.” (interview 14, industry).*

Whilst these were seen as important criteria there was a general sense that these factors are beyond the control of individuals or individual researchers and therefore they are insufficient reason to forego research into therapies.

### **6.3.3 Values based arguments**

Values-based arguments articulated by innovation communities were grouped into three themes.

- Improved knowledge and understanding of basic biology.
- Therapies for hitherto incurable diseases.
- Scientific freedom.

#### **i) Improved knowledge and understanding of basic biology**

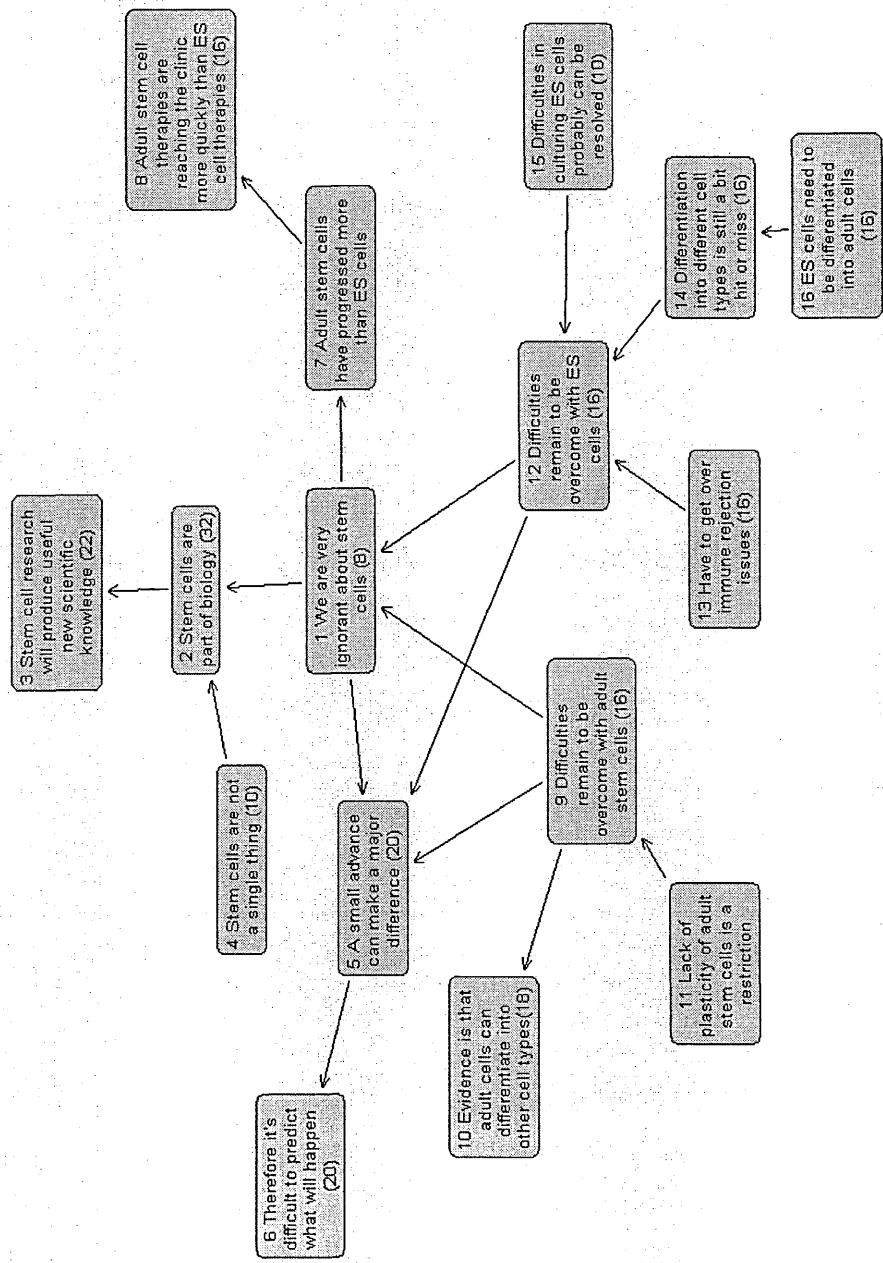
A strong theme arising from these interviews was furthering understanding of basic biology and using human ingenuity as expressions of basic human values. Figure 6.1 gives a cognitive map of an interviewee viewing stem cell research as primarily furthering knowledge of biology (a similar theme can be seen in figure 6.3). Cognitive maps are described in Chapter three, section 3.5. Note that concepts are numbered to aid navigation. The number in parenthesis indicates a paragraph number in the transcript of the interview in order to maintain an evidence trail. These maps are a way of summarising the information given in individual interviews and demonstrate clearly the links between different arguments made by interviewees.

For this interviewee, the main driver of stem cell research is to produce useful scientific research (3). Stem cells are not a single entity (4) but are part of biology (2) of which we are very ignorant (1). Difficulties remain to be overcome with adult stem cells (9) and Embryonic Stem (ES) cells (12) but adult stem cells have progressed more quickly (7) and therapies are expected sooner from them (8). ES cells raise questions of culture methods (15), differentiation into adult cells (14, 16) and immune rejection (13). Adult stem cells lack the plasticity of ES cells (11) although evidence is beginning to suggest they can form different cell types (10). However, a small advance in understanding (5) has the potential to make a big difference to progress and hence it is difficult to predict what will happen (6). Stem cell scientists appeared to have a strong commitment to their work. One interviewee made reference to working at weekends, bank holidays and suffering abuse (e.g. being called a Nazi). This commitment was seen to be justified due to the value of the research, e.g.

*"I said to my wife, one day when I open the incubator and my hands don't shake, I will not do any more of this research, which means I'm not excited any more or something, so it's time to leave, definitely"* (interview 12, stem cell researcher working with human ES cells).

The strength of the statements made around working to further scientific knowledge suggest something that goes beyond self-interest. Researchers continued to work in the area despite suffering abuse, and put aside their other interests, such as free-time, in order to further their work implying that some values-based commitments are being called-upon.

Fig 6.1 Cognitive map of an interviewee viewing stem cell research as furthering knowledge of biology (interview 23, stem cell researcher)



## **ii) Therapies for incurable diseases**

The promise of therapies from stem cell research is a strong theme as already noted in section 6.3.2. The quote below implies that what is at stake is something more than the scientists' self-interest in terms of career and financial reward, suggesting that a basic value is being appealed to. This basic value is not defined in this quote but other evidence gathered suggests that the value is allied to the value of health benefits.

*"We don't do this for bigger salary or for acknowledgement and all these things because all this will come if you have nice results. But we should not forget that actually we are doing for other people and that's the aim of this story"* (interview 12, stem cell researcher).

Most of the scientists interviewed also recognised that despite feeling confident in the research, there is a possibility of no cures being developed as a result. Also that it would be a considerable time before any therapies would be available: e.g.

*"On my dark days, my fear for stem cell research is that the present enthusiasm will not be rewarded with a significant breakthrough"* (interview 1, stem cell researcher).

*"it shouldn't be a shock that over 50 years we'll still be learning how to grow cells, how to think differently about cells, as well as how to actually use them"* (interview 8, stem cell researcher).

Nevertheless, there remained a strong drive towards the prospect of stem cell therapies and for many a stated commitment to alleviate suffering.

*"The bottom line, if you or someone that you love is affected by illness, you're going to grasp at anything, you're going to want anything in order to live longer"* (interview 1, stem cell researcher). It is perhaps noteworthy that several of the researchers spontaneously mentioned family members who were ill, not necessarily with diseases that may be treated with stem cells in the future. This is not to suggest that the motivation for research is necessarily illness in the family (indeed this seems rather unlikely given the nature of the illnesses mentioned) but rather that experience of illness forms part of the context for the researcher and is used as a rhetorical device when seeking to explain their visions and

motivations. Thus it is less an expression of concern for those with whom we have close relationships or even self-interest (although both may also be true as can be seen in section 6.3.2) but rather a willingness to commit to a social good, an expression of altruism and communitarian values. A technician working with human ES cells for example spoke of how much she had valued contact with the people her earlier research was aimed at helping

*"we actually opened a new centre and we invited relatives or people who had actually survived breast cancer to the centre. And that really opens your eyes because you see the other side, the people that have suffered, and they just want help to get better, they're sort of clinging to life in a sense...For me that was life-changing"* (interview 3, stem cell technician).

The importance of therapies is also illustrated in figure 6.4.

### **iii) Scientific freedom**

As already indicated earlier in this section the furtherance of scientific knowledge is one of the key motivations for many in the innovation communities. One interviewee suggested that the freedom to be able to pursue scientific knowledge without hindrance underlies much of the debate around the use of embryonic vs. adult stem cells.

*"It's got much more to do with prejudice and a perceived need for scientific freedom and reacting against what's perceived as a threat from the religious right, which clearly doesn't exist in this country in the same way it does in America."* (interview 23, stem cell researcher).

Whilst this view was expressed only by one interviewee, there are indications that this tension has been played out in more detail in the subsequent debates around hybrid embryos (Williams *et al.* 2009).

Having considered individually the types of interests-based and values-based arguments advanced by innovators, I now turn to consider in more depth how individual innovators view the moral status of the human embryo, given that it is one of the major aspects of public debates about hESC research as played out in the media.

#### 6.3.4 Moral status of the human embryo

Views about the moral status of the early embryo among innovators varied. For some it had no moral status as it is just a ball of cells or biopsy, for example:

*"I don't see an early embryo, myself personally as a scientist, I don't see a collection of cells without a nervous system or a cerebellum as an entity, a human entity capable of conscious thought" (interview 1, stem cell researcher working with human ES cells).*

Others, while content to work with hESCs felt that their origin in embryos constituted a precious resource e.g.

*"if you know the lab has no experience in deriving lines and they get a licence, and they start getting embryos, I just feel vaguely uncomfortable at that because I think there's so much expertise out there already that they shouldn't be allowed just to do that, that they should have to have somebody who's got proven competency or they have to be trained up by somebody, so that means embryos aren't wasted. And I don't think that's something I felt so strongly about before. And I don't know if that's, as I've got older and had kids, I don't know if that's become a sensitive topic for me...it just seems silly not to minimise the wastage really." (interview 19, stem cell researcher- female).*

A number of interviewees in the innovation community spontaneously indicated their Christian commitment (including a practicing Catholic), although they still held that it was morally legitimate to derive and research hESCs. This view was present among research scientists but was most clearly articulated by consultant physicians, e.g.

*"I suppose conception is an easy time to think of it [beginning of human life] but then equally well, I'm not so convinced that that is the time, partly because, from a Christian perspective, I can't believe that heaven is full of pre-implantation embryos where 75% of conception projects are basically aborted naturally anyway. So I think that it's a, obviously it's an essential part to get a created being but I think that there*

*are many other things as well which are also essential"* (interview 25, consultant physician).

Figure 6.2 provides a cognitive map of the argument processes used by a consultant geneticist who self-identified as a practising Christian.

This consultant physician uses the Bible as a basis for an ethical view (27) and argues that a careful investigation of the Bible shows that it does not teach that life begins at conception (28). The key issue is relationship (29) and hence implantation is a key stage (21, 22, 77, 30) and hence embryonic stem cell research is acceptable. By considering conception as the key stage, too much emphasis is given to genetics (26, 51) also many early embryos are lost naturally (31). The loss of these is very different to the mother from loss of a baby (32) and stem cell research is very different from abortion (82) which is not acceptable (34, 76, 19) as a late embryo and baby are a person (17, 16). However, we do not really know what ES cells are (15) and should therefore treat the early embryo with respect (35) and ES cells should be obtained in an ethical manner (12). Producing cells from very early embryos for therapies is preferable to forcing poor people to donate organs for economic reasons (36, 37) and justice to poor people is more important than agonising over the status of the embryo (80).

Here, the value of embryos is contrasted with the interests of poor people exploited for their organs rather than with ill people requiring therapies, the balance clearly falling in favour of poor people. The interviewee questions the basis for valuing an early embryo and argues that too much emphasis has been given to genetics and the creation of a genetically-unique entity at conception rather than the establishment of a relationship between mother and child. However, because of the status of the embryo is unclear, the early embryos should be treated with respect and embryo donation should be ethically conducted to respect the donors.

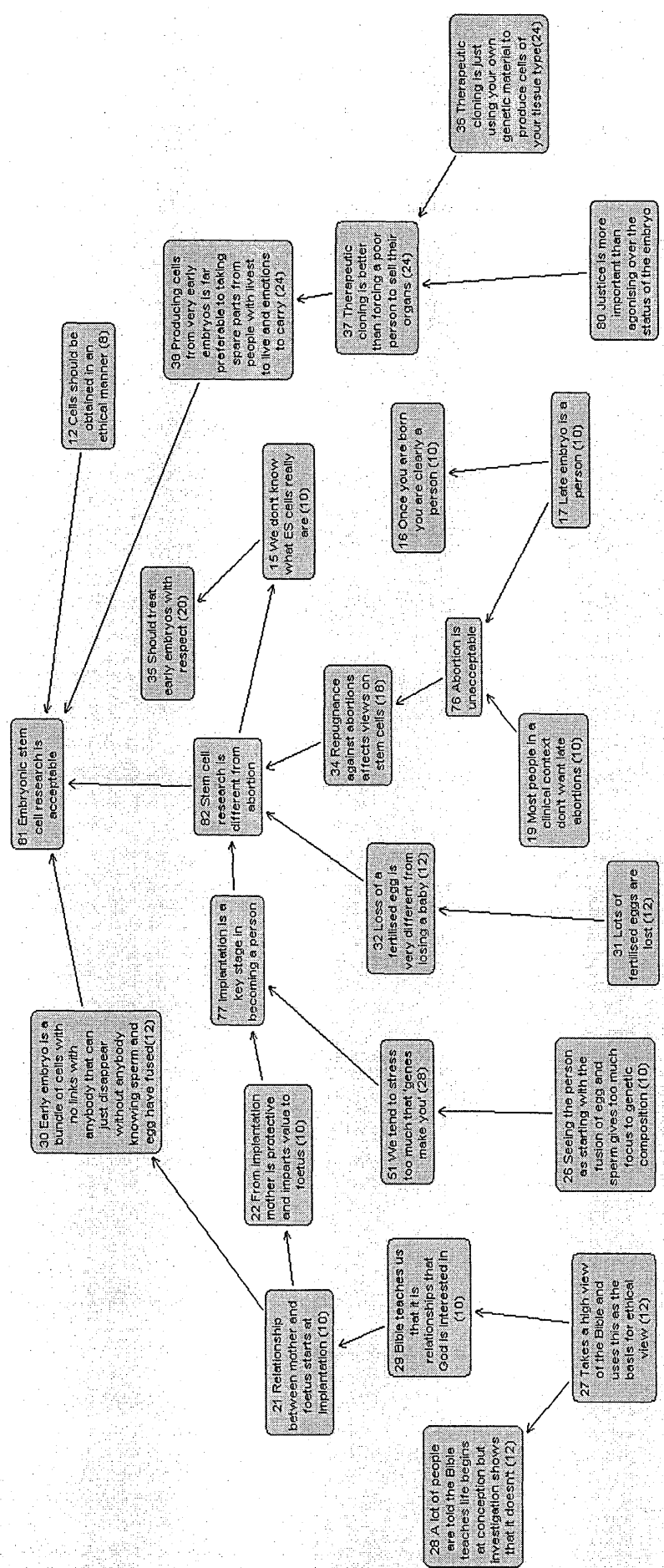


Figure 6.2 Cognitive map of the views of an innovator who is a practising Christian consultant physician (interview 10)



Several scientists also thought that there is a lot of misunderstanding about what embryonic stem cell research involves and a public perception that this involves 'chopping up babies'. There was therefore a need for scientists to explain that this research involves a very early stage embryo that does not look in the least like a baby.

*"An egg with sperm sitting beside it is legally an embryo but it is not an embryo in the way that most people think of embryos. A cell, 2 days later, where the sperm has actually got into the egg is still an embryo but again it's not what most people think of as being an embryo. And I think a lot of people, misunderstanding about what it is we're doing disappear completely when it is explained to them. Some people still think that we take a little fully-formed baby and we chop it up and we take the bits out, and some of the media still portray it like that."* (interview 11, IVF clinician).

Here the strategy of the scientists is to appeal to alternative ways of evaluating the worth of an embryo. Emphasis is placed on the ways in which early embryos are ontologically distinct from adult humans. Thus the value of an early embryo is discounted to something less than the value of an adult human.

Within the innovation community, the status of the embryo, whilst varied, is not held to be such as to prohibit embryonic stem cell research and is held to be widely misunderstood by citizens. The evidence indicates, in common with the findings of Wainwright *et al.* (2006), that a number of practicing Christians, including hESC researchers, do not find the status of the embryo to be such as to prevent all hESC research.

The prospective benefits from stem cell research are one of the key justifications for research, balancing out any harm to early embryos, and resulting in arguments around the relative merits of hESC research and research on adult stem cells. It is to these arguments that I turn next.

### **6.3.5 Prospects from research on different types of stem cells**

Among the academic researchers, commercial scientists and clinicians there was disagreement as to which type of cell would provide the best prospects for future

therapies, although almost everyone agreed that research was needed on both adult and embryonic stem cells. Many also thought the ultimate aim was to enable the patient's own cells to conduct the required repair and to avoid the use of any cell-therapies altogether. An examination of the reasons why particular forms of research are advocated by different innovators is important as it forms the ground on which many of the battles around stem cell research have been fought.

On the basis of the interviews conducted, most researchers (whether in the adult or embryonic stem cell field) despite expressing a favoured approach, also viewed research on each as complementary, as exemplified in the following three quotes.

*"If you leave with the impression there's a sort of antagonistic war between embryonic stem cell and adult stem cell research, it's not true at all" (interview 23, stem cell researcher).*

*"I think embryonic stem cells are not the only stem cells that we have to work with and there are a few other stem cell types that can be grown and used in the laboratory for study. There are many other stem cells that clearly exist in the body, being able to access them and study them and make them do what you want them to do is often a major challenge, is a major challenge and I think it's important that the research is done on, not just on embryonic stem cells but also on so-called adult stem cells because work on one type will inform work on the other and we have no clue as to which is going to be ultimately the best type of cell to use in any particular treatment, or for any particular purposes." (interview 18, stem cell researcher working with mouse embryonic stem cells).*

*"my emotional tendencies come down on adult stem cells because that's what I do. But I think if you really look at the evidence, it's difficult to know, it depends what you want to do" (interview 16, stem cell researcher working with adult stem cells).*

For some, there was also an ultimate aim of harnessing the body's own regenerative capacities to repair damage, a vision that was shared with groups advocating research on adult stem cells only (as we shall see in section 6.4.3).

Review articles from the innovation community similarly call for research on cells from both adult and embryonic sources. A report from the UK Stem Cell Foundation (a charitable foundation with a commercialisation focus, backed by several business leaders) notes that

*“To date, adult stem cell research has yielded a greater number of clinical trials and applied treatments than embryonic research. In part because adult stem cells have proved easier to manipulate in the laboratory but also because the stigma associated with embryonic research has deterred investors. However, embryonic stem cells have properties which adult stem cells do not and it is critically important that we pursue both research avenues in parallel if we are to benefit fully from the potential which stem cells hold”* (The UK Stem Cell Foundation web site).<sup>46</sup>

A major scientific review by the European Molecular Biology Organisation (EMBO) (European Molecular Biology Organisation, 2006) also stresses the complementarity of adult and embryonic stem cell research

*“Although the development of stem cell applications is sometimes presented as involving choice between ES cell research and adult tissue stem cell research, biomedical advances can be foreseen equally from both approaches”* (p7)

In this next section I will consider the extent to which values-based and interests-based arguments inform these evaluations. The arguments fell into three broad categories; researchers who i) argued for an equal balance of research between the two cell types, ii) advocated embryonic stem cell research and iii) advocated adult stem cell research. An example of each three of these argument-types is presented in the following.

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<sup>46</sup> Available from: <http://domain 883347.sites.fasthosts.com/research/benefitsandhopes.html> [accessed 5/12/06]

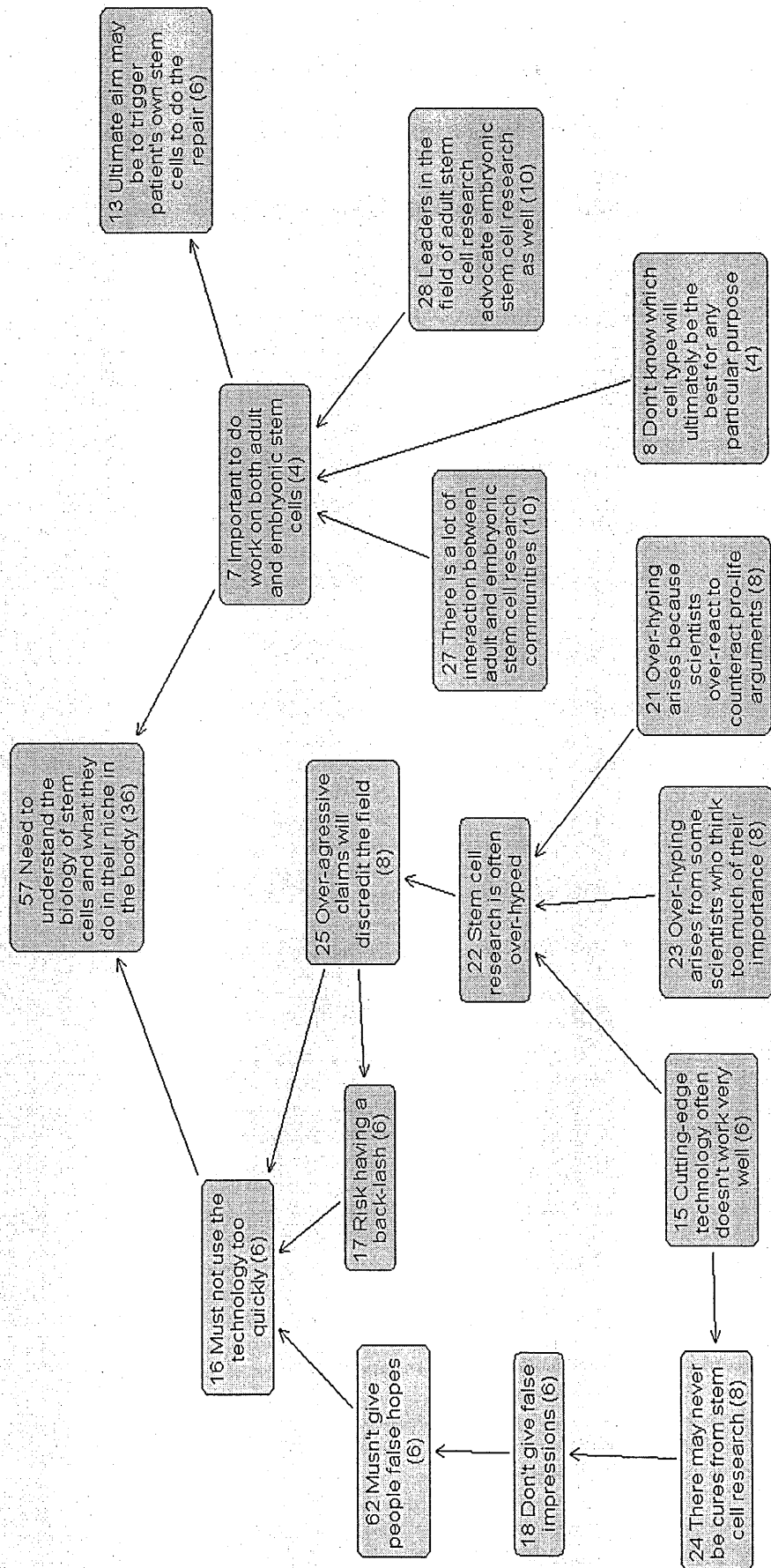
**i) Innovators arguing for an equal balance of research between adult and stem cells**

Figure 6.3 presents a cognitive map of an interview with a research scientist who expressed a cautious but optimistic approach looking to research on both adult and embryonic stem cells and ultimately to understanding enough of the biology to trigger the patient's own stem cells to carry out the repair.

For this research scientist, the aim is to understand biology better and specifically how stem cells behave in different niches in the body (57). Because of this, it is important to research both adult and embryonic stem cells (7) with the ultimate aim of being able to trigger the patient's own stem cells to repair the damaged tissue (13). At the moment it is not clear whether adult stem cells or embryonic stem cells will work the best in specific circumstances (8), researchers in the field of adult stem cells advocate research also in embryonic stem cells (28) and research in adult and embryonic stem cells inform each other (27). This researcher was also aware of the possibility of the research being hyped (22) and suggested this was partly by over-confident researchers (23), the reaction to negative comments from pro-life activists (21) and also that cutting-edge technology may not work very well (15). As a result there may never be 'cures' from stem cell research (24) and researchers should not give false impressions (18). Over-hyping will give patients false hopes (62) and potentially discredit the research (25), risking a back lash (17). The technology should therefore not be adopted too quickly (16).

The main value driver in this argument is furthering an understanding of biology. The implication here is that the knowledge is of value of itself, irrespective of any immediate prospect of therapies. I thus categorise the argument as predominantly values-based. The remaining arguments are around a biological evaluation of possibilities and the recognition of uncertainty. Thus the interviewee deems the uncertainties to be such that research on both adult and embryonic stem cells is advocated. There is no apparent over-riding value or interest that drives the research in one direction rather than the other.

Figure 6.3 Cognitive map of a cautious but optimistic approach to both adult and embryonic stem cell research (interview 18, stem cell researcher, working with mouse embryonic stem cells)



## **ii) Innovator advocating embryonic stem cell research**

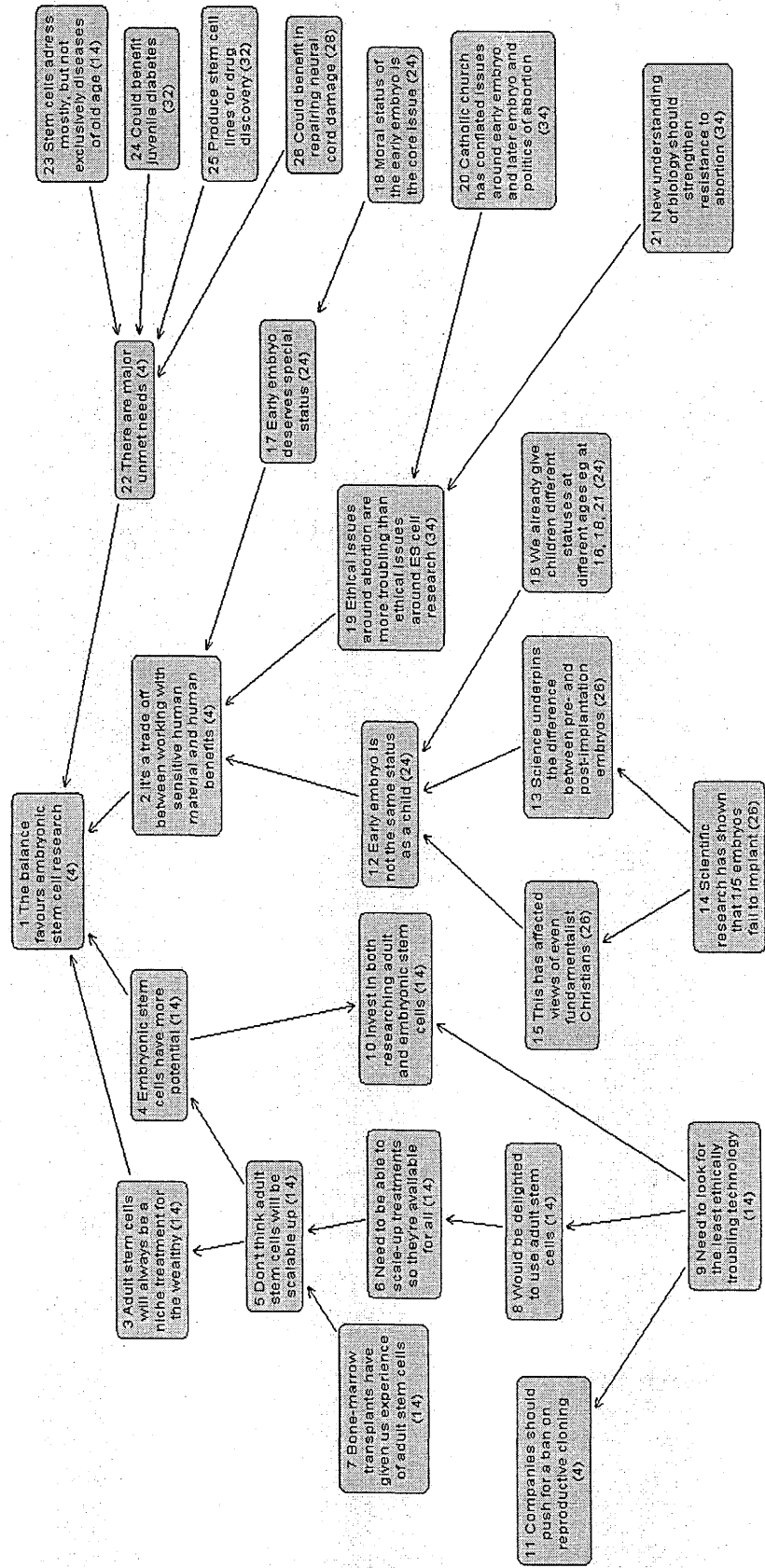
Some of the innovators tended to favour one type of stem cell over another. Figure 6.4 illustrates the cognitive map of an interviewee considering the relative merits of embryonic and adult stem cell research and concluding in favour of the potential from embryonic stem cells. Whilst representing industry, the interviewee was not personally involved in stem cell research.

This research scientist in a commercial context argued that embryonic stem cell research has more prospects than adult stem cell research (1) but research should continue in both (10). Stem cell production needs to be scaled up to provide enough cells for treatments (6). The researcher believes that experience with bone marrow transplants (adult stem cells) indicates there are problems scaling up the number of cells (5, 7) and thus adult stem cell treatments are likely to remain as a niche treatment for rich people (3). We should also use the least ethically troubling approach (9) and because of this, companies should push for a ban on reproductive cloning (11) while proceeding with embryonic stem cell research. The key issue with respect to embryonic stem cells is the status of the early embryo (18). The early embryo deserves protection (17) but this does not equate the early embryo to the same status of a child (12). There are scientific reasons for giving different status to pre- and post-implantation embryos (13) and it is not inappropriate to give different status at different ages (16). The Catholic Church has conflated issues around early embryos with those of abortion (20), but there are scientific reasons for resisting abortion (21). The concerns about the status of the early embryo have to be balanced against unmet needs that could be addressed with stem cells (22), including many diseases of old age (23). Thus there is a need to achieve a balance between working with sensitive human material and human benefits (2).

Here, unmet needs of people who are ill and ethical concerns around early embryos are explicitly considered and the balance seen to fall on the side of unmet needs of people who are ill. Adult stem cell research is seen to be scientifically more challenging than embryonic stem cell research and embryonic stem cell research to be less ethically challenging than research on cloned embryos. Thus, the interviewee believes embryonic

stem cells are ethical to research and offer better prospects for therapies than adult stem cells and values-based arguments are used to favour unmet needs of sick people. It is by no means clear whether the respondent holds that early embryos have some intrinsic value or that those who hold this viewpoint have to be taken into account and their ethical interests balanced against the biological interests of those with illnesses. It seems likely from the context that this particular interviewee attributes some value to early embryos but does not accord them the same value as adult humans, but also that the views of people who hold this viewpoint should be taken into account. Nevertheless, for this interviewee the biological interests of people with unmet health needs should win over the ethical interests of others. Finally, the main arbiter for the direction of scientific research is an evaluation of the scientific prospects of each approach.

Figure 6.4 Cognitive map of an interviewee arguing the relative merits of embryonic and adult stem cell research (interview 9, industry representative)





### iii) Innovator advocating adult stem cell research

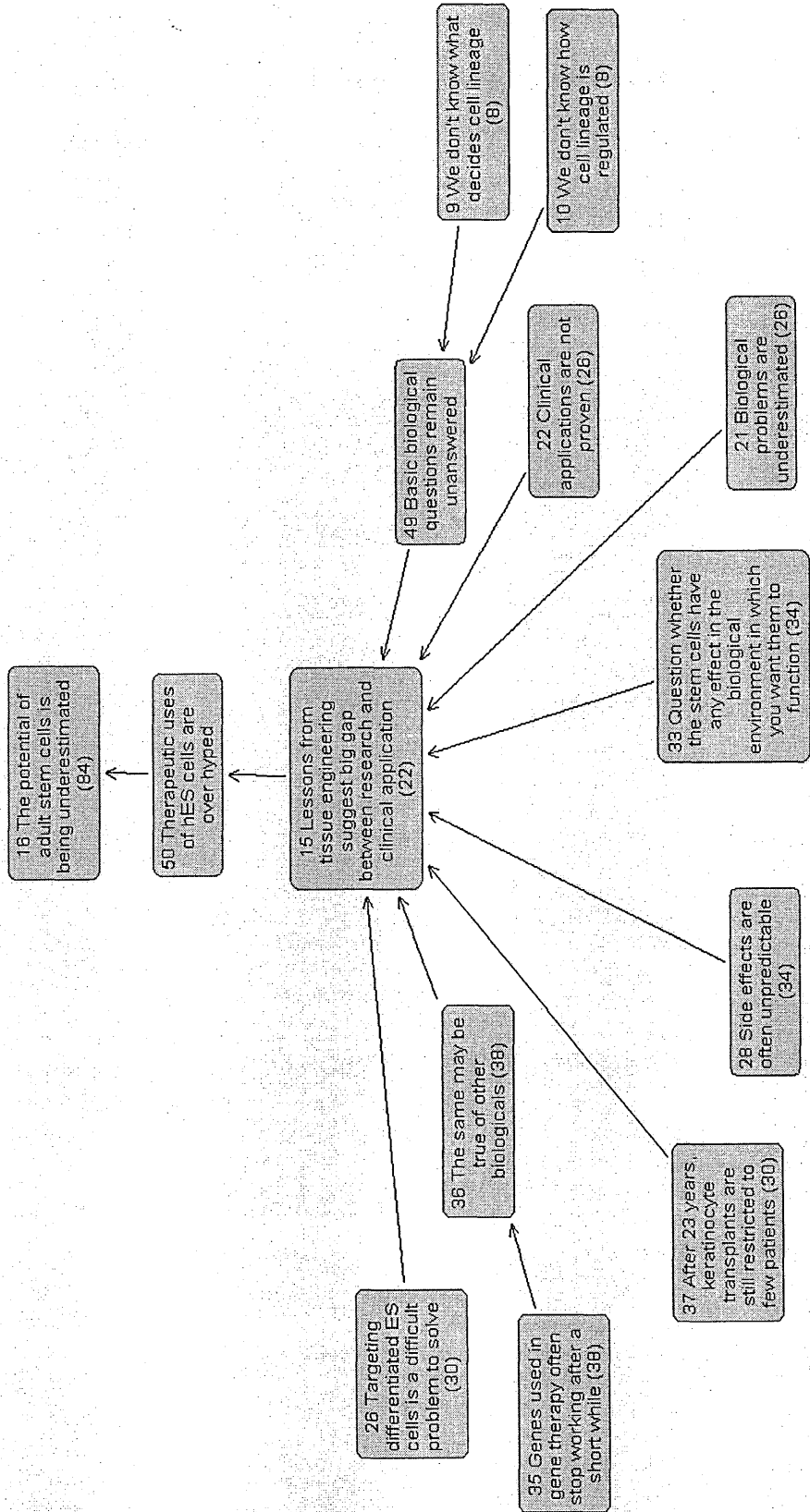
Of the stem cell scientists interviewed for this research those working in a clinical context, experienced with adult stem cells tended to be more sceptical of the promise of embryonic stem cell therapies than more academic researchers, largely because they saw there was a big gap between experimental results and therapeutic potential. For example, a researcher expressed his concern at the apparent over-selling of the prospects of stem cell research.

*"I really hope that stem cells can help cure some of the ghastly degenerative diseases that many of us are going to suffer from and many of us will know people who suffer from, that would be wonderful. But it's this enthusiasm with which it's embraced is disproportionate wholly to the amount of scientific evidence in support of it, is my perception."* (interview 23, stem cell researcher working with adult stem cells).

Figure 6.5 shows a cognitive map of the argument processes used by a clinician/researcher suggesting that the potential of adult stem cells is being underestimated.

This researcher, who has a strong clinical background, feels the potential of adult stem cells is being underestimated (16) because embryonic stem cell therapies are being over-hyped (50). The lessons from tissue engineering are that there is a big gap between research and clinical application (15) as evidenced by the limitations of transplantation of keratinocytes (37). There are a number of biological problems to be solved which are underestimated (21, 49, 9, 10), targeting stem cell treatments to specific tissues is difficult (26), they have to function appropriately in that environment (33) and there may be unpredictable side effects (28) and clinical applications are not yet proven (22).

Figure 6.5 Cognitive map of the argument processes used to suggest the potential of adult stem cells is being underestimated (interview 15, clinician/medical researcher)



Thus a very strong preference for adult stem cell research is expressed on a scientific, medical and experiential basis. There may be an element of self-interest in supporting their own area of research but there is no evidence of a bias against embryonic stem cell research for ethical or values-based reasons.

#### **iv) Conclusions on relative merits of different stem cell types**

The choice of adult vs. embryonic stem cells among innovators seems to be much more science or biology based than values-based. These are cells that researchers are already familiar with and therefore want to continue working with, (whether adult stem cells or animal or human embryonic stem cells), and where expectations from previous experience and scientific knowledge suggest one route in preference to another. Finally, it should be noted that at least one researcher was working on both adult and embryonic stem cells in an attempt to identify which cell type was more appropriate in which circumstances in the context of repairing one particular tissue type, suggesting a lack of value-commitment to one approach over another.

Thus, any simplistic view that all research scientists and innovators advocate embryonic stem cell research does not hold. There is more complexity among views of innovators regarding the prospects from either adult or embryonic stem cells. Much of this seems to be driven by different evaluations of the prospects from either adult or embryonic stem cell research based on scientific understanding and personal experience (and perhaps self-interest) rather than ideologically based or driven by ethical concerns. Innovators expressing a preference for one type of stem cell over another almost always advocated research on both. The desire to expand scientific knowledge as a major value to uphold was explicitly stated. It could also be inferred from the desire to increase knowledge to the point that the mechanisms for regeneration within the body itself could be harnessed. Therefore, among these respondents the values advocated were less about the value of the embryo and more about the inherent value of furthering knowledge and differences in evaluation of adult and embryonic stem cell research based around the expected consequences of the research rather than based on different values attached to early human embryos.

### 6.3.6 Industry views

Industry views are here separated from researcher views because of the rather different way in which issues have been framed by the two groups, although there is considerable overlap between them. Industry views varied but in some cases were less sanguine about the prospects of cell therapies and much more positive about other uses of stem cells, such as for toxicity testing, although this possibility was also mentioned by academic researchers. Thus the rationale for stem cell research was different and hence the arguments made in support of the research also varied. It should however be noted that the four interviewees from industry came from different sectors (big pharma, small and medium sized enterprise and industry representative body) and they did not all use the same framing and not all were active as research scientists.

The role of the US was seen by some as key to whether commercialisation of stem cell therapies would proceed or not. The view was expressed that the importance and size of the US market is such that there would not be widespread commercialisation until the US changed its mind and allowed embryonic stem cell research. There was concern that therapies based on ES cell research and developed in the UK may be rejected in the US and there was always the possibility of any adverse reaction impacting on other products of the company. This led to caution in involvement by industry in the embryonic stem cell field.

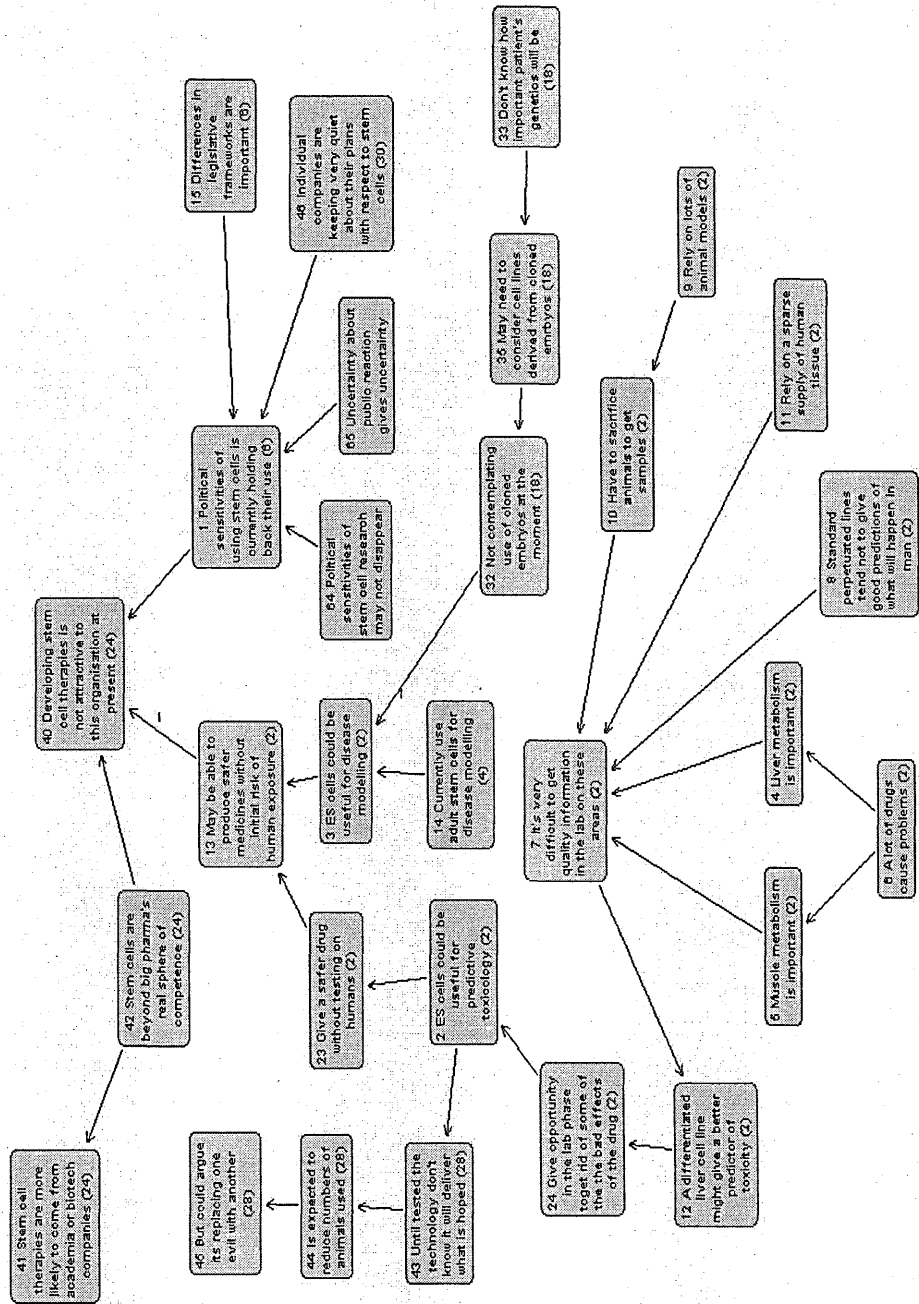
*“The US for a population of whatever it is, 217 million, is 50-60% of the global market. If you think that a technology, even one with a lot of potential might never be commercialisable in the world’s biggest market, you won’t lend money to develop it, and that’s the reality at the moment. So I don’t think there’s going to be rapid commercial development until you’ve actually seen a political, ethical, religious and a big change in the US environment that makes global venture capitalists think that the US will be open for business in this area.” (interview 9, industry).*

Figure 6.6 gives a cognitive map illustrating the views of a representative of a commercial pharmaceutical company on embryonic stem cell research.

At the time of the interview, the development of stem cell therapies was not attractive to the organisation (40) due to political sensitivities (1) that may not disappear (64), due to uncertainties about public reactions (65), and different legislative frameworks in different countries (15). Competitors were generally secretive about their activity in this area (46). Nevertheless, stem cells were perceived to have potential medical benefits particularly with respect to developing safer medicines (13). The improved safety could arise because of the better ability to model disease in human cells (3) and the ability to use embryonic stem cells in predictive toxicology (2) with the potential to give a better predictor of toxicity than existing tests (2) and thus provide safer drugs (23). Currently toxicity testing is conducted on human tissue that is in sparse supply (11) or on animals (9) which may not give a good predictor of what happens in humans (7). The use of human embryonic cells could reduce the amount of animal testing (44) although ethically this might be replacing one undesirable action with another undesirable action (45). Currently stem cell therapies were expected to arise from academia or biotech companies (41) as the area is outwith the company's sphere of competence (42).

In this chain of argument, interests-based arguments predominate, whilst being aware of values-based views that are believed to exist within citizens. The importance of the US market as noted in the earlier quote influenced the strength of concern about public reactions and political sensitivities. At the time of the interviews, George Bush Jnr. was President of the USA and held strong views on the sanctity of embryos such that research on embryonic stem cells was seriously limited. Applying stem cell research to toxicity testing to improve the safety of drugs was seen to have a strong benefit component. This would also reduce animal testing and satisfy the values-based commitments of some citizens, while recognising that whether animal research or research on embryonic stem cells is ethically better will be contested by different groups of citizens.

Fig 6.6 Cognitive map of embryonic stem cell research in the context of a commercial pharmaceutical company (interview 24)



### **6.3.7 Conclusions on innovation communities**

Innovation communities perceive stem cell research to be a fruitful area of research, supported by both value commitments and interests based arguments. Industry is not currently hugely involved in hESC research, although the area is seen by policy makers (see section 6.5) as an area of considerable potential for economic growth. Political and public acceptance issues, particularly with respect to the US market, appeared to be the main basis for this lack of industry commitment, although commercialisation at this early stage of development would also be risky. At the time of these interviews, interest appeared to be most in the potential of stem cells for toxicity testing in the immediate future rather than in cell therapies, although much of the justification for research on ES cells is based around future benefits in terms of cell therapies. Clinicians interviewed tended to be more sceptical of the promises of hES cells and more optimistic about the potential of adult cells but on scientific and practical grounds. However, the sample interviewed is small and does not claim to be statistically representative, so extensions to the wider community of clinical researchers should be treated with caution. There was no evidence in these interviews of a values-based commitment to adult stem cell research in preference to hESC research. The polarisation into an embryonic stem cell research community and an adult stem cell research community was not apparent and neither was the polarisation into Christians against hESC research and scientists supportive of it. A number of research scientists were practising Christians (including Catholics and evangelicals which are groupings usually associated with antagonism to hESC research).

Thus the detailed data collected show that there is considerable complexity in attitudes to stem cell research that is not always recognised. The potential benefits are often portrayed simply as stem cell therapies whereas stakeholder communities recognise a number of other benefits that may prove to be more important, for example, simply improved understanding of biology or use of cell lines for toxicity testing. The route to therapies is also sometimes portrayed as a simple linear process from research to clinic. It is clear that the experience of clinicians in adult stem cell therapies suggests the process

is not so straightforward and the involvement of industry in producing therapies is influenced by a wide-range of strategic considerations other than scientific knowledge and public benefit. Finally, even among innovation stakeholders there is heterogeneity about whether and how early embryos should be valued.

## **6.4 Citizens/civil society advocacy groups**

In this section I will consider citizens as well as patient and patient advocacy groups and adult stem cell advocacy groups as being the main identifiable groups involved in the debates to date.

### **6.4.1 Citizens**

The evidence for this section is primarily based on a public engagement exercise conducted by British Market Research Bureau (BMRB) (MRC *et al.* 2009) as detailed in Chapter three. As noted earlier, the author was on the advisory committee for this project. The engagement exercise provided strong support for medical research (which was a source of national pride) but also a desire that medical research should be driven by social needs rather than purely by profit. In terms of the source of cells, adult cells were viewed as least controversial and having proven clinical value, although technical limitations were recognised. Foetal stem cells were considered the most controversial. There was general support for use of cord blood cells when made publicly available but mixed views about banking cord blood for a family's own use. There was majority support for use of hES cells (around 75%) but very strong views against the research from around 10% of those sampled. For these participants the ends did not justify the means, indicating a strong value-basis for rejecting the hESC research.

The availability of stem cell therapies for serious disease was an important consideration for these citizens. However, the definition of what constitutes a disease that is serious enough for stem cell therapy was contested and the circumstances under which stem cell research is justified was therefore also contested. The moral status of the embryo was important to many of the participants but other factors were also very important, such as issues around egg donation.



Thus, these data suggest there is a general (but not unanimous) support for stem cell research, including embryonic stem cell research. Some of this support seems to be conditional on the applications being for serious benefits reflecting a degree of negotiability suggesting an interests-based argument within the definitions used in this thesis. Other interests are implicitly being weighed against the health benefits. For those strongly against embryonic stem cell research, these views are strongly held and cannot be overturned by considerations of benefits, suggesting they are primarily values-based.

#### **6.4.2 Patient advocacy groups**

Data here are drawn primarily from the recording of a conference held in Brussels in 2005 with the specific aim of engaging patients, as detailed in Chapter three. Additional material is provided from an interview with a patient advocacy group representative conducted as part of the main interviews for this case study.

The patients and representative groups were very supportive of stem cell research (including human embryonic stem cell research). A range of views were however expressed within this context and a minority of the patients/patient advocates rejected embryonic stem cell research altogether as well as any treatments that would arise from them. Among those who welcomed embryonic stem cell research, some accepted research on 'spare' embryos from IVF treatments that would otherwise be discarded but rejected the creation of embryos specifically to derive embryonic stem cells. Yet others expressed strong views that failure to proceed with embryonic stem cell research would be immoral given the suffering that exists. Some argued that non-patients should not be allowed to prevent the research taking place and the personal concerns of some should not be allowed to prevent future therapies. Often an appeal was made to the commonality of suffering and to the difficulty of a healthy person being able to comprehend what it was like to have one of these serious diseases. There was an expectation of therapies but this hope was tempered by a realisation that therapies would be some time in the future.

Thus, there was a strong element of interests-based argument being expressed, but in some cases tempered by values-based arguments in that not all forms of embryonic stem

cell research would be acceptable. The interests-based arguments were so strong that in many cases this became the only interest to be considered. Alternative views linked to the intrinsic value of embryos were to be overridden by these interests. Whilst the argument could be categorised as one of self-interest or the interests of future fellow sufferers, it draws on a common value of respect for dignity of life. Furthermore people with a diagnosis of a serious illness have knowledge about the impacts of the disease and living with the consequences that are not easily open to those unaffected and hence their interests were strongly emphasised by those that do have such an understanding.

Some were against creating embryos for stem cell (SC) research in principle but argued that given the spare embryos from IVF treatments in many countries, which would otherwise be destroyed, they should be used for research. The parallel was drawn with cadaveric organ donation. Failing to use spare embryos for research would be inconsistent with a pro-life view of early embryos as the embryos would still be destroyed. This is an interests-based argument, that it is better to use the embryos for 'useful' purposes rather than just destroy them.

The arguments made within the EU patients' conference broadly reflected the in-depth interview with the patient advocate (Interview 5). Figure 6.7 shows a cognitive map of the argument the interviewee made for patient benefits from embryonic stem cell research.

This interviewee stressed the horrendous nature of some medical conditions and the possibility of stem cell therapies to address them (14). There are some families struggling with some very serious diseases (1) through no fault of their own (2) who would like some alleviation for them (3). Because we as a society care for these people (10, 11) we will need very robust reasons if we are to reject possible sources of treatments (13). The interviewee accepts that the disaggregation of an embryo destroys a potential human being (44) and this should not be done lightly (45) and the ends don't always justify the means (12). Nevertheless, the suffering of existing people needs to be balanced by the frustrated potential of the embryo (36) and in this case the benefits to existing people are greater (42). The interviewee acknowledged that other people might not agree and that as a society we need to respect other people's values (45) and that living in a society can

prescribe what is done (78) because actions have ethical consequences (55). However, the ethical high ground does not necessarily lie with those who wish to prevent an action (54). Other people's values do not necessarily over-ride your own (47) and nobody will be forced to accept stem cell therapies (53).

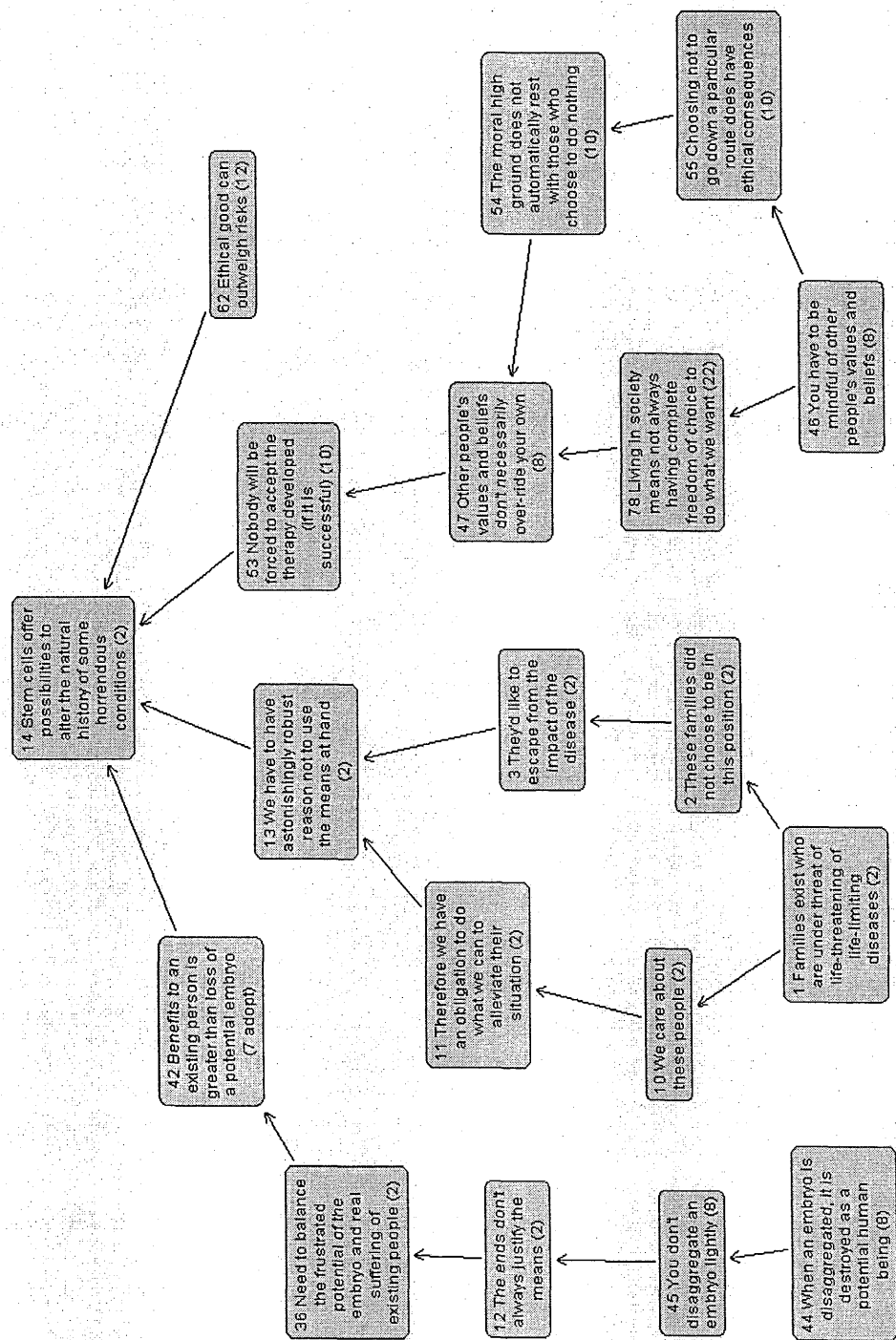
This interviewee also engaged with the issues of resource allocation for research, recognising the tendency for profit rather than necessarily the greatest need influencing research resourcing. However, the interviewee felt unable to affect this tendency.

*"I'd rather see research, whether it's public, private or voluntary, being addressed to finding effective treatments for whatever, cystic fibrosis or motor neuron disease or cancer or something, than for products for treating male pattern baldness. But the person who finds a cure for male pattern baldness will never have to worry about paying the gas bill ever, ever again. I think that's a shame, personally, but I can't do too much about changing that so, whereas I can express an opinion and I can raise a voice and say, this seems to be a distortion of priorities and shouldn't we do something else, I'm not going to waste my time and energy on trying to change things which I know I can't" (interview 5, patient advocacy).*

The interviewee also addressed the issue of 'hype' about medical research but felt that this would be inevitable.

*"The day you see a newspaper headline, 'Scientific experiment confirms what most people thought, a few scientists quite pleased', you will know that we have entered the era of rational nuanced debate about resource allocation, but I fear we are some way from that." (interview 5, patient advocacy).*

Figure 6.7 Cognitive map from a patient advocate arguing for patient benefits from embryonic stem cell research (interview 5)



The issue of potential for 'hype' and raising of unrealistic expectation was also raised in the EU patients' conference. However, besides recognising hype as happening and the role that media play in the raising of hopes, there were few solutions suggested.

#### **6.4.3 Civil society advocacy groups**

A number of civil society advocacy groups exist which are against embryonic stem cell research, but supportive of adult stem cell research. The possibility of therapies from embryonic stem cell research appears to be almost completely discounted by pro-adult stem cell advocacy groups. Three representatives of different organisations were interviewed as part of this research. It should be noted that they did not all come from religious perspectives. Cognitive maps are presented from two of these interviews, one where the potential for research on ES cells to stimulate genetic modification (and so-called 'human enhancement') is the major concern (figure 6.9) and the other where 'human dignity' is the critical factor identified (figure 6.10).

In this extract from the interview with an advocate of adult stem cell research (figure 6.8), the main concern expressed is that of embryonic stem cell research providing the basis for genetic modification of humans (108,66) which is seen to be wrong (109). While enhancing existing capacities can be acceptable (64) going beyond these is not (69) and giving humans power over themselves (59) can lead to humans becoming manufactured entities (60). The driver for this desire is seen to come from the trans-humanists whom the interviewee does not trust with decisions about the future of human kind (68). The HFEA is seen as confusing regulation and policy (65) and hence not trustworthy as a guardian to ensure stem cell research is used appropriately (110). The status of the embryo is seen as an important consideration (56) but germ line modification is seen as more threatening (58) particularly with the advent of cloning (SCNT) (57). Thus the debate should be about how to harness these technologies to become more human (62, 54, 55).

In figure 6.9, the interviewee concludes that creating embryonic stem cells should not be allowed (72). The interviewee does not see this as a science-religion debate (15) which has already been lost, regarding embryos (17) and is committed to scientific advances

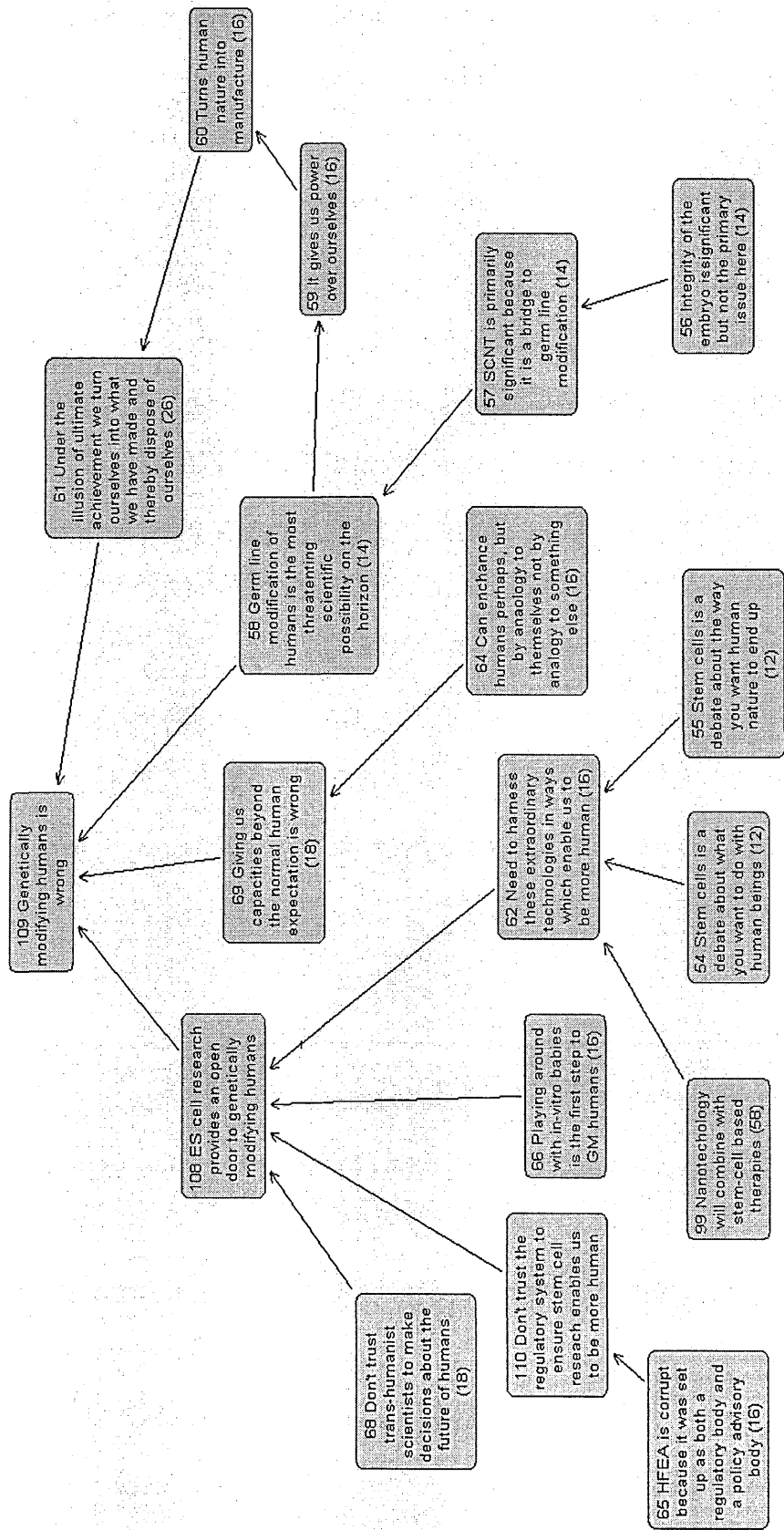
(16) and believes the issue is about human dignity (39). The interviewee accords full human rights to the embryo from conception (5) and hence views the destruction of one human life in order to create another (cloning) as absurd (1). Furthermore the interviewee believes that there should not be any surplus embryos (49, 51, 48) that the supply of embryos could dry up in future with technological developments (50) and therapies should not rely on the availability of surplus embryos (79). Even if stem cells are produced from embryos deemed to be non-viable (81) this is problematic as the identification of an embryo as non-viable is not exact (42, 43) and poor quality embryos are unlikely to be acceptable as sources for therapies in any case (45).

These advocates primarily argued on the basis of how things ought to be. As this is a normative argument it is in the values-based category for the purposes of this thesis. In Figure 6.9 the interviewee explicitly indicates that they give early human embryos the same status as an adult human being. The intention to weigh the interests of one (adult) human being against another (embryonic) human being was seen to be 'absurd'. The argument here appears to be drawing on an absolute barrier not to be transgressed, a values-based argument in this thesis.

In common with research scientists, the ultimate aim was seen to be to harness the body's own regenerative capacities, the difference here being that this is linked only with adult stem cell research.

*"the incredible capacity of human beings, to sort of follow the salamander, and re-grow limbs, not because we're clever but because the body can do that, it was designed to do that and as ironically you end up with stem cell research essentially as a kind of alternative medicine. This basically is freeing the body to heal itself by a certain amount of rearrangement, rather than imposing some clever human scheme upon it, and that is certainly the mechanism for adult stem cell research"* (interview 13, adult stem cell research advocacy).

Figure 6.8 Cognitive map of an interviewee with objections to embryonic stem cell research due to concerns about genetic modification of humans (interview 13, adult stem cell advocacy)



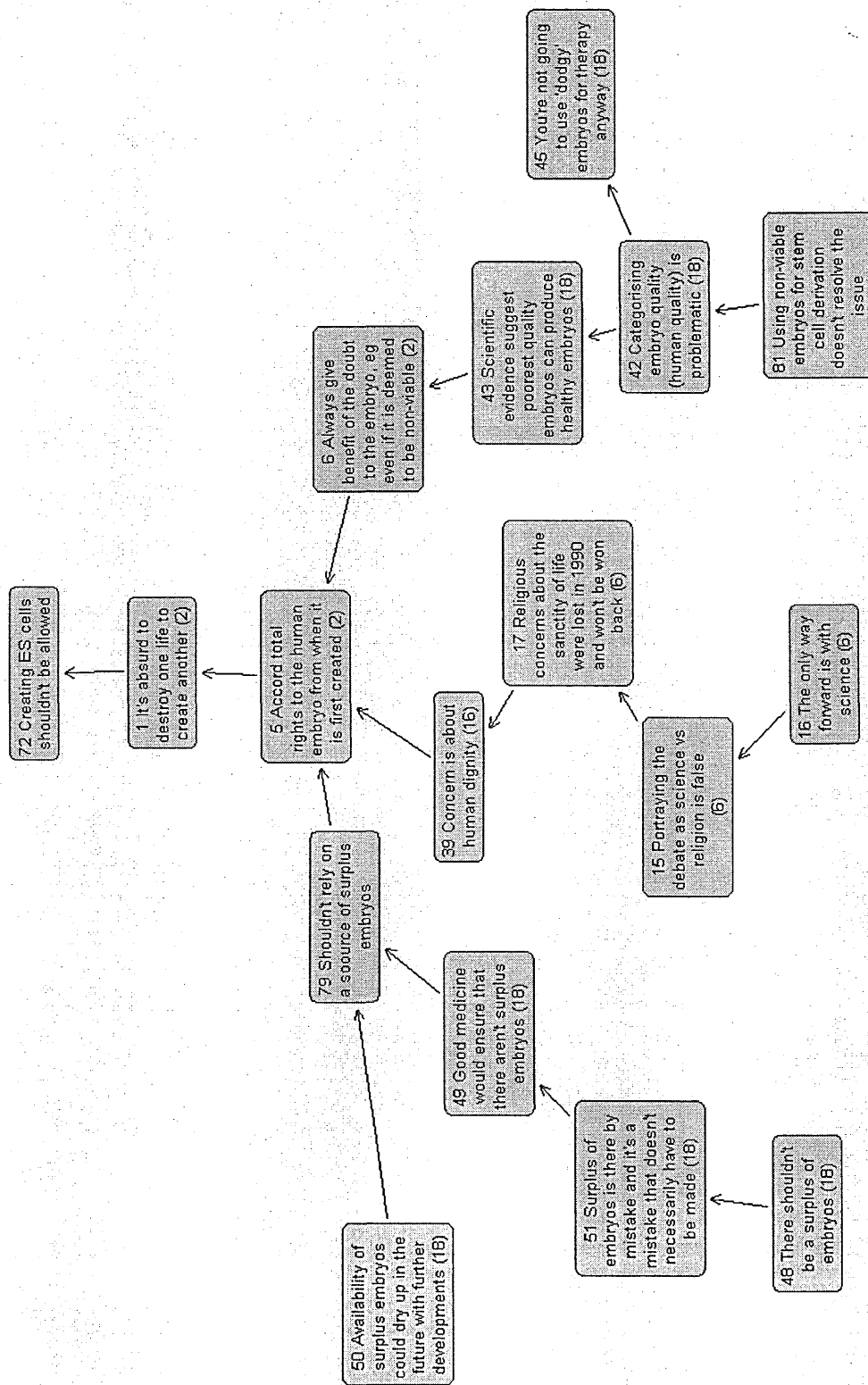
There are also echoes of the dispute over authority that was identified by one of the research scientists as the main underlying reason for disputes around embryonic stem cell research. Here, the interviewee felt that scientists are too powerful and are not willing enough to consider alternatives to ES cell research.

*"I felt that science had taken over the role of, certainly the role of religion but also philosophy that it was a sort of sense that if you were a scientist you were automatically the depository of all wisdom and that anything you said was gospel truth."* (interview 22, adult stem cell advocacy).

These arguments suggest the dispute is not just about specific technological decisions but also at the powerful role that scientists have in society, an aspect also identified in other contexts by Nelkin (1992) as identified in Chapter two.



Figure 6.9 Cognitive map of a second interviewee with objections to embryonic stem cell research (interview 22, adult stem cell advocacy)



### **6.5.5 Conclusion about citizens/civil society advocacy groups**

In summary a range of values-based and interests-based arguments are advanced by citizens and advocacy groups both supporting and resisting hESC research. Citizens argued for hESC therapies on the basis of promoting the interests of patients, although in many cases these interests were balanced against other concerns. For some, therapies should only be developed using hESC cells if the disease was serious or if embryos used to derive stem cells were of particular categories, such as spare IVF embryos. A minority of citizens rejected hESC research altogether on values-based considerations.

Patients and patient advocacy groups supported the interests of patients in hESC research. For some, this took on the characteristics of a values-based argument, appealing to expressions of solidarity and patient rights. Yet others recognised the interests of patients in hESC research but weighed these interests against other factors so that some sources of embryos were acceptable but others were not. The other factors weighted against the benefits from hESC research related to the value attributed to embryos. And for a minority, even though they might personally benefit from stem cell therapies, hESC research was deemed wrong and unacceptable based on values-considerations.

Advocacy groups against hESC research argued primarily on a values-basis either appealing to the value of an embryo or to normative and values-based arguments on how things ought to be. Underneath these arguments was a suggestion that a further important consideration is the power of scientists which over-rode other considerations.

In the next section I will examine the policy and regulatory responses to these arguments.

## **6.5 Policy and regulation**

Stem cell research straddles a number of policy areas and human embryonic stem cell research has generated specific legislation in the UK. UK government departments in the two main policy domains; health and innovation, have both issued a number of policy documents. The UK Parliament has also become involved in debates around embryonic stem cell research. Both the House of Lords and the House of Commons have debated

embryonic stem cell research and the Human Fertilisation and Embryology Authority (HFEA), hitherto responsible for licensing *in-vitro* fertilisation clinics and regulating research on human embryos, has had its remit extended to include derivation of human embryonic stem cells. Within the EU, legislation around the acceptability of embryonic stem cell research is a matter of national regulation. However, EU regulations intersect with some aspects of stem cell research, notably whether European Framework research funding should include research into hESCs, and the patentability of hESC lines. The European Group of Ethical Advisors has produced opinions on embryonic stem cell research and patenting (EGE 2000, EGE 2002). Five key policy/regulatory bodies are considered in this section, namely:

- Department of Health
- UK Parliament
- Human Fertilisation and Embryology Authority
- European Patent Office.
- UK Stem Cell Initiative.

Each will now be considered in turn briefly.

#### **6.5.1 Policy communities considered**

##### **i) Department of Health**

In 2000, hESC research was considered by a specially convened expert committee – the Donaldson Committee (Department of Health, 2000), under the auspices of the Department of Health. The Committee, with a membership of 14, consisted primarily of medical specialists together with law and ethics representatives. It was therefore strongly in the tradition of medical ethics. The committee was invited to assess benefits, risks and alternatives to stem cell research and to advise what new areas of research should be permitted. The committee concluded that embryonic stem cell research should be permitted (including the specific creation of embryos for research including by cloning);

reproductive cloning should remain a criminal offence and the mixing of adult human cells with the eggs of animals (cybrid embryos) should not be permitted.

## **ii) UK Parliament**

The UK parliament debated embryonic stem cell research (House of Commons 17<sup>th</sup> Nov and 19<sup>th</sup> Dec 2000, House of Lords 22 Jan 2001). Parliament concluded that research on human embryonic stem cells should be allowed, including creation of stem cell lines from embryos specifically created for the purpose of stem cell derivation. Parliament also agreed to permit the creation of embryos by somatic cell nuclear transfer (cloning). Primary legislation was introduced to ensure that reproductive cloning, the placing of these cloned embryos in recipient women to produce fully-developed humans, is prohibited. Analysis of these debates presented in this thesis has previously been published in Bruce & Harmon (2009).

## **iii) Human Fertilisation and Embryology Authority**

Research involving human embryos must be licensed by the Human Fertilisation and Embryology Authority (HFEA). This is a regulatory body admired in many other jurisdictions e.g. Fukuyama & Furger (2006, p169), although with some caveats relating to the openness and accountability of membership and procedures. Different constituencies vary in how effective they believe the regulatory mechanisms to be and the way in which these regulations are implemented by the HFEA in practice have been questioned. The openness and transparency that the HFEA exhibits in order to maintain legitimacy to its decisions has slowly been evolving (e.g. the amount of publicly-available information given about licence applications and the Authority's reasons for a given decision and the introduction of meetings open to the public). The primary analysis presented in this thesis is of three debates within the licensing committee of the HFEA (Bruce & Harmon, 2009) based on written notes of meetings held on 17<sup>th</sup> May, 11<sup>th</sup> July and 14<sup>th</sup> September 2006.

## **iv) European Patent Office**

Patenting of stem cell lines is seen as an important factor in the commercial development of stem cell therapies. However, patenting of hESC lines has become extremely

controversial. The main determinant of European patents is the European Patent Convention 1973, which has a multiplicity of functions including supporting innovation (Bruce & Harmon, 2009). Patents can only be granted if certain conditions are fulfilled (such as novelty and involving an inventive step). There has been considerable debate about the patentability (or otherwise) of human embryonic stem cell lines within the European Patent Office.

#### v) UK Stem Cell Initiative

Stem cells have been described by policy makers as an important future driver for the UK economy. The goal of ensuring UK competitiveness in the area of stem cell research is highlighted in a number of policy documents. It is evident that the UK government saw stem cell research as a key scientific area to nurture, witness for example the stress that HM Treasury gave to maintaining UK at the global cutting edge of stem cell research:

*"In March 2005, The UK Stem Cell Initiative was established by the Chancellor, Rt. Hon. Gordon Brown, to produce a vision and strategy to keep the UK at the leading edge of global stem cell research over the next decade"* (my emphasis) (UK Stem Cell Initiative, 2005 p40). This ten-year (2006-2015) vision and strategy for stem cell research in the UK developed by the UK Stem Cell Initiative (UKSCI) – known as the Pattison report – outlined UK thinking on the subject. This report forms the main basis of the analysis presented here.

The commercialisation aspects of stem cells have developed greatly since the interviews for this research were conducted in 2005, including the development of the UK stem cell bank, regulation of potential therapies and involvement by the Technology Strategy Board, however, these are considered outwith the remit of this thesis.

I turn now to the responses of these bodies first to interests-based arguments and then to values-based arguments.

### 6.5.2 Interests based arguments

As seen above, the Pattison report was produced in the context of commercial benefits for the UK from stem cell research and the report responded with the following vision (UK Stem Cell Initiative, 2005, p5) *"The UKSCI vision is for the UK to consolidate its current position of strength in stem cell research and mature, over the next decade, into one of the global leaders in stem cell therapy and technology"*. This reflects a strongly interest-based argument, calling on the supremacy of the UK in the area, although underpinned by the value that is attributed to being in global leadership. The expectation of commercial benefit was also mentioned in Parliamentary debates, although with more negative connotations:

*"...[B]ut does he accept that the key issue at stake in the Government's introduction of these regulations is the defence of the United Kingdom's pharmaceutical and biotechnological research base?"* (Hansard, 2000, col 1194)<sup>47</sup>

In interviews, policy makers stressed the importance of research in stem cells and the huge potential that these are seen to have. A major concern was that UK should be able to capitalise on its excellent research in terms of commercial and employment benefits. Parallels were drawn with monoclonal antibodies, discovered by UK scientists, with great commercial potential but where the UK had failed to realise these commercial benefits. In this sense there was a strong drive to protect the UK's interests in the stem cell research area.

Decisions made within the HFEA's licensing committees have relied on a step-wise process that tests the research activity against regulatory criteria for licensing (Bruce & Harmon, 2009). Thus, the committee tests the research application to ascertain that it is not prohibited by the HFE Act 1990 and 2001 Regulations and that it is necessary or desirable to pursue the permitted purposes of increasing knowledge about development of embryos, increasing knowledge about serious disease or enabling such knowledge to be applied in developing treatments for serious disease. Only then are any particular features

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<sup>47</sup> Available from House of Commons Hansard, 17 November 2000, col 1194 Available from: <http://www.publications.parliament.uk/pa/cm/cmse9900.htm> [accessed 7/1/11]

of the application considered. Thus, the committee effectively provides a series of 'gates' through which the application must pass. Similarly the European Patent Office (EPO) can only consider any opposition to patents on the basis of permissible arguments; e.g. that the criteria for patenting have not been met, the disclosure is insufficient, the claims are over-inclusive or contravene public morality. These arguments used in regulatory situations are therefore clearly not values-based (nor would they be expected to be so, as the values are already enshrined in the legislation). However, particularly in the case of the EPO, the public morality clause allows some room to negotiate values-based arguments, all be it in a political context. I shall return to this in the next section. The arguments used within the HFEA and EPO are also not really interests-based, there is no attempt made to balance different interests. Rather they are instrumental, almost ritualistic in nature, requiring a formal evaluation to ensure fair treatment of all parties.

The dominant interests-based arguments are therefore found in the commercialisation arena, with the need to secure economic benefit to UK in this research domain and a belief that investment in the area will be worthwhile.

### **6.5.3 Values based arguments**

#### **i) Health benefits**

Debates in Parliament recognised the need to balance the value of the embryo against expected health benefits, exemplified by this quote:

*"I am driven to my view on the issue not by science, although that is an important factor, but by the ethical duty. I believe we as representatives have to do what is right. After careful examination, I have judged that, although it will entail the curtailment of the rights of some early embryos, allowing research into life-saving therapies is the right thing to do."*<sup>48</sup>

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<sup>48</sup> House of Commons Hansard, 17 November 2000, col 1217 Available from: <http://www.publications.parliament.uk/pa/cm/cmse9900.htm> [accessed 7/1/11]

The reference to 'ethical duty' suggests that what is really at stake here is a value, although in this case two values are pitted against each other (the embryo vs. life-saving therapies).

A strong element relying on the hope of therapies was also apparent e.g.

*"As a non-scientist, I cannot know whether even that analysis is right. I do not know whether stem cell research- adult and embryonic – will ever deliver a solution to Parkinson's. However, we should allow those who have identified potential in that route the chance to realise the ambition of a solution to the disease."*<sup>49</sup>

Thus, the hope of therapies is enough to give the benefit of the doubt in favour of potential therapies.

Within policy documents the enormous health benefits expected from stem cell research are also stressed e.g. The Pattison report (The UK Stem Cell Initiative, 2005) p 9 states that:

*"The picture presented to the Expert Group by the scientific community was of the enormous potential of stem cells as a source of new tissue for therapeutic uses in the repair of damaged tissue and organs for a wide range of currently incurable disorders" and that this "great potential to relieve suffering and treat disease meant that research was warranted across the whole range of possible sources of stem cells in the first instance, including embryos."*

Although a key vision presented in the Pattison report is the potential for providing cures for hitherto intractable and degenerative diseases, the potential to use stem cells in other ways was also recognised:

*"Our vision encompasses the UK being in the vanguard of this area by developing novel stem cell therapies, but also by exploiting stem cell research and technology to develop safer and more effective pharmaceuticals, by illuminating the processes*

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<sup>49</sup> House of Commons Hansard, 17 November 2000, col 2000 Available from: <http://www.publications.parliament.uk/pa/cm/cmse9900.htm> [accessed 7/1/11]



*leading to cancer and by continuing to deepen our understanding of basic stem cell biology” (UK Stem Cell Initiative 2005, p6)*

The Pattison report also recognised that it will take time to achieve useable results:

*“we must also accept that it is probable that this area will take several decades of small incremental advances in science and medicine to come to fruition.” (p5)*

There was acknowledgment among policy interviewees that progress was not guaranteed, however, the perception was that research scientists were more optimistic about prospects from stem cell research than at a similar phase in gene therapy research and hence there was a general expectation of positive results.

*“I don’t think it’s going to, it’s not going to evaporate this area, it’s not like cold fusion which promised everything and never delivered, it was actually a bit of a blind. I don’t think, it doesn’t feel like a blind alley because stem cells is not one thing, it’s a whole range of activities and it’s very, it’s fundamental biology which, it’s like gene therapy, it kind of makes sense, if you can get it to work it makes sense.” (interview 17, policy maker).*

Generally policy interviewees downplayed the prospect of therapies in the near future e.g.

*“I think they [the benefits] will [pause] be far and wide but I think it’s going to be a long time. I think there will be some form of therapeutic cures and such-like but I think it’s a long way off, and I think you’re looking at 15-20 years, in my limited understanding of the science but I think it’s going to be a while off.” (interview 7, policy maker)*

Thus the prospect of new cell-based therapies is a major driver among the policy communities, even though there is recognition of other benefits, such as improved toxicity testing for drug therapies. There is also an appreciation of the uncertainty of benefits, allied with an expectation that therapies are not imminent. Nevertheless, the policy communities appear to be strongly driven by hope of therapies.

## ii) Status of the embryo

In Parliamentary debates a range of arguments including both values-based arguments and interests-based arguments were advanced (Bruce & Harmon, 2009), but a debate about the status of the embryo was not explicitly re-visited. However, values-based arguments were deployed on both sides regarding research on embryonic stem cells and these arguments included consideration of the value of embryos e.g.

*“As a mother and grandmother...the fact that we have scientists who think of these [embryos], who are definitely human, simply as a source to be exploited in obtaining cells and tissues, I find frightening”* (Hansard, 2000, col 1204).<sup>50</sup>

Whilst the Pattison committee recognised a range of views on the status of embryos, they felt that no fundamentally new issues were raised by stem cell research beyond those already legislated for by the Human Fertilisation and Embryology Act, 1990 (HFE Act 1990) and therefore this aspect was not considered further in the Pattison report.

The value of the embryo has caused particular problems for the patenting regime. Patenting can only be argued against on specific grounds, mostly technical but there is also a prohibition on patenting anything contrary to morality or *ordre public*<sup>51</sup>. The interpretation of this clause in the context of human embryonic stem cell lines has been a major focus of discussion and has opened up the patenting system to values-based debates. The morality provision states that (1) patents shall not be granted for inventions the exploitation of which would be contrary to morality or *ordre public*, and (2) inventions which concern the use of human embryos for industrial or commercial purposes are so contrary.<sup>52</sup> As a result, European patents are not available for human embryonic stem cell lines and the lack of patents for human ES cell lines has been seen as a disincentive to commercial development.

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<sup>50</sup> House of Commons Hansard, 17<sup>th</sup> November 2000, col. 1204 Available from: <http://www.publications.parliament.uk/pa/cm/cmse9900.htm> [accessed 7/1/11]

<sup>51</sup> Article 53 European Patent Convention

<sup>52</sup> Article 53(a) European Patent Convention, and Rule 23d(c)

#### **6.5.4 Conclusion on policy and regulatory communities**

In summary, the basic framework for the values and interests underlying stem cell research were debated in parliament and decided on a free vote following discussion in other ethical fora, such as the Donaldson committee. The implementation of the basic value-framework and the negotiation of different interests have taken place within the HFEA, and this has in turn become the target of different interest groups and the subject of judicial reviews of its decisions. There has been strong government support to stem cell research in the UK partly because of expected therapies and partly because it appears to be seen as an opportunity for future prosperity but a number of important factors remain unresolved in the context of commercialisation, including the availability of European Patents for stem cell lines.

Policy stakeholders have generally resisted oversimplification of arguments around stem cell research. Potential benefits are seen to be contingent rather than certain. Benefits are expected to take a long time to accrue, although within the context of this case study there appears to have been little engagement with the practicalities of commercialising and delivering therapeutic benefits at the time of the interviews. These would be likely to occur as therapies become closer to realisation and have now begun to emerge. Policy communities have largely avoided engaging with the complexity of attitudes to embryos and have preferred to consider that these discussions have already been concluded.

In the next section I will examine how the various sectors: innovation communities, policy/regulators and stakeholder groups interact with, react or adapt to different values-based or interest-based arguments.

### **6.6 The role of values and interests in debates around stem cell research**

#### **6.6.1 A summary of arguments**

In this section I summarise the values-based and interests-based arguments in the area of hESC research based on the evidence presented. The main arguments are summarised in table 6.2. Conditional arguments are those conditions that are identified as key to being met for the technology to be acceptable.

**Table 6.2 Main values-based and interests-based arguments with respect to human embryonic stem cell research**

Stakeholder groups					
	Innovators <sup>53</sup>	Industry	Civic Society groups	Patient advocacy groups	Citizens
Arguments favouring stem cell research					
Values-based arguments	Health benefits	Health benefits	Health benefits	Health benefits	Health benefits
	Scientific knowledge				National Pride
	Freedom of scientific research				
Interests-based arguments	Relieving suffering		Relieving suffering	Relieving suffering	Relieving suffering
	Reduced animal testing	Reduced animal testing			
	Wealth and job creation	Safer medicines			
Arguments against embryonic stem cell research, or in response to concerns					
Values-based arguments			Minority rejection of hESC research	Immorality of destroying embryos	Minority rejection of hESC research
Conditional arguments	The principle of justice underlies the conditionality of protecting embryo donors from exploitation				
	The principle of justice underlies the conditionality of ensuring therapies are available to rich and poor alike				
Interests-based arguments	Respect for views of those in opposition	Reactions of the US market		Scientists have too much power	For social need not purely for profit

The first question of this thesis asks the extent to which values-based and interests-based arguments are found in areas of genomic technologies other than GM crops?

The data presented in this chapter indicate the presence of both values-based and interests-based arguments in debates around stem cell research and particularly hESC research. The main arguments advanced by proponents of hESC research relate to their

<sup>53</sup> Innovators by definition are unlikely to argue against a technology but may be responding to criticism

potential to provide therapies for serious diseases. This has been argued both on an interests basis and a values basis drawing on concepts of solidarity and community as well as individual benefit. Thus therapies can become a right or an absolute good that should be sought as well an obvious interest. From an innovation community perspective there is also a strong element of advocating advances in scientific knowledge, and hESC research as a part of this, as something of fundamental value. Arguments about the freedom of scientists to conduct research as an inherently right action also form part of debates. The potential for beneficial consequences in terms of reduced use of animals for research and reduced pressure for poor people to sell organs for transplant have also been used as part of the arguments advanced by some advocates of hESC research.

The data also suggest a series of conditional arguments, conditions under which hESC research will be acceptable, namely preventing the exploitation of embryo and egg donors and ensuring that therapies are available for poor people. These conditional arguments are founded on appeals to basic principles of justice. However, the innovators feel unable to impact on the availability of therapies to poor people, so this aspiration tends to be delegated to other social actors.

Opposition to hESC research draws on the inherent value of early embryos. Where early embryos are given the same status as adult humans, respecting values becomes a common good that should be adhered to by everyone. Although it follows logically that these embryos have interests that should be respected, in the same way that other adults' interests should be respected in wider society, this interests-based argument is not strongly made. On the other hand respect for individuals who hold the view that embryos have the same status as adult humans was used as a reason to take the interests of these individuals into account.

The result is a great deal of complexity. Disputes may be about the interests of patients vs. the values of embryo advocates, about the value of health research vs. the value of embryos, the values of health research vs. the interests of embryos (that have no interests in the views of some) or even the value of health research vs. the interest of embryo advocates. It is often not easy to discern which is the case in a specific situation. This

complexity raises the prospect of conflict where one party considers the issue to be a negotiable interest and the other a non-negotiable value. This form of conflict was identified in Chapter two as particularly difficult to negotiate (Acland & Hickling, 1998). It is also interesting to note that industry benefit was not raised as a major motivator for the research although it was recognised as a driver by policy-makers.

By and large, the arguments advanced represented considerable ambiguity about the value that should be attributed to early human embryos. Some research scientists working in the area exhibited nuanced views on which embryos were legitimate to be used for stem cell derivation, some patients and patient advocacy groups similarly held a range of views on which embryos it was acceptable to use and citizens again showed discrimination with respect to which embryos could be used for stem cell derivation. This is not to deny that a proportion of scientists, patient groups and citizens were in principle opposed to hESC research and that similarly a proportion saw that there were no problems or limitations with such research.

### **6.6.2 Configuring stakeholders**

The second thesis question asks how these values-based and interests-based arguments are aligned between different stakeholders?

Research scientists have been influential in the development of human embryonic stem cell research which is congruent with their values and interests. The possibility of therapies from these developments is very much in the interests of patients with relevant diseases and for most will be congruent with their values as well as their interests, although individuals with a disease diagnosis who are nevertheless strongly opposed to embryo research can be found. Interviews with research scientists involved in stem cell research also identified a group of researchers for whom the prospects of therapies from embryonic stem cell research seemed remote as compared to therapies from 'adult' stem cell sources or from a better understanding of basic biology. For industry, there was also considerable interest expressed in using stem cell lines in testing for drug toxicity.

Citizens are shown to be largely supportive of embryonic stem cell research, on the expectation of future therapies. Activist groups have been vocal in promoting 'adult' stem cell research but rejecting embryonic stem cell research on the basis of their value-positions. Policy makers have been supportive of stem cell research, including embryonic stem cell research. Stem cell research is seen as a potential driver of economic development as well as providing future health benefits. The advantage of UK's research base with its established expertise in the area and permissive regulatory regime is highlighted in this context. Commercial companies are currently largely absent from the scene, although this situation may be changing.

The arguments made around embryonic stem cell research appear similar across innovators, citizens and patient groups, and involve a range of values-based and interests-based arguments. Within each group a range of different values-positions relating to the status of the human embryo can be found. However, adult stem cell advocacy groups seem to hold to different arguments, stressing the intrinsic value of the embryo and appropriate ways of treating humans as over-riding concerns resulting in the rejection of hESC research.

There is clearly no single agreed understanding of the value of an early human embryo, but neither are there only two polarised opinions held by protagonists and antagonists. Attitudes are in many instances complex and nuanced, including within the research community. The prospects for useful therapies from either adult or embryonic stem cell research were contested within the research communities as well as by some advocacy groups. In the case of research communities the basis for disagreement appeared to be primarily scientific rather than based on ideology.

There are a number of other important arguments that were made that sometimes fail to have much profile in the public sphere. Developments in stem cell research are expected (at least by policy makers) to proceed in a way that will allow future commercialisation of products, devices or services thus providing a financial and employment return on the public funding committed to research. There is a strong desire in several of the communities that any therapies should be available to resource rich and resource poor

countries and to people within them. As stem cell research moves from purely the research phase to becoming closer to commercialisation, these aspects may become more salient.

### **6.6.3 Policy-regulatory responses**

The third thesis question relates to where are the values and interests-based arguments being negotiated and how does the policy-regulatory framework relate to these arguments?

Debates in UK parliament have taken into account a full-range of values-based and interests-based arguments. The resulting decision, to permit hESC derivation and creation of embryos specifically for this purpose, is implemented by the HFEA while the UK Stem Cell Initiative has been active in promoting all forms of stem cell research. These conflicting ambitions co-exist uneasily but so far without tipping over into unmanageable conflict in the style of GM crops. Since the view of parliament has become enshrined in law, policy communities have largely avoided engaging with the complexity of attitudes to embryos and have considered that these discussions have already been concluded. The HFEA has become the locus where disputes around different interests and values takes place but as a regulatory body is only able to negotiate between interests.

Policy stakeholders have generally resisted oversimplification of arguments around stem cell research. Potential benefits are seen to be contingent rather than certain and benefits are expected to take a long time to accrue. Patents on hESC lines are seen as an important component in successful commercialisation of the products from stem cell research. To date, the European Patent Office has disallowed such patents on grounds of morality, citing the majority view of the population of the EU as sufficient reason to do so.

In summary, the way in which arguments have often been portrayed in the popular media has resulted in an oversimplification in a number of different aspects: in the potential benefits from the research, in the routes to therapies including commercialisation and in attitudes to embryos in different stakeholder communities. The benefits were readily described in terms of stem cell therapies for serious diseases by citizens, patient groups,



advocacy groups as well as research scientists and regulators although with the latter two the potential for toxicity testing is raised and research scientists particularly valued the furthering of biological knowledge. Toxicity testing was the main benefit identified by some of the industry interviewees. Medical researchers experienced in developing cell therapies based on adult cells, suggest that realising the benefits of cell therapies in clinical situations is very challenging. Attitudes to early human embryos among research scientists, citizens and patient groups ranged from treating them as having the same value as a reagent to something with a value that is less than an adult human. This resulted in different views as to what types of embryo; spare-IVF or specially created, could be used for stem cell derivation. For some citizens, patient groups and the advocacy groups interviewed, early human embryos are perceived as equivalent in value to adult humans and therefore should not be researched. This diversity of views can result in disputes that involve negotiation between two values-based arguments or a 'values-interests' type negotiation. There may therefore be differences in conceptions about the benefits, the sources of embryos, the views of different groups in society and whether it primarily involves a negotiation between different interests or strongly held values. The way in which the issue has been negotiated means that there is an uneasy tension inherent in the regulatory system. These tensions have been negotiated into workable regulations within the UK although the situation should not be viewed as a static one but rather an uneasy and dynamic one where actors holding different viewpoints continue to engage on behalf of their viewpoints.

## **6.7 Conclusions on stem cell research**

In this chapter I have investigated the case of stem cell research and in particular research on embryonic stem cells derived from humans. Stem cell research offers hope of cures for currently intractable diseases and although several different potential sources of stem cells exist (categorised broadly as embryonic and 'adult'), the most discussed are stem cells derived from human embryos.

For research scientists, this area opens up a new and potentially exciting area of biology to explore. Although research scientists emphasised the complementarity of research on embryonic and 'adult' stem cells, those researchers specialised in 'adult' stem cells were less optimistic at the prospect of therapies from embryonic stem cells. Both groups shared the long-term goal of harnessing the body's own regenerative potential but in the short-term several interviewees emphasised the benefits of stem cell research for toxicity testing and drug discovery. Most of the research scientists interviewed recognised that there is a possibility of no cures being developed as a result of stem cell research but they felt confident in the research. The involvement of commercial companies in developing stem cell therapies was seen as a 'necessary evil' but some interviewees thought commercial companies became involved at too early a stage of the science.

Government policy is supportive of stem cell research because it is seen as an opportunity for future prosperity as well as therapies. It is generally held that citizens are broadly in support of stem cell research including embryonic stem cell research.

Opposition to embryonic stem cell research (but not 'adult' stem cell research) is generally presented in the media as coming primarily from religious groups, who consider research on these embryos as akin to unlawful killing of an adult human (e.g. Williams *et al.* 2003). However, the data presented here suggest this perception hides a considerable amount of complexity regarding views on embryos. Patient advocacy groups are influential in promoting ES cell research but have been relatively restrained in active campaigning against those resisting ES cell research on an ethical basis. The acute need for therapies may result in this group becoming more vocal in the future and putting forward their interests more strongly. Protecting the interests of the embryo donors in the derivation of embryonic stem cells has also had increasing profile in recent years.

Contestation around embryonic stem cell research is often seen as balancing different values, the intrinsic value of the embryo with the unmet needs of sick people. The status of the embryo has become such a strong argument that it is in danger of drowning out other equally important questions, such as justice to resource poor people, which will not

naturally be answered by the bodies charged with regulating human embryonic stem cell research, such as the HFEA, since they have no mandate in the area.

The legality of research on human embryos to derive stem cells has been determined by the UK Parliament (building on the concepts developed in the prior legislation legalising research on embryos up to 14 days old for specific purposes) and is implemented on a case-by-case basis by the Human Fertilisation and Embryology Authority. Citizens have been involved in consultation around aspects of stem cell research and are generally supportive of it, including embryonic stem cell research. A minority is however strongly against hESC research.

In Chapter four, I considered GM and particularly cloned animals and identified a mixture of interests driving the technologies and both values and interests resisting the development but with a strongly precautionary approach being adopted by the European Parliament. In Chapter five, I considered biobanks with their strong interests-based discourse, commitment to public engagement and establishment of project-based ethics committees to negotiate values and interests. In this chapter, I have considered the case of stem cell research, particularly hESC research, and have identified a great deal of complexity within a debate that is frequently simplified and where the issue of the value of the embryo has come to be so dominant that other concerns are barely addressed. The status quo remains contentious however, as scientists seek to extend the boundaries of research and others seek to limit the range of research. Much of this dispute is being directed at regulatory bodies such as the HFEA and the European Patent Office. Nevertheless, in general stem cell research, including human embryonic stem cell research appears to be supported by citizens largely based on the expectation of therapies.

In the next chapter, I will bring together themes from these three case studies and highlight how they inform the use of values-based and interests-based arguments in the context of new genomic technologies.

## **Chapter 7**

### **Synthesis**

#### **7.1 Introduction**

In the previous three chapters I have explored how values-based and interests-based arguments have been deployed in three different applications of genomics; GM & cloned animals, population biobanks and stem cell research. Each case was examined in its own context with varying responses from the policy and regulatory community. This chapter synthesises the findings from these three case studies. It falls into two parts. The first section summarises from each case themes around values and interests, and the policy and regulatory response. The second section revisits the notion of values and interests, and examines the extent to which this approach constitutes an appropriate and useful way of distinguishing between arguments around innovation in genomics. I suggest a more nuanced analysis of the cases, using greater discrimination of both values- and interests-based arguments.

#### **7.2 Themes from chapter findings**

##### **7.2.1 Values-based and interests-based arguments**

Based on the case study data reported in chapters four, five and six, Table 7.1 summarises the main values-based and interests-based arguments advanced around the development of the relevant genomic technologies.

**Table 7.1 Values-based and interests-based arguments by stakeholder group**

**Cloned and GM animals**

	Stakeholder groups		
	Innovators	Civil Society groups	Citizens
<b>Arguments favouring cloned/GM animals</b>			
<b>Values-based arguments</b>	Scientific knowledge		
<b>Interests-based arguments</b>	Economic and other benefits		Some acceptance of specific benefits
	Equity of competition		
<b>Arguments against cloned/GM animals, or in response to concerns</b>			
<b>Values-based arguments</b>		Morally wrong	Morally wrong
		Not consistent with sustainable agriculture	
		Driven by profit rather than need	Driven by profit rather than need
<b>Hybrid of values &amp; interests</b>	Potential harms to animals acknowledged, but seen as resolvable (primarily interests)	Harm to animals expressed both as a value and an interest	Harm to animals, values-interests basis not established
	All knowledge required for human cloning already exists	Could lead to human cloning	Could lead to human cloning
<b>Interests-based arguments</b>	Concerns about inbreeding acknowledged, but can be managed		Concerns about inbreeding
			Risk to safety of food
	Consumer antagonism could mean the technology is not in the interests of food retailers		

## Population biobanks

	Stakeholder groups			
	Innovators	Civic Society groups	Patient advocacy	Citizens
<b>Arguments favouring biobanks</b>				
<b>Values-based arguments</b>	Scientific knowledge			Altruism
	Health benefits		Health benefits	Health benefits
<b>Interests-based arguments</b>	Research resource		Relieves suffering	Relieves suffering
	Wealth and job creation			
<b>Arguments against biobanks, or responses to concerns</b>				
<b>Values-based arguments</b>		Ignoring the real causes of disease.		
<b>Conditional arguments</b>	The principle of justice underlies the conditionality of preventing harm to participants			
	The principle of respect for autonomy underlies the conditionality of protecting individual autonomy			
	A requirement for efficiency underlies the argument for ease of access to biobank data			
<b>Interests-based arguments</b>	Avoid conduct of non-desirable research	Potential for conduct of non-desirable research		Potential for conduct of non-desirable research
	Recognise need to control inappropriate access	Access by organisations with a different agenda		Access by organisations with a different agenda
	Ensure pharmaceutical companies have sufficient access to realise benefits	Exploitation by pharmaceutical companies	Ensure pharmaceutical companies have sufficient access to realise benefits	Exploitation by pharmaceutical companies

Stem cell research

Stakeholder groups					
	Innovators	Industry	Civic Society groups	Patient advocacy groups	Citizens
Arguments favouring stem cell research					
Values-based arguments	Health benefits	Health benefits	Health benefits	Health benefits	Health benefits
	Scientific knowledge				National Pride
	Freedom of scientific research				
Interests-based arguments	Relieving suffering		Relieving suffering	Relieving suffering	Relieving suffering
	Reduced animal testing	Reduced animal testing			
	Wealth and job creation	Safer medicines			
Arguments against embryonic stem cell research, or in response to concerns					
Values-based arguments			Minority rejection of hESC research	Immorality of destroying embryos	Minority rejection of hESC research
Conditional arguments	The principle of justice underlies the conditionality of protecting embryo donors from exploitation				
	The principle of justice underlies the conditionality of ensuring therapies are available to rich and poor alike				
Interests-based arguments	Respect for views of those in opposition	Reactions of the US market		Scientists have too much power	For social need not purely for profit

Whilst this table lists the arguments being made, it does not indicate the strength of the argument nor give any indication of how widely that viewpoint is held. These will be critical in determining the direction of a future debate. The strength of the evidence-base for different categories also varies.

The question arises whether there is something special about genomics that is common to all these cases? Some similarities are evident. Firstly, because these are technological developments, inevitably research scientists have a strong role in developing visions for the future. Furthering scientific knowledge is an inherent concern for scientists, which is

part of their professional commitment. This heavy involvement of scientists can, however, engender resistance if it is thought that scientists have too much power. This in turn may provoke a response by research scientists seeking to secure freedom for scientific research. The tension between seeking to constrain the power of scientists and defending freedom for research is primarily apparent in the hESC case study.

Secondly, wealth and job creation feature as prospective benefits in both the medical application case studies. However, the extent to which these are genuine motivations rather than strategic responses of researchers to government priorities is not clear. Thus, wealth and job creation could justify expenditure on research rather than provide a motivation for research. The evidence suggests that, particularly in the case of hESC research, the policy community is strongly influenced by the prospect of economic growth. An alternative approach is apparent in the animal cloning case study, where wealth and job creation are not advanced as benefits by advocates of the technology. Instead these are primarily expressed in terms of social goods - such as reduced environmental impact and improved disease resistance. Where economic impact is argued, it is on the basis of production efficiency, a benefit (or even necessity) for livestock producers. This then becomes an issue of continued competitiveness of the industry rather than creating economic growth.

Thirdly, across the case studies, citizens consistently argue for technology to be developed out of social need rather than being purely for profit. This concern is not a denial of the principle of profit, but seems to relate to ensuring that there are some 'real' benefits from developments from citizens' point of view and that publicly-funded research or altruistic donations to biobanks are not unfairly exploited by private companies for trivial purposes or merely for profit. In the definitions used for this thesis, balancing the interests of citizens and companies appears initially to be a negotiable, interests-based argument but in practice, negotiations may be underpinned by strong values-based positions. This may be about the appropriate role of commerce in supplying life-science benefits (whether as health care products or food) or about different concepts of what constitutes a benefit perhaps linked to concepts of holistic health or holistic agriculture. These data also



suggest that citizen acceptance of technologies is often contingent on a range of conditions being met, such as the technology being applied in just ways.

The prospect of health benefits is a strong argument in both the stem cells and biobanks case studies and constitutes a source of hope. In the definitions used for this thesis, health benefits can be categorised as both a value and an interest depending on the way in which arguments are constructed. I have used the terminology 'relieving suffering' for more interests-based arguments and 'health benefits' for more values-based arguments, to attempt to distinguish them. However, in practice, the two are likely to coexist and a strict distinction may be impractical and achieve little in furthering the understanding of sources of conflict. Health benefits and relieving suffering are widely held 'goods' in society. However, health benefits may come into conflict with other values, as in the case of hESC research, or there may be disagreement as to what constitutes a health benefit, a potential conflict in the biobanks case. The value of altruism is also important in the context of health benefits. Altruism can be defined as behaviour that is voluntary, other regarding and in the form of an unrewarded gift (Haddow, personal communication). This definition may well describe the motivations and actions of donors to UK Biobank.

Arguments concerning animal welfare are complex, as already noted in Chapter four. The concept can cover just physical harm, in which case there is some prospect of negotiation, or it can refer to concepts of intrinsic value of animals, which are likely to be more difficult to negotiate. Reducing the need for animal testing by use of cultures of hESC or derivatives from them, is argued to be in the interests of animals (less animals are harmed so the net benefit is higher). The action is also likely to benefit the organisation's public image (and may reduce drug development costs) and so conceivably also be in the organisation's or industry sector's self-interest. Underlying this argument is a value-position that considers that animals matter and the number used for research should be reduced (although accepting that animals may be used in research). Again, if harm to animals is linked to physical harm, the argument stands. If it is linked primarily to concepts of animal integrity, the use of animals for pharmaceutical toxicity testing drugs would be challenged which would strengthen the case for use of human cells. This latter case,

however, was not made in any of the data considered for this research although it probably exists given the public activity of anti-vivisectionist groups.

Several of these arguments focus on the appropriate conduct of the research, e.g. protecting embryo donors from exploitation and respecting the autonomy of donors to biobanks, rather than being arguments for or against the genomic application itself. However, if these conditions are not met, then support for the development may well disappear. Although these arguments (which I have termed conditional) relate to the conduct of research, the exact boundary between acceptable and non-acceptable practice is not necessarily agreed by everyone. Drawing boundaries can reflect underlying values-based positions which may not be articulated. Many of the interests-based arguments are also underpinned by basic values relating to the appropriateness of balances between different interests. Even the acceptability of commercial competition as an appropriate mechanism for societal functioning may be disputed by minority groups, such as the Amish (Kraybill, 1991). It is also worth bearing in mind, in case the analysis gives an impression of polarisation as being inevitable, that acceptability or otherwise of a technology can be more nuanced than just 'agree' or 'disagree'. It may be possible for stakeholders to agree partially with something but decide that, whilst this is not perfect, it is a situation that they can live with.

From the above discussion, I draw two conclusions:

- i) Values and Interests are complex concepts.
- ii) Each case examined is in a specific context and unique.

I will now examine this complexity and specificity in more detail.

Values and interests are used in this research as an analytical, heuristic device. They represent ideal-types that in reality rarely exist. The real world is more complex and does not readily parse into the distinct categories 'value' and 'interest'. As evident in the discussion above, values and interests are often inter-related and it is sometimes difficult to identify which is the most dominant, requiring resort to devices such as hybrid categories and conditional arguments.

It is also evident that there is no one single pattern of argument across the differing applications of genomic technologies. In the case of GM and cloned animals, proponents mainly argue on the basis of fair competition in markets, whereas opponents argue primarily on the basis of animal welfare, sometimes allied to alternative conceptions of 'holistic' agriculture. Criteria for good animal welfare may vary between individual stakeholders, underpinned by values-based concerns around animal integrity for some. The evidence regarding GM and cloned animals suggests that there are opposing forces pulling the technology in different directions. Scientific research continues to develop new techniques, new approaches and lead to new ideas on how animal biotechnology might be used. In the other direction, animal welfare concerns, a desire to maintain the integrity of animals and uncertainty as to the acceptability of applications of genomic technologies to the public act as restraints on developments. However, it is not clear that commercial companies in Europe are keen to promote either cloning or GM animal production.

The main arguments advanced by proponents of biobanks relate to their potential as a research resource for understanding diseases and improving their treatment as well as the expectation of future economic benefits. Underpinning what at first sight appear to be interests-based arguments about relieving suffering, are values-based arguments for increasing knowledge and providing medical benefits. Values-based critiques of excessive focus on genetics, at the expense of environmental and social causes of disease, have been made by advocacy groups but by and large, biobanks do not seem to threaten underlying values of UK citizens.

The role of citizens with respect to biobanks is different from the other genomics developments considered here. The relationship of citizens to stem cell research and GM/cloned animals is primarily in the role of consumers, patients or as members of society more generally. With respect to biobanks, some citizens are additionally expected to be participants. Thus, much of the focus in the governance of biobanks is around maintaining the confidence of participants and ensuring they do not feel exploited and their autonomy is respected. Critiques of these arrangements, however, point out that the

'participation' is entirely passive, with no role granted to participants in future decision-making.

The arguments made around embryonic stem cell research have many similarities among innovators, citizens and patient groups, and involve a range of values-based and interests-based arguments. The differences are less about the types of argument made and more about reaching different evaluations regarding which types of embryos can be researched. However, groups advocating adult stem cell research tend to employ different arguments, stressing the intrinsic value of the embryo and appropriate ways of treating humans as over-riding concerns, and some research scientists holding the opposite view that human embryos have no special status.

The values-based and interests-based arguments regarding hESC research proved particularly complex to disentangle. While this is frequently portrayed as a conflict between rational scientific researchers seeking to benefit seriously-ill patients by developing stem cell therapies vs. irrational values-based arguments advocating the sanctity of early human embryos, the evidence suggests the situation is more complex. Benefits may initially be in the form of improved toxicity testing in drug development and cell therapies may be difficult to transfer from labs to clinics. A range of views around the value of early human embryos is found among each of the stakeholder groups- research scientists, citizens and patient groups - leading to numerous ways of evaluating the appropriateness of hESC research. These may be argued in terms of conflicting values (protecting embryos vs. medical benefits), a conflict between interests and values (relieving suffering vs. protecting embryos) or a conflict between competing interests (relieving suffering vs. respecting the interests of those with alternative views in society). By and large, arguments advanced around hESC research represented considerable ambiguity and hence it is likely that each of these types of tension is present at the same time.

The analysis across case studies also reveals a complex range of alignments among innovation communities, citizens and advocacy groups. In each case the interests and values of research scientists have been important. Cloned animals are the furthest

developed in terms of commercialisation with products on the ground. But if the animals prove not to be economic, the technology is unlikely to be adopted. However, in terms of commercial involvement, much of the industry involved appears ambivalent, if not negative, about the development and there is no strong advocate apparent for use of cloned animals in the food chain. With respect to hESCs, clinicians are involved in developing cell therapies and there is increasing industry involvement (much of it post-dating the fieldwork for this research). Commercial companies are yet to become overtly involved in the two publicly-funded biobanks studied. These are therefore three very different cases; providing a research resource, having a 'product' in the market rejected for values-based reasons, and research where hopes of the potential outweigh ethical qualms.

The evidence demonstrates that both values-based and interests-based arguments are found in the development of GM/cloned animals, biobanks and hESC research. There is no one single pattern of argument that can be discerned across these cases: instead each presents a unique combination and texture of argumentation. Sometimes values-based arguments predominate, sometimes interest-based arguments predominate and sometimes the issue is one of interests-based arguments competing with values-based arguments. Whilst values and interests can be viewed as a heuristic device, for analytical purposes, these concepts embrace a great deal of complexity.

### **7.2.2 Policy responses**

One of the main arguments that Tait (2001) made was that in the context of regulating GM crops in Europe, a wrong or simplistic identification of the underlying human motivations led to difficulties in engaging in a meaningful dialogue with different stakeholders. Arguments about risks to the environment simply did not address issues around different agricultural production systems or the ownership of the food chain. How then do the case studies examined here relate to their policy contexts? Are the regulatory responses in these different applications of genomics reflecting the main aspects of the debates about these technologies?

Table 7.2 provides a summary of the range of policy and regulatory instruments used across the case studies.

**Table 7.2 Summary of main policy and regulatory instruments used**

Case Study	Policy and regulatory instruments used
Cloned & GM animals	Food safety, animal welfare and environmental impact evaluation by EFSA, Novel foods regulation agreed in European Parliament. Ethical opinion from EGE, international trade agreements, Directive on release of GM animals into the environment and on animal welfare.
Biobanks	Data Protection Act, Human Tissues Act, common law of confidentiality, IP law, ethics committees, project specific ethics board for ongoing oversight.
Human embryonic stem cell research	Parliamentary debate, ethics committees, case by case licensing by HFEA, IP law, government support for research and development of industry.

Unlike the GM crops situation that forms the starting point for this thesis, risk regulation has served a relatively minor role in the case studies presented. The case of cloned animals is the only one with an explicit risk component. Here, technical risk evaluation by EFSA suggests an absence of safety concerns with respect to products from cloned animals whereas evidence on public attitudes suggests a very high level of evidence of safety will be demanded. Therapies based on hESC research will also incur risks but these were not raised by interviewees as it was research rather than therapies that was being discussed.

Policy makers have been supportive to biobanks to the extent that funding has been made available for them but there is little evidence of support for developing cloned and GM animals. Only in the case of hESC research has there been a concerted effort by policy-makers in the active promotion a particular technology. As noted in Chapter two, Levitt (2003) highlights the potential conflict for policy makers between producing technological competitive advantage and taking citizens' views into account. This conflict has been

negotiated by UK policy makers in the context of hESC research to achieve an uneasy truce, whereby hESC research is allowed but only in specific circumstances.

Ethics committees have formed an additional level of policy making that was relatively absent in the early stages of development of GM crops. Thus, there is recognition in policy that dealing with animals and human subjects raises questions of right and wrong and requires moral evaluations to be conducted.

I am taking moral here to mean beliefs about the rightness or wrongness of certain things which may just be 'felt' and ethical to mean an analysis of the moral arguments to evaluate their justification, (after Reiss & Straughan, 1996, p45-47). Moral reasoning is not just restricted to values-based arguments. The balancing of interests is equally a moral question since it presumes an agreement that some interests are morally significant.

Ethical reflection has been largely in the form of specialist committees or specifically convened advisory groups but in the case of biobanks, a novel form of ethical governance that is ongoing during the project has emerged. The number of public engagement exercises conducted in each case study subject area suggests also an increasing tendency also to take wider public values into account (e.g. Wynne, 2001) rather than relying purely on opinions of ethics committees.

Ethics has become an important tool of governance of biobanks. Ethics committees of specific biobanks are however restricted in what issues they can and cannot address. They are unlikely for example, to have the remit to ask whether the establishment of the biobank represents good value for money or not. Such decisions are for the wider policy community to make, whether by default based on a series of independent decisions or otherwise.

In the context of cloned animals, the EU appears to have a process that will consider the human, environmental and animal welfare risk as well as ethical concerns. However, examining this in more detail, EFSA is experienced in assessing risks from food but the extent of their expertise with respect to animal welfare, environmental risk or the risks from reduced biodiversity is not clear. While the EGE is an advisory body it has an

important role in EU policy making. The mechanism for resolving contradictory advice from EFSA and EGE is not clear. As far as cloned animals are concerned, the preferences and political expediencies of the European Parliament have been consistent with the ethical opinion of the EGE. Finally, animal products are traded on an international basis, in which context an objective basis is normally required to justify a trade exemption for products. Deriving such a basis seems unlikely at present. Ethical concerns are seldom accepted as reasons to prevent trade under WTO agreements.

The ethical framework for hESC research in the UK has been determined by debates and votes in the Parliament. But debates have been influenced by reports from ethics committees, such as the Donaldson Committee report (Department of Health, 2000), and the basic approach to research on early embryos traces its origins to the influential Warnock report (Warnock, 1984). Debates in Parliament have taken into account the full range of interests and values-based arguments. Having established the legality of research on human embryos to derive stem cells, there is no standing ethics committee. Licenses are issued on a case-by-case basis by the Human Fertilisation and Embryology Authority, which has consequently become a locus for negotiation. In this case, the status of the embryo has become such a dominant argument that it is in danger of drowning out other important questions, such as justice to poor people, which will not naturally be answered by the bodies charged with regulating hESC research.

Evidence varies on the degree of influence of civil society advocacy groups on policy and regulation. In the context of hESC research, opponents of the research have been vocal but apparently have only been influential in so far as they maintain the objections of a sector of citizens. Patient groups appear to have been effective to some extent in promoting the need for cell therapies. The response of the European Parliament to the prospect of cloned animals has been congruent with the values and interests of advocacy groups against cloning but it is not clear if one has influenced the other or whether common assessments have been arrived at.

The evidence therefore suggests that issues around genomics-related developments are negotiated in multiple institutions but particularly in parliaments and ethics committees.



Both values-based and interests-based arguments are recognised in the policy sphere in the context of hESC research and cloned animals whereas biobanks have received relatively little attention. It is, however, noteworthy that each of the cases considered are situations under development and flux. What is provided here is a snapshot in time that is subject to change. For example, at the latter stages of this research, the discovery that 'adult' cells could be induced to produce stem-cell like cells simply by activating four genes (to produce so-called induced pluripotent cells), without the need for an egg/embryo stage (Yu *et al.* 2007, Takahashi *et al.* 2007), is very likely to alter the dynamics of the debates around human embryonic stem cell research. The evidence illustrates that the development of biobanks has been strongly influenced by an alliance between the interests and values of research scientists with government funding bodies. But they are dependent in the long term on maintaining the support of participants and interest from the commercial sector.

The context for the genomics applications considered here is very different to that of GM crops. In contrast to the GM crops situation, in the cases studied here, values-based arguments have been recognised as important, risk issues have not been high profile and in two of the cases (biobanks and stem cell research) health benefits rather than food are being cited as the benefits. There is an explicit acknowledgement in all three cases that advances in genomic knowledge, and technologies arising from this knowledge, need to take into account societal values as well as a range of interests. Mechanisms have been put into place in recognition of this values element in the form of ethics and regulatory committees. These committees have come under increasing pressure as they have become the location where power to make decisions appears to reside.

### **7.3 Values and Interests as policy-relevant concepts**

In the previous section I have provided evidence that both values-based and interests-based arguments exist in each of the three case studies and that each individual case demonstrates a nuanced and textured interaction between the arguments advanced by different stakeholders, and the policy and regulatory responses. The question to be

addressed here is whether parsing arguments in this way reveals aspects of the debates that are both interesting and potentially of practical use. I therefore now turn to consider the fourth and final question to be addressed by this thesis, namely is the values-interests approach an appropriate and useful way of distinguishing between arguments around innovation in genomics? Firstly, I will consider how to evaluate appropriateness and usefulness and secondly I will consider the extent to which the values and interests approach has been able to distinguish between values-based and interests-based arguments

### **7.3.1 Is the values-interests approach an appropriate and useful way of distinguishing between arguments around innovation in genomics?**

Appropriateness and usefulness are linked together in this thesis. One of the original motivations for this study was pragmatic: that of identifying typologies of argument that would enable more manageable methods of dealing with disputed areas of technology. The *usefulness* of the values-interests distinction is therefore whether it can identify salient features of disputes that could be informative for policy responses. I am going to argue that the values-interests approach has indeed enabled some useful insights to be gained from the empirical data presented in the case studies.

In Chapter two, evidence was presented from literature arguing that, if evidence-based policy only considers scientific evidence, and if conflict of values is present, values are likely to become hidden and unacknowledged and the scientific evidence will become disputed rather than stakeholders changing their position (e.g. Fisher & Ury 1987, Jasanoff 1990, Nelkin 1992, Schön & Rein 1994, Sjöberg & Wählberg 2002, Poortinga & Pidgeon 2004, Earle 2004, Kahan *et al.* 2006, Pielke 2007). The empirical data presented here do not contradict that conclusion.

The example of hESC research is currently the most contested of the cases, and here there is evidence of dispute about whether scientific evidence suggests that pursuing research in 'adult' stem cells is providing scientifically more promising than pursuing human embryonic stem cell research. The hESC case also demonstrates how opening up a

debate to values-issues does not necessarily mean that a single value comes to dominate decision-making processes. However, neither does this imply that decision-making under such conditions will be easy, partly because the *status quo* will continue to be challenged by protagonists at every possible opportunity (Harmon, 2006). Constant re-opening of disputes may result in a hardening of opinions as protagonists strive to further their position in increasingly strident ways

The UK Biobank Ethics and Governance Framework is one attempt at providing an explicit statement of values together with an ongoing engagement between the scientific developments, organisational elements and the values framework (Laurie *et al.*, 2009). The commitment of biobanks to ethical governance in order to maintain confidence and trust in the biobank means that, as situations change, the governance arrangements can be adjusted to reflect these changes. However, the biobank governance model is yet to be tested by commercial access to biobank data.

The complex and situated nature of lay understandings of risk was stressed in Chapter two (Horlick-Jones, 2005). A close examination of the values-based and interests-based arguments advanced by research scientists in this study demonstrated that scientists are not immune to these influences. Research scientists may dispute certain interpretations of scientific evidence but they also hold a range of different views on values, for example the range of views on appropriate ways of dealing with embryos exhibited in this hESC case study. This has also been noted by Wainwright *et al.* (2006) in a single research lab. As seen in Chapter two, studies of scientific knowledge have also held to this view (Barnes & Mackenzie 1979, Harvey 1981). However, the evidence presented in the hESC case study suggests that this range of views on values is held in the context of a value-commitment to furthering knowledge and freedom of scientific research, and promoting these interests. The range of values held by research scientists suggests that engaging with a wide range of scientists is likely to provide a more nuanced view that may reflect better the complexities and assumptions that are made. The policy-process may therefore benefit from talking to scientists from a range of endeavours relevant to the subject rather than purely those deemed to be in positions of high influence, such as members of the

Royal Society. Pielke (2007) suggests that scientists may act (whether on purpose or inadvertently) as 'stealth advocates', that is, promoting a particular policy position on the basis of their own values and interests, but introducing this under the guise of scientific evidence. Engaging with a wider-range of scientists could reduce this tendency.

In the stem cell research case the analysis revealed issues that are 'hidden', in other words that their prominence and profile has fallen below the attention line. As a result the dispute can become simplified and framed in particular ways at very early stages of the development. The extent to which this initial framing can be changed subsequently is not clear, nor whether the original framing then forces subsequent arguments to take the same form. Further research would be required to unravel these aspects. In the case of cloned animals, strong rejection by the European Parliament (whether on the basis of their own values or the values imputed to others) has meant that the implications of banning cloning on for example, the impact on the animal breeding industry in Europe, and any knock-on effects on food security, have apparently been discounted without thorough examination. On a broader level, within the cloning case study there appears to be little engagement with what might constitute a sustainable animal agriculture and whether cloning could be some part of such agriculture, if only for storage of genetic material at risk. Similarly, in the biobank case study, biobanks appear to be treated as research resources which are 'good' in themselves. There appears to have been little engagement with how benefits from biobanks should interact with other public health initiatives or initiatives relating to environment, nutrition and the effects of poverty. In other words, acknowledge explicitly that genetics is only one component of health.

Public engagement is a subject where there has been considerable academic research and it is not the intention here to engage with this literature. However, there is one lesson to be drawn from the data presented here. In the hESC case, discussions were undertaken in a context of research to enable stem cell therapies, rather than in the context of using hESCs for toxicity testing or furthering basic biological knowledge. The latter two applications were thought to be more immediately likely by many research scientists and industrialists. Citizens in the hESC case study were apparently not aware of

the prominence that use of hESC cells for toxicity testing has. Thus, I would argue, the benefits of stem cell research have not been fully investigated in some engagement exercises (although the MRC-BBSRC dialogue referred to in Chapter six did stimulate citizens to discuss this aspect – MRC *et al.* 2009). In a similar way, public engagement in the context of cloned animals appears to be working in a context in which existing regulation was not taken account of and where there were no practical limitations apparent. The lesson I draw from these pieces of evidence is that public engagement needs to be with the whole range of considerations, including the practical and regulatory. Most evaluations of genomic technologies involve difficult trade-offs and it is not helpful to disguise these difficulties in portraying a utopian and simplified scenario.

As outlined in Chapter one, part of the motivation for this research was to identify ways of managing potentially disputed areas in ways that would reduce conflict. Some insights can be gained from the values and interests analysis conducted. For example, for policy-makers negotiating an acceptable level of welfare for cloned and GM animals, there is a challenge in dealing with a negotiable interest on the one hand and a non-negotiable value on the other, under the guise of the same argument.

The mediation literature (Fisher & Ury 1987, Burton 1990, Acland 1995) suggested that overlaps in values and interests provide a basis for negotiation. To what extent has the analysis of the case studies using the values-interests approach identified cases where there appears to be potential for negotiation?

It was argued earlier in this chapter that the analysis revealed considerable overlap between many of the stakeholders in the hESC case study in terms of the values and interests being expressed. This suggests, perhaps counter-intuitively, that at least in the context where the principle of limited embryo research has been established, there is potential for resolution in this case. However, if the dispute is raised to a higher-level of argument, for example that of scientific freedom vs. excessive power of scientists, then the above may no longer hold.

In contrast, the biobanks case study appears to be a situation where there is no dispute and a standing ethics committee is being effective in negotiating between the interests of different parties. The question remains whether an advisory ethics committee will be strong enough to be able to balance future challenges. For example pharmaceutical companies might wish to use the information in the biobanks to develop therapies for conditions that may be borderline in terms of the definition of benefits but which may be commercially very advantageous, for example therapies for Attention Deficit Hyperactive Disorder. This pressure may become particularly acute in the context of declining public funding to support the biobank resource.

Five observations flow from the discussions in this chapter so far. Firstly, it is important to make values explicit and open to allow them to be acknowledged and negotiated rather than forcing them to be expressed as interests. Secondly, appropriate spaces are needed to engage with the values-dimensions and also manage expectations such as overly positive evaluations of the prospects of the developments. Given the likely political nature of decisions around genomic developments, these will need careful management but also potentially ongoing engagement. Thirdly, recognise that scientists, as well as other stakeholders, hold a range of views. This range should be reflected in evidence-based policy rather than relying on a few scientists who have achieved prominence in their field. Fourthly, be alert to hidden issues. It may be appropriate to give them lower prominence but this should be done openly and deliberately rather than by default. Fifthly, in order to address the critique that scientists present evidence from an overly narrowed perspective, engagement with public values may be appropriate, but this should be done in ways that reflect the constraints on possible action and difficult trade-offs that may need to be made.

I therefore conclude that the values-interests approach has been an effective method for revealing salient aspect of potentially disputed situations which could have practical policy relevance, although in such complex situations, these considerations are unlikely to provide a panacea to disputed situations.

Having considered the usefulness of the values-interests approach, I will now move to the second consideration, the extent to which the values and interests approach has been able to distinguish between values-based and interests-based arguments.

### **7.3.2 The extent to which the values-interests approach is able to distinguish between values-based and interests-based arguments**

The first point to re-iterate is that the division into values-based and interests-based arguments is a division into two ideal types, the reality from the case study evidence is that values-based and interests-based arguments interact with each other in complex ways. Views expressed by individuals may combine more than one category of argument. Thus, as noted in the case studies, a range of negotiations between different interests may be underpinned by the underlying value of 'justice'. Whilst individual values are usually congruent with interests, this is not necessarily so. For example a patient who would potentially benefit from stem cell therapies might nevertheless hold a value that hESC research is wrong.

It was also apparent that the same argument made with a slightly different emphasis can result in a different stress on values or interests. For example, arguments regarding the status of human embryos could be made in four different ways:

- Status of the embryo precludes research absolutely (values-based argument)
- Use of human embryos is ethically questionable (values-based argument but not as strongly against embryo research as above)
- The consequences of not doing hESC research may be more negative than doing the research (using an interests-based argument to arrive at a balance between two competing values, the reluctance to derive stem cells from human embryos and the imperative for health benefits)
- Need to balance the unmet needs of the sick with sensitivity towards the embryo and those who attribute human embryos with high value (interests).

Moving between categories within an argument, whether deliberately or accidentally, is easy, so that value-based arguments can be replaced by interest-based arguments thus causing the focus of the argument to change.

The four ways in which embryos can be referred to, as noted above, suggest that there are sub-categories to the two categories of 'values' and 'interests'. Some of the other arguments also fit rather awkwardly with the values-interests framework, e.g. the concern that GM and cloned animals are a slippery slope to such applications to humans. This is not clearly an argument furthering a particular interest nor is it an argument relating to a specific value-position. Yet others, such as those suggesting that biobanks are expressions of excessive geneticisation, reflect a measure of degree based around cultural values, rather than moral absolutes.

Examined more carefully, four sub-categories were identified, which I have termed: issues of principle, views of the world, consequences and interests-based. A fuller description of what is included in the categories which follow.

#### **i) Issues of principle**

Issues of principle reflect fundamental values that need to be respected, principles that are esteemed and underpinning deontological arguments. They call on values that are deemed to be shared within a community. Typical questions are whether there are barriers that we should not be breaking? Are there absolute goods that we need to be seeking? These may be expressed in terms such as 'playing God' or 'going against nature'. These issues are a description of how things are. Examples include whether an early embryo is considered to have the full moral status of a human being, or non-human animals to be morally equivalent to humans.

Arguments based on fundamental values are often conceptualised as being negative, for example, holding that the moral status of the human embryo is such that research on embryos should not be allowed. But holding the opposite view that research on human embryos should be completely unrestricted also reflects a fundamental value position. The value is the absence of any special recognition of the status of an embryo; it is merely



another bunch of cells. These cells are attributed no special worth because of their particular nature and there is therefore an imperative to use them for research. At the philosophical level these two fundamental value positions that embryos have the full moral status of an adult human or that they have no status and therefore the moral imperative favours research are typically defended by David Albert Jones and John Harris, respectively (Jones 2004, Harris 1998).

## **ii) Views of the world**

This category of argument includes views of the world, cultural presuppositions or cultural values or ideals. Note that the terminology used here is 'views of the world' not 'world views'. This is because the views of the world may not be organised into a philosophical system as would be implied by the terminology 'worldview'. In some cases the 'views of the world' may be in the context of a thought through entire system (e.g. anthroposophy). More often they reflect individual preferences and concepts of the world, that may contain contradictory elements, and where the consequences of the view being held may not have been entirely thought through. A typical question is, whether this development is compatible with the sort of world we want to create? Is our focus of attention wrong or right? This is an argument about how things ought to be. There is often a sense of adjusting the balance of current practice. They answer questions such as 'what future did they have in mind when they created Dolly the sheep?' Cultural ideals are focussed on concepts of a desirable future and whether particular developments are moving toward or away from that desirable future. For example, a view which holds that scientists should have absolute freedom of research in order to maximise the amount of knowledge will in turn influence what that person feels about restrictions on the research for moral reasons. A restriction in one area may be seen to threaten the whole of the scientific enterprise. These arguments deal with trends rather than cut-off points, although the two are often closely interlinked. If commodification of animals is wrong (in principle argument), furthering the trend of increasing commodification is undesirable (view of the world argument), for example.

The utility of distinguishing between 'in principle' arguments and 'views of the world' type arguments is particularly obvious in the biobanks case study, where there is no fundamental value or principle that is being challenged, rather questions are raised about excessive focus on genetics at the expense of other non-genetic measures to improve health. This does not imply that all genetic research should stop but rather implies that too much emphasis has been placed on genetic information. Similar arguments can be found with respect to critiques about technological approaches to food production, with proponents seeking to restore 'harmony with nature' and 'holistic' agriculture. Criticism of the role of commercial organisations in society often also fit into the views of the world type of argument, that innovation is being excessively driven by the profit motive rather than real human needs.

### **iii) Consequences**

Here the criterion is whether the consequences of doing an action are good or bad? Examples of the types of argument that come under this 'consequences' category would be that the adoption of farm animal cloning will lead to human cloning, or that stem cell research will result in therapies for serious diseases. Whilst there are some observations that people will agree on, in the context of scientific research, uncertainties, poorly understood areas, and need to predict the future mean that there is likely to be little agreement on the evidence-base between competing groups. Those people advocating human embryonic stem cell research and those advocating research using adult stem cells may not agree on the prospects from each type of research based on current scientific evidence. This may be due to genuine disagreement among scientists as to the rigour and meaning of a piece of research that is reported. It may include judgements based on past experience, but it may also be influenced by different fundamental value-positions. In each case the future is uncertain and unknown but from the point of view of the protagonist a particular course of action will most successfully lead to the desired outcome. This category is about the expected consequences of an action and brings expectation of risk into play, for example citizens fearing food derived from cloned animals.

#### iv) Interests

This category implies a balancing of interests. Who wins, who loses, and how are these balanced out? There are several different types of interest that are possible. There is self-interest that seeks to further one's own place or values. There are interest-based arguments that are other regarding and concerned with the interests of others which we either impute to those other selves or hear directly from them. Finally, there are the interests of third parties which do not have a voice but to which those who have voice can impute value (such as animals or the environment). Thus, more nuance can be recognised under the broad category 'interests'.

Self-interest is largely self-evident. Individuals and groups would be expected to seek to reflect what is to their own benefit. Self-interest may also be expressed by organisations. The concerns expressed by citizens about the potential for pharmaceutical companies to act in the interests of the companies rather than wider society, is an example here. While acting out of self-interest is on the one hand seen as perfectly natural and normal, on the other hand it can also become the subject of moral opprobrium when behaviour is deemed to be selfish and self-centred, failing to consider the interests of others in society. Conflict can therefore arise between an individual or group interest and a common good (or interests of a broader social grouping).

Interests-based arguments that are other-regarding can also be recognised. The 'other' may be another human or group of humans, who are at least in principle capable of expressing their own desires (except in specific instances such as young children). The issue of whether the people being spoken for agree with the arguments purporting to be in their favour may be questionable, for example what is the relative emphasis that people with a disease diagnosis would place on the promise of future cures as opposed to current help in living with the diagnosis?

The 'other' may be morally relevant entities which are not able to express their views, but to which humans feel a responsibility, such as animals or the environment. In these situations it is not possible to ask their views on the issue (except sometimes to answer

very simplistic questions by the use of choice experiments with animals). Interpretation of others' presumed interests is undertaken by intermediaries, but in doing so may primarily be reflecting their own value-positions. As seen earlier (section 4.6.1) arguing for the welfare of animals may be possible from an interests-based position that focuses on preventing physical harm or it may be holding to the intrinsic value of animals. Similarly, arguing for the environment to be given consideration can reflect a general sense that this is the right thing to do (possibly even a self-interested action on behalf of humans) and may be negotiable as to whether these interests have been adequately met. However, the argument can also reflect underpinning values-based positions related to a philosophy that demands respect for the environment or even to views on the intrinsic value of plants (e.g. Van Bueren *et al.* 2003). The underlying key element in actions relating to the interests of others is then the motivation for these actions. Thus, an environmental organisation may appear to be arguing for the interests of the environment, but in reality be seeking to further their own interests, membership and their own values.

Based on the above, a scheme of six categories emerges. Three values-based categories (in principle, views of the world and consequences) and three broad ways of understanding 'interests' (self-interests, other-regarding interests and interests of non-human entities).

The parallels between Nelkin's (1992) four categories of sources of conflict (outlined in Chapter two) and the categories identified from this analysis of empirical data is worthy of note. Nelkin's four categories were:

- v)      Infringement of values (e.g. with respect to embryos or animals)
- vi)     Different political priorities (e.g. environment, economy)
- vii)    Fear of risks (e.g. health hazards) and
- viii)   Threat to individual rights (individuals vs. community).

The infringement of values is in the category of 'in principle' issues and recognises the same types of concern related to human embryos and animals. In the second category, in Nelkin's case the different political priorities are related to the emphasis given to economic

While it would be naive to suppose a simplistic and direct link between argument category and policy, the above suggests there is some merit in going beyond the categories of value and interest in terms of informing policy. Careful examination of arguments around developments in genomics could assist decision-makers on how their decision may be understood, what value positions are implicit in their decision, how those might affect the future and what other decisions they might need to consider.

#### **7.4 Conclusions on thesis questions**

In drawing conclusions from this synthesis chapter, I will return to the four thesis questions.

1. To what extent are value-based and interest-based arguments found in areas of genomic technologies other than GM crops?

The evidence demonstrates that both values-based and interests-based arguments are found around the development of GM and cloned animals, biobanks and hESC research. There is no one single pattern of argument that can be applied across these cases, instead each presents a unique combination. In the case of hESC research, the hope of therapies overcomes ethical qualms for many, but for some, the technology presents a serious challenge to values-based arguments associated with the status of the embryo, which has resulted in a search for alternative sources of stem cells that do not require the destruction of a human embryo. A similar issue of principle can be seen in the case of cloned animals, where cloning technology threatens what some see as an appropriate way of treating animals. The industrial agriculture that it is mostly associated with cloning present additional threats to broader values about types of agriculture that are viewed as desirable. Cloning currently results in harm to a proportion of animals, giving an additional argument for restricting the use of the technology. In the case of biobanks, the dominant influences on developments have been researchers' interests for a research resource, allied to measures taken to ensure continued trust by citizens participating in the project. Future challenges are likely once commercial companies are able to access the resource. In the case of hESC research and GM and cloned animals, issues of principle are being

growth vs. environmental protection. This category is close to the different 'views of the world', although in the 'views of the world' tensions go beyond environmental concerns and are connected to, for example, holistic medicine or holistic agriculture and how these relate to economic and other drivers. Nelkin's category 'fear of risks' approximates to the 'consequences' arguments (if risks are understood in their broadest context and include for example societal risk). Threats to individual rights are close to interest-based arguments, although the latter is focussed more on protecting the interest of specific groups not necessarily pitting the individual against a group.

I propose that these six categories (in principle, views of the world, consequences and three aspects of interests) are more discriminating than the original two categories of values and interests-based argument (Tait, 2001) and include more complexity than in the four categories identified by Nelkin (1992), for example providing the three broad ways of understanding 'interests'. The question remains whether these six new categories can give policy-relevant information beyond that already identified by a values-interests approach?

The nature of the arguments, based on these six categories, could have some implications on the relevant policy responses. Issues of principle (which are consistently identified in all of the above categorisation systems) are unlikely to be resolved (for example issues around abortion in the USA, referred to both by Nelkin (1992) and Pielke (2007)). Perhaps the best that might be achieved in such circumstances is to reach a considered policy conclusion and explain why this conclusion has been arrived at.

Views of the world reflect political tensions and are likely to be determined by political decision. However, it may be worth paying attention to how incremental decisions can have unintended impacts in terms of confirming a particular trajectory that may not have been specifically advocated, as for example in the case of biobanks. Here, individual decisions, perhaps in different policy domains, could result in inappropriate stress on genetic causes of disease. In terms of the category 'consequences' many things can be done with regulation e.g. banning animal cloning in order to prevent it leading to human reproductive cloning.

raised. In the cases of biobanks and GM and cloned animals, alternative future scenarios are being appealed to.

2. How are these values-based and interests-based approaches aligned between stakeholders in potentially disputed areas?

The analysis across the case studies reveals a complex set of alignments among innovation communities, citizens and advocacy groups. The evidence demonstrates that the development of stem cell research has been strongly influenced by an alliance between the interests and values of research scientists with policy bodies. Policy bodies appear to be influenced by expectation of commercial developments although such developments are still in their infancy. A percentage of advocacy groups continue to resist stem cell research from a values-basis. In contrast, in the case of cloned and GM animals there is little evidence of industrial or policy advocacy for these developments in the EU, indeed the European Parliament has voted to ban animal cloning for food production. The main driver for cloned animals is industry overseas with EU industry appealing for a technological level playing field. In the case of biobanks, in the short-term the developments are supportive of the values and interests of research scientists, but in the longer-term they are expected to be in the interests of both citizens and companies producing therapies and diagnostics.

3. Where are values- and interests-based arguments negotiated and how does the policy-regulatory framework relate to the main values and interests being expressed?

The evidence suggests that issues around genomics-related developments are negotiated in multiple institutions but by parliaments and ethics committees in particular.

Implementation may be left to regulatory bodies, such as the HFEA. Both values-based and interests-based arguments are recognised in the policy sphere in the context of hESC research and cloned animals, whereas values-based challenges to biobanks have received relatively less attention. Biobanks are dependent in the long term on maintaining

the support of participants and interest from the commercial sector, and it is these aspects that have dominated.

Unlike the GM crops situation that forms the starting point for this thesis, risk regulation has served a minor role in the negotiation of values and interests except in the case of cloned animals. Thus, in contrast to the GM crops case, the locus of negotiation has relocated from risk regulation to ethics committees and parliaments, allowing a wider-range of considerations to be deliberated. In the case of hESC research, derivation of stem cell lines continues to be licensed on a case-by-case basis by the HFEA whose decisions will continue to be examined and if necessary challenged by protagonists on either side of the debate, particularly where some element of novelty is introduced (e.g. payment of egg donors, or alternative sources of eggs).

4. Is the values-interests approach an appropriate and useful way of distinguishing between arguments around innovation in genomics?

The case study evidence demonstrates that values-based and interests-based arguments interact with each other in complex ways. Values and interests may be strongly linked. Behind a set of interests are value positions and behind balancing different values is a preference for particular interests. Sometimes it is not clear whether an argument is being advanced on a values-basis or an interests-basis. The values-interests method is therefore difficult to apply in an analytical way but is an effective heuristic device that enables major characteristics of arguments to be elucidated in ways that can inform policy. It is possible to derive more nuanced categories, giving three categories of values and three categories of interests which may complement the values-interests approach in terms of understanding a dispute in specific circumstances. The three categories of values allow issues of principle, alternative futures and fears of consequences to be separately identified (although fears of consequences are somewhat of a hybrid between values and interests). The three categories of interest allow self-interest, other-person-regarding interest and the interests of other morally relevant agents to be distinguished.



Although each of the case studies has a particular texture, a number of more widely applicable inferences can be made for policy from the analysis of the case studies.

Firstly, values-based considerations were found to be important in each of the cases. As noted in Chapter two, if evidence-based policy only considers scientific evidence then values are likely to become hidden and unacknowledged and result in scientific evidence becoming disputed. It is therefore important to provide space for making values explicit and open to allow them to be acknowledged. This has been recognised to a large extent in the cases examined, although in-principle arguments (such as the value of an embryo or animal) appear to be more readily recognised as issues of debate than alternative views of the world or fear of consequences (for example in the biobanks case study).

Secondly, the cases tended to be addressed in rather simplified portrayals of the arguments and there was a tendency to have 'hidden' issues that are not being widely discussed. This was particularly noticeable in the stem cell case study. As a result the disputes can become simplified and framed in particular, potentially unhelpful ways, at very early stages of the development making generalisations about potential benefits and disbenefits.

Thirdly, it is important to recognise that scientists as well as other stakeholders have a range of views regarding a specific genomics development, and therefore engaging with a wider range of scientists is likely to provide a nuanced view that may reflect the complexities and assumptions that are made in each case. Addressing this aspect may in part help address the simplification issue identified above.

Fourthly and finally, where public engagement exercises are conducted, the difficult trade-offs and uncertainties involved in most evaluations should be made explicit and not disguised. Again, this is likely to avoid the tendency to simplify arguments but will also counteract the tendency to demand unrealistically utopian situations.

## Chapter 8

### Coda – Textures of Controversy

#### 8.1 Limits and simplifications

In this thesis I set out to examine the relationship between interests-based and values-based arguments and contested or potentially contested applications of genomic technologies. Previous research (e.g. Burton 1990, Nelkin 1992, Pielke 2007) strongly indicates that values components are important in disputes around technologies. More specifically Tait (2001), examining values-based and interests-based arguments in the context of GM crops, suggests that identifying the extent to which values-based and interests-based arguments are involved in disputed areas of technology could provide information that would be of help in managing disputes. In particular this might ensure there was a match between the policy or regulatory instrument and the issues of primary concern. With this in mind, I have considered three case studies covering different genomic technologies, affecting humans, animals and the natural environment as well as a range of emphases between values and interests. I have extended the values-interests approach to situations where risk (to humans or nature) is not the only or even the main consideration. The three case studies selected were GM & cloned animals, population biobanks and stem cell research.

Before reprising the main conclusions from this research, I recapitulate some of the limits and simplifications made to enable the research. Firstly, values- and interests-based arguments have been treated in this research as though they are ideal types. I have used them as heuristic devices for the purposes of analysis. They are to some extent artificial constructs intended to capture something about social reality. In practice any one position is unlikely to consist of a single value or interest argument. It is much more likely that a range of interacting values and interests are under consideration at the same time. However, it is entirely plausible that some of them come to dominate evaluative processes.

Secondly, the analytical approach has been offered as a means of obtaining policy-relevant information for the better evidence-based management of disputes. It has been suggested as a complementary approach to both upstream engagement and the use of scientific evidence in resolving complex problems, whether in the context of foresighting, technology assessment or other activities. The evidence presented in this thesis suggests that such a role could be useful. However, it is unlikely that the approach will be a panacea to all difficult and contested decisions. A detailed examination of links to evidence-based policy is beyond the scope of this thesis.

Thirdly and finally, this is a meta-level analysis. The implication is that some factors, such as institutions or individual contexts within organisations, which are likely to be important in disputed situations, are too detailed to be included in this analysis. The failure to include detailed analysis in a meta-level consideration does not suggest that such detailed factors are not important in specific circumstances.

Having cautioned the reader about some of the limitations of this research and the context in which it should be understood, I now turn to summarise the main findings.

## **8.2 The Cases**

Animal cloning is the sole case where real 'products' are available in the market place, (although some products from stem cell research have come on the market since the conclusions of the field work for this thesis). In this case, live cloned cattle and pigs are in existence (albeit in small numbers), have been traded across countries, and progeny from the clones may have produced milk and meat for human consumption. In the EU, risk evaluation and the interests of industry have apparently been overwhelmed by rejection of cloning by European Parliament on largely values-based grounds.

The Biobank case differs in that rather than using advances in genomics knowledge to provide new and innovative products, the case is about setting up a research resource. Teams of researchers can access the resource, conduct research which may further knowledge about biology, but also to develop innovative products.

The case of stem cell research, particularly human embryonic stem cell research, is a unique situation where values-based arguments against the development are strong. However, at least in the UK, the hopes raised by the prospect of future stem cell therapies, outweigh any moral qualms for the majority.

There is no one single pattern of argument that is used consistently across the cases. Interests-based arguments predominate in the biobank case, values-based arguments in the stem cell research case and values-based arguments conflict with interests-based arguments in the case of cloned animals. Each of these three cases is distinctive. They describe a range of textures of potentially disputed developments in genomics. Each case has an individual quality, depending on scientific characteristics, social contexts and the values and interests that come into play. Just as a material might consist of a structure of interwoven elements, so each case consists of a range of similar and different elements which interact with each other, forming diverse patterns and consistencies.

Texture is a tactile quality, it is possible to visualise something about texture but the best way to realise the nature of the texture is by interacting physically with it. By analogy, an examination of the values- and interests-based arguments in each of the cases provides some insights regarding the nature of a potentially disputed area of genomics. Examining arguments carefully can help discern their features. But it is only in interacting physically with arguments, for example in dialogue or mediation, that the texture of a specific dispute can be fully appreciated. I have argued that the values-interests concepts are fruitful in such a detailed examination. But categorisation on the basis of documentary evidence and individual interviews can only go so far. There may remain ambiguity that is only resolvable by interacting directly with the people advancing those viewpoints.

### **8.3 Implications for policy and theory**

In contrast to GM crops situation, policy makers have recognised the inherent values aspects in the genomic developments considered in this thesis. This is most clearly seen in the cloned animals case study where policy response has gone beyond considering risk from food and to the environment, to include values-based arguments. In this case the

values-based arguments have promoted an extremely negative stance by policy makers to cloned animals. The case is also an example where such public engagement as has taken place, has tended not to engage with the trade-offs and international contexts inherent in the case. Instead, citizens appear to have been offered unrealistic situations without any practical restraints.

In the cases considered for this thesis, policy-makers have generally recognised the need for spaces where values-based issues can be negotiated. But how good are these spaces for dealing with on-going challenges to the *status quo*? Biobanks have introduced a novel method of governance, that of a standing ethics committee, which has been tasked with negotiating between the interests of biobank researchers and maintaining the confidence of people who participated in the development of the resource. However, this approach is not intended to negotiate deeper policy issues, such as whether investment in biobanks represents a good use of resources in comparison to investment in public health measures. This is a much more difficult task to undertake because it crosses many policy domains, but, it is an aspect that may be worthy of attention.

The case of stem cell research became strongly focused on the use of human embryonic stem cells in research. In this case, high profile arguments (regarding the status of the embryo) tend to dominate discussions to the extent that other salient features are ignored. Capturing complexity of arguments by talking to a wider-range of scientists could help the policy process by providing a more nuanced picture of the prospects and promises of stem cell research. This is not to denigrate the importance of the main values-based argument but to suggest that other aspects might also be worthy of examination.

The above arguments highlight a number of policy-relevant concerns raised by this thesis. I therefore suggest that the values-interests approach has revealed a great deal of complexity within the concepts of values and interests in ways that could be useful for policy makers.

This thesis offers a more nuanced method of parsing values-based and interests-based arguments by offering three different ways in which values are expressed and three

different ways in which interests can be understood. Arguments may be about strongly held principles that are adhered to, different views of the world and concepts of the future or an evaluation of the consequences that are felt to be inevitable. Interests may be about self-interests (which is not necessarily synonymous with selfish interest or vested interest), about advocating the interests of others who may be felt to be less powerful or advocating the interests of morally relevant entities that are unable to speak for themselves, such as animals or nature. This thesis has therefore extended the values-interests approach to offer an approach drawing finer distinctions of categories.

#### **8.4 Thesis originality and importance**

The subject of study for this thesis is important because disputes in the area of genomics are of consequence. They cause challenges for policy-makers aiming to secure economic growth at the same time as ensuring legitimacy for decisions. While seeking more scientific evidence may improve the decision-base or serve as a delaying tactic for making controversial decisions, more scientific evidence is unlikely to resolve disputes where there is a strong value basis, like those in genomics (e.g. Fisher & Ury 1987, Jasanoff 1990, Nelkin 1992, Schön & Rein 1994, Pielke 2007). Therefore alternative approaches to policy making in scientific areas under values-conflict are needed. The values-interests approach is one such.

This thesis is unique in that it combines case studies in a range of genomics applications with an approach derived from considering the motivations of a range of stakeholders, and in that it examines the values and interests at stake in great detail. It is also distinctive in its interdisciplinary approach to the questions. The cases – GM and cloned animals, biobanks and stem cell research - were chosen to examine a range of social relationships. To my knowledge, this is the first time anyone has undertaken to apply the values-interests approach developed by Tait (2001) across a wide range of applications. This approach revealed that each case had a unique texture and were not just further instances of the GM crops situation. Thus, this thesis avoids treating all future genomics

developments as a case of 'another GM crops' yet gains from the insights from detailed, long-term study of the development of GM crops.

This thesis demonstrates that applications of genomics should be viewed individually, each in their own context. The approach also reveals a great deal of complexity within the concepts of values and interests in ways that could be useful for policy makers. This thesis contributes a richer understanding of disputes and potential disputes in genomic developments and suggests a discriminating use of the values-interests framework. This thesis is put forward in the belief that it can contribute to addressing the problems of policy making in disputed and potentially disputed areas of genomics.

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## Annex 1 Events attended

Date	Event name	Speaker/organiser	Venue
3/11/2004	The Development of Genomics Capabilities in the Pharmaceutical Industry - an alternative to the revolution model	Paul Nightingale, SPRU, Sussex University	Innogen seminar
8 /11/2004	Public engagement with genomics	Prof. Brian Wynne Lancaster University	Innogen seminar
9/11/2004	Should scientists tamper with nature?	ESRC	Royal Society of Edinburgh
10/11/2004	Science and the Parliament	Royal Soc. Chemistry	Dynamic Earth, Edinburgh
12/11/2004	'Coping with new ideas' talk by Prof. Alison Murdoch, Newcastle, on stem cells	Scottish Society for Experimental Medicine	New Royal Infirmary, Edinburgh
1/12/ 2004	Hierarchy in Organisations: It's Impact on Innovation, Governance and Stakeholder Interactions	Gerard Fairtlough	Innogen seminar
16/12/2004	Patenting stem cells	Scottish Stem Cell Network	Royal Society of Edinburgh
9/12/2005	From families to populations: impact of disease genes	Prof. Leena Peltonen, University of Helsinki	MRC Human Genetics Unit, Edinburgh
25/2/2005	Judgment under Siege: The Three-Body Problem of Expert Legitimacy	Prof. Sheila Jasanoff, Harvard University	Innogen seminar
4-5/3/2005	Stem cells: Progress to Therapy conference	Scottish Stem Cell Network	Edinburgh
16/3/2005	The Burdens and Blessings of the New Genetics (Eric Cohen – President's Council on Bioethics lecture)	Genomics Forum	Edinburgh
3/4/2005	What if ... we find a cure for ageing	Edinburgh International Science Festival/BBC	Our Dynamic Earth, Edinburgh
4/4/2005	Remaking humans – the implications of nanotechnology	Edinburgh International Science Festival	Royal Museum, Edinburgh
5/4/2005	Nanotechnology and Nanoscience	Reith-Lecture-by Lord Broers	Glasgow
11/4/2005	Risk-related judgements and decisions about GM food: The role of affect	Ellen Townsend, University of Nottingham	Innogen seminar
28/4/2005	Launch of AEBC report on drivers of agricultural research	AEBC	London
11/5/2005	Talking Off the Record: Conversations between Scientists and Government. Seminar.	Centre for Research in the Arts, Social Sciences and Humanities	University of Cambridge

18/5/ 2005	Korea Scotland life Sciences Seminar: Stem cells and regenerative medicine	Scottish Development International	Edinburgh New Royal Infirmary
5/9/2005	Nanotechnology: promising a revolution in healthcare? Conference.	Institute of Nanotechnology	Edinburgh
18-19/9/2005	European Farm Animal Functional Genomics conference	ARK-Genomics	Edinburgh
24-25/11/2005	Ethical and Legal aspects of Farm Animal Cloning	Invited workshop for EC Specific Support Action 'Cloning in Public'	Prague
7/2/2006	Medicine and the Media	Lecture by Dr Michael Shea	Royal College of Physicians, Edinburgh
20/2/2006	Future scientific research priorities and responsible funding	BBSRC Open Meeting	Manchester Town Hall
9-11/3/2006	Evaluation of Genetic Services	Expert workshop organised by Genomics Forum	Edinburgh
30/3/2006	BBSRC institutes science & society	Open evening	London
5-7/4/2006	Animal genomes in science, social science and culture	Expert workshop organised by the Genomics Forum	Edinburgh
24/5/2006	Implementing the promise of stem cells in science and medicine	Caledonian Research Foundation prize lecture	Royal Society of Edinburgh
14/6/2006	The power and precision of QTL mapping using 10,000 SNPs	Prof. Mike Goddard University of Melbourne	Roslin Institute
5-6/9/2006	Genomics for Development? The life sciences and poverty reduction	Innogen Annual conference 2006	London, Regent college
12/9/2006	Sustainable animal breeding	Genesis Faraday, SABRE and EFFAB annual conference	Edinburgh
20/9/2006	Herding cats? A partisan view of the science and society debate	Prof. Chris Pollock, Director IGER	Roslin Institute
21/9/2006	Engendering Trust or Engineering Consent? Public engagement in recent biobanks developments	Prof. Alan Peterson, University of Plymouth	Genomics Forum
13/10/2006	Workshop on biobank governance		Genomics Forum
31/10/2006	Hype not Hope exhibition/public dialogue on stem cell science	BBSRC/MRC	Our dynamic earth, Edinburgh
23/11/2006	Women donating eggs for stem cell research – a public debate	Organised by ESRC project 'The social dynamics of public engagement in stem cell research'	Our dynamic earth, Edinburgh



28-29/11/2006	EADGENE ethical matrix workshop	Applying ethical matrix theory to developments in animal genomics	Ce-BRA-KVL, Copenhagen, Denmark
23-25/1/2007	The regulation of stem cell research	ESRC CBAR workshop	Exeter
25-27/1/2007	Governing Genomics conference	Egenis international conference	Exeter
31/1/2007	BBSRC Open event		Glasgow
13/2/2007	ERRC Peter Wilson Lecture 'Does science matter?'	Royal Society of Edinburgh	Professor Anne Glover
14/2/2007	The 10 Years of Dolly – past, present and future	Ian Wilmut, Keith Campbell, Alan Holland, Donald Bruce	The Royal Museum, Edinburgh
11/4/2007	Open Meeting – Generation Scotland: Genetics Research and Health	HGC event organised with Genomics Forum	Edinburgh
14/5/2007	Stem cells identities, governance and ethics conference	University of Nottingham	Nottingham
18/5/2007	The Life Sciences Entrepreneur – Translating Ideas to Business seminar	University of Edinburgh	Edinburgh
24-25/6/2007	Responsible Research in Europe – Science & its publics conference	German Federal Ministry of Education & Research	Munich
26/6/2007	Publications launch of ESRC Science & Society Programme	Edinburgh University	ESRC Science & Society programme
27/6/2007	Consultation on creation of animal-human hybrids for research	Organised by ESRC project 'The social dynamics of public engagement in stem cell research'	Glasgow
17/10/2007	Defra Scientific Advisory Council open meeting		London
29/11/2007	Coalition for Medical Progress annual general meeting	Presentation of research on attitudes to animals	London
27/5/ 2008	Developing stem cell applications: what role for the private sector?	Public engagement event as part of ESRC 'Social dynamics and stem cells' project	Edinburgh

31/5/2008	MRC/BBSRC stem cells public engagement stage 3 workshop (commercialisation)	On oversight group & attended to provide social science specialist knowledge	Bristol
24-27/6/2008	1 <sup>st</sup> Global conference on GMO analysis	European Commission Joint Research Centre	Villa Erba, Como Italy
17/7/2008	Commercialising regenerative medicine	Scottish stem cell network	Edinburgh
27/8/2008	Programming pluripotent cell identity	Various speakers (including Kazutoshi Takahashi)	Edinburgh
11/11/2008	Food security in a climate of change	SAC 2008 Outlook conference	Edinburgh
17/12/2008	HFEA Open meeting		Edinburgh
17/2/2009	Global challenges in a changing world	Professor John Beddington	Edinburgh
25-26/2/2009	Future of farming consultation- GM technology	St George's House, Windsor	Participant
11/3/2009	TB or not TB, that is the question	Professor John Woolliams	Roslin Institute
24/3/2009	Cellular therapies: progress to the clinic	Scottish Stem Cell Network	Various speakers
25/3/2009	Advances in pluripotent stem cell research	Scottish Stem Cell Network	Various speakers
30-31/3 2009	Governance of new technologies: the transformation of medicine, information technology and intellectual property	SCRiPTed, Edinburgh	Various speakers, attended and chaired sessions
3/4/2009	KT Scotland: Policy & Practice	GRAD skills, St Andrews	Various speakers
7/4/ 2009	The persistent influence of failed scientific ideas	Edinburgh Medal (Edinburgh Science Festival)	Prof Jon Beckworth
8/4/2009	The Arup lecture 2009: our future – considerations in times of profound change	Edinburgh Science Festival	Dr Chris Luebkmann, Arup
16/4/2009	Hot-bed of genius: the future of innovation in Scotland	Edinburgh Science Festival (ITI sponsored)	Rohit Talwar

7-8/5/2009	Beyond Pattison: challenges for stem cell transplantation and policy conference	ESRC Stem Cell Initiative	London
3/6/2009	Viruses, vaccines, pandemics and paranoia	Dr David Onions, Bioreliance	Edinburgh
25/6/2009	International Federation for Animal Health Europe conference		Brussels
30/9/2009	Defra Science Advisory Council open meeting		London
13/10/2009	Innovate 2009	Technology Strategy Board	London
7-9/10/2009	Genomics Network conference 'Mapping the genomic era'		Cardiff
12-14/4/2010	British Society for Animal Science Annual Conference		Belfast
27-28/5/2010	Ten years after mapping: the societal genomics landscape conference	Centre for Society and Genomics	Amsterdam
8/7/2010	Agrigenomics world congress	Select Biosciences	Brussels
26-30/7/2010	International Society for Animal Genetics Conference		Edinburgh

## **Annex 2 Invitation letters**

### **1) Biobank interviews**

Dear xx,

#### **Consultation on public acceptability of 'Generation Scotland'**

We are currently undertaking a consultation of specialists about issues that may determine the acceptability of 'Generation Scotland' among the general public and stakeholders. We would like to consult you as a key specialist.

As you may already know, 'Generation Scotland' is a proposed, large research project involving many scientists working across Scotland. It aims to create an ethically sound, population and family based infrastructure to identify the genetic basis of common complex diseases. 'Generation Scotland' would focus on the identification, study and follow-up of individuals with a disease diagnosis and their 'at risk' relatives. The aims would be to discover the nature of the genetic contributions to risk, to treatment response and to long-term outcome.

The knowledge would be valuable to:

- a) NHS Scotland (and other health services), for healthcare planning and resource allocation, in health surveillance and in treatment choice,
- b) The life sciences sector (nationally and internationally), for medical diagnostics and devices, drug discovery, clinical trial design and the avoidance of adverse drug reactions,
- c) Individuals and the public at large, for the benefits that would accrue from improved health monitoring, prevention, intervention and treatment choice.

It is envisaged that 'Generation Scotland' would comprise the following structural elements:

- a database of medical information, retained within NHS Scotland;
- a research and technology arm to conduct and interpret genetic studies

- a communications arm to develop awareness of, engagement in, support for and understanding of the requirements for success and the outcomes of the programme;
- a commercialisation arm to develop and exploit the application of programme findings both within Scotland and elsewhere.

As a preparatory component, we wish to interview several specialists, such as yourself, to ascertain your views on critical elements to ensure public acceptability of 'Generation Scotland'. This will be followed by a series of focus groups with members of the public and scenario setting meetings to combine 'expert' and 'lay' views. Three reviews pertaining to consultation, social and legal issues have also been commissioned.

A member of the research team (Dr Sarah Cunningham-Burley, Dr Nina Hallowell, Sarah Parry, Ann Bruce or our clerical assistant, Eileen Mothersole) will be telephoning you shortly to see if it would be possible to arrange a time for an interview. This interview should take no longer than one hour, and will be loosely structured around a few key topics. In the meantime, if you have any questions or issues arising out of this, please do not hesitate to contact me.

We very much hope that you will be willing to take part in this consultation.

Yours sincerely

## **2) Stem cell research interviews**

Dear xx,

### **Research on value and interest dimensions of stem cell research**

We are currently undertaking research on the causes and characteristics of disputes in stem cell research and are interviewing stakeholders as part of this research. We would like to consult you as a key stakeholder.

Our aim is to explore the utility of distinguishing between the 'value' based and 'interest' based aspects in order to understand and potentially help to resolve contentious issues in biotechnology research. We would be very grateful to have the

chance to hear your perspective on stem cell research, what you think the key issues are, what your views are on how the area is being regulated, and what your vision is for the future of the research.

Innogen is an Economic and Social Research Council funded research centre and forms part of a network of 3 such research centres across the UK studying the evolution of genomics and life sciences and their social and economic implications.

I will be telephoning you shortly to see if it would be possible to arrange a time for an interview. This interview should take no longer than one hour, and will be loosely structured around a few key topics. In the meantime, if you have any questions or issues arising out of this, please do not hesitate to contact me or Professor Tait. I also attach a short briefing note to give further background to this research.

I should point out that any interview would be treated confidentially but you should note that I am a part-time employee at Innogen and I am also employed as a part-time Scientific Administrator at Roslin Institute. This is a completely separate employment and any information imparted to Innogen will not be communicated to Roslin Institute. Additionally, my husband, Dr Donald Bruce is Director of the Society, Religion and Technology project of the Church of Scotland and has occasionally commented on the ethical issues arising from stem cell research. Again, let me assure you that any information you give to this research project will not be communicated to the Society, Religion and Technology project.

We very much hope that you will be willing to take part in this research.

Yours sincerely

## **Annex 3 Interview guides**

### **1) Biobank interviews**

**Topic guide for specialist consultation on key issues that may determine the feasibility and acceptability of 'Generation Scotland'**

**V3 21.4.03**

#### **Opening questions:**

Just to start, can you say a little about your professional expertise and any interest you may have in Generation Scotland?

1. What are your first thoughts about Generation Scotland?

Leave this open ended to start with, then probe, as appropriate along these lines:

- In your view are the key issues that may determine the public acceptability of 'Generation Scotland'?
- What contribution do you think it will make to improving the health of the public?
- Are there any key concerns that come to your mind at this stage?

*We shall now turn to discuss several issues in more detail. Please draw on your own area of expertise in answering these questions, and also feel free to add other issues that we may not have thought of.*

#### **Ownership and control of genetic data**

Issues of ownership and control of the data collected for Generation Scotland need to be considered carefully.

2. What are your views about the ownership of genetic data created through Generation Scotland? (probe legal vs moral dimensions)
  - How do you think others may feel (probe public, scientists etc) ?
  - What are your views about the granting of Intellectual Property Rights (probe if should be granted at all)?

3. How should access to the database be controlled
  - Who should control it (should the public be involved)?
  - How can database management be kept accountable?
4. What are your views about benefit sharing eg from IP generated income through Generation Scotland (probe donation to charity, feed into NHS etc)
  - How should Intellectual Property be handled to ensure public as well as private benefit?
  - Who might be considered beneficiaries (probe individuals, families, communities, patients, researchers, Generation Scotland, industry, society in general)?

#### **Use of the database**

**There are likely to be many public and private bodies interested in the database**

5. How should these interests be managed?
  - What if there are conflicts of interest (probe issues around stakeholder influence versus public influence)?
  - How might equity be ensured in terms of who benefits from the database (probe public/private interests and boundary)?
6. How might private interests be effectively managed?
  - Should data be made available and in what way?
7. How might academic interests be effectively managed?
  - Should data be made available and in what way?



## **The public interest and public health**

Generation Scotland has as its aim the improvement of health through monitoring, prevention and treatment. We want to consider issues relating to the public interest and the public health.

8. What do you think the issues relating to the public interest (or 'collective good') are in relation to Generation Scotland?
  - Do you see any conflicts between individual and collective interests?
  - Who should define the public interest?
  - What are your views about commercialisation?
9. How can effective mechanisms be set up to ensure research results are disseminated to various stakeholders, including the public, their representatives as well as health policy makers?
  - Who should be involved in research and policy agenda setting and how should they be involved (probe also around issues relating to future research)?

## **Public consultation and public engagement**

Generation Scotland is committed to public consultation and public engagement. We would like your views about aspects of this process.

10. What do you think the issues are relating to public trust and genetic databases for medical research?
  - How might trust be ensured/compromised?
11. What do you think makes for effective consultation?
  - Appropriate methods?
  - Feedback to participants – general or individual (probe issues around disclosure of medically relevant information to participants and implications for privacy and anonymisation)?

- Feedback to and involvement in research process and management of database?
- Feedback and involvement in policy process?

12. What do you think are the barriers to consultation?

- Probe issues relating to civic processes (activism/apathy, education, notions of expertise, consultation vs engagement/involvement)

## **Research Participation**

Generation Scotland, like other DNA collections, raises important issues relating to research participation. The research is open ended meaning that specific consent will not be possible, and we need to explore how this should be handled.

13. What particular issues relating to informed consent arise?

- Probe for: issues around specific/non-specific consent for what type of use, when and how (should participants be recontacted for further consent for unanticipated use?); whether information could ever be used without participant's consent; obtaining consent from family members/patients – possibility of pressure to participate?
- How can a right to withdraw be managed and what might this mean for data already collected and used?

14. How might people be recruited?

- Probe different routes and particular issues relating to minority groups

15. What do you think are the potential benefits or harms that might result from participation?

16. What issues relating to privacy and confidentiality are raised?

- Probe anonymisation and encryption as ways of addressing privacy
- Probe feedback to participants

17. How do you think people will respond to being asked to participate in this research?

### **Generation Scotland and other areas of genetic research**

You may have some specific comments to make about Generation Scotland or other areas of genetic research.

18. Are there any areas of genetic research that you have any concerns about?

19. Are there uses of Generation Scotland that you would not condone?

20. What are your views about the direction of medical research

## **2) Stem cell interviews**

Explain the project:

- ESRC funded project
- Seeking to understand various stakeholder views on stem cell research
- Not Roslin/SRT work
- Conversation will be kept confidential but might like to use quotes
- Permission to tape record
- Consent form

### **Questions**

1. Can you tell me a bit about how you got involved in stem cell research?
2. What do you think are the most important issues around stem cell research?
3. Do you think that your views on this have changed over time?
4. What sort of benefits do you think are likely to come out of stem cell research?

5. What do you think are the key issues from the point of view of policy makers?
6. Why do you think some people advocate/object to stem cell research?
7. [What sort of experiences have you had in talking to others about stem cell research?  
e.g. friends, peers, other groups?]
8. How influential do you feel scientists have been in guiding the direction of stem cell research ? What about patient groups? Pro-life groups?
9. What role do you think commercial companies have in delivering stem cell research?
10. How do you feel about patenting stem cell research?
11. How do you see events worldwide influencing stem cell research in the UK?
12. Where do you see stem cell research in 20 years time?
13. What would you like to see happen now?
14. What does stem cell research mean to you?
- (what picture comes to mind when you think of stem cell research?)
15. How do you feel about the general direction of medical research?
16. Is there anything else you'd like to add or comment on?
17. Are there other key stakeholders you think I should interview? What about those who might take a different view?
18. How would you like your expertise to be identified?

## **Annex 4 Consent form for stem cell interviews**

**Id number**.....

### **CONSENT FORM**

**Project title:** Interests and values in stakeholder interactions

**Name of researcher:** Ann Bruce

**Institution:** INNOGEN Centre, University of Edinburgh

**Contact:** Old Surgeons' Hall, High School Yards, Edinburgh EH1 1LZ

**Tel:** 0131 650 9106, **Email:** [ann.bruce@ed.ac.uk](mailto:ann.bruce@ed.ac.uk)

#### **Description of research project**

This interview is part of an Economic and Social Research Council (ESRC) funded project led by Professor Joyce Tait at the University of Edinburgh. The purpose of the interview is to inform the research project by seeking to understand what stakeholders think about various aspects of stem cell research.

Ann Bruce, a Research Fellow at INNOGEN will conduct the interview at a mutually agreed time and place. The interview will be tape-recorded with your permission and the tape will be transcribed in full. The tape and resulting transcript (anonymised through use of a code number) will be kept in a locked office at INNOGEN and on a University of Edinburgh server and access will only be permitted to the INNOGEN project team. Both will be destroyed after 10 years. The transcript will be analysed for the purposes of this research project and may be used in subsequent research publications from INNOGEN. We are very happy for you to have sight of any draft publication, if you so desire. We will not use any names in the reports but may wish to attribute an area of expertise (e.g. research scientist, NGO representative, commentator, policy and regulatory).

As part of the conditions of grant, ESRC may request that the transcript or data derived from it are also preserved in the UK Data Archive at the University of Essex. The aim of this is to preserve and share high quality social science data generated as a result of ESRC-funded research. The data will be kept anonymously. The material will be preserved as a permanent resource for use in research and publication and may be used for verification, comparative research, re-analysis or secondary analysis, for research design and methodological advancement or for teaching purposes. The transcript will be web accessible and free to use for bona fide researchers only. We will ask to be notified in advance and given copies of any publications arising from the use of this research and will ask to be acknowledged as the source of the data.

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I have been given information about the research project and the way in which my contribution to the project will be used and I agree to participate in this research project. I understand that:

- The nature of my participation is an interview.
- At the time of the interview my permission will be sought to tape-record and transcribe the interview.
- I agree to notes being taken during the interview. If permission for tape-recording is refused, these will form the sole record of the interview.
- My participation is entirely voluntary and I understand I can withdraw my consent within the next 6 months.

Please tick as appropriate:

☐ I give my permission for the information I give to be used for research purpose (including research publications and reports) with preservation of anonymity but with my expertise indicated

☐ I give my permission for the information I give to be used for research purposes (including research publications and reports) with preservation of anonymity and without my expertise indicated.

At the end of this project we are required by the funder to consider depositing the transcript with the UK Data Archive at the University of Essex. This archive is for academic research. Please indicate below if you are prepared to have the information you give us deposited in this way.

☐ I give my permission for the information I give to be deposited in the UK data archive in an anonymous form, and I give my permission for it to be used for the following purposes:

☐ verification of the current research

☐ for future research

☐ for teaching purposes.

Signed respondent ..... Date .....

Title:..... Organisation .....

I would like to see a copy of the draft report resulting from this Innogen project

(please tick) ☐

Signed researcher ..... Date .....

On behalf of ESRC INNOGEN Centre

Annex 5 Example full cognitive map of an interview. Interview 17, policy maker

