

**Destruction, Creation and Immortality
Australian Public Policy and Nascent Human Life**

**by
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Abstract

This thesis examines the public policy outcomes in Australia in two distinct but related policy domains; Assisted Reproduction Technology (ART) and Embryonic Stem Cell (ESC) research and cloning. Central to each policy domain is an important actor; the extra uterine human embryo. Without the surplus embryos created by default through ART, ESC research would not have eventuated. The possibility of cloned human embryos through Somatic Cell Nuclear Transplant (SCNT) technology represents the ultimate in ART. Each of these policy domains are characterised by divisive and irresolvable ethical conflicts over the moral status of the embryo or what it means to be human in the 21st Century. Each policy domain is also characterised by technological innovations which require policy solutions to new and complex policy problems. The central dilemma is how to elucidate policy when the problems are multidimensional, grounded in medicine, science and technology and deep conflicts over values exist.

The standard response of disaggregating complex policy issues into their constituent components and referring them to a technocratic elite for solution is unsatisfactory because the essential contestation is not over *facts* but over *values*. In each of these policy arenas, there are multiple actors who form distinct coalitions to promote a particular policy stance. The policy stances however are not informed by shared beliefs and values. Rather the policy outcomes emerge from the contest between competing narratives which allow interests with different values and beliefs to come together around a shared storyline.

Hajer's Discourse Coalition framework was used to identify the interests, discourses and narratives operating in each policy domain. In ART, particular health, science, ethics and industry interests form a discourse coalition around the dominant narrative of hope to promote public policies allowing increasingly wider access to ART for the involuntary childless. In this policy arena the extrauterine embryo is ambiguously constructed as both the desired child and a quality product. In the Australian context, ART policy remains within the private sphere of reproduction and the health policy domain under the jurisdiction of State and Territory governments despite efforts to place it on the national policy agenda.

In ESC research and cloning, specific ethical, health and wellbeing, science and industry interests form a discourse coalition around the dominant narrative of 'saviour science' to promote a relatively permissive policy position on embryo research and therapeutic cloning. The embryo moves out of the private sphere of reproduction into the public sphere of international biotechnology, and is thoroughly commodified as a scientific and economic resource. The ESC policy domain requires a national policy response because it impacts on Australia as a scientific innovator and producer in the globally competitive biotechnology arena. Thus, two very different policy outcomes emerge despite a shared essential actor in the extrauterine embryo.

The Discourse Coalition approach provides an alternative analysis of policy issues with seemingly irresolvable conflicts. It also provides a potential alternative policy making paradigm that allows interests with different norms and belief

systems to form policy coalitions around a shared narrative to advance a particular policy position without sacrificing their underlying values.

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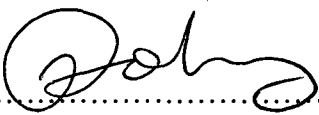
Also thanks to my family, particularly my sister Dr Kathleen Doherty, who could see the light even when I could not and to the many friends who have supported me.

Finally I would like to dedicate this thesis to my father Jimmy who is not here to see it and to my mother Catherine who is.

DECLARATION

This thesis contains no material which has been accepted for a degree or diploma by the University or any other institution, except by way of background information and duly acknowledged in the thesis, and to the best of the Candidate's knowledge and belief no material previously published or written by another person except where due acknowledgment is made in the text of the thesis.

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ACRONYMS

AAS	Australian Academy of Science
ABS	Australian Bureau of Statistics
AHEC	Australian Health Ethics Committee
AIHW	Australian Institute of health and Welfare
ART	Assisted Reproductive Technology
ARTCR	Assisted Reproductive Technologies Review Committee
ASC	Adult Stem Cell
CAMRA	Coalition for the Advancement of Medical Research Australia
CEDAW	Convention on the Elimination of All Forms of Discrimination Against Women
CDC	Centres for Disease Control
ESC	Embryonic Stem Cell
FINRRAGE	Feminist International Network of Resistance to Reproductive and Genetic Engineering
FSA	Fertility Society of Australia
GIFT	Gamete Intra Fallopian Transfer
HERP	Human Embryo Research Panel
HREOC	Human Rights and Equal Opportunity Commission
ICSI	Intra Cytoplasmic Spermatozoa Injection
IVF	In Vitro Fertilisation
LRC	Legislation Review Committee
NBAC	National Bioethics Advisory Council
NHMRC	National Health and Medical Research Council
NHS	National Health Service
RTAC	Reproductive Technology Accreditation Committee
SACRT	South Australian Council on Reproductive Technology
SCALC	Senate Community Affairs Legislation Committee
SCLCA	Standing Committee on Legal and Constitutional Affairs
SCNT	Somatic Cell Nuclear Transfer
SLCLC	Senate Legal and Constitutional Legislation Committee
UN	United Nations
UNESCO	United Nations Educational Scientific and Cultural Organisation
VLRC	Victorian Law Reform Commission

1 Chapter 1 Introduction

The new technologies make a public discourse on the right understanding of cultural forms of life in general an urgent matter. And philosophers no longer have any good reasons for leaving such a dispute to biologists and engineers intoxicated with science fiction. (Jurgen Habermas, 2003, 15)

The latter half of the twentieth century has witnessed a rapid development in the biological sciences. In 1953, Watson and Crick published their seminal paper on the structure of DNA which, as they predicted, proved to be ‘of considerable biological interest’ (Watson and Crick 1953, 737). Fifty years later, in 2003 the international Human Genome Project announced it had successfully mapped the entire human genome (Collins et al. 2003, 835, Coghlan 2003, 19, Pennisi 2003, 409). The era of genomics had finally arrived and was heralded a brave new world¹ for biomedical research. Genomics was acclaimed as the ‘...central and cohesive discipline of biomedical research’, (Collins et al., 2003, 835) offering biologists the research tools to analyse the human organism at its most basic molecular level. Molecular science could now disaggregate a human being into its component parts; genes, and developments in biotechnology held the promise of not only creating new human beings² and replacement body organs but manipulating genes and changing the germ line of future generations. In this post genetic era, ‘...the once moral being, shaped by culture, society and individual choices becomes the biological being of genetic reductionism and determinism’ (Kolleck 2000, 147).

The biotechnology revolution and the new human genetics present policy makers with a number of challenges. Ironically the more we disaggregate the human species down to its molecular components, the greater the contest over what it means to be human. Science shows that humans share 60% of their genes with chickens, 88% with rodents more than 98% of our DNA with chimpanzees (Gunter and Dhand 2005, 47), making us far less unique amongst the species than

¹ ‘O brave new world, that has such people in it!’ *The Tempest* William Shakespeare adopted as the title of Aldous Huxley’s futuristic novel in 1945.

² Through the cloning technology, somatic cell nuclear transfer.

we had perhaps hoped. Science had already demonstrated that each human was part of a continuum from conception through to birth and maturity into an adult but had not resolved the argument over where in that continuum one could claim the status of human being and its attendant rights. In short, while the biological facts of human life become ever clearer, what it means to be a human being becomes more contested and biotechnology policy making becomes more fraught.

In the biotechnology policy arena there are fundamental conflicts over values and powerful sectional interests compete to influence both public opinion and legislators. It is an arena where the rational scientific world appears to clash with the world of firmly held but conflicting beliefs over the value of human life itself. An arena which promises great scientific and commercial benefits but at a price which is still being negotiated. It is an ethical minefield which needs to be traversed warily so that public interests are protected as well as private interests. In short the era of biotechnology confers, at least potentially, intriguing and demanding issues on the policy agenda.

Thus scientific and technological innovations in biomedicine bring deep seated conflicts over values to the fore and competition between sectoral interests for policy supremacy. They produce 'powerful but conflicting social reactions' (Australian Law Reform Commission, 2003) supported for their potential breakthroughs in health care but creating concerns over the possibility of genetic discrimination and over society's capacity to control and regulate genetic science. Mulkay (1993, 723) described these opposing positions as a contest between the rhetoric of hope and the rhetoric of fear. The former has an idealised vision of the relationship between society and science where science based technologies will deliver society from death, disability and disease while the latter promotes an alarming vision of moral decline and social disruption courtesy of an uncontrollable scientific community (Mulkay 1993, 728-9).

1.1 Science and Public Policy

When it comes to policy making in scientific realms, the *content* of sophisticated and complex science tends to privilege the voice of experts in the relevant

disciplines. While such experts have a legitimate stake in policy formulation, the policy issues which emerge are rarely concerned only with apprehension of scientific fact. Policy making decisions, even in science and technology arenas, are generally concerned with weighing complex and non-technical issues focused on whom gets what in society and at what cost. Thus, policy choices are always political in their allocative consequences despite any veneer of objectivity and value free analysis that science confers, especially where scientific evidence is ambiguous or contested by warring experts (Haas 1992, 11). Privileging the advice of specialists may lead to poor decisions or ignoring important social ends (Haas, 1992, 24). In the case of biotechnology, there is a distinct bioethical context to consider as well as the scientific context, thus more than one knowledge elite has a claim to policy legitimacy. The tendency, however, is for bioethics to serve as the handmaiden in policy debates, used by elites to provide the 'imprimatur of ethical review' rather than providing the critical eye (Root Wolpe and McGee, 2001, 193).

In the biotechnology arena there are important normative and social issues to consider. The norms which drive scientific or commercial imperatives do not necessarily serve social imperatives. Thus debates about biotechnology are not only about the possible, they are also about the desirable, and in a just society this debate must take place in an open discussion *between* experts and publics in a meaningful deliberative process. Where there is public investment in science, the public has a vested interest in access to and equitable distribution of the goods that science produces and an interest in policy which mirrors shared visions of health, promotes society's best interests and pursues social justice and transgenerational justice (McLean, 2001, 200-4). Rhetoric thus plays an important role in public policy making with competing interests vying for rhetorical supremacy and with it, the right to define the policy issue and the rules and context for possible policy solutions (Root Wolpe and McGee, 2001, 185).

Biotechnology thus raises a number of significant questions for public policy. First, how does policy emerge in arenas characterised by deep ethical conflicts and continuously evolving and disputed science? Secondly, what models of policy analysis are best equipped to deal with policy which is complex, contested

and engaged across multiple dimensions? Thirdly are there policy arenas with similar characteristics which can serve as a guide for navigating the future?

1.2 Research Question, the Scope and Limitations of the Research

This central research question for this thesis is how does the policy process respond to issues of emerging biotechnology characterised by irresolvable ethical dilemmas? The central hypothesis is that irresolvable value conflicts get subsumed by other less contentious conflicts in an instrumental policy process. Thus controversial and contested policy issues are reconstructed in ways which make them more amenable to resolution. The role of discourse in this process is important for policy analysis and policy outcomes. The secondary hypothesis is that standard instrumental rational policy frameworks, which disaggregate complex policy issues into their constituent components and refer them to a technocratic elite for solution, are unsatisfactory when the essential contestation is over *values*. In such a contest, a discourse analysis provides a clearer insight into the interplay of interests and power relations. A discourse analysis exposes the competing discourses which inform interests which in turn seek to define the policy issue in terms that promote their own policy preferences.

To test these hypotheses I will investigate two contemporary policy problems which are characterised by conflicting values and novel science; Assisted Reproductive Technology (ART) and Embryonic Stem Cell (ESC) Research and Cloning.

While ART and ESC research and cloning are separate and distinct policy arenas, I argue that they are linked in a number of significant ways. Both present issues which excite strong moral responses from different sectors of the polity and bring questions of public versus private interests to the fore. For both, an advance in science, namely the creation of an extrauterine human entity, able to live indefinitely in a suspended life state, created a whole new set of issues which required policy responses. Each is multidimensional, crossing sectoral boundaries of science and technology and health and wellbeing. Central to both cases are constructions of nascent human life and the subsequent conflicting truth claims

over when a human life constitutes a human being. In both ART and ESC research and cloning policy in Australia, this essential conflict remains unresolved but public policy has still eventuated.

Despite the shared characteristics, the Australian policy outcomes in each case have been quite different along important parameters. I argue that this is a result of different constructions of the embryo, informed by the historical and social context, in the separate domains. That is, the embryo is situated in different narratives which promote different policy responses. The ART embryo is situated in the private world of reproductive medicine whereas the ESC embryo is situated in the public world of international science and technology. The fact of the entity, as nascent human life, is subsumed by the meaning attached to it in the separate contexts. Thus the embryo is ambiguous, interpreted in different ways to serve different interests and to promote particular policy outcomes.

It is beyond the scope of this thesis to provide a detailed analysis of the science behind ART or ESC research and cloning. That is the domain of the biomedical sciences and I make no claim to such expertise. It is the social repercussions of the science and technology and the policy responses they engender which are of interest to this dissertation. Where technical information is necessary for comprehension of the policy issues, such details have been included.

1.3 Methodology

There are a number of possible analyses which could have been applied to this subject matter but in this thesis a critical discursive approach is used. Assisted Reproductive Technology and Embryonic Stem Cell Research and Cloning case studies were chosen as having relevant features which made them analytically comparable to each other *and* to the broader question of how to traverse the policy challenges of the new biotechnology.

In investigating these policy problems I took a qualitative approach, using only publicly available sources. This a deliberate strategy to capture the public utterances and publicly stated positions of a range of stakeholders, both individual

and institutional, as the policy process unfolded rather than relying on *ex post facto* interviews with key witnesses. Policy debates in both arenas were played out in public under the scrutiny of the media. In the ESC research and cloning arena particularly, much was made of the need for wide stakeholder consultation on contentious issues. Consequently the thousands of submissions to government inquiries, from individuals and organisations, as well as the formal reports of those inquiries provided a rich resource for research purposes. Media releases, policy statements and Hansard were also essential resources for establishing the policy stance of elected representatives. Unusually for the Australian context, conscience votes were allowed in the passage of key national legislation. Individuals were thus obliged to articulate their positions, unable to conceal them behind party platforms or cabinet room decisions.

I have focused particularly on interests and stakeholders in the broad categories of science, health, ethics and industry, who make public claims for legitimacy in the two policy arenas. These include elite science institutions such as the National Health and Medical Research Council (NHMRC) and the Australian Academy of Science (AAS), major nongovernmental health advocacy organisations and ethical elites both secular and religious, particularly the Catholic and Anglican Churches. I also identify key individual players who have played a ‘policy entrepreneur’ (Kingdon, 2003) role in proceedings.

1.4 Chapter Outline

Examining the outcomes of ART and ESC and cloning research policy illuminates possible policy approaches to comparable complex issues emerging from future developments in genetics and biotechnology. Indisputably, these policy questions will require policy frameworks which are capable of dealing with the complexities of multiple interests, values and beliefs and ethical conflicts. In Chapter 2, I review four contemporary frameworks of analysis; Policy Communities and Networks; Advocacy Coalition Frameworks; Epistemic Communities and Discourse Analysis and consider their utility in the ART and ESC and cloning policy arenas.

Chapter 3 is divided into two parts. Part one includes a short description of contemporary ART practice and ascertains the contested issues in this policy arena in both the international and Australian contexts. Part two details the Australian policy response to ART spanning more than twenty years. Germane to this discussion are the institutional arrangements for health policy making and the provision of health services in Australia, which includes an intergovernmental dimension and a particular mix of public/private service delivery and funding. It is however beyond the scope of this thesis to provide an in depth analysis of these structural features.

Chapter 4 is similarly divided into two sections. The first section includes a brief introduction to the science of ESC and cloning research and identifies the contested issues which have emerged worldwide. The second part will detail the policy responses to ESC and cloning in Australia, beginning with early responses to embryo research as a by product of ART in the mid 1980's but focusing mainly on the period following the successful cloning of a live mammal in the late 1990's.

In Chapter 5, I will identify and discuss the interests which emerged in the policy process in both case studies. These interests can be broadly grouped into ethical, health and wellbeing, science and industry dimensions. Within these dimensions however, I will argue that interests are not homogenous but are fragmented and shaped by competing discourses. As a result, competing policy stances in either case study cannot be conceptualised simply as competing sectoral interests based on shared belief and value systems. Rather, coalitions form across the sectors, bound together by shared narratives or storylines. Using Hajer's' Discourse Coalition Framework, I identify the storylines in each policy domain which inform the policy outcomes. I conclude that the storyline which allows the most actors to further their own interests without sacrificing their underlying values forms the dominant discourse coalition. The policy stance favoured by this coalition is legitimised as being in the public interest and adopted.

In Chapter 6, I draw conclusions from this research and discuss the implication of my findings for other policy domains characterised by ethical conflicts. I conclude

the Discourse Coalition approach provides a useful framework of analysis for policy issues with seemingly irresolvable conflicts. It provides a potential alternative to the instrumental objective policy making paradigm thus rescuing policy from the fallacy of the rationality project (Stone 1997). A discursive approach to policy analysis allows for a critical analysis of policy problems and their solutions. Rather than the nihilistic relativism with which it is often tainted, discourse offers a method for exposing and interrogating the assumptions which underline policy decisions.

The following Chapter will discuss suitable frameworks of analyses and evaluate their utility to test the hypotheses under investigation.

2 Chapter 2 Frameworks of analyses: Interests, beliefs, values and discourses

The Assisted Reproductive Technology (ART) and Embryonic Stem Cell (ESC) Research and Cloning policy domains present a number of policy challenges. In both arenas, actors, interests and institutions interact against a backdrop of continuing scientific innovation and, particularly in the case of ESC, a high degree of scientific uncertainty. The presence of a new actor, the extra uterine embryo, whose moral status remains unresolved, adds a particular ethical dimension, bringing the contest over values to the fore. In both policy arenas there are multiple claims to expertise from industry, scientists, medical specialists, secular and religious ethicists, feminists, consumers of health services and their advocates, all of whom stake claims to policy legitimacy. Policy however does not simply emerge from the struggle *between* multiple interests. *Within* these groups there are diverse and contradictory beliefs and values, adding a further level of complexity to policy analysis.

2.1 Interests

Navigating diverse and multiple interests is the central challenge for all public policy. It falls on public policy to resolve public problems via concrete policy interventions (Hajer 2003, 181) and to serve the public interest and the national interest whilst reconciling powerful but diverse sectional interests.

The public interest is a contested concept. Stone (1997, 21-22) proposes a number of meanings; individual interests held in common; goals on which there is a consensus; and things which are good for a community *as* a community. In neoliberal ideology, the public interest is an economic construct. It is simply the social outcome of aggregate individual choices by free and competing actors and the role of public policy is to provide a framework which allows for fair competition. However, such ideal market models deny the impact of culture and the powerful sectional interests in 'shaping' the available choices which inform this public interest (Johnson and Peterson 2008, 717).

The public interest can also be conceptualised in terms of an analytic framework which frames the ideas and discussions which inform public policy making in the democratic state (Hess and Adams 1999). It is distinguishable from sectional and private interests because it reflects some underlying common social values as a 'basis for justification of action' (Hess and Adams 1999, 5). However it is often invoked by sectional interests to legitimise their own policy claims and is a favourite political strategy of self interested actors trying to present their own normative values as a 'pre existing social reality' (Hess and Adams 2003, 23). In the idealised democratic state, the public interest should inform public policy which then should result in laws which are consistent with and promote commonly held community values (de Jersey 2002). However determining those community values in contentious and complex policy domains is no easy task. The public interest is not fixed but subject to shifts in society and culture. Even assuming one could confidently distil the public interest and craft the appropriate policy, there is still the problem of keeping it contemporary (de Jersey 2002).

In arenas such as ART and ESC research and cloning, the challenge is complicated by the breadth of stakeholders which includes medical and other health practitioners, scientists, researchers and research institutes, universities, biotechnology firms, people with medical conditions and disabilities and their carers, ethicists, religious leaders, governments, nation states, communities and in these case studies, the embryos themselves. These stakeholders all want their own interests served by policy decisions. The interests, however are multiple and competing, overt and covert and all make claims for legitimacy.

The policy process must engage with these interests and negotiate outcomes and for much of the twentieth century, rational objective³ analytic models dominated the

3 See Marsh and Smith 2001. Instrumental rational policy seeks to apprehend truth through the application of scientific method to policy problems. Scientific method, applied to social sciences, make a number of key assumptions; a real [objective] world exists independent of actors' knowledge of it; this world can be observed; hypothesis can be made and tested empirically; through proper research

policy sciences (Hill and Ham 1997, 2). These models however, with their technocratic focus are based on assumptions which deny the reality of contemporary policy. Namely, policy objectives are able to be determined and agreed, the relevant information is available, that expertise is uncontested and the best policy solution will emerge from a rational objective analysis of the facts.⁴ Positivist methodologies such as this have trouble sealing with values which are not readily amenable to 'rational' analysis (Amy 1987, 48). Stone (1997, 7) calls the twentieth century rationality project an 'impossible dream' which unsuccessfully attempts to separate out rational policy from irrational politics. Policy problems are really decisions an actor must make to achieve a desired end but political decision making is rarely rational. Goals and objectives are ambiguous rather than explicit, shifting and redefining as political situations change and the policy process unfolds (Stone 1997, 255). Politics cannot be separated out from policy making, policy analysis is political argument and vice versa (Stone 1997, 375). Any policy problem can have multiple constructions emanating from multiple world views. Therefore how the problem is framed has a significant impact on what is considered a viable or feasible policy solution, which actors are considered legitimate, which voices are heard and more importantly which ones are silenced. Policy alternatives which protect the interests of the powerful whilst claiming to serve the 'public' are most likely to prevail (Stone 1997, 255).

Habermas (1987) criticises technocratic positivist policy making as concealing and distorting communication between actors and privileging science as a method of enquiry. In the Habermasian context, the 'lifeworld' of public interest, the domain of democratic exchange between citizens is colonized by the knowledge elites and their positivist methods resulting in the scientisation of policy problems. Policy issues are moved out of the public sphere, where citizens can openly debate them, effectively depoliticizing contested issues. Professional experts serve elite interests and once removed from the public view they can distort policy deliberations to either promote

methods [science], causal relationships between social phenomenon can be determined; general theories, similar to those which explain the natural world, can explain the social world.

⁴ See discussions in Stone (1997) and Hill and Ham (1997); Herbert Simon and Harold Lasswell are the champions of twentieth century scientific approaches to policy making.

their own interest or that of their employer. They can conceal or exaggerate findings, interpret knowledge to suit particular ends and impede dissent by denigrating alternative views (Fischer 2003, 36).

Consequently, interests and how they operate are important to policy analysis and a number of different analytic traditions and theoretical approaches have emerged in the late 20th century. The policy communities and networks approach of Homeshaw (1995), Jordan (1990), Pross (1986), Rhodes (1985, 2002), Richardson and Jordan (1979) and others focuses on alliances and interplay between pluralist interests and institutions of government. The Advocacy Coalition Framework (ACF) of Sabatier and Jenkins-Smith (1994) and their collaborators focuses on competing beliefs and values of different interests; while the Epistemic Communities (EC) approach of Haas (1992) looks to the privileged position of science. The discourse approaches of Stone (1988, 1997), Dryzek (1990), Fairclough (1992), Habermas (1987), Fischer (1993), Hajer (1993, 2003, 2006) takes a critical, post positivist, interpretivist stance which perceives knowledge as constructed by the knower rather than apprehended in some rational objective manner. All of these approaches contribute to an understanding of contemporary policy making in novel scientific domains. They help identify the actors and institutions, the coalitions they form and the discourses which construct them.

In this chapter I will discuss these different analytic traditions and assess their utility for explaining policy outcomes in the ART and ESC and cloning domains. I will argue that in policy arenas where there is conflict over both values and beliefs *and* over facts, that narrative plays an important role in explaining policy outcomes. I conclude that Hajer's model of discourse coalitions provides the most salient framework for analysing policy in the ART and ESC and cloning domains.

2.2 Policy Communities and Networks

The policy community and policy networks literature is an explanatory framework for how actors with substantive sectoral knowledge, interact with each other and the formal institutions and mechanisms of government to impact on policy outcomes. There is a rich and varied literature on the concepts of policy communities and policy networks, complicated to some extent by different meanings and usage of these terms by different analysts. Typically policy networks are viewed as being immersed in the larger policy communities (Fischer 2003, 33).

For Pross (1986, 98) the policy community is 'that part of the political system that by virtue of its functional responsibilities, vested interest and specialised knowledge acquires a dominant voice in determining policy in a specific arena of public activity.' Jordan (1990, 327) views the policy community as a 'special type of stable network which has advantages in encouraging bargaining in policy resolution' operating in the context of shared community understanding of the problem at hand. Rhodes (1985) also views policy communities as a type of network characterized by stability of membership, continuity of restricted membership, high vertical interdependence, limited horizontal articulation and high integration in terms of interaction. Other analysts focus more on the relationships and interactions between the actors within the networks and communities (Coleman and Skotgstad 1990, Richardson and Jordan 1979).

Policy community literature has its origins in the iron triangle concept of US pluralist theories which argue policy results from the interaction between government agencies, peak lobby groups and congressional committees (Botterill 2005, 208). Heclo (1978, 102) expanded the iron triangle concept to that of an issue network, which included a much wider array of groups and individuals with varying levels of power and influence in a specific policy arena. Fischer (2003, 32) says Heclo's purpose was to demonstrate that policy subsystems were more fluid than previous depictions of 'closed' systems of interest representation. In the Australian context, Homeshaw (1995, 520) also focuses on the interaction aspect of 'pluralist interests

groups' attempting to influence governments in the allocation of resources.

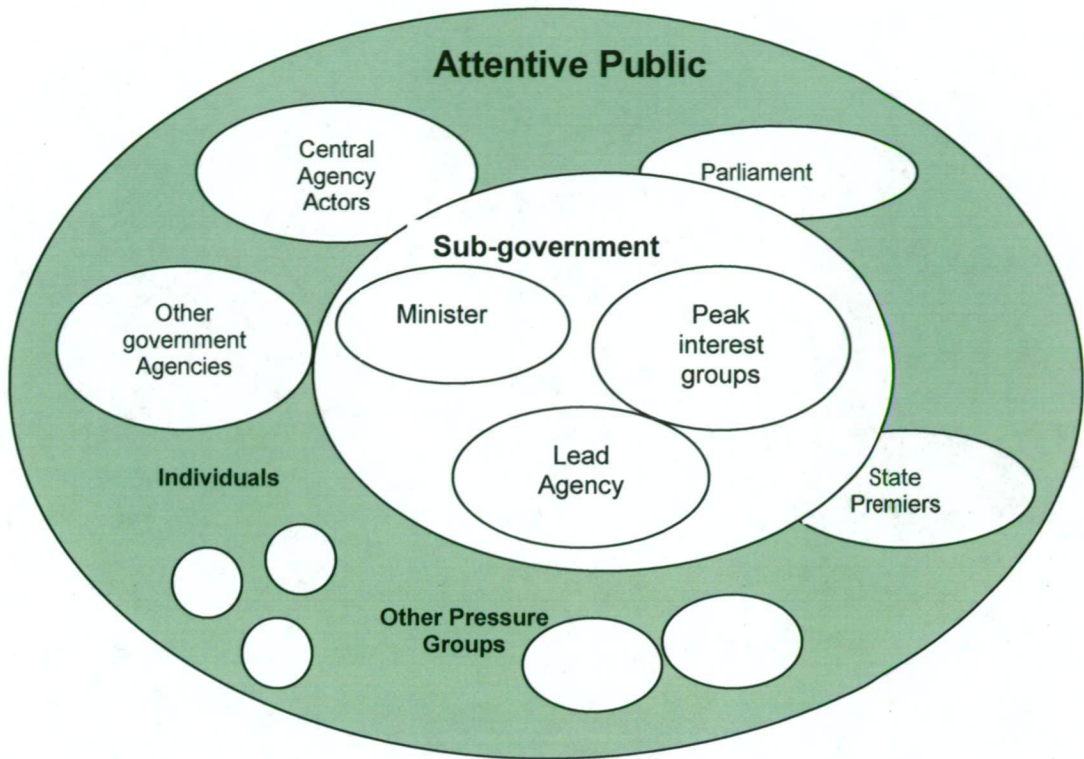
Richardson and Jordan (1979, 73-74) use the label policy community to describe policy making which is '...made and administered between a myriad of inter connecting, interpenetrating organisations'. Policy in this understanding is more the outcome of the relationships between actors rather than party platforms or parliamentary processes. In the British government context, Rhodes (2008, 1245) originally conceptualised policy networks as sets of formal and informal institutional linkages between government and other actors around shared interests in a policy arena with policy emerging from bargaining between the members of the network. More recently, however Rhodes(2002) has argued for a constructivist approach which sees networks not as social structures which determine participants' beliefs but as constructed by the actions and beliefs of the individuals who constitute them (Rhodes 2002, 400-1).

The idea that policy actors can be 'grouped together in conceptual units active at the sectoral and subsectoral levels of policy making (Howlett and Ramesh 2003, 16) forming 'subgovernments' and 'subsystems' is a key concept in policy community models and again there are different interpretations. In the US, Berry (1989, 239) defined a subgovernment as '...primarily a limited number of interest group advocates, legislators and their aides, and key agency administrators who interact on a stable, ongoing basis and dominate policymaking in a particular area.' Jordan and Maloney (1997, 558) view the policy community as a sort of subgovernment defined as a '...stable, tight, and continuing arrangement'. They introduce the idea of subsystem as '... a settled and sought-after policy-making convenience...' which allows for bargaining in sectoral environments, predictable and enduring coalitions and substantial agreement on problem definition; the subsystem being characterised by a small number of participants, low politicisation of issues and low conflict within the community. McCool (1998, 558) sees the utility of subsystems not in their structure but in their functional strategies, principally to control conflict in policy making. Fischer (2003, 32) sees the difference between traditional subgovernments and issue networks to be one of fluidity; actors move in and out of issue networks

which are consequently less stable and less institutionalised than iron triangles. The actors' self interest may be subordinate to emotional or intellectual convictions, and ideas as well as interests have a role in determining policy outcomes. There is however an assumption that actors in networks are bound by common understandings of policy problems and policy solutions.

Pross (1986, 99) presents a more fully developed policy community model which includes relevant government agencies, pressure groups, other organised interests, media, academics, professionals and individuals who attempt to influence policy outcomes in any sector, by virtue of their specialised knowledge. As demonstrated in Figure 1, the policy community model has two main components; the subgovernment and the wider attentive public. The sub-government is the policy making centre, made up of the relevant minister, senior bureaucrat from the lead agency, key stakeholder representatives and perhaps representatives of central agencies or other government agencies which also have a stake in the outcomes. The attentive public is a larger and looser arrangement comprising stakeholders with a particular interest in the policy sector who exercise their limited power through media and networking. They have a 'perpetual policy review' role, are a source of new ideas, offer diversity in policy debates and militate against the subgovernment tendency toward maintaining consensus (Pross 1986, 99).

Figure 1 Pross Policy Community Model



Source: Adapted from Pross (1986, 100)

For Pross (1986, 107) the policy community is primarily a protective device, concerned with preserving current policy direction and limiting opportunities for major policy shifts. In particular the role of the sub-government is to keep policy making routine or technical. The public, the media or exogenous shifts, for example, major technical innovations, are the sources of change which act to overwhelm the sub-government system of formal exchange. These are the factors which cause the policy debate to broaden, bring conflicts to the surface and allow issues to become politicised at the highest levels demanding a response which sometimes results in a very different policy community.

Homeshaw (1995, 527-30) expands on Pross' sub-government and attentive public concepts with the addition of the executive core, the international attentive public and the coordinating subgovernment as detailed in Table 1. The executive core is

composed of central agency actors, able to exercise power and make crucial resource allocation decisions in the particular policy arena (Homeshaw, 1995, 527). The international attentive public adds the dimension of actors and institutions able to work across national boundaries to influence policy outcomes which promote specific interests, while the coordinating sub-government is a mechanism for coordinating policy implementation across two or more sectors or portfolios (Homeshaw 1995, 529).

Table 1 Homeshaw Policy Community Model

Component	Actors
Executive Core	occupy central positions in key political institutions not members of the policy community implicit or explicit agreement needed for key decisions
Coordinating Subgovernment	members of agencies designed to coordinate policy across two or more sectors in a policy community participate in decision making
Subgovernment	exert most influence in the policy community decision making authority
Attentive Public	have special interest in policy arena can influence decision making do not participate directly in decision making processes
International Attentive Public	international or single nation organisations with interests and information in the policy arena may act as consultants to sub-government may act in opposition to policy formulated by sub-government

Source: Homeshaw (1995, 530)

2.2.1 Pressure Groups

Within the policy community, pressure groups take on a number of important roles. They coalesce interests, articulate concerns, mobilise support from special publics, function as a collective memory, communicate across boundaries using informal networks and evaluate policy and options (Pross, 1986, 107). Further, pressure groups are a useful mechanism for defusing potentially divisive issues. Political leaders can relegate these issues to experts within a pressure group, to be dealt with as technical rather than political problems. While this allows for a degree of political flexibility, it raises legitimacy concerns in the liberal democratic polity particularly where pressure groups already wield significant power (Pross 1986, 208-9). Pressure groups have the capacity to rouse the public and place ideas into the public domain which favour their

own preferred policy choices (Pross 1986, 156). Homeshaw (1995, 527) agrees that pressure groups, mobile between the attentive public and the sub-government, are the agents of change within a policy community where they can disrupt consensus and challenge the status quo.

The policy community approach is concerned primarily with actors and institutions, including relevant government agencies, pressure groups, other organised interests, media, academics, professionals and individuals with specific knowledge and how they interact to influence policy outcomes and has considerable utility in explaining incremental policy making in established policy arenas. Policy is the outcome of a process of adjustment based on mutual needs to achieve objectives (Homeshaw 1995, 521). Importantly, policy outcomes are seen as the result of bargaining and consensus. Challenges to and shifts in existing policy are the result of continuous actions of actors in the 'attentive public', where individuals and groups jockey for influence, sometimes taking several years to make an impact. However, they can also account for what Pross (1986, 105) terms 'spontaneous eruptions' of issue oriented pressure groups into a policy arena shattering the 'carefully contrived appearance of consensus', and forcing new issues onto the policy agenda.

This framework privileges the voice of experts whom governments can call on for 'neutral' advice which will underpin rational policy. While this works reasonably well when there are technical facts amenable to the deliberations of experts with specialist knowledge, it is not so successful when there are competing constructions of those facts based on competing values and beliefs. In the case of ART and ESC research, the extra uterine embryo is a biological 'fact'. To date it is created from the fusion of ovum and sperm, which if implanted in a uterus and successfully brought to term will result in a new human being. The policy conflict is not over this biological fact but over the moral status of the embryo. This is not a conflict which can be resolved by appeal to fact because how one considers the embryo is a matter of value and belief. While the policy community/policy network framework can account for how a 'major technical innovation' such as the extra uterine embryo brings conflicts

to the surface, politicising issues in the process and demanding a policy response (Pross 1986, 107), it cannot fully explain how that response is formulated. With its orientation toward stability and equilibrium, policy community frameworks provide little insight into how the policy process deals with irresolvable value conflicts. As discussed in Chapters 3 and 4, fragmentation rather than stability is a crucial characteristic in both ART and ESC policy domains and policy debates. This necessarily requires an analytic framework which explicitly deals with conflicting values and beliefs.

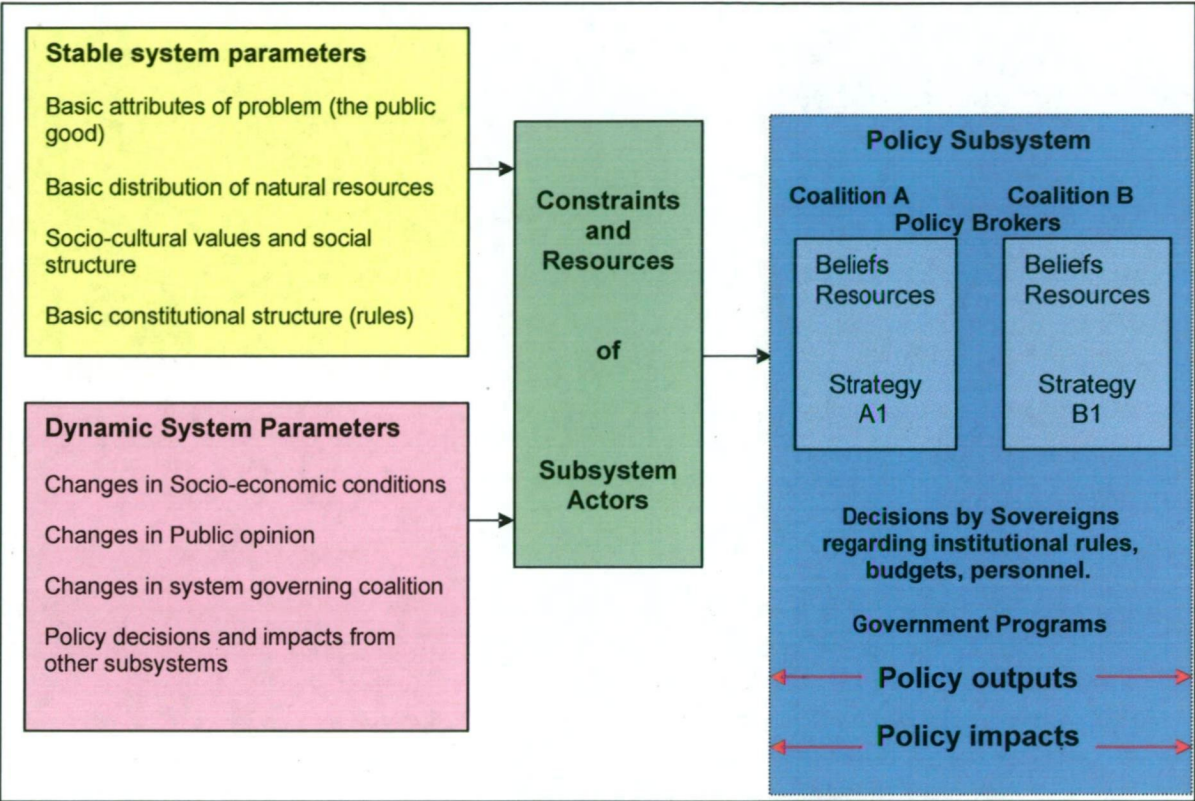
2.3 Advocacy Coalition Framework

Sabatier (1988) introduced the Advocacy Coalition Framework (ACF) as a conceptual framework which focuses on coalitions of actors, within policy subsystems, who share a set of normative beliefs. The ACF gives voice to other actors, outside of the traditional 'iron triangle' framework of administrative agency, legislative body and peak interest group who generate and disseminate ideas which influence policy (Jenkins-Smith and Sabatier 1994, 179). Within the ACF, subsystems are significant in policy formulation and implementation as are the relationships within policy sectors (Fischer 2003 94-5) with policy formation and change emerging from competing advocacy coalitions within a subsystem (Schlager 1995, 245).

Figure 2 illustrates the components of the ACF. There are two sets of exogenous factors which impact on the subsystem which act as both resources and constraints upon subsystem actors. The first set are the 'relatively stable' system parameters such as the basic attributes of the policy issue, distribution of natural resources, fundamental socio-cultural values and social structure and basic constitutional structure or rules. The second set is more dynamic and include changes in socioeconomic conditions, public opinion and governing coalitions and policy decisions and impacts from other subsystems. The ACF proposes that within the subsystem, a number of coalitions will form around those actors who share a set of

normative beliefs and act in concert with each other (Jenkins-Smith and Sabatier 1994, 180).

Figure 2 Advocacy Coalition Framework



Source: Jenkins-Smith and Sabatier (1994, 181)

Jenkins Smith and Sabatier (1994, 181-2) argue a hierarchy of beliefs exists within each coalition. The deep core contains basic ontological or normative beliefs which are resistant to change. Less rigidly held are the policy core beliefs which consist of the basic normative commitments and causal perceptions across the policy domain. These beliefs frame the policy problem and identify appropriate policy instruments to deal with the problem. Under the core sits a large set of less stringent beliefs, about the seriousness of the problem and causal relationships, which are more amenable to change, especially in the light of new evidence. Coalitions are held together by agreement over core beliefs, making the coalition stable over a long time period. Each coalition wants its world view to direct policy outcomes and works to influence government institutions in favour of its own objectives. Policy change comes about

through an enduring change in beliefs and behaviours which may result from an exogenous shock or paradigm shift which alters the distribution of political resources within the subsystems. Major disruptions to social and economic conditions external to the subsystem can alter meanings and salience of pertinent political ideas which disrupt the core beliefs which hold a coalition together and create the opportunity for new relationships amongst crucial actors who form new coalitions and propose new policy solutions (Fischer 2003, 97-8).

Knowledge, acquired through policy learning is used to press for change but really change depends on factors external to the subsystem which provide an opportunity for actors to promote their goals (Schlager 1995, 245), a similar approach to Kingdon's notion of policy windows (2003, 165). New information, in itself, is unlikely to cause change, because it becomes a new arena for contestation between competing coalitions before it is incorporated into policy (Schlager 2003, 245). That is the coalitions must first interpret new information in the context of their own belief systems to judge how it can enhance their own policy position. Coalitions resist information which undermine their core beliefs and use formal policy analysis to further their own beliefs or attack their opponents. Conflicting strategies are mediated by 'policy brokers' who attempt to reduce conflict through compromise resulting in government policy. Based on the policy outcomes a coalition may re-evaluate its beliefs or alter its strategies (Jenkins-Smith and Sabatier 1994, 182-3).

In the ACF, the dominant coalition retains power as long as it is able to deflect exogenous shocks from outside the subsystem. The coalition will remain stable while the actors confirm consensus on core beliefs. Policy learning or change is unlikely without very strong evidence to refute these core beliefs. This evidence must be accepted as valid by competing parties which is more likely to occur in the natural sciences where quantitative data is available and professional norms for evaluating evidence exist⁵ (Jenkins-Smith & Sabatier 1994, 183-5). The political struggle for

⁵ For example publication in major peer reviewed journals such as Nature or Science or citation indices.

policy control is played out through argumentative interactions of actors holding different policy belief systems within a sector where knowledge plays a key role in the struggle (Fischer, 2003, 95).

Fischer (2003, 94) criticises the ACF as a restatement of the ‘...empiricist research agenda in policy studies’. It is empiricist⁶ in orientation because it tries to establish a causal relationship between system parameters and policy subsystems in order to explain policy outcomes and policy change. The assumption is that changes in parameters impact on belief systems in coalitions and policy is the outcome of the struggle between competing coalitions for their beliefs to inform public policy (Fischer 2003, 95). The role of discourse and rhetoric in coalition forming is neglected reducing the ACF to a classic means-ends rational analysis where problems and solutions are well defined, coalitions favouring different policy solutions can be easily identified and there is a reliance on technical solutions advanced by experts (Fischer 2003, 99). Schlager (2003, 259) disagrees on this point arguing the ACF is ‘...not grounded in instrumental rationality’ because it looks beyond ‘preferences’ to account for human action. She says it has the promise to develop into a ‘general theory of policy’ but it falters because it cannot ‘...relate beliefs to action and action to the larger institutional framework in which it occurs’.

Schlager (1995, 264-5) proposes that shared belief systems alone fail to account for heterogeneous actors coordinating their actions to achieve shared goals. Propitious

⁶ Jenkins-Smith and Sabatier (1994) identify a number of testable empirical ‘hypotheses’ for the ACF:

1. Coalition is stable due to core beliefs;
2. Core beliefs are in fact stable;
3. Coalition wants core beliefs transferred into public policy;
4. Policy core remains stable as long as the dominant coalition retains power;
5. Changes will occur due to exogenous shocks originating outside subsystem;
6. Policy learning across coalitions occurs when there is a high enough level of informed conflict and coalitions have the resources to engage in debate;
7. Policy learning is more conducive when quantitative data is available and accepted by the parties;
8. Policy learning more likely in natural science rather than social sciences due to easier quantification of variable in former;
9. Policy learning more likely when a prestigious forum involving experts from different coalitions exists.

circumstances or characteristics of the situation are also necessary. Also important is the extent and type of interaction between actors who share beliefs, the degree of coordination amongst them and the strategies they adopt to operationalise beliefs into policy and the impact of exogenous shocks on those strategies.

The ACF is a useful tool in analysing policy domains characterised by deeply conflicting ethical standpoints. It accommodates different belief systems and the battle which ensues over which belief system will inform public policy. Scientific breakthroughs resulting in 'new knowledge' which demand new policy responses can be thought of as exogenous shocks which occur outside the subsystem. However, there is an assumption that policy learning can occur as new evidence is unearthed and new facts are brought to the policy table. The emphasis is on cognition and redefinition of interests on the basis of new knowledge which effects fundamental beliefs and ideas behind policy approaches (Stone 1999, 52). Change occurs when an external event allows the minority coalition the advantage and allows their belief system to dominate (Wilson 2000, 251).

However in ART and ESC policy conflict is NOT over the biological fact of an embryo but over the meaning and value of the fact. Prestigious experts in molecular biology who argue that human life has a scale of value depending on its developmental stage will not sway those who believe that a human life is a human being irrespective of age⁷. Quantification of human life as human being at 14 days, 24 weeks or at birth does not make for policy learning because this sort of information does nothing to shake core beliefs. Problem definition is not about objective description; it is about interpretation and different actors create portrayals to promote their own favoured policy course (Stone 1988 cited in Wilson 2000, 253). While on one level coalitions do form around Pro- and Anti-ART and Pro- and Anti-ESC research positions, they are not necessarily bound by a set of shared beliefs or norms. As will be demonstrated in forthcoming chapters, especially in the case of ESC research and cloning, coalitions do not form around groups who share professional

7 Pro life groups and the Catholic Church in particular.

norms such as scientists and doctors or groups who share the lived experience of disability and their advocates. Rather coalitions form *across* these groups where some doctors will align with some scientists and patients around one policy position, while others will form alliances around the opposite position.

2.4 Epistemic Communities

The Epistemic Community (EC) framework, arising from the international relations literature, again has some utility in analysing policy in technical/scientific policy arenas dominated by value conflicts. Haas (1992, 3) describes the EC as ‘...a network of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy relevant knowledge within that domain’. Crucially, these actors have a shared ontology and epistemology and shared intersubjective understandings.

An EC is characterised by:

- A shared set of normative and principled beliefs which provide a value based rationale for social action;
- A shared set of causal beliefs derived from analysis of practices within their domain which serves as the basis for determining linkages between policy actions and outcomes;
- Shared notions of validity i.e. intersubjectively defined criteria for evaluating truth and knowledge;
- A common policy enterprise (practices which will result in outcomes which will enhance human welfare) (Haas, 1992, 3).

The EC approach is resonant of the ACF particularly around notions of policy networks where actors are bound by shared beliefs and value systems, however the EC framework explicitly accommodates the concept of interpretation in policy analysis. In the context of uncertainty, policy makers need information that goes beyond depictions of social or physical processes to include an expert assessment of

the likely consequences of actions. Thus information is more than just raw data or fact; it is the 'product of human interpretation of social and physical phenomena' (Haas, 1992 4). Within the EC, networks of experts capable of performing this interpretive function, are important actors, eventually becoming institutionalised into the policy process, exerting influence not only in their own domain of expertise but in the wider policy process (Haas, 1992 4).

Decision makers become reliant on this expert interpretation of new knowledge to guide policy responses. How the knowledge is framed is an important aspect of how interests are articulated, and what issues become part of the legitimate debate, which in turn shapes possible policy options. Thus control over knowledge and information is an important dimension of power (Haas 1992, 3-4). The instrumental rational policy process with its reliance on technical solutions to complex policy problems fosters a deference to technical experts and their specialist knowledge. Science becomes 'the source of cognitive authority' (Barnes and Edge cited in Haas 1992, 11) and decision makers happily delegate authority to the experts. However policy making is more than technical analysis of issues in the liberal democratic state. Policy decisions are inherently political in their allocative consequences despite any veneer of objectivity and value free analysis that science confers especially where scientific evidence is ambiguous or contested (Haas 1992, 11). Notwithstanding, ECs are criticised for their tendency to see science as standing outside of politics and as knowledge divorced from power, imposing the rationality of objective fact over the irrationality of politics. The political debate becomes recast in scientific terms and the contest over values recast as a contest over facts which can then be scrutinized through application of scientific method (Litfen 1994, 4).

ECs have authoritative knowledge, therefore legitimacy⁸, in the policy domain but they interpret this knowledge in ways that are congruent with their own world view

⁸ Weingart (1999) says authoritative science, or knowledge, has a legitimising function in politics leading to a competition for expertise which intensifies controversies rather than eliminating them. In the post WW2 western democracies, scientific elites were given access to decision makers who quickly became reliant on them for advice particularly in scientific technical policy domains, an outcome Weber called rationalisation of the state.

(Haas 1992, 16). The EC may build coalitions of support and promote policies which serve their own interest in much the same way as an ACF, but they differ from interest groups because of their shared causal beliefs and 'cause-and-effect understandings' (Haas 1992, 17). They differ from professional groups who have a 'consensual knowledge base' but not necessarily a shared set of normative beliefs. For example a group of molecular scientists have a shared knowledge of molecular biology but can assign different meanings and values to this knowledge. Unlike the professions, the EC tends to pursue only those activities that are congruent with their own belief system and values and affiliate themselves with others who hold the same values and beliefs. They differ from bureaucrats, who operate to preserve their own missions and budgets irrespective of their normative beliefs whereas ECs apply their policy expertise selectively to enterprises which reflect their own epistemic and ontological positions. ECs use their privileged position, that is, policy relevant expertise and knowledge, to influence policy debates, exercise power, legitimise only certain voices and exercise leverage over bureaucrats (Haas 1992, 18-20).

Haas (1992, 23) claims the EC provides consensual knowledge but do not necessarily generate truth. Truth becomes the outcome of whichever actor has successfully articulated reality in the specific policy conflict, giving that actor significant social and political influence which can have negative impacts on political values such as democracy and participation (Haas 1992, 24). In complex and highly technical areas, policy can result from the collusion of key actors who formulate policy options, congruent with their own interests, which are then brokered to decision makers outside of the formal policy making apparatus (Haas 1992, 31). Further the EC can significantly influence the views of policy makers, making them congruent with their own (Haas 1992, 29).

ECs have some utility for analysing policy in the ART and ESC research and cloning domains, particularly in the latter. Successive Australian Governments over the past twenty years have looked to elites such as the NHMRC, the AAS and the Australian Health Ethics Committee (AHEC) for advice on novel science and technology and its

implications. Each of these institutions effectively functions as an EC, filtering new knowledge through its own epistemological and ontological lens, framing the policy issues in ways that reflect their own particular expertise. As discussed above, these policy domains are not only about novel science but are about the normative decisions on what to do with that science. The institutionalised EC, indispensable to policymakers because of their knowledge in their own discipline, have a tendency to encroach on the broader policy landscape, their voices privileged even when they have no legitimate claim to expertise (Haas 1992, 4). In this sense one can think of ECs as capturing bureaucratic and political actors by providing policy solutions to complex problems whilst perpetuating their own world view again redolent of Habermas (1987) and the colonisation of the lifeworld.

Litfen (1994, 15) says there is a modernist fallacy which assumes that scientific and technical knowledge provides an objective body of facts from which policy can be rationally generated. A discursive approach however emphasizes the rhetorical nature of scientific evidence, argumentation and persuasion. Information does not emerge from the void but is incorporated into pre-existing stories (narratives) which make it meaningful and favour particular policy prescriptions. Through their specialist knowledge, the experts in the EC exercise power over policy direction, claiming legitimacy for their own particular story.

2.5 Interpretation and Discourse

Discursive approaches offer an alternative to the instrumental rational analytic frameworks which privilege scientific method in policy analysis. They explicitly acknowledge that analysis is itself political in nature, concerned as it is with crafting argument, creating ambiguities and paradox to resolve issues in one way rather than another (Stone 1997, 7, Fischer 2003, 183). Thus in policy analysis, there is a need to transcend standard empirical methodology and embrace the methods and practices of interpretive inquiry (Fischer 2003, 160, Bevir and Rhodes 2005, 170-1). The interpretative approach concentrates on meanings, beliefs and discourses as opposed to laws and rules, correlations and deductive models. It privileges meanings as ways

to understand actions (Bevir and Rhodes 2005, 170-171) rather than technical rationality as a means to solve policy problems. Interpretive and discursive techniques seek to demonstrate that policy and politics are grounded in subjective factors and the objective 'truth' of rational analysis is just a product of deeper, less visible political presuppositions. A focus on the discursive constructions of policy institutions, actors and processes directs the analyst toward the 'crucial role of language, discourse, rhetorical argument and stories in framing both policy questions and...the ways normative presuppositions operated below the surface to structure basic policy definitions and understandings' (Fischer 2003, 14).

Discourses shape the way people understand their roles in society and how this influences political action (Fischer 2003, 13-14). They represent specific systems of power and the social practices which produce and reproduce them (Fischer 2003, 73). Discourses are collections of ideas, concepts and categories, which are used to give meaning to social and physical phenomena (Hajer 2006, 67). Such meanings are 'shaped by social and political struggles in specific historical periods' (Fischer 2003, 73). Discourse forms the context in which phenomena is understood which predetermines the definition of the problem.

'Discourse structuration' occurs when a particular discourse dominates the way a society conceptualises the world and 'discourse institutionalisation' occurs when a discourse solidifies into institutional and organisational practice (Hajer 1993, 46). For a discourse to become dominant in a political realm central actors must accept the rhetorical power of the discourse and the discourse should be reflected in the institutional practices of the domain (Hajer 2006, 70-1).

Central to understanding discourse analysis is the role of language and argumentation. In the positivist tradition of the social sciences, language is seen as a means, a neutral system of signs to describe the world. In the post positivist framework, language is recognised as a medium, a system of signification through which actors create their world (Hajer 1993, 44). Thus language is understood to

shape our world views not just reflect them so the analyst must examine how the political issue relates to the 'particular narrative' in which it is discussed (Hajer 2006, 66). Fairclough (1992, 4-5) proposes a three dimensional model of 'discourse analysis' which sees any event as simultaneously a piece of text, an instance of discursive practice and an instance of social practice. The discursive practice dimension specifies the nature of the text production whilst the social practice aspect attends to 'issues of concern in social analysis such as the institutional and organisational circumstances of the event' (Fairclough 1992, 5). Litfen (1994, 3) also identifies the textual and the social in her definition of discourse as a '...set of linguistic practices and rhetorical strategies embedded in a network of social relations'.

Such approaches recognise the world is socially constructed. So too is the policy world, its institutions and processes. A discursive approach sees the policy process as mediated through competing discourses that reflect the distribution of power (Fischer 2003, 46). Political struggle is the struggle over ideas, beliefs and values (Stone 1988) and for Fischer (2003, 44) discursive policy analysts are interested in the way ideas and values are embedded in discourses of institutions, seeing these discursive patterns as reflecting a pervasive system of power. Institutions are themselves constituted by the discourse and have no meaning outside of the discourse. Where policy network theorists understand experts to exercise power by virtue of their knowledge base, discourse theorists see experts to be part of a larger power-knowledge relationship where they can '...control, constitute and legitimise the very issues that we take to be the subjects of deliberation.' Further, network theorists perpetuate the fact-value distinction between causal knowledge and normative belief that characterise rationalist policy analysis whereas discourse analysts see facts and values as constructs of how particular experts frame and interpret information (Fischer 2003, 45). By contrast reflective approaches understand policy making as a problem solving activity which incorporates cognitive factors, belief systems, ideologies and consensual knowledge (Litfen 1994, 4).

The interpretive approach is holistic. It sees beliefs and practices as constitutive of each other where beliefs are situated in a web of wider beliefs and meanings. It is linked to critical analysis through the exposure of unquestioned assumptions and inconsistencies. Agency is always situated, allowing actors to interpret their situation and interests in a number of ways, exposing the fallacy of the natural or inexorable (Bevir and Rhodes 2005, 170-172). Interpretivism rejects the notion of prediction in political science in favour of a looser concept of 'informed conjecture'. The 'provisional narrative' becomes the analytic construct linking together beliefs and traditions and practices and actions (Bevir and Rhodes 2005, 181). Positivist methods use notions of vindication and falsification for ascertaining 'truth' based on the assumption that objective facts about the external world can be apprehended but holistic interpretive approaches believe there are no such '....pure experiences of the world , only perceptions based on a web of beliefs' (Bevir and Rhodes 2005, 182-3). As with critical analysis, interpretive approaches are subject to accusations of relativism but, as Bevir and Rhodes (2005, 183) argue, objectivity can be defined as evaluation of competing narratives using reasonable criteria. Objectivity arises from using agreed facts to compare rival interpretations. In other words the authority of a good argument (Dryzek 1982, 665) prevails. Analytic power arises from the capacity of any particular narrative to enhance understanding (Bevir and Rhodes 2005, 185).

Lieberman (2002, 709) suggests that public policies are best understood as the results of political conflicts in which particular elements of national culture and ideological repertoires are mobilized and enacted into policy. These political struggles take place within historical and institutional contexts that define the exercise and allocation of power especially by constraining political behaviour through the operation of norms, rules and organizational settings. Similarly political ideas and cultural traditions constrain policy making by limiting the number of policies considered rational and giving policymakers a set of legitimising tactics to further their favoured policies. Policy making is not simply the process of optimizing choice between policy instruments to solve social problems but entails formations of coalitions of actors who represent interests vying for power and diverse political ideas.

Within the political landscape, problems are strategically represented by actors who wish to promote their own favoured course of action (Stone 1997, 133-4). In representing the policy problem, actors make use of symbols, metaphors and narratives allowing for multiple representations and interpretations of the issues. Symbols are used to control and influence, metaphors to compare one thing with another and narratives to embed policy problems in different understandings of the world and how it operates (Stone 1997, 137). Thus the very determination of the problem depends on deeply rhetorical and interpretive practices (Fischer 2003, 183). Ambiguity is an important feature of symbols and while it is anathema to science, it is essential to politics (Stone 1997, 157). Ambiguity allows for cooperation between actors who hold different views because it allows for simultaneous and multiple interpretations of the policy problem. It masks conflict, facilitates negotiation and allows coalitions to form where material interest divides (Stone 1997, 161). Narratives are important in a number of ways. They tie a story together and make a claim for how the worlds 'is' (Fischer 2002, 181) which in turn prescribes the possible courses of action, in other words, the possible policy options. Metaphors are important devices because the claim to likeness or comparability is also a claim for equal treatment in the name of justice and equity (Stone 1997, 148).

In the ART and ESC research and cloning debates the embryo is a powerful symbol. To many scientists it is a cellular entity, to a Catholic priest it is a human being, and to an infertile woman it is the promise of child. The meaning, therefore the value of the embryo is interpreted by the narrative it inhabits rather than any intrinsic meaning or value embodied in the embryo itself. If one considers an embryo to be a human being then it belongs to a family, where it is embedded in kinship relationships, protected by the law and entitled to protection like any other human being. If it is considered less than human, then it is embedded in an alternative narrative; perhaps as human tissue or an experimental medium which gives it no claim to such protections. Alternative constructions of the embryo situate it in alternative narratives which allow for alternative policy responses.

2.5.1 The Discourse Coalition Model

Hajer's concept of Discourse Coalitions begins as a critique of the failure of the ACF to explain change because it neglects the sociohistorical context⁹ in which change occurs (Fischer 2003, 101). A discourse coalition is essentially a group of actors who share a social construct, which is an instrument for allocating meaning to ambiguous social circumstances. This in turn is a highly significant element of the political process. Actors try to impose their world view on others through debate and persuasion and the exercise of power. Social constructs emerge out of a historical discourse which contains knowledge of how similar phenomena were dealt with in the past (Hajer, 1993, 45).

Rather than shared cognitive beliefs, Hajer proposes that shared 'storylines', which interpret events and actions in social contexts, are the ties that bind coalitions together (Fischer 2003, 102). The story line or narrative incorporates different discursive elements which allows for coherence in complex policy problems, where there may be a number of different sets of expertise from different normative traditions. For example the ESC and cloning policy debates are informed by scientists and ethicists, who come from very different professional disciplines. Thus experts must rely on other experts for a full understanding of the issue. The storyline has an organizing function which allows actors with different arguments but similar ways of conceptualizing the world to come together. A discourse coalition will produce a shared storyline which all the actors can use to further their own ends (Hajer 1993, 46). In contrast to evidentiary arguments, storylines emphasise the complex ways that cognitive elements are located in competing normative interpretations of political phenomenon. Ambiguity is the key to effective storylines. Ambiguity allows different actors to relate their own values to the story in ways that allow for a variety of values to coexist within a coalition. They also allow the same actor to claim different values

⁹ Fischer (2003) contends that in the attempt to develop a universal theory of politics with testable empirical hypothesis, Sabatier places important factors in a 'black box' outside of the analysis. The things that are put into the black boxes are the symbolic normative factors which are the primary subject of discourse analysis. The key to explaining policy change is contextual examination of circumstances in specific cases rather than the search for some empirical generalizations.

in different contexts (Fischer, 2003, 107). For example an actor in the ESC domain can be an eminent scientist, a business entrepreneur, a spokesperson for a non government organisation and an advocate for people with a disability. The concept of storyline rather than fixed set of beliefs allows for this freedom.

In the Hajerian model, politics becomes the process whereby different actors from various disciplines and traditions, form specific coalitions around specific storylines. The storyline becomes the medium through which actors define policy problems, propose policy solutions and condemn the alternatives (Hajer 1993, 47). Storylines are instrumental in constructing the policy problem. Where the ACF presents problems and solutions as relatively well defined, and analysis focuses on identification of coalitions arguing for particular policy options, discourse coalitions suggest the analyst needs to examine how different coalitions define and refine the problem through argumentation and their own orientations (Fischer 2003, 106). Storylines are situation specific; a response to a particular time and context (Hajer 2006, 70). Thus, the discourse coalition approach offers a robust alternative to instrumental rational analytic frameworks because it:

- Analyses strategic action in a specific socio historical context;
- Moves explanation beyond reference to interests to how interests are played out within a specific discourse;
- Illuminates how different actors help reproduce or fight a given bias without necessarily orchestrating or coordinating actions or sharing deep values (Hajer 1993, 48, 2006, 71).

Figure 3 shows an indicative model of how a discourse coalition could work. There are multiple interests and multiple narratives operating within the policy issue. The narratives are social constructs thus are ambiguous. This allows different stakeholders with different interests to interpret the narratives in ways that serve their own ends. Coalitions will form when a particular narrative serves many interests. The dominant narrative promotes the policy position, which if adopted, will serve the interests of

the coalition members. Other narratives which promote alternative policy stances are unsuccessful because they cannot attract coalition members.

In the illustrated model, Narrative A can serve Interests 1 and 2, Narrative B serves Interest 3 and Narrative C interest 4. Each of these narratives favours Policy Position 1. However no coalition forms between Interests 1 to 4 because the individual narrative attracts insufficient support thus policy position 1 is rejected.

Narrative D however can accommodate Interests 5 to 8. These interests, though different can all interpret Narrative D in ways that serve them individually therefore a coalition forms. Narrative D promotes policy position 2 which is adopted. The subsequent policy outcomes serve Interests 5 to 8. The Discourse Coalition model will be applied to the ART and ESC research and cloning policy case studies and its utility evaluated.

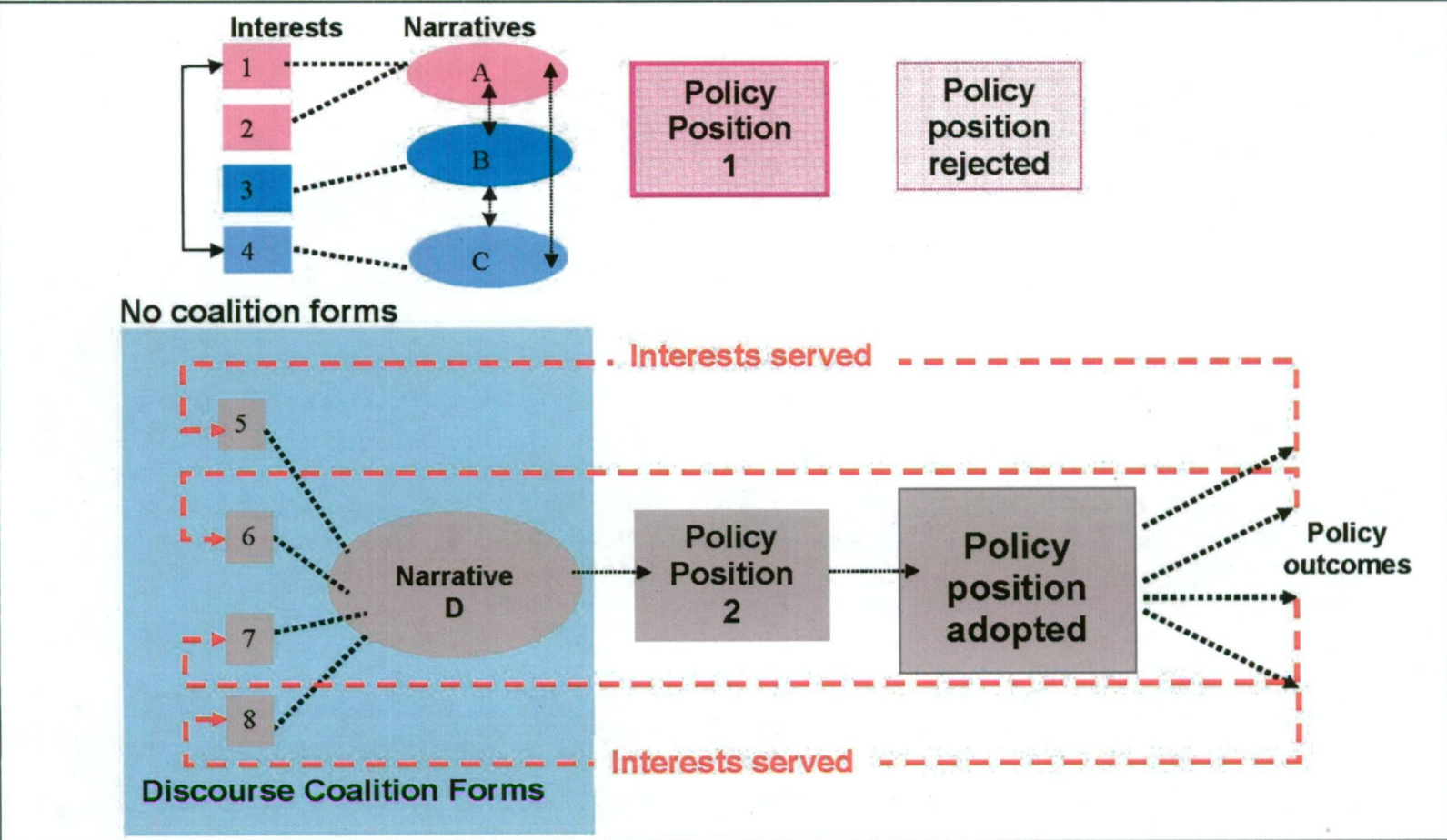


Figure 3 Indicative Discourse Coalition Model

2.6 Towards an Inclusive Framework

The policy community/networks literature helps to identify actors and their expressed interests but does not adequately explain how those interests are shaped and how power relations are maintained. Critiques of the policy community/networks approach demonstrate important theoretical and analytic limitations. Chief amongst these is the descriptive nature of this methodology and its limited capacity to explain policy change. While the literature identifies challenges to existing policy and new ideas emanating from the attentive public, it does not detail how this translates into policy change or how shifts in power occur. Further in an age of multiple actors in multiple roles, it is not always clear what actors' interests are or how those interests reflect underlying value and belief systems.

The Advocacy Coalition Framework (ACF) has the advantage of explicitly identifying competing beliefs within a sector and the capacity to identify which beliefs underpin policy outcomes. Importantly the ACF works on a suitable timeline for tracking change in complex policy domains such as biotechnology. That is it allows for a policy cycle to be 'complete' and subject to review. The capacity to identify two or more coalitions competing for authenticity and legitimacy in the policy process allows for power relationships to be explored and for 'hidden' interests to be exposed. Further it is useful to track how concepts of interest might change over the time period involved and which factors impact on how those interests are constituted. The idea of policy broker is useful in domains dominated by expertise versus amateur. It also allows for the role of institutions to be considered either as components of the coalition or as system parameters.

The epistemic community literature provides an understanding of the privileged position of expertise in scientific /technical policy domains, particularly under conditions of uncertainty and explicitly acknowledges that knowledge is interpreted through the lens of experts. The multi dimensional nature of the ESC and ART policy domains is problematic for the EC approach as there is more than one knowledge

elite who could claim legitimacy in the policy process. Depending on the construction of the problem, appeals can be made by the expertise of science or ethics or medicine. Further the EC cannot accommodate the wider public who have a stake in the policy outcomes but lack the relevant expertise to participate in the policy process.

Discourse analysis and interpretivist approaches allow policy analysis to move beyond explanation towards understanding how policy is a creature of context. In consort with critical analysis theory, underlying assumptions and power relations can be exposed. The discourses at play become useful analytical tools for illuminating policy outcomes where there are deeply contested value conflicts such as ESC and ART. Hajer's discourse coalition methodology operationalises discourse analysis as policy analysis. It offers a tool for analysing policy outcomes where there are multiple competing interests, where there are multiple positions *within* that interest and where allies form across interests. The concept of storyline allows actors with different belief system to form a coalition which frames a policy problem in a specific way to promote a specific outcome which promotes their own interests.

3 Chapter 3 Assisted Reproduction Technology

Assisted reproduction technology (ART) is the umbrella term for any procedure or method 'designed to enhance fertility or to compensate for infertility' (Rose, 1999, 1136). It ranges from the relatively low technology artificial insemination (AI), with partner or donor sperm, and hormonal therapy to high technology procedures including in vitro fertilization (IVF), intra cytoplasmic sperm injection (ICSI), egg donation, surrogacy and in theory, reproductive cloning. ART separates the act of sexual intercourse from the process of reproduction and offers otherwise infertile couples the opportunity to have a child of their own, biologically related or not. Heitman (1999, 23) says IVF 'epitomizes the ability of medical technology to redefine the boundaries of life and its tendency to move intimate human activities out of the private realm and into the control of experts and institutions.'

The first recorded case of assisted reproduction took place in 1885, when a doctor in Philadelphia, using sperm donated by a medical student, successfully inseminated a woman. The public were outraged by this intervention in the usually private act of procreation (Peterson 2005, 280). Less than 100 years later, the birth of Louise Brown in 1978 heralded a new era in assisted reproduction technology. As the first live human birth¹⁰ to result from an IVF procedure she was the object of scientific and moral debate and outrage amongst some sectors of the public. Australia was quick to adopt the new technology carrying out its first IVF procedure in 1979 and the first Australian IVF baby, was born in 1980, the first frozen embryo twins in 1982 and the first donor egg baby in 1983¹¹. Since then, as techniques have improved and success rates increased, hundreds of thousands of babies¹² have been born as a result of ARTs worldwide. The Fertility Society of Australia (FSA) estimates one in six Australian couples suffers from infertility, usually of a physical nature. Wang et al.

10 Sarah Franklin (2001, 319) says IVF 'was reportedly developed in Bombay before the birth of Louise Brown' however there does not appear to be any prior recorded live human births as a result of the technology.

11 See Monash IVF Milestones at <http://www.monashivf.com/default.asp?action=article&ID=21851>
Also see Bell 2006 for comprehensive summary of ART in Australia up until 2005.

12 Peterson (2005) estimated 300,000 worldwide in 2005.

(2006, 6) report a total of 38,823 ART cycles undertaken in Australia in 2004 for women of reproductive age resulting in 7029 live births however it is difficult to accurately determine the number of women using services because current data collection systems are treatment cycle based rather than client based (Assisted Reproductive Technologies Review Committee (ARTCR), 2006, 54).

The technological breakthrough of IVF introduced a 'new human player', the preimplantation embryo, created outside of a woman's body (Krones et al. 2006, 1), and able to live indefinitely. This created a whole new set of issues for policy makers worldwide as conception and reproduction, gender roles, kinship, genealogical ties and the very concept of 'the human' appeared on political agendas worldwide. The once relatively straightforward meanings of mother and father become complicated by those ARTs which separate the biological from the relational aspects of parenthood. New social relationships are formed by the multiple actors in the reproductive process causing potential for confusion and ambiguity¹³ (Levitt, 2004, 48). The definitions of parenthood become increasingly legalised but the social definitions of mother, father and child become blurred. A child can have a biological mother who provides the ovum, a gestational mother who carries and births the child and a social mother who rears the child. Similarly fatherhood can be defined in terms of the biological sperm donor, or the social. The woman who carries or rears the child may be genetically related to the provider of the ovum or the sperm or to neither party (Heitman 1999, 27).

Once more, advances in technology called society to examine its existing beliefs and consider how they might change alongside changing images of reproduction (Krones et al. 2006, 2). These beliefs include perceptions and competing constructions of 'parent', 'infertility', 'treatment' and 'health'. How these matters are resolved impacts on how the public policy system deals with matters such as funding and access to services and continued research in the field. Fundamental questions include

13 See discussion in Levitt 2004 on Onora O'Neill's 'confused relationships' when several individuals make a claim to one role and 'ambiguous relationships' when one individual holds several roles.

what is appropriate *public* policy in the largely private realm of reproduction and which policy instruments and levers should be used by which level of government in a federal system such as Australia.

In this first section of this chapter I will briefly describe ART procedures and identify the key contestations which continue to confront policy makers. In part 2, I will discuss the Australian policy context and the Australian policy response.

3.1 Assisted Reproductive Technology Procedures

In Australia the vast majority¹⁴ of ART procedures used are in-vitro fertilisation (IVF)¹⁵ and intra-cytoplasmic sperm injection¹⁶ (ICSI) (Wang et al. 2006, 7). In the former, an ovum extracted from a woman is fertilized by a sperm in the laboratory, resulting in an embryo which is then implanted into a woman's uterus. In the latter, a single sperm is injected into an ovum for fertilisation outside the body and then replaced into the uterus (Australian Institute of Health and Welfare (AIHW) 2004, 177). A less common technique is gamete intra-fallopian transfer (GIFT), where ova and sperm are placed in the uterus for fertilisation inside the body (Yueping et al. 2008, 4). ICSI has now replaced IVF as the most common ART technique used in Australia (Yueping et al. 2008, 4). The ovum and sperm donors may be the biological couple who desire the pregnancy, a close genetic relative of either partner or completely unrelated. Thus IVF opens up an opportunity for surrogacy¹⁷ whereby

14 Wang et al. (2006) report in around 95% of ART procedures involved IVF or ICSI in 2004.

15 IVF has five fundamental steps: controlled ovarian hyperstimulation; oocyte retrieval; sperm retrieval and preparation; in vitro fertilisation; and embryo transfer. Sperm are washed, spun in a centrifuge and incubated in a specialised medium in preparation for fertilisation. Retrieved oocytes are separated from follicular fluid and classified to identify mature oocytes suitable for fertilisation. The selected samples of sperm and oocytes are combined in a culture medium in a Petri dish and inspected for fertilisation after 16 to 20 hours. Oocytes that are not fertilised or that have fertilised abnormally are discarded. At fertilisation, the resulting cell contains a pronucleus from both the oocyte and sperm (referred to as gametes) and is known as a pronuclear zygote. The two pronuclei then fuse and cell division commences, reaching a 4-cell stage at approximately 40 hours. Embryos are inspected at this stage to assess viability (ARTRC 2006, 28).

16 Intracytoplasmic sperm injection (ICSI): an IVF procedure in which a single spermatozoon is injected through the zona pellucida into the oocyte. The process increases the likelihood of fertilisation when there are abnormalities in the number, quality or function of the sperm (ARTRC, 2006, 11).

17 Rose (1999) distinguishes between 'biological surrogacy' where the surrogate mother provides the ovum and 'gestational surrogacy' where the surrogate is implanted with a fertilized egg harvested from

one woman carries the foetus to term for another woman. The surrogate may or may not be biologically related to the embryo she is carrying or to either of the gamete¹⁸ donors. In Australia, however, the majority of ART procedures involve autologous¹⁹, rather than donor gametes and embryos (Yueping et al., 2008, 12).

ART success rates vary depending on the technique used and whether embryos are fresh or thawed. The AIHW (2004, 178) reported an overall 20% success rate²⁰ in 2001 for all ART techniques in Australia. This had increased to 23.4 % in 2003, (AIHW 2006) and 26.4% in 2005 (AIHW 2008). Yueping et al. (2008, 12) report that 32.1% of embryo transfer cycles resulted in a clinical pregnancy and 25.0% in a live delivery²¹ in 2006 in Australia and New Zealand. In the USA in 2005²² live births resulted from 34% of fresh and 28% of frozen autologous transfers with even higher success rates from donor procedures. However, as in Australia the vast majority²³ of procedures in the USA use autologous embryos and oocytes (CDC, 2005, 15). IVF success rates reduce with maternal age and duration of infertility (ARTRC 2006, 14). Single embryo transfer cycles more than doubled between 2002 and 2006²⁴, resulting

another female donor. Biological surrogacy is both a social and legal relationship where the surrogate agrees to contribute half of the genetic material, carry the foetus until full gestation, and then relinquish the child to the male donor and (usually) his female partner. In gestational surrogacy, there is typically no biological relationship between the surrogate and the foetus.

18 Gametes are defined as the haploid reproductive cells that unite during sexual reproduction to form a diploid zygote. Male gametes are sperm and female gametes are eggs or ova. See <http://biology.about.com/bldefgametes.htm>

19 Sperm and ova come from the couple wishing to conceive.

20 AIHW (2006) report a viable pregnancy (at least 20 weeks gestation) was achieved in 20.8% of all IVF egg retrieval cycles, 25.9% of ICSI cycles and 19.7% of GIFT cycles using fresh embryos or gametes with thawed embryos, a viable pregnancy was achieved in 15.5% of all IVF embryo transfer cycles and 14.7% of all ICSI cycles.

21 Again the success rates vary with ART technique, fresh or frozen embryos and the age of the woman. Reporting of data is further complicated by which statistics are used. Live births per oocyte harvest or live birth per embryo transfer. The pertinent point is that success rates overall have increased.

22 CDC (2005) reports that from 1996 through to 2005 the percentage of transfers resulting in live births for fresh–nondonor cycles increased by 22%, from 28% in 1996 to 34% in 2005. Over the same time period, the percentage of transfers resulting in live births increased 68% for frozen–nondonor cycles, 34% for fresh–donor cycles, and 49% for frozen–donor cycles.

23 CDC (2005) report that in the USA, 72% of ART cycles carried out in 2005, used fresh nondonor eggs or embryos. 15% of ART cycles used frozen nondonor embryos. In about 12% of cycles, eggs or embryos were donated by another woman.

24 Single-embryo transfer cycles accounted for 56.9% of embryos transfer cycles in 2006, compared with 48.3% in 2005, 40.7% in 2004, 32.0% in 2003 and 28.4% in 2002 (Wang et al. 2008).

in more singleton deliveries. In 2006, singletons accounted for 88% of IVF births and twins 11.7%, the lowest ever proportion of twins reported (Wang et al. 2008, xi). Controversially, reproductive cloning has been posited as an ART choice if there is no other reasonable alternative. Proponents suggest that experimental trials should not be prohibited and if the procedure can be demonstrated to be safe and efficacious then it could be offered as another reproductive option. Further if society already subsidises existing ART treatments there would be a case for subsidising reproductive cloning (Elsner 2006, 600). The cloning technique, somatic cell nuclear transplant (SCNT), offers the chance of a genetically related child to those populations unable to use existing ARTs to achieve that aim, including lesbian couples and women unwilling to use donated sperm (Rose 1999, 114). Cloning does however represent a departure from established ARTs because it does not require gametes from two different people, making it more akin to replication than reproduction (Rose 1999, 115). Where ART has already forced society to re-examine conceptions of 'mother', 'father', 'child' and create new categories such as gestational/ birth mother, biological/genetic mother/father, social mother/father, the potential to use reproductive cloning further confounds an already complex situation. It adds a layer of intergenerational confusion to the structure of the family, where the cloned 'child' can be a genetic twin of one of the 'parents', a delayed twin of an existing child (Rose 1999 114) or the 'grandchild' of the birth mother. The ethical implications of reproductive cloning will be discussed fully in chapter 4.

IVF also offers the possibility of preimplantation genetic diagnosis (PGD) which allows embryos to be tested for specific genetic disorders prior to selection for implantation into the uterus. Most commonly offered to parents at risk of having a child with a serious genetic disorder, for example cystic fibrosis, thalassaemia, sickle cell disease or muscular dystrophy, PGD stimulates its own controversy over what the implications of 'choosing' mean for the future parent– child relationship (Ehrich et al. 2006, 1214, Ehrich et al. 2007, 1092). Even more controversial is the use of PGD for social reasons such as sex selection (Seif 2002, 461, Pennings 2002, 1123) or for matched stem cells to treat an existing person (Boyle and Savulescu 2001). The

potential of PGD to eventually test for non disease traits such as intelligence brings forth a debate over procreative beneficence which implies a moral obligation to select the best children possible if the technology exists (Savulescu 2001, 415). Whether or not this constitutes a new era of eugenics²⁵ remains contested.

ART raises important medical, legal and ethical concerns. Debates about ART are entwined with other debates about feminism, reproductive politics, public health policy and funding and ethical concerns about the production of human beings. Yet in these debates not all are 'equally authorised to speak' (Van Dyck, 1995, 17), and the voices of scientists, medical specialist and the Church all make claims to that authority to exclusion of others. Peterson (2005, 280) says it is inevitable that 'new [reproductive] technologies and capabilities prompt medical and legal discourses, usually representative of the dominant power groups within society, which may act to either encourage or discourage consequential social adjustment.' Reproductive technology, however, like any other technology is also a manifestation of cultural values, thus ART becomes a tool for social reproduction as much as physical reproduction (Hafstein 2006, 2). The subsequent policy issues are embedded in competing social and cultural discourses of procreation, infertility, parenthood, kinship relationships and family structure.

3.2 Contested issues

Despite being widely available for nearly three decades, ART still engenders public controversy²⁶. Contested issues such as the moral status of the embryo, constructions of fertility, parenthood and other kinship relations, commodification of body parts, exploitation of women and access to ART services remain on the public policy agenda. Social conservatives argue that the 'rights' and wellbeing of IVF children are subsumed by the 'rights' of same sex couples and single people to parenthood (Muhlenberg, 2007, Shanahan 2007). Social reformers argue legislation must reflect the reality of contemporary family structures (Fuscaldo and Russell 2008). Debates

25 See discussion by Gilgott on <http://www.prochoiceforum.org.uk/and3.php>

26 See media coverage of Victorian legislation to allow gay men, lesbian and single women access to ART in The Australian 05/12/2008, Gold Coast Bulletin 6/12/08, Herald Sun 6/12/08..

continue over funding for IVF services for both the medically and socially infertile (AAP 2009, Gordon 2009, Rose 2009).

3.2.1 Ethical Dilemmas

The creation of an extra corporeal human entity poses a number of ethical questions on the rights and status of the embryo. At one extreme is the view that the potential of the pre-implantation embryo to grow into an individual human being confers on it the full moral status of a human being. At the other extreme, the preimplantation embryo is seen as a non-sentient, non-conscious cellular entity without any moral status or interests. The third perspective accords special respect to embryos by virtue of their potential; more than a group of cells but less than a fully human person. Thus the embryo as an important symbol of human life but this symbolic value is distinguishable from any intrinsic value it might possess²⁷ (Robertson 1999, 117-8). In 1994, the Human Embryo Research Panel (HERP) in the US rejected the argument that embryos have the same moral status as human beings due to the

absence of developmental individuation of the preimplantation embryo, the lack of even the possibility of sentience and most other qualities considered relevant to the moral status of persons and the very high rate of natural mortality at this stage (Biotechnology Law Report 2090, 1995)

but accepted the embryo warranted serious moral consideration as a developing form of human life. In doing so they proposed a middle path between two radical positions; the embryo is a person and the embryo is property. HERP reasoned the former position was unable to be imposed upon all citizens and the latter denied the reality that the entity could become a human being. Therein lies the dilemma; the moral status of the embryo cannot be ascertained through empirical investigation but workable public policy requires some such determination. The role of the policy

²⁷ The 1984 Warnock Report found that legally, the human pre-implantation embryo did not have the same status as a living child or adult, but the pre embryo of the human species did have a 'special status'. Similarly in the United States, in 1979, an Ethics Advisory Board for the Department of Health Education and Welfare found the 'human pre embryo is entitled to profound respect but this does not necessarily encompass the full legal and moral rights attributed to persons' (Cited in Robertson 1999, 120)

making apparatus is to '*implicitly or explicitly interpret moral status*' in a defensible process (Parens 2001, 41).

Concerns over the moral status of the embryo are important because fully human status confers certain rights including the right to life and the autonomy to make decisions over one's own body. The embryo cannot exercise these rights of its own accord therefore if considered fully human, those rights must be legally protected and enforceable. In Australian common law, the pre implantation embryo possesses potential or contingent interests which are only realised at birth. It is only with live birth that the legal status and ensuing rights of the human person are conferred (Law Reform Commission NSW, 1987). There is a difference, however, between legal status and moral status. In the Roman Catholic tradition the embryo 'from the first moment of its existence. . . demands the unconditional respect that is morally due to the human being in his bodily and spiritual totality'(Congregation for the Doctrine of the Faith 1987). The claim to full moral status lies primarily in religious notions of sanctity of life²⁸ ; from the moment of fertilisation each embryo is made in the image of God for its own God given purpose. The religious metaphor of 'playing God' is frequently invoked by opponents of ART, concerned that reproductive technologies overstep too many boundaries in the desire to control nature to the detriment of all humans (Barns 1996, cited in Levett 2004, 28). A further ethical concern for the traditional Christian churches and pro life groups is the high embryo wastage associated with IVF. Destruction of 'unwanted fertilized ova becomes a significant, moral problem', if an embryo is accorded the status of a human person (Carnley 2002, 3).

The Catholic Church²⁹ has additional ethical concerns with ART outside of the moral status of the embryo. These concerns lie in the separation of procreation from the

28 See final communiqué on 'the dignity of human procreation and reproductive technologies, 'Anthropological and ethical aspects'

http://www.vatican.va/roman_curia/pontifical_academies/acdlife/index.htm

29 See Vatican Instruction on Respect for Human Life in its Origin and on the Dignity of Procreation, Donum Vitae

http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html

sexual act. In Catholic teaching, responsible procreation can only occur within marriage where 'sexual intercourse has both a unitive and a procreative function' (Congregation For The Doctrine Of The Faith 1987). ART, which engages a number of different parties in procreation and relies on technical intervention, represents the 'domination of technology over the origin and destiny of the human person' (Congregation For The Doctrine Of The Faith 1987). In 1987, the *Donum Vitae* judged that relationship of domination was contrary to the dignity and equality of parents and children, a position reaffirmed by the 2008 *Dignitas Personae*.

The deliberate creation of the embryo through IVF implies a certain commodification and instrumentalisation of human life which even in a secular context is considered morally suspect, no matter the eventual outcome. Of further concern is the preselection of only 'viable' embryos for transplantation as they are most likely to result in a successful pregnancy. Decisions over viability are made in the laboratory based on 'objective' criteria of 'fitness' for reproductive purposes. This 'genetic welfare worldview' implies that choices over reproduction and disability become the province of science and technology rather than individuals, community and society allowing scientific ascendancy through claims of expertise, authority and credibility (Ehrich et al. 2006, 1215-6). Further constructing embryos in terms of quality is profoundly disrespectful to some people undergoing fertility treatments, denigrating their personal investments and denying the potentiality embodied in their embryos (Parry 2006, 2354).

IVF as an industry has legitimate commercial interests, including new product development. For example, in the United States, fertility clinics offer embryos for 'adoption'. These embryos, created from donor sperm and donor ova, are not legally related to either of the gamete donors and can be made to specification for ethnicity or nationality. The clinic creating them is their only legal guardian (Heitman 1999, 30). Heitman (1999, 31) says the use of the term adoption '...harkens back to the social response to infertility that preceded ART and '....captures the ambiguity of society's response to the technologically created child.' The IVF embryo is

simultaneously the desired child and a quality product. The unviable are discarded or used for training purposes. Thus IVF sparks wider moral debates about perceived 'ownership' and control over gametes including their disposal (O'Donnell 2000, 138).

Allegations of commodification and instrumentalisation are not limited to the embryos in ART. The feminist critique³⁰ of reproductive technology argues women, their bodies and their reproductive labour is medicalised, commercialised and appropriated by processes which reduce them to test sites and laboratories for science or dysfunctional bodies in need of therapeutic rescue (FINNRAGE, 2002).

3.2.2 Exploitation of Women

Initially IVF was perceived as a liberating technology for women, giving them greater freedom over reproductive choices. However the debate quickly changed to one of medicalisation, scientisation and male dominance over women's reproductive labour. Van Dyck (1995, 89) says that by the mid 1980s feminists had '...acquired a public image of being radically opposed to all reproductive technologies', perceiving them to be instruments of male control and a threat to women's reproductive freedom. This account was challenged by other feminists who called for consideration of the individual interests of and situations of infertile women and how new technology might serve their interests arguing the focus of feminist dissent should be on treatment facilities and their discriminatory policies (Van Dyck 2003, Barnett and Steuernagel 2005, Steinberg 1997).

IVF and attendant technologies have serious implications for women. Women bear the physical and emotional burdens associated with low IVF success rates³¹, higher risks of multiple and premature births and can become technologically dependent,

30 There is an extensive feminist literature on ART which is beyond the scope of this thesis. See McCormack 1991. Michelle (2006) gives a comprehensive summary of the post modern feminist critiques which have moved away from understandings of ART as reiterating patriarchal relationships to the implications and consequences of ART for different groups of women, depending on the wider cultural and economic contexts of their regulation and use.

31 See earlier discussion on ART outcomes (Wang et al. 2006, 2008).

trapped in a position of 'infinite irresolution' where there is always a new technique to try (Kolleck 2000, 148)³². More than this, radical³³ feminists argue that ART reinforces traditional patriarchal stereotypes of dominant (mostly) male scientists and passive female participants (Bell 2006, 20). When the woman is fertile but her male partner³⁴ is not, the IVF treatment site is still the woman's body with all the associated risks and discomfort (O'Donnell 2000, 138).

The anti ART feminist critique argues reproductive technologies threaten to replace woman centred reproduction with a superior technology centred reproduction (Corea 1988 cited Bell 2006, 20). The continuing medicalisation of childbearing and motherhood and the male expropriation of reproductive power from women operate to subordinate women further. Reproductive technologies are tied to patriarchal concepts of womanhood, parenthood, and family, which have potentially dire potential consequences for women as a class, despite the promise they hold for the individual infertile women. Their desperation for a child is exploited by ART clinicians to legitimise the further advancement of artificial means of reproduction (Sandelowski, 1990). Ironically radical feminist critiques of ART found themselves unwilling allies of the anti abortion lobby who also argued against IVF as interfering with the 'natural reproductive processes' (Van Dyck 2003, 101).

3.2.3 Welfare of Children

For some socially conservative stakeholders the ethical concerns over ART are not bound up in arguments about the moral status of the embryo or whether reproductive technologies exploit women or represent an offence against God or nature. Rather, they have concerns over the welfare of children born as a result of reproductive technology. Central to their concerns are the 'rights' of children to both a mother and a father. The postulated 'right' to two parents of opposite sex infers that single men or

32 ICSI allows men to genetically father their own children but existing genetic dysfunction may be transmitted, necessitating PID to select a suitable embryo. Further there are unresolved issues over the safety of the technique due to lack of adequate evaluation through controlled trials.

33 See discussion in Parks 2009

34 Around 50% of infertility is attributed directly to women. The remainder due to sperm disorders or other inexplicable factors see <http://www.medterms.com/script/main/art.asp?articlekey=3977>

women or same sex couples make less competent or loving parents and children from traditional families are socially and psychologically advantaged (Del Villar 2002). Brennan (2006, 28) argues that while same sex couples living in a stable monogamous relationship are in essence no different to a similarly stable heterosexual couple who cannot bear children without intervention, the State is entitled to restrict 'assisted reproductive technology births of children to opposite-sex couples who can provide the children with a mother and a father (until there is compelling sociological evidence to the contrary)'. While there is some evidence that children of single mothers have poorer outcomes than children in two parent families, this is mainly attributed to the social and economic disadvantages common to single motherhood rather than the absence of a male parent per se (Rickard 2002). Existing evidence also suggests that quality of parenting, rather than family structure or parental sexual orientation, is the more important determinant of child development (Baumrind, 1991, Rickard 2002^a, McNair 2004, 2). Children's welfare and development are generally understood to be best served by stable, secure warm and loving relationships (Peterson 2005, 281).

The policy debate over rights of ART children to particular family structures are situated in competing discourses of procreative liberty, family and fertility. In turn, these discourses shape public policy on funding, provision and access to fertility services

3.3 Procreative Liberty

Procreative liberty encompasses a normative view that individuals have the right to choose when and if to have children and the freedom to control their reproductive capacities without interference from the state, unless there is a compelling reason to do so (Robertson 1986, 1994, Callahan 1995, Elsner 2006, 598). Procreative liberty is recognised as a universal right through Article 16 of the United Nations (UN) Universal Declaration of Human Rights 1948 which provides that '...men and women of full age, without limitations due to race, nationality or religion, have the right to marry and found a family'. Article 12 of the UN Convention on the

Elimination of All Forms of Discrimination Against Women (CEDAW) 1979 protects women from discrimination in access to health services including fertility control and Article 16 grants the right to decide on the 'number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights.'

Notions of reproductive liberty flow from a historical protection of intramarital reproductive rights and safeguarding family autonomy. Consequently if the right to produce coitally is protected then so should the right to produce non-coitally, if the technology is available, because infertility is a result of the 'natural' lottery (Ryan 1990, 7). For procreative liberty to be realised, however people generally must have access to fertility treatments. To deny such access through selection or qualification criteria constitutes a denial of basic personal respect and dignity (Peterson 2005, 281). Fertility services were initially developed to treat physical reproductive dysfunction which prevented couples from conceiving naturally. In this context procreative liberty is seen as an entitlement to treatment for a medically diagnosed condition. However infertility is not only an undesired medical state, it is also an undesired social state and in contemporary society this is not limited to heterosexual couples. ART offers the opportunity to single people and same sex couples who also desire children. Thus the understanding of procreative liberty shifts from an essentially negative right, the freedom from interference in reproductive choice (Robertson 1986, 2001, 9) to a positive right to parenthood. If the right to reproduce non-coitally, because of available technology, (Boivan and Pennings 2005) applies to one person then should it apply to all persons, including those who *choose not* to reproduce coitally due to sexual preference or marital status?

3.4 Constructions of Fertility

The concept of infertility is contested. The incapacity to procreate can be conceptualized as an illness, an unfulfilled wish, or a serious handicap to realising one of life's important goals '... to parent a genetically related child or a child created within the current relationship' (Pennings et al. 2008, 772).

Clinical medicine defines infertility in terms of inability to conceive after a period of 12 months of unprotected sex (Marchbanks et al. 1989, 260). Reproduction however is not merely a biological activity; it has profound social value and meaning. In both western and non-western cultures, throughout history, childlessness has been a source of shame, social judgment, rejection and isolation particularly for women (Whiteford and Gonzales 1995, Heitman 1999, 36, Alesi 2005, 135). Prior to the development of successful and accessible ART, infertile couples had few options for children outside of adoption. Often shrouded in secrecy, adoption fulfilled the social norms of having a family and addressed the socially undesirable condition of 'involuntary childlessness' (Becker and Natchigal 1992, 457). With the advent of ART, the social problem of childlessness became the medical problem of infertility (Becker and Natchigal 1992, 457) shifting the issue from a social framework to that of a medical model that stressed clinical diagnosis and treatment (Heitman 1999, 23). Medicalising infertility reconstructs the childless as 'patients' seeking a possible solution to their 'illness' and offers a new social role that makes childlessness more acceptable (Heitman (1999, 24). By concentrating efforts on technological solutions, O'Donnell (2000, 138) says '...the extent to which infertility is socially constructed as an illness, the causes of infertility, and other means of dealing with infertility' are largely left unexplored. Medicalisation of infertility also delivered rewards to medical researchers, clinicians and pharmaceutical companies (Heitman 1999, 25), turning ART into a lucrative industry.

Initially IVF was used to treat physical infertility such as blocked fallopian tubes, but its wider applications were soon realised and by the early 1980s it was established as *the* solution to infertility (Levitt 2004, 42). It has been used to successfully treat a range of different problems including oligospermia³⁵, inherited genetic diseases, infertility as a result of immunological or hormonal factors and idiopathic³⁶ infertility (Law Reform Commission NSW 1987). In an ironic twist the technologised solutions

35 Low sperm count.

36 No discernable cause.

to medical infertility recast infertility as a social issue. However the *new* social infertility centres on providing solutions to involuntarily childlessness in groups with no physical impediments, most often lesbians and single heterosexual women. In combination with surrogacy, however, fertile single men and homosexual male couples can also become biological parents using ART. A somewhat different understanding of social infertility is applied to otherwise heterosexual fertile couples who use PGD in combination with IVF to select embryos without an inherited abnormality (Peterson 2005, 282), for sex selection or selection for specific genetic characteristics as in the case of 'saviour siblings'³⁷. From its initial objective of providing a solution for specific infertility conditions in a limited set of circumstances, reproductive technology is 'now promoted as extending the right to a child' by anyone who has the resources to access services (Levitt 2004, 44).

The new productive technologies demonstrate that heterosexuality is not a prerequisite for reproduction (Dempsey 2006, 31). Were cloning to become a practical alternative, reproduction could be entirely asexual. Through technology, biological parenthood transcends the body and ART disrupts 'conventionally exclusive definitions of the 'family' as properly patriarchal, heterosexual and nuclear' (Michelle 2006). Non traditional families are increasingly acceptable and the desire for children drives demands for extension of reproductive services to same sex couples, post menopausal women, and single parent families which in turn drive policy debates over access to and public funding for those services (Levitt 2004, 48).

3.5 Access to Assisted Reproductive Technology Services

Reproduction for the fertile is private with no criteria imposed on who should or should not become a parent. The situation, however, is different for the infertile,

³⁷ See Sheldon and Wilkinson 2004. A saviour sibling is a child who is conceived in order to donate life-saving tissue to an existing sibling. Tissue typing in conjunction with preimplantation genetic diagnosis is one method of selection. This avoids the risk of conceiving naturally and testing in utero to find if an embryo is a suitable donor. Consequently choices to abort unsuitable donor embryos are avoided.

where eligibility criteria³⁸ are the norm, particularly for those wishing to access publicly funded 'treatments'. Lifestyle factors, physical attributes, maternal age, marital status and sexual orientation can all be used to determine eligibility for fertility programs (Steinberg 1997, 34, Levitt 2004, 41, Peterson 2005, 280). The often high out of pocket costs associated with IVF programs can restrict participation by people from low socioeconomic backgrounds (Peterson, 2005, 281) thus capacity to pay can be an important factor. A number of different ethical principles underpin eligibility including efficient allocation of resources (Devlin and Parkin 2003, S2), fairness as a basis of rationing and moral character of prospective parents (Levitt 2004, 43). Selection criteria operate partly to control demand for services (Levitt 2004, 41) but are often justified in terms of protecting the welfare of children. For example, older mothers might die before the child reaches adulthood or people who are overweight or smoke tobacco, drink and take drugs are considered unfit to be parents. Elsner (2006, 599) argues that if such a selection process is necessary to protect the welfare of ART conceived children then in the interest of justice, it should be applied to all prospective parents. To do otherwise is to question the motivations of and the capacity of the infertile to be good parents.

ART creates new consumer demands for infertility treatments. Where age determines a biological boundary for fertility in women, IVF with donor oocytes³⁹ makes childbirth possible for older women, including the post menopausal (Heitman 1999, 25). As discussed above, the socially infertile constitute another source of consumer demand. Decisions about who should be allowed access to services are grounded in

38 See Levitt 2004. In the UK, assisted reproductive services were originally limited to infertile couples who met strict National Health Service (NHS) conditions including living arrangements, number of existing children, history of infertility, age, body mass index, lifestyle factors such as smoking, alcohol and drug use, mostly to control demand. Women who had been sterilised were excluded although some forms of sterilisation, such as tubal ligation, would not necessarily impact on IVF success rates. The rationale for exclusion may be related to a perceived ambivalence about having children because of a previous choice not to be fertile. However this would appear to discriminate against those who had 'completed' their family with a previous partner but now wish to share a biological child with a new partner or indeed people who had suffered the death of one child and yearned for another.

39 See Peterson, 2005. Traditionally the excess eggs of younger women undergoing their own fertility treatments were used. These are now in shorter supply due to improved techniques which result in the creation and implantation of fewer embryos in order to achieve a successful pregnancy.

understandings of who has the rights to parenthood which again must be balanced out against the interests of the prospective child.

While the state has no interest in the private sex lives of citizens, it does have an interest in the welfare of children including those created through ART, thus the policy debate about access is partially informed by understandings of what constitutes a safe and nurturing environment for children (Brennan 2006, 28). Peterson (2005, 281) claims that ART medical professionals take on this role of 'social and psychological evaluator' in limiting the procreative choices of some clients in the interests of the welfare of potential children. Similarly Steinberg (1997, 35) describes the medical profession's constructions of what constitutes a proper family as impacting on women's reproductive choices and access to specific ART services.

Apart from consideration of children's welfare, equity of access and managing consumer demand, policy makers need to balance out provision of ART services against other demands on the health system. ART is costly to provide and in a public system may come at the expense of other programs which provide wider benefits such as screening and treatment of sexually transmitted disease, itself a contributor to infertility (Peterson 2005, 211). With infertility, the usual arguments for public provision of costly treatments are more difficult to justify (Devlin and Parkin 2003, S3). Infertility is not a life threatening condition and as discussed above there is contention over whether it should even be classified as an illness. In the case of social infertility it could merely be considered as an unfulfilled desire. ARTs are provided by the health sector and use health sector resources but it is arguable that they result in improved health outcomes⁴⁰, making it more difficult to justify funding for ART over other services (Devlin and Parkin 2003, S3).

40 See discussion in Devlin and Parkin. 2003. For example vaccination programs and other primary health care programs accrue benefits to the community not just individuals accessing the service.

3.6 Funding Assisted Reproductive Technology Services

How ART is funded is intimately linked to who can access services, which in turn reveals much about constructions of infertility and family. Devlin and Parkin (2003, S2) claim funding for fertility services ‘...is characterized by low public (or other third party) funding, a greater reliance on user-pays than in most other health services, and variations in funding and provision.’ Most health systems need to ration services usually based on ‘criteria of effectiveness and efficiency, mediated by community values’ (Giacomini, Hurley and Stoddart 2000, 1486). If public funding or health insurance only applies to medically determined infertility then this legitimises the ‘illness’ viewpoint and implies that social fertility is a matter of private choice which has no claims on the health sector. If funding for medically diagnosed infertility is subject to further restrictions such as age, health and lifestyle choices of clients then this legitimises particular understandings of who is deserving of parenthood and who is not. If services are entirely user pays it implies those from lower socio economic classes have reduced rights to parenthood and arguably commodifies children as desirable consumer goods, particularly in the case of social infertility. If ART services are excluded altogether from health insurance or public health funding this implies even medically diagnosed infertility does not *necessitate* medical treatment because it does not pose a direct threat to a client’s health (Neumann 1997, 1217). Again this places involuntary childlessness in the context of an undesired social state which individuals can choose to ameliorate or not.

Dilemmas over funding ARTs are not limited to jurisdictions with universal health insurance programs. Even in jurisdictions which rely heavily on private insurance there is much emotional debate over the status of infertility as a disease, cost of services, success rates, use of resources and equity (Neumann 1997, 1219). For example, in the USA, inclusion of IVF in insurance plans is a matter for individual states. Jain, Harlow and Hornstein (2002, 666) found that state-mandated private health insurance coverage for IVF resulted in greater utilization of services but mixed outcomes including a lower number of embryos transferred in each cycle and a lower number of cycles resulting in pregnancy. Bundorf et al. (2007, 28) similarly found

increased utilisation but a decline in outcomes as measured by the number of births per cycle, multiples per birth, and the number of embryos transferred per cycle which were all lower in states with comprehensive insurance mandates than those without. Further, state mandated inclusion did little to improve access to IVF by ethnic minorities and poor women; clients remained predominantly white and middle class (Jain and Hornstein 2005, Jain 2006, Bitler and Schmidt 2006).

In Canada, exclusion of IVF services from the social insurance system in Ontario in 1994 caused controversy. A review panel determined that only women with completely blocked fallopian tubes would continue to be eligible for insured IVF. Doctors could still provide IVF for other causes of infertility but clients would be charged a fee (Giacomini, Baylis and Robert 2000, 1487). This decision was based on specific interpretations of medical necessity and equity considerations. Due to high out of pocket expenses already associated with publicly subsidised IVF, the service was disproportionately accessed by wealthier women resulting in inequitable distribution of services. As a result, the review panel considered it inappropriate to continue subsidising a service which in practice discriminated against the poor and which the wealthy could already purchase in the private market (Giacomini, Baylis and Robert 2000, 1490). The reaction from some quarters however was that public funding acts symbolically to protect the right to reproduce, whereas withdrawal of public support violates that right (Giacomini, Baylis and Robert 2000, 1494). The debate over IVF funding continues in Canada, with continuing pressure on provincial governments to provide services amid claims that reduced access has led to increased use of fertility drugs leading to increased premature and multiple births necessitating expensive neonatal treatment (Infertility Awareness Association of Canada, 2009).

In New Zealand, the National Clinical Assessment Criteria (CPAC) limits publicly funded services to clients who are unable to conceive after at least one year of unprotected intercourse or those whose health would be compromised if attempting a normal pregnancy or carrying a baby to term (Michelle 2006, 14). A complex points system which takes social and physical criteria into consideration determines who can

access publicly funded services and who cannot. Factors which make clients ineligible include smoking, obesity, aged over 40 years (women) and existing children aged less than 12 years who live at home. Lesbian women who have a biological cause of infertility of at least one year's duration and single fertile women who have not become pregnant following 12 cycles of privately funded DI are also eligible for public services⁴¹. Private ART services are widely available in New Zealand on a user pays basis but fertility treatments are usually excluded by private health insurance⁴².

In the UK, fertility services are strictly limited in the NHS due to high cost and perceived low success rates and not usually covered by private medical insurance (Devlin and Parkin 2003, 52). The National Institute for Clinical Excellence (NICE) Guidelines (2004, 1) advises that while the NHS funds investigation of infertility, access to NHS funded treatment, particularly ART techniques, is limited. The guidelines recommend up to three cycles of IVF or ICSI for eligible women⁴³. Implementation, however, varies from region to region in England and Wales with decisions made at the local level by Primary Care Trusts some of whom choose only to fund one cycle of IVF or ICSI and some none at all. Scotland and Northern Ireland also place limits on publicly funded services for eligible persons⁴⁴.

As with other jurisdictions worldwide, the Australian policy system⁴⁵ has grappled with the new policy challenges resulting from ART. In the next section I will discuss the policy responses to these challenges in the Australian context. As with other jurisdictions, this constitutes a balancing act between providing assistance to the infertile, rights of ART progeny, eligibility, funding and access to services and

41 See <http://www.fertilityassociates.co.nz/> Accessed 10 August 2009.

42 See 'making sense of health insurance' on <http://www.everybody.co.nz/> Accessed 10 August 2009.

43 see <http://www.hfea.gov.uk/1896.html> Eligibility criteria vary across the primary care trusts but generally criteria for treatment are based on age, cause of infertility, history of infertility, obesity, number of existing children if any and previous fertility treatment.

44 *ibid*

45 Waller (1987) says there has been at least one inquiry of some sort in each Australian State since 1982

engagement with new constructions of family and kinship relationships (Waller 1987, 21).

3.7 The Australian Policy Context

Infertility is a social issue but ART is a health policy issue in that services are provided by medical professionals in a health service setting. Decisions about funding and provision of ART and managing demand become a matter for health policy specifically even though they impact on wider social policy. In Australia, health policy is complicated by the federal system of government whereby States and Territories are responsible for the delivery of health services but the funding for services comes mostly from the national government through a number of different mechanisms⁴⁶. Health service delivery is further complicated by the private public mix. Medical services are usually provided by private practitioners on a fee for service basis subsidised by the universal insurance program Medicare with some patient co-payments (Hall 1999). The health insurance industry is an important actor in the Australian context and provides access to a range of services, usually in private hospitals, which would be considered elective in the public sector thus require long waiting list times.

There is no federal government legislation in Australia governing reproductive technology despite calls for a national regulatory and legislative framework going back as far as 1985⁴⁷. Rather, the individual states control ART services, with four states, Victoria, Western Australia, South Australia and New South Wales enacting specific legislation and the remaining States and Territories adhering to the NHMRC guidelines for ethical practice. The Northern Territory generally adheres to the South

46 See Hall (1999). The Australian Government established and operates the Medical Benefits Scheme (MBS) and Pharmaceutical Benefits Scheme (PBS). All permanent residents have the right to public hospital treatment at no charge. States and territories operate public hospitals and are responsible for the provision and delivery of services therein which are funded largely by the Australian government. The Australian Health Care Agreements (AHCA) are the main policy instrument for managing this arrangement. The AHCA are bilateral five-year agreements between the Australian Government and each state and territory which determine levels of funding and the services to be delivered. See <http://www.health.gov.au/internet/main/publishing.nsf/Content/aust-health-care-agreements.htm>.

47 See Chapter 4 of the Senate Select Committee Report, 'Human Embryo Experimentation in Australia' (The Tate Report).

Australian guidelines⁴⁸. In addition, specific surrogacy legislation has been enacted in Queensland and Tasmania. The policy responses of the individual States and Territories are discussed in detail later in this chapter.

The Fertility Society of Australia (FSA)⁴⁹, the peak body representing the ART sector, sets accreditation standards and a code of practice for the industry. The FSA created the Guidelines for Centres using Assisted Reproductive Technology in 1986 which were amended to the Code of Practice (CoP) for Assisted Reproductive Technology Units in 2002. The Reproductive Technology Accreditation Committee (RTAC) of the FSA, created in 1987, was responsible for accrediting ART service providers up until 2008 when FSA introduced the new RTAC Scheme⁵⁰. This included an independent certification of ART units as the basis for consideration for issue of an RTAC licence (FSA 2008, 5). In 2009, there were 71 accredited clinics throughout Australia⁵¹, the majority in the private sector.

There is widespread public support in Australia for ART. Support for IVF, embryo donation and 'altruistic surrogacy for infertile couples rose significantly in the 20 year period, 1981 to 2001. Public support for ART services for single women and lesbians also increased but from a much lower baseline. Community approval for Medicare funding for IVF for infertile couples also rose significantly⁵² for the same time period (Kovacs et al. 2003, 536-7).

In the next section I will discuss Australian policy responses to ART, specifically the major national policy instruments; the NHMRC guidelines and the Medicare Benefits Schedule, and the State based legislation. I will argue that within Australia, ART is

48 See SACRT website <http://www.dh.sa.gov.au/reproductive-technology/other.asp#NT>

49 The Fertility Society of Australia is the peak body representing scientists, doctors, researchers, nurses, consumers and counsellors in reproductive medicine in Australia and New Zealand. <http://www.fsa.au.com/>

50 see <http://www.fertilitysociety.com.au/wp-content/uploads/20080924-rtac-scheme-final2.pdf>

51 see FSA website <http://www.fertilitysociety.com.au/wp-content/uploads/20090420-rtac-accredited-units-listing1.pdf>

52 Kovacs et al. (2003) report 70% approval in 1981, 64% in 1992, 73% in 1997 and , 79% in 2000.

primarily situated in a health context characterised by the essentially private transaction between client and health provider. I will examine how Australian policy constructs the ART embryo arguing that its value lies in its capacity to fulfil other's needs rather than any intrinsic value of its own. While the embryo remains in its 'private' health context it stimulates little national debate but when it ventures in to the 'public' research context the situation changes considerably.

3.8 National Policy Responses

3.8.1 The National Health and Medical Research Council Guidelines

The NHMRC first issued ethical guidelines on the *research* aspects of ART in 1982 as supplementary note 4 to its *Statement on Human Experimentation* (NHMRC 1996, iv). The supplementary note observed both the experimental and clinical dimensions of IVF stating that clinical use was well established for the treatment of infertility within an established family relationship (NHMRC 1988, 14). As Peterson (2005, 281) observes, this relationship was not defined. The guidelines specified the ethical circumstances in which gametes could be donated but the issue of surrogacy was considered to be ethically unresolved at that point in time. Gametes and any resultant embryos belonged to respective donors who retained control over their use, storage and disposal. In the event of disagreement amongst the donors, the ART facility took responsibility for such decisions (NHMRC 1988, 15). The status of the embryo was not directly addressed in the supplementary note but given its relationship to the ethical statement on human experimentation, perhaps it was implicit that embryos were human. The 1985 Tate review had previously recommended that for the purposes of experimentation, embryos were to be considered human subjects (Senate Hansard, 8 October 1986, 970).

Following a 1993 review by the Australian Health Ethics Committee (AHEC), the NHMRC released *Ethical Guidelines on Assisted Reproduction Technology* in 1996. The NHMRC noted that in the field of ART there was a broad overlap between clinical practice and research, which made separation of one from the other difficult, but the guidelines sought to provide direction in both areas (NHMRC, 1996, iv). The

NHMRC acknowledged a number of social implications of ART including eligibility, surrogacy, gamete donation and embryo storage but considered these issues as beyond the scope of the guidelines and recommended they be dealt with by complementary state based legislation, preferably uniform throughout the nation (NHMRC, 1996, v). Such legislation is yet to eventuate. The new guidelines identified the values which should underpin the practice of ART; principally protection of the long term welfare of any children born and the welfare of persons undergoing ART procedures. Further the whole of society should be served by the development of the technologies and the *human* nature of the embryo be considered in aspects of research and experimentation related to ART (emphasis added) (NHMRC 1996, 1).

The guidelines covered accreditation and approval processes for reproductive medicine units (RMU) and specified the role of institutional ethics committees (IEC) in approving both new clinical procedures and any research on ART embryos for the purposes of improved clinical outcomes (NHMRC, 1996, 3). Informed decision making was considered crucial to ethical ART practice for all clients including gamete donors. Information about the nature of procedures, costs, success rates, physical and psychosocial risks, information collection and storage were considered critical to informed consent (NHMRC 1996, 5). Any children born as a result of ART were entitled to knowledge of their biological origins and any information identifying gamete donors would be released to any resulting children (NHMRC 1996, 6). Gamete providers continued to retain responsibility for the future of their embryos and in the case of disputes, embryos would be stored until an agreement was reached. If one gamete donor died, the other would assume responsibility for decision making, taking into consideration the deceased partner's wishes if they were known. If both gamete providers died, embryos would be stored in accordance with advance directives where available. In the absence of such a directive, or if conditions could not be complied with, the embryos were allowed to succumb (NHMRC, 1996, 7).

Sections 6 and 11 of the guidelines provided guidance on embryo research and prohibited practices which will be fully discussed in Chapter 4. Germane to this discussion however was the NHMRC acknowledgement of the unresolved issues surrounding the moral status of the embryo and their subsequent conservative approach to embryo experimentation. Namely non therapeutic research which did not harm the embryo was allowed and destructive non therapeutic research was acceptable only in exceptional circumstances and with relevant IEC approval and the permission of gamete providers. Significant advances in knowledge or treatment techniques were considered the only justification for non therapeutic destructive embryo research (NHMRC 1996, 10).

In 2004, the NHMRC published the revised '*Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*' which replaced the existing guidelines and took into account the 2002 national Australian legislation on cloning and embryo research⁵³. In terms of clinical practice, compliance with the revised guidelines remained 'a key element in the accreditation processes for ART clinics' (NHMRC 2004, 4). The new guidelines reiterated the requirement of respect for both persons involved in ART procedures and for embryos which were not to 'be treated as mere tissue' (NHMRC, 2004, 13). Such respect incorporated minimising the numbers of embryos created and used to achieve a successful pregnancy, where possible. Section 5.3.1 specified the need for explicit protocols for 'access to, and eligibility for, treatment'. Again the welfare of ART children was articulated as a principle ethical value as was children's right to knowledge of their genetic heritage with some specified exceptions⁵⁴ (NHMRC, 2004, 17).

In the case of donated gametes, clinicians were charged to take into consideration the

53 Prohibition of Human Cloning Act 2002 (PHC Act), Research Involving Human Embryos Act 2002 (RIHE Act)

54 See section 6.1.5 NHMRC Guidelines 2004. The use of donor gametes without consent to release of identifying information is permissible if

- the recipient has a child who was born before the introduction of these guidelines using the same gamete donor; or
- Embryos created using donated gametes have been stored before the introduction of these guidelines but the donor cannot be contacted.

‘physical, psychological and social wellbeing of the person to be born and the participants’. This required restriction of the number of people born from any one gamete donor so to protect any offspring from the consequences of too many genetically related siblings or other relatives. The onus was placed on ART clinicians to decide on the number of families which could use gametes from a single donor, taking into account the number of genetic relatives that progeny would have and the risk of future children inadvertently having a sexual relationship with a close biologic relative. Where gamete donation came from a relative, clinics were required to alert parties to the relevant ethical issues of misleading a child about their genetic parent and the impact on families of cross generational gamete donation⁵⁵ (NHMRC, 2004, 17-8). Recipients of donor gametes were entitled to relevant knowledge of the donor medical history and donors were entitled to relevant knowledge of their offspring. Children born as the result of ART gamete donation were entitled to knowledge of their genetic parents including relevant medical and family history, identifying information and the number and sex of any siblings. Identifying information about siblings could only be released with their prior consent (NHMRC, 2004, 18-9).

Clinics had a responsibility to maintain ‘clear procedures for the transfer of responsibility for gametes and the resulting embryos’ (NHMRC, 2004, 21) at each stage of the donation process. Where there was no specified recipient, the clinic retained responsibility regarding gamete storage, use and disposal, subject to any limitation expressed by the donor. Where there was a known intended recipient, the responsibility for the gamete was transferred to that recipient subject to the same limitations. Donors could withdraw their consent for donation at any time prior to insemination or fertilisation. Once fertilisation occurred, the recipient was responsible for decisions regarding embryo use for their own reproductive treatment, medical use of the embryo, storage and disposal (NHMRC 2004, 21). Strict guidelines were established for the management of posthumous embryo use⁵⁶, an analogy drawn

55 For example an uncle might provide the sperm for his nephew’s partner. The resulting child would be a genetic cousin (same generation) to the social father as well as his ‘child’ in the new generation.

56 Section 6.15 permits use of posthumous embryos when a deceased or dying person or a person in a vegetative state has left clearly expressed and witnessed directions consenting to the use of his or her

between the tragedy of a parent dying before a child is born and the use of an embryo or gametes from a deceased, dying or person in a vegetative state. Facilitating such an act whereby a child would never know the genetic parent was considered 'of profound significance for the person born' (NHMRC 2004, 21).

Section 7 of the guidelines was devoted to donated embryos where the analogy to adoption was made; that is the child is not genetically related to either social parent. As with donated gametes, the rights of the child were paramount including the right to knowledge of their genetic parentage thus procedures which resulted in confusion over genetic parentage were not allowed⁵⁷ (NHMRC, 2004, 22). Clinics were accountable for maintaining clear procedures for the chain of responsibility for the embryo at each stage in the donation process. Once the donors had relinquished the embryo, the recipient (and partner) took responsibility for its use, storage and disposal subject to any limitations imposed by the donor or the law. If there was no specified recipient, the clinic retained responsibility until a suitable recipient for the embryo was found. Donors could vary or withdraw their consent up until transfer of the embryo to the uterus (NHMRC 2004, 24).

Section 8 dealt with storage of gametes and embryos; Section 9 information, counselling and consent processes; Section 10 record keeping and data reporting and Section 14 innovations, training and quality assurance. The ethically controversial issues of sex selection, preimplantation genetic diagnosis and surrogacy were dealt with in sections 11, 12 and 13 respectively. Sex selection was ethically permissible only to reduce the risk of transmission of a serious genetic condition, thus by default could not be used for social or trivial reasons (NHMRC 2004, 39). Similarly PGD could be used to detect serious genetic conditions, to improve ART outcomes and for

gametes. The prospective parent must receive counselling regarding the consequences of the action and any resultant child is entitled to knowledge of the biological parent(s). Further, clinics should ensure that those involved seek advice and guidance from a clinical ethics committee on the ethical issues and, if necessary, seek advice regarding the application of relevant laws.

⁵⁷ Section 7.2 specified that transfer embryos to the uterus of a woman from more than one source at any one time not be allowed. Section 7.2.1 specified that clinics should not facilitate donation of an embryo that has been created using a donated gamete or gametes or 'on-donation' of a donated embryo (NHMRC 2004, 24)

the selection of a compatible saviour sibling. However this remained contentious as there was continuing debate over what constitutes a serious genetic condition or disability and the implications of selection against specific disabilities for those people already living with that disability. Further concerns were raised over the technical limitations of PGD to accurately detect abnormalities and the moral implications resulting from the disposal of healthy embryos (NHMRC 2004, 40).

Commercial surrogacy was considered ethically unacceptable and altruistic surrogacy was illegal in some jurisdictions. Where non-commercial surrogacy did *not* contravene existing State and Territory legislation, ART clinics were responsible for ensuring that all parties understood the ethical, social and legal implications and the social and psychosocial significance for themselves and the future child⁵⁸ (NHMRC, 2004, 42).

In 2007, the guidelines were again revised to accommodate national legislative changes. The creation of hybrid embryos⁵⁹ for the purposes of testing sperm quality in the clinical setting was now permitted. This could only occur under license at an accredited ART centre and with the informed consent of the sperm donor (NHMRC 2007, 31). Otherwise the clinical practice component remained largely unchanged from the 2004 version and the welfare of people born as a result of the use of ART remained paramount (NHMRC 2007, 9).

The guidelines aimed to be

sensitive to all the relevant ethical dimensions of ART: to recognise the basic human goods at stake; to distinguish goals and purposes from means chosen; to clarify relevant moral principles and motives; to distinguish the moral evaluation of human acts themselves from the moral evaluation of their likely consequences;

58 See http://nhmrc.gov.au/publications/synopses/_files/e56.pdf

59 Section 6.17.1(NHMRC 2007) states

‘ For the investigation of male infertility, sperm quality may be tested, under licence, by the fertilisation of an animal egg by a human sperm, and use of such embryo up to, but not including, the first mitotic division. Hybrid embryos may not be formed for any other purpose and their creation or use must occur in an accredited ART centre.’

to identify the virtues or character traits that facilitate responsible conduct in ART; and, to recognise that, while related in complicated ways, ethical questions cannot be wholly separated from social and political questions (NHMRC 2007, 9).

Respect for persons, respect for embryos, protection of privacy, chain of responsibility for gametes, informed consent, maintenance of the integrity of genetic parenthood and children's entitlement to knowledge of genetic inheritance were all reiterated as important guiding values in the clinical practice of ART.

3.8.2 Medicare Benefits Scheme

A range of ART services attract a rebate through the Medicare Benefits Scheme (MBS). These services must be provided by a medical practitioner for the treatment of medically diagnosed clinical infertility (Assisted Reproductive Technologies Review Committee (ARTRC) 2006, 16). The Federal government introduced Medicare rebates for ART in 1990, initially with a limit of 6 cycles but this limit was removed in 2000 (Health Insurance Commission (HIC) 2005). At that stage only selected procedures were rebatable leaving clients to manage the full costs of some treatments, including ICSI (Melbourne IVF, 2004). Clients also typically faced a range of fees for associated costs like anaesthetist fees, day admission to medical facilities, biopsies, pathology, post-treatment medication and administration charges⁶⁰.

Out of pocket costs are variable depending on the procedures used, the fees set by IVF medical specialists and client's private health insurance coverage but amounts of around \$1000.00 per cycle are not unusual⁶¹. Given that most couples undergo multiple cycles before they achieve a pregnancy, costs can be very substantial. Chambers, Ho and Sullivan (2006, 155) estimated the average cost per non-donor

60 See IVF Australia website for current costs and Medicare rebates in Australia.

<http://www.ivf.com.au/Page/SitePageFirstLevel.aspx?pageName=Costs>

61 See Monash IVF for comprehensive list of services and charges.

<http://www.monashivf.com/default.asp?action=article&ID=21854>

ART live-birth event was \$32 903 for women aged 30 to 40 years old. This increased to \$182 794 for women aged greater than 42 years. The average treatment cost per fresh cycle was \$6940, compared with \$1937 for a frozen embryo transfer cycle. This includes Medicare costs, private insurance cover and patient out-of-pocket expenses.

In 2004, the government introduced the Extended Medicare Safety Net scheme (EMSN). When the scheme was introduced the general threshold was \$700 for singles and families. The thresholds were indexed to the Consumer Price Index at the start of every calendar year and had reached \$1000 by 2006 (CHERE 2006, 1). The EMSN allowed Medicare to cover 80% of out-of-pocket costs for ART services provided outside of the hospital setting once the annual threshold⁶² was reached. On current ART costs⁶³, the EMSN can be reached after just one cycle of ART treatment. In 2003 Medicare expenditure for ART services was \$50 million but had reached \$108.4 million by 2006, a 117% increase over two years. The overall effect of the EMSN was to transfer a large proportion of costs of ART back to the federal government, removing a very significant cost constraint for clients and foretelling an escalation of government expenditure in this area (ARTRC 2006, 13).

In 2005, the Health Minister Tony Abbott announced a review of the costs and benefits of ARTs for 'the purposes of public funding under Medicare' in the light of increasing IVF expenditure. The review would not consider the regulation of ART which remained a State and Territory responsibility (Abbott, 2005). In 1996 the Australian government released the report of the Assisted Reproductive Technologies Review Committee (ARTRC) which found ART success rates begin to decline after age 33, significantly declined after age 37, and showed a 'marked decrease' in women over 40 years old (ARTRC, 2006, 67). There was also a decrease in birth rates with successive treatment cycles but while the number of cycles and duration of infertility impacted on success rates, maternal age remained the most significant factor (ARTRC 2006, 71-2). In evaluating the cost effectiveness of ART, the review

62 In 2009, EMSN was \$1111.60 per individual or family

63 see Monash IVF <http://www.monashivf.com/default.asp?action=article&ID=21854>

found the cost of a live birth ‘...increased with maternal age and the number of treatment programs undertaken’ (ATRCR 2006, 95). Despite these findings the government decided not to limit funding for ART by maternal age or the number of cycles (Abbott 2006). In 2007, ICSI was added to the MBS as a rebatable item for the treatment of male infertility (Abbott 2007).

Changes to the EMSN were announced in the 2009/10 Federal Budget. The government noted there was some evidence that the EMSN had ‘...enabled some specialists to charge excessive fees’ (Roxon, 2009). The changes included a cap on all ART services. As a result clients will receive the standard Medicare rebate for services but once the EMSN threshold is reached will be eligible for an additional benefit of up to the amount of the EMSN benefit cap (MBS 2009, 3). These changes generated heated debate and claims that out of pocket costs would escalate⁶⁴ thus discriminating against poorer women. Claims that medical costs had increased dramatically and medical specialists were using the EMSB as a vehicle for increasing services were hotly contested by the Australian Medical Association (AMA 2009).

The Australian government has very limited jurisdiction over the regulation of ART in Australia because the provision of medical treatments is the responsibility of the individual States and Territories. Policy instruments such as the Medicare Benefits Schedule however are a powerful policy lever in that they place particular limits on access to ART services which serve particular understandings of infertility.

3.9 State and Territory Policy Responses

As discussed above, four Australian States have enacted specific legislation to regulate assisted reproductive technology services. All legislative frameworks specifically identify the wellbeing of children born as a result of ART as the guiding principal but make little if any reference to the wellbeing of embryos. Rather, the focus is on licensing of ART, eligibility for treatment, consent, record keeping and information management and management of gametes and embryos as a resource.

64 See ACCESS Infertility Network <http://www.access.org.au/>

3.9.1 South Australia

The Reproductive Technology (RT) Act 1988 first came into operation in April 1988. The Act was amended first in 2000 and then again in 2003 when the current Reproductive Technology (Clinical Practices) (RTCP) Act 1988 received assent⁶⁵. The act regulates ‘...the use of reproductive technology and research involving experimentation with human reproductive material’ (RTCP Act, 2003, 1).

The Act established the South Australian Council on Reproductive Technology (SACRT), an 11 member multidisciplinary⁶⁶ body appointed by the Governor (RT Act, 1988, Part 2). The council has a wide range of responsibilities including review of ethical practice in the use of ART, conduct of research into the social consequences of reproductive technologies, promoting research into the cause of human infertility and promoting informed public debate on ethical and social issues (RT Act, 1988, s10.1). The ‘welfare of any child to be born in consequence of an artificial fertilisation’ is the fundamental guiding ethical principle underpinning the action of the Council (RT Act, 1988, s 10.2). As part of its mandate, the SACRT oversees the Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995 which were most recently amended in 2005⁶⁷. The Code of Practice encompasses prohibited practices, eligibility for treatment and gamete donation, consent processes for treatment and gamete donation, confidentiality and record

65 The changes were made as a result of passing of the Prohibition of Human Cloning Act 2003 (SA) and the Research Involving Human Embryos Act 2003 (SA) in response to the Federal Government's legislation. The new acts removed the regulation of embryo research from the Reproductive Technology Act 1988. See <http://www.dh.sa.gov.au/reproductive-technology/legislation.asp>

66 The Act specified nominations from:

- Council of the University of Adelaide;
- Council of the Flinders University of South Australia;
- Royal Australian College of Obstetricians and Gynaecologists;
- Royal Australian College of General Practitioners;
- Heads of Churches in South Australia Law Society of South Australia; and
- Others as nominated by the Health Minister.

67 In December 2003, the Reproductive Technology (Code of Ethical Research Practice) was revoked because it was replaced by the national legislative scheme regulating embryo research. However SACRT is still required to monitor all research conducted in South Australia that uses embryos or gametes, whether for research into infertility or other areas, and to include their findings in future Annual Reports.

<http://www.dh.sa.gov.au/reproductive-technology/regulations.asp>

keeping requirements. ART clinics are licensed by the Minister for Health and must abide by the Code of Practice and NHMRC Guidelines⁶⁸.

The RT Act Part 3, Section 13.3(i) specifies that licence for ART treatment is for married couples where the husband or wife or both 'appear to be infertile' or there is a risk of transfer of a genetic defect if a child was to be conceived naturally. For the purposes of the legislation married couple includes two heterosexual people cohabiting in a long term de facto relationship⁶⁹. The marital status requirement was successfully challenged in the South Australian Supreme Court in 1996⁷⁰ on the grounds it discriminated on the basis of marital status thus contravened the Commonwealth Sex Discrimination Act (1984). The South Australian legislation has not been changed, as federal law takes precedence over State law, and any *medically* infertile woman can access reproductive technology treatment in South Australia, including medically infertile lesbians. Fertile lesbians are not eligible for IVF nor can they access screened donor sperm from licensed clinics for the purposes of artificial insemination. They can however make private arrangements using donor sperm in their own homes or through a medical practitioner registered to provide such services⁷¹.

3.9.2 Western Australia

ART in Western Australia is regulated by a range of legislation and guidelines: the Human Reproductive Technology (HRT) Act 1991, the Surrogacy Act 2008 (WA), Human Reproductive Technology Amendment 2004 (WA), Surrogacy Regulations 2009 (WA), Surrogacy Directions 2009 (WA), Family Court (Surrogacy) Rules 2009 (WA), the NHMRC Ethical Guidelines and RTAC Guidelines⁷².

68 see <http://www.dh.sa.gov.au/reproductive-technology/documents/eligibility-fact-sheet.pdf>

69 For at least the preceding 5 years or an aggregate of 5 years in the preceding 6 years (RT Act.1988, Section 13.4)

70 Pearce v South Australian Health Commission, (1996) 66 SASR 486. See discussion in Del Villar (2000)

71 See Reproductive Technology Council SA

<http://www.dh.sa.gov.au/reproductive-technology/documents/eligibility-fact-sheet.pdf>

72 See Reproductive Technology Council WA <http://www.rtc.org.au/legislation/index.html>

The Western Australian Reproductive Technology Council (RTCWA) was established under the HRT Act 1991 and like its South Australian counterpart has a number of mandated roles and functions. It oversees the licensing of ART, has monitoring and compliance functions, assesses applications for ART research and promotes informed public debate about reproductive technology. The original Act did not provide for access to identifying information for children born as a result of donor gametes and did not address the issue of surrogacy (RTCWA 1996, 1). More recent amendments to the Act require that donors give permission for release of identifying information as a condition of donation⁷³.

Under the Act the primary purpose and only justification for IVF was to 'assist persons who are unable to conceive children naturally due to medical reasons or whose children are otherwise likely to be affected by a genetic abnormality or a disease, to have children' (HRT Act 1991, 1). Section 23 (HRT Act 1991) specified that people seeking ART should be married or living in an established de facto relationship. The Act was reviewed in 1997 and in 1999, the WA Minister of Health tabled a report⁷⁴ by the Select Committee on Human Reproductive Technology (SCHRT) Act 1991 (SCHRT, 1999, xvii). The Committee reiterated that the best interest of the child should underpin the practice of reproductive technology (SCHRT, 1999, xvii). They found, however, that defining 'best interests' was complex⁷⁵ and there were competing views on whether gestation to birth is always in the embryo's best interest or whether certain circumstances adversely affect that embryo's eventual outcomes, for example, being born to significantly older parents or into a family where one or both biological parent is deceased, as in the case of posthumous embryo donation. Consequently they referred this issue to the Reproductive Technology Council and the Family and Children's Policy Office to determine appropriate guidelines (SCHRT 1999, 16).

⁷³See Reproductive Technology Council WA
http://www.rtc.org.au/faqs/index.html#anonymous_known

⁷⁴ The Minson Report

⁷⁵ United Nations (UN) Convention on the Rights of the Child and The Family Law Act 1975 (section 68F) were identified as possible suitable reference points (SCHRT, 1999, 15)

The Committee recommended a number of changes to eligibility criteria including removing the previous five year time constraints on couples living in a stable de facto heterosexual relationship and placing a 55 year old age limit on access to IVF for either member of a couple. They retained the medical infertility criterion but relaxed restrictions for women who were *at risk* of infertility as a result of disease or medical procedure. The majority of the committee however did not recommend relaxing eligibility criteria for single and lesbian women (SCHRT, 1999, xviii)⁷⁶. In 2002 the Acts Amendment (Lesbian and Gay Law Reform) Act 2002 was passed which amended Section 23 of the HRT Act to allowed same-sex couples to access IVF treatment if medically infertile.

In 2003, the Human Reproductive Technology Amendment Bill 2003 and Human Reproductive Technology (Prohibition of Human Cloning) Bill 2003 amended the HRT Act 1991 to incorporate the prohibited practices and regulation of uses of excess ART embryos detailed in the Commonwealth RIHE and PHC Acts of 2002. The new Human Reproductive Technology Amendment (HRTA) Act 2004 and the Acts Amendment (Prohibition of Human Cloning and Other Practices) Act 2004 came into operation in December 2004. A bill proposing further amendments to incorporate the 2006 changes to the Commonwealth legislation, to allow for the creation of certain embryos for research purposes but prohibit their use for reproduction, went before parliament in 2007 (Parliament of Western Australia 2007, 2) but was not agreed to at the second reading in mid 2008⁷⁷.

76 SCHRT 1999

Recommendation 5d

That section 23(c)(ii) of the Human Reproductive Technology Act 1991 be amended to read 'are living in a stable, heterosexual relationship'.

Minority Recommendation 5f (Members for Kalgoorlie and Thornlie)

That section 23(c) of the Human Reproductive Technology Act 1991 is amended to allow access to women regardless of sexual preference or marital status.

77

<http://www.parliament.wa.gov.au/parliament/bills.nsf/BillProgressPopup?openForm&ParentUNID=F8EB995A9A54CB1C82572AC0011ED67>

In 2008 the Surrogacy Act was passed allowing for non commercial surrogacy in Western Australia under certain conditions⁷⁸. The Act permits eligible persons to enter into surrogacy arrangements up to and including the birth and registration of the child, and to transfer the legal parentage of a child through a 'parentage order' from the WA Family Court. The Act specifies that the best interests of the child remain paramount (Surrogacy Act 2008).

Part B of the preamble to the original HRT Act 1991 provides that the legislation 'respect the life created by this process by giving an egg in the process of fertilisation or an embryo all reasonable opportunities for implanting'. The HRTA Act 2004 retains the provision for respect but removes the qualification that this is demonstrated through all reasonable opportunity for implantation (HRTA Act, 2004, 2).

3.9.3 Victoria

Assisted reproduction in Victoria was originally regulated under the Infertility Treatment (IT) Act 1995. As with legislation in other states, a woman was not eligible for treatment unless she was 'unlikely to become pregnant from an oocyte produced by her and sperm produced by her husband' as determined by a doctor, that is she must be clinically infertile, or at risk of having a child with a genetic abnormality (Section 8(3)). Further a woman had to be married (Section 8(1) (a), (b)) and have the consent of her husband to undergo treatment (Section 8.3(1)). The IT Act was amended in 1997 to 'extend access to treatment procedures under the Act to de facto couples living together as husband and wife on a genuine domestic basis' (IT Bill 1997, 1). The Act was further amended in 2001 to remove the requirement for a spouse's consent, in specific circumstances, where a couple no longer lived together; to provide for the posthumous uses of gametes or embryos and to provide for voluntary inclusion on the donor register and release of information related to donations and procedures undertaken prior to 1 July 1988 (IT Bill 2001, 1-2). From

⁷⁸ See <http://www.bioethicsperth.org.au/Upload/Surrogacy.pdf>
Individuals and couples wishing to use surrogacy must complete comprehensive medical and psychological assessments, as well as seek independent legal advice.

January 1998, offspring resulting from donor procedures had the right to access identifying information about their birth origins⁷⁹. Further amendments were made as a result of the Health Legislation (Infertility Treatment and Medical Treatment) Bill (HL) 2006. 'with respect to licensing of infertility treatment service providers' (HL Bill 2006, Section 1).

As in South Australia and Western Australia, the Victorian Infertility Treatment 1995 Act created a statutory body, the Infertility Treatment Authority (ITA) to administer the regulation of the Act. Similar to the bodies in the other jurisdictions, the ITA had a number of functions; licensing of treatment facilities; monitoring and reporting of ART activity; maintenance of the donor register system and maintenance of statutory time limits in relation to the storage of sperm, eggs and embryos for use in treatment procedures. The ITA was also responsible for 'approval' of ART practitioners, including doctors, counsellors and clinical and research scientists; cross border movement of gametes and embryos; and research as required under the Act⁸⁰.

Subsequent to the high profile *McBain v State of Victoria* case (see Box), in 2002, the Victorian Law Reform Commission (VLRC) began a review of the legislation governing access to reproductive services in Victoria and 'how the law should recognise parents in different types of families and how surrogacy arrangements should be regulated' (VLRC 2007, 2).

In 2007, the VLRC report (2007, 6) said that that ART regulation had 'failed to keep pace with the emergence of new families and developments in reproductive technology.' Consequently, certain categories of people were excluded from accessing ART, and certain relationships within families received no legal recognition (VLRC, 2007, 6). The VLRC reiterated that in all decisions related to ART, it was the interests of the child which should prevail, noting the existing law implied the best interests of children were served by limiting ART to women in

⁷⁹See <http://www.dh.sa.gov.au/reproductive-technology/other.asp#VIC>

⁸⁰ See Infertility Treatment Authority <http://www.ita.org.au/>

heterosexual relationships, a view which was not substantiated by evidence (VLRC 2007, 6). The report identified a number of 'objective and verifiable' criteria, to be used in assessing eligibility for ART, which would protect the best interests of any children born as a result of the technology. To this end, people convicted of sexual or violent crimes or who had previously had a child removed from their care would not be eligible for treatment unless an independent review panel was satisfied that future children would not be at risk of harm. Where there were concerns that a prospective child might be at risk for other reasons, then an expert clinical ethics committee should decide on whether ART treatment should proceed (VLRC 2007, 6).

The report also found that the provision that a woman was 'unlikely to become pregnant' was applied inconsistently. Furthermore women who could not legally access clinic services could still become pregnant through private arrangements to self-inseminate with unscreened sperm which posed health risks for them and their children. Where the implications had not been fully discussed and considered, these informal arrangements also created potential conflicts over the respective roles of the multiple actors⁸¹ in any future child's life (VLRC, 2007, 7).

The Commission recommended some changes to the management of donor information to enhance the rights of donor conceived people to information regarding their genetic heritage. While the law recognised the right of the donor conceived person to identifying information about their donors, the birth parents did not always inform children of their origins. The commission argued that secrecy about a child's origins could lead to feelings of betrayal and mistrust and grief within the family (VLRC, 2007, 8).

In summary there were a number of principles identified which the Commission believed should underpin ART regulation:

- The welfare and interests of children are paramount;

⁸¹ For example the sperm donor who might be a family friend or relative and the rights and responsibilities of the non birth partner in the case of same sex couples, should the relationship later dissolve.

- Exploitation of any party undergoing ART or any future children was unacceptable;
- Children born from donor gametes have a right to information about their genetic origins;
- Protection of the health and wellbeing of people undergoing ART is essential;
- Discrimination on the grounds of sexual orientation, marital status, race or religion is unacceptable in the provision of ART services (VLRC, 2007, 9).

In 2008, the Assisted Reproductive Treatment Bill 2008, based largely on the recommendations of the VLRC report (Higgins 2008, 1) was introduced into the Victorian parliament. The new laws made provisions for checks for criminal records and child-protection orders for potential parents and established a state-wide review panel to consider appeals. They provided access to ART for women irrespective of marital status or sexual orientation and made changes to the requirement that surrogate mothers must be infertile to access treatment in a clinic. Legal recognition was given to the non birth mother in same sex relationships and to the commissioning parents in a surrogacy arrangement (Victorian Deputy Premier, Attorney-General and Minister for Health, 2008).

The Assisted Reproductive Treatment (ART) Act 2008 was passed, on a conscience vote, in the Victorian Parliament on 4 December, repealing the IT Act 1995. The new Act regulated ART and AI procedures, regulated access to information about treatment procedures performed under the Act; made provision for surrogacy arrangements and established a new statutory body, the Victorian Assisted Reproductive Treatment Authority to take over the functions⁸² of the ITA (Part 10, ART Act, 2008).

Section 10.2(a) of the Act specified eligibility for ART treatment if 'a doctor is satisfied, on reasonable grounds, that in the woman's circumstances, the woman is unlikely to become pregnant other than by a treatment procedure.' This clause in

⁸² See Appendix 1

effect removes the clinical infertility requirement to access ART treatment. The new Act also required that a presumption against treatment does *not* apply to the woman (or her partner if any) on the grounds of previous convictions for sexual or violent crimes or previous child protection order (section 12). Section 15 outlines the appeals process should a presumption against treatment decision be made. Part 4 of the Act deals with surrogacy arrangements⁸³ and Part 9, the creation of the Patient Review Panel which amongst other functions⁸⁴ considers all applications for surrogacy arrangements and the circumstances under which a presumption against treatment is sustained (ART Act 2008, Section 86(b)).

Section 36 (ART Act 2008) bans destructive research on embryos created for 'treatment purposes' but the legislation makes no reference to the moral status of the embryo. In Victoria, the Research Involving Human Embryos Act 2008 regulates 'activities that involve the use of certain human embryos created by assisted reproductive technology or by other means' which includes research on embryos considered to be excess to ART requirements.

83 Ibid

84 Ibid

The McBain Case

In 2000 Dr John McBain, a Melbourne IVF specialist was consulted by Ms Lisa Meldrum, a single woman who wished to become pregnant using donor sperm in an IVF procedure. The client was advised that she was ineligible for treatment under existing Victorian law because of her marital status. The Royal Women's Hospital, where Dr McBain was based, had previously been found in violation of the Sex Discrimination Act (SDA) 1984 for refusing to treat a single woman and ordered to pay damages of \$8,551 by the Human Rights and Equal Opportunity Commission (Walker 2002). Dr McBain commenced proceedings against the State of Victoria on the grounds that the legislation was '...inconsistent with the SDA 1984, and hence inoperative to the extent of the inconsistency' (Del Villar, 2000^a).

The State of Victoria neither asserted nor denied any inconsistency, but the Australian Catholic Bishops Conference and the Australian Episcopal Conference of the Roman Catholic Church (The Catholic Church) were granted *amici curiae* (friends of the court) and opposed the application (Dower 2001). The Catholic Church argued there was no inconsistency between the Infertility Treatment Act 1995 and the SDA 1984 on two main grounds:

- ART is not a service; and
- The right of a child to be born into a family with a mother and a father (Skene 2000).

In July 2000, Justice Sundberg ruled in the Federal Court that Victorian treatment agencies must not refuse single women access to ART (Skene 2000). In his ruling, the judge held that fertility treatments were services provided by a medical practitioner and it was a contravention of Section 22 of the Sex Discrimination Act 1984, to discriminate in the provision of goods and services on marital grounds. The counter argument that services should be read as 'consistent with the rights of the child under international instruments to know and be brought up by both parents' was dismissed (Del Villar ^a2000). The argument that fertility treatment services were exempt from the Sex Discrimination Act under section 32 because discrimination is not applicable where services can only be provided to members of one sex, was also rejected. Justice Sundberg reasoned that fertility treatments were not only applicable to women; rather they aimed to overcome obstacles to pregnancy which could be due to the physical features of a man or a woman. He argued that fertility services were typically directed toward achieving a pregnancy for a couple and the placement of the embryo into the *woman's* body was the simple biological fact at the conclusion of the procedure (Del Villar 2000^a).

Following the judgment, the Australian Government announced it would amend the Sex Discrimination Act 1984 to exempt State laws which restricted access to IVF and other fertility treatments on marital grounds (del Villar, 2000^b). The Prime Minister, John Howard, saw the issue as one of the right of a child to have the 'reasonable expectation of the care and affection of both a mother and a father' (Skene 2000).

In August 2000, the Australian Attorney General introduced the Sex Discrimination Amendment (SDA) Bill 2000 into the House of Representatives to 'amend the Sex Discrimination Act 1984 to revive or preserve State and Territory laws which deny access to assisted reproductive technology to a person on the basis of that person's marital status' (Del Villar, 2000^c).

In November 2000, the Senate referred the Sex Discrimination Amendment Bill (No. 1) 2000 to the Legal and Constitutional Legislation Committee (LCLC) for inquiry and report. The committee reported in 2001 concluding that the Bill was an ineffective instrument to ensure children's rights, and while no compelling case had been made to advance the rights of children, passing the amendments would diminish the rights of some women (LCLC 2001, 36). The Sex Discrimination Commissioner agreed that the Bill did nothing to protect the rights of children 'because it had nothing to do with quality parenting and much to do with preventing certain categories of women from having a child' (HREOC Media Release 2001^a). The Sex Discrimination Amendment Bill (No 1) 2001 was passed by the House of Representatives on 3 April 2001 and introduced into the Senate on 22 May 2001. Ultimately it did not go to a vote in the Senate (Coorey 2002).

In 2001, the Catholic Church challenged the original Sundberg ruling in the High Court. The Attorney General granted them a partial fiat '... to ensure that they had standing to bring proceedings in the High Court' to their case. The Human Rights and Equal Opportunity Commissions appeared before the High Court to argue that the Convention on the Elimination Of All Forms of Discrimination Against Women (CEDAW) allowed the Commonwealth to pass laws preventing discrimination on the ground of marital status and any change to the marital provisions in the SDA to accommodate State ART laws had wider implications for women's rights. The Sex Discrimination Commissioner stated it was not '...appropriate for fertility or other medical services to be restricted or denied to women depending on their marital status' (HREOC Media Release, 2001^b). In May 2001, the Court granted the Women's Electoral Lobby (WEL) the right to intervene in the case, leading spokeswoman Lisa Solomon to say 'it was the first time a women's lobby group would represent the interests of the public in the High Court' (Doez 2001).

On 18 April 2002, the High Court upheld the Sundberg ruling, its decision based on 'questions of procedure, jurisdiction and the exercise of judicial discretion'⁸⁵ (Hansard, 2002, 4554). Following the High Court decision, another Sex Discrimination Amendment Bill 2002 was introduced into the Australian House of Representatives. In essence this was the same as the SDA Bill No.1 (2000). As with the original, the Bill sought to amend the SDA 1984 to allow State and Territory legislation to limit access to ART services to married women or those living in a stable de facto relationship. The Bill recognised the limited constitutional power of the Commonwealth to legislate in this field and the States' responsibilities to regulate for the provision of medical care and treatment including access to ART services (Attorney General 2002). At its second reading in the House of Representatives on June 27 2002, the debate on the Bill was adjourned (Hansard, 2002, 4555) and the proposed amendments were not enacted. In 2005, when the Coalition regained control of the Senate, social conservative liberal Senator Guy Barnett attempted to have the amendment resurrected, on the grounds that children were entitled to a mother and a father (Price, 2005). He did not succeed.

85 Chief Justice Murray Gleeson said in his ruling that the court had been asked by people who were not parties to the Federal Court action to quash its decision on the grounds it was wrong (See Farrant and Doe, The Age April; 10 2002).

3.9.4 New South Wales

New South Wales (NSW) enacted legislation for reproductive technology in December 2007 through the Assisted Reproductive Technology Act 2007, however the Act has not yet commenced⁸⁶. Prior to this, ART providers were essentially self regulated and adhered to the NHMRC Guidelines and RTAC Code of Practice if accredited under the FSA (NSW Health, 2003). Semen donation was regulated by the Human Tissue (HT) Act 1983 and research on human embryos was regulated by both Commonwealth and State legislation (HWL Ebsworth 2008).

The original HT Act 1983 regulated:

- Donations of tissue by living adults and children;
- Blood donations;
- Removal of tissue after death;
- Post mortem examinations; and
- Prohibition on trading in tissue.

The HT Act was amended first in 1985 to ensure that blood and semen donations were screened for diseases such as HIV and then again in 1987 to protect suppliers of semen and blood products from litigation in relation to transmission of diseases and to regulate private suppliers of such products⁸⁷.

In 1997 the NSW Health Minister initiated a review of the HT Act as part of a process of determining an appropriate regulatory framework for assisted reproductive technology in that State. At that stage there was no requirement for a special licence for a registered medical practitioner to provide ART services. A key issue for NSW was whether the practice of ART was substantively different to other medical practices so as to justify a separate licensing system (NSW Health 1997, 13). Related to this was eligibility of access to ART; should it be limited to the medically infertile

⁸⁶ Due to commence on 1 January 2010

⁸⁷ see http://www.austlii.edu.au/au/legis/tas/consol_act/hta1985160/s33.html

or inclusive of those who chose not to reproduce through coitus. Again the issue was whether this private decision between a medical practitioner and client should be regarded any differently to any other decision for medical intervention or treatment (NSW Health 1997, 17).

Following an extensive consultation process with ART providers, churches and church organisations, various community groups and individuals (NSW Health 2003), a draft exposure of the Assisted Reproductive Technology (ART) Bill was tabled in the NSW parliament in 2003. While the consultation found that clinical practice of ART had been effectively self regulated, a range of issues relating to the social and ethical aspects of ART needed to be addressed through specific legislation (NSW Health, 2003, 3). NSW already had a raft of regulations for medical practice and some aspects of ethical practice related to ART⁸⁸ thus the focus of the new legislation was on aspects which were currently unregulated and posed social or individual harms. These were identified as harms to donor offspring and their families from denial of information about genetic parentage; ensuring that gametes and embryos were used only in ways consistent with the wishes of their donors; and harms to society from the introduction of commercialism into human reproduction (NSW Health, 2003, 6).

⁸⁸ See NSW Department of Health (2003, 6)

1. Registration and a disciplinary framework for various health professional groups including medical practitioners and nurses;
2. The resolution, investigation and prosecution of complaints under the Health Care Complaints Act 1993;
3. The regulation of drugs, poisons and other therapeutic goods under the Therapeutic Goods Act 1989 (Commonwealth) and the Poisons and Therapeutic Goods Act 1966 (NSW);
4. A quality assurance mechanism through voluntary membership of the Fertility Society of Australia;
5. Licensing under the Private Hospitals and Day Procedure Centres Act 1988 (many ART providers are licensed day procedure centres)
6. The collection of clinical data through the National Perinatal Statistics Unit
7. Common law actions by individuals who suffer personal injury through the negligent provision of ART treatment.
8. The prohibition on cloning and other unethical practices and regulation of research on embryos by the NHMRC under the complementary Commonwealth and NSW Human Cloning and Other Prohibited Practices and Research on Embryos Acts.

The draft Bill proposed a licensing system for ART providers under the Director General of Health and the regulation of ART treatment including requirements that services be provided by a medical practitioner and counselling services be available (NSW Health, 2003, 7-8). A core component of the regulatory framework was the establishment of a central donor register, to be administered by the Department of Health, which would store information on gamete donors, persons undergoing ART treatment using donated gametes and persons born from donated gametes and provide donor born children access to 'comprehensive identifying information about their genetic parentage' (NSW Health 2003, 15).

Unlike other jurisdictions, the NSW Bill proposed no eligibility criteria for access to ART treatment. Arguing that, as the law does not impose any restriction on people in the general community who wish to become parents and it is considered a fundamental right to have children if and when one chooses, then the law should not distinguish between classes of people who can become parents through ART. The law had a role in protecting children who suffer harm from their parents and would continue to do so (NSW Health, 2003, 7). As with other jurisdictions there were provisions in the Bill for storage of gametes and embryos, consent processes for use of embryos including posthumous use and limitations on the numbers of women who could receive treatment using the gametes of any one donor.

Somewhat controversially NSW proposed that donors could place criteria on the recipients of gametes leading to claims of discrimination if restrictions were based on gender, religious beliefs or sexual orientation. The rationale was children's interests are best protected when the genetic parent has given consent to the circumstances in which the child is to be raised but this was criticised as enshrining bigotry and discrimination in legislation (Edwards, 2007).

The stated objectives of the NSW ART Act 2007 are:

- (a) To prevent the commercialisation of human reproduction; and
- (b) To protect the interests of the following persons:

- (i) A person born as a result of ART treatment;
- (ii) A person providing a gamete for use in ART treatment or for research in connection with ART treatment;
- (iii) A woman undergoing ART treatment (ART Act 2007, Section 3).

The Act regulates a number of other aspects of ART treatment, including surrogacy, export and import of gametes and infection control standards for ART providers (HWL Ebsworth 2008). It clarifies and reinforces the rights of donor conceived children and donors. Specifically it protects the rights of future children through access to information of their donor parent through mandatory storage of information on a central register. Individuals who previously donated anonymously are not required to provide information for the register, but can volunteer to do so (NSW Health 2007).

The NSW legislation does not explicitly address the moral status of the embryo, merely defining the embryo as ‘... the single entity formed by the combination of a human sperm and a human ovum until the time it is implanted in the body of a woman’ (ART Act 2007, Part 1 Section 4)

3.9.5 Surrogacy Legislation

In 1991, a joint meeting of the Australian Health and Welfare Ministers agreed for the need for consistent national legislation to restrict and discourage surrogacy arrangements to protect ‘women and children from exploitation’ (Krohn, 1996). As with ART legislation this has not occurred and there are a range of regulatory arrangements for surrogacy throughout Australia.

As discussed above, in Western Australia the Surrogacy Act 2008⁸⁹ permits altruistic surrogacy under certain conditions and allows judges of the Family Law Court to

⁸⁹ see <http://www.familycourt.wa.gov.au/S/surrogacy.aspx?uid=1460-8294-1524-5599>

make parentage orders which transfers legal parentage of a child from the surrogate birth parent to the child's arranged parents.

The Tasmanian Surrogacy Contracts (TSC) Act 1993 prohibits advertising, promoting, organising or providing technical arrangements for surrogacy and makes surrogacy contracts 'void and unenforceable' (TSC Act 1993, Section 7). The Tasmanian Legislative Council Select Committee (LCLS) on Surrogacy reviewed surrogacy regulations in 2008 and made a number of recommendations for change. They recommended a continuing ban on commercial surrogacy and a range of conditions for altruistic surrogacy including a requirement that 'prospective parties to an altruistic surrogacy agreement to enter into a formal pre-conception agreement detailing all of the anticipated roles, contributions, expectations and potential outcomes (both short-term and long-term) relating to the agreement' (LCLS 2008, 4). As with ART legislation, protecting the best interests of any children born as a result of surrogacy arrangements underpins all recommendations.

The Australian Capital Territory Substitute Parents Agreement (SPA) Act 1994 prohibited commercial surrogacy and regulated the application and granting of parentage orders. No offence was committed in the case of an altruistic agreement but any such agreement had no legal validity except to establish the circumstances in which a parentage order could be made. The SPA was repealed when the new Parentage Act 2004 became law but the new Act continues the provisions of the SPA Act in relation to surrogacy arrangements (ACT Legislative Assembly 2003, 8).

The Queensland Surrogate Parenthood Act 1988 proscribes all forms of surrogacy in that State.

3.9.6 State and Territory Legislation on Embryo Research and Cloning

Following the enactment of national legislation to regulate embryo research and cloning, State and Territory ministers committed to enacting consistent legislation in their own jurisdictions. Relevant legislation has been enacted in all States and

Territories⁹⁰ with the exception of the Northern Territory where legislation is being drafted. In some cases, the new legislation has impacted on the research aspects of ART and resulted in amendments to State based ART legislation as discussed above.

3.10 Family, Liberty and Rights

ART is simultaneously a clinical service, a scientific endeavour and a commercial venture. In Australia it is heavily subsidised through public funding in the name of access and equity.

As the ART policy domain has matured a number of very significant shifts can be detected. From its origins as a miracle technology for the treatment of very specific clinical infertility problems it has become the treatment of choice for infertility of all origins. From early concerns about the potential risks of ART to children and women, reproductive technologies are now an established routine specialist medical service in Australia. Relatively low success rates have not reduced demand for services and as women continue to leave childbearing until a later age, it is unlikely demand will decrease.

The controversies in the Australian policy debate, as in other developed countries have centred on access and public funding. These debates are embedded in contests over who has a right to be a parent and the interests of ART conceived children. Feminists, initially critical of ART as an instrument of patriarchal power now view the technologies as potential instruments to undermine patriarchal constructions of family and reproduction (Michelle, 2006). Debates over the rights and interests of embryos themselves rarely cause a ripple outside of the Catholic Church despite the

90 ACT: Human embryo (Research) Act 2004, Human Embryo (Research) Act 2004.

NSW: Human Cloning and Other Prohibited Practices Act 2003.

QLD: Research Involving Human Embryos and Prohibition of Human Cloning Act 2003.

SA, Research Involving Human Embryos Act 2003.

Tasmania: Human Embryonic Research Regulation Act 2003.

Victoria: Research Involving Human Embryos Act 2008, Prohibition of Human Cloning for Reproduction Act 2008.

WA: Acts Amendment (Prohibition of Human Cloning and Other Practices) Act 2004.

embryo being central to the practice of ART. While the conservative pro life lobby voice concern over ART practices that result in the loss of embryonic life and the construction of embryos as quality products, they fall short of taking an anti IVF stance. Rather, along with other social conservatives, they focus on promoting policies that limit access to services to people in traditional nuclear family structures. Again this was justified as protecting the interests and wellbeing of future children.

Recent changes to legislation in Victoria and NSW, as discussed above, indicate that this policy battle is lost. The very possibility of ART provides a solution to involuntary childlessness for all who find themselves in that position. Implicit in this is a right to fulfil the child wish. Just as the state has no right to interfere with reproductive choices of the fertile, it has no right to limit the reproductive choices of the infertile. Contemporary ART policy in Australia is driven by a new construction of procreative liberty. In this policy framework the ART embryo is a means to an end. Its value lies not in its intrinsic worth but in its capacity to fulfil other needs. Contemporary ART policy also reconstructs ideas of family and the rights of children. Where family was once constructed as a traditional kinship arrangement of biologically related father, mother and children, it now takes many other forms. Where the interests and wellbeing of ART conceived children were situated in a rights based claim to a mother and a father in a traditional family arrangement, they are now situated in the rights to knowledge of their genetic heritage.

The situating of ART policy within the health policy context results in a fragmented policy response. Prior to the implementation of the various State legislations, ART was a self regulated medical enterprise much as any other. ART is still essentially a private transaction between client and doctor in the private world of reproduction. The Australian federal system, which places responsibility for provision of health services under the jurisdiction of States and Territories, gives the Australian Government little control over the regulation and practice of ART. Medicare is essentially the only policy lever available and as discussed above, the IVF lobby is quick to protect their position when any undesirable changes to existing arrangements

are proposed. Despite intermittent calls for a national regulatory framework, it has never eventuated.

Clinical practice and scientific research are inextricably intertwined in ART. Scientific research in ART has focused on improving ART outcomes, ultimately measured in live births. Scientists working in ART were guided by the NHMRC (1994) guidelines which cautioned respect for embryos and recognition of their special status, and institutional ethics committee approval of research. While research on embryos remained in the context of ART, it received little attention from the outside world but things were about to change. In the 1990s with the cloning of Dolly the sheep and the establishment of the first embryonic stem cell lines, the embryo and the scientists took central stage in one of the most contentious policy debates of the early twenty first century.

In the next Chapter I discuss the controversies and policy responses to human embryonic stem cell research and cloning in Australia.

4 Chapter 4 Embryonic Stem Cell Research and Cloning

Stem cell science has captured the imagination of scientists, clinicians and the public worldwide because of its' immense *potential* for therapeutic applications particularly for human health and well being. How and when that potential is realised remains contested. Stem cells are the 'precursors of functional tissue' defined by their capacity to reproduce themselves and to differentiate into specialised cells (Panter 2002, 1). Stem cells derived from embryos are known as embryonic stems cells (ESC) and those derived from humans after birth are termed adult stems cells (ASC).

ESCs were first isolated from mouse blastocysts in the early 1980s and from humans in 1998. Australia quickly moved to the forefront of the new biotechnology, with the development of stem cell lines from ESC derived from human embryos in 2000 (Dodds and Ankeny 2006, 3). ESCs are pluripotent⁹¹ which means they can differentiate into a large number of different specialised tissues. This capacity for self renewal and differentiation into a variety of cell types has broad applications for research and potential therapeutic purposes (Robertson 1999, 109) particularly for regenerative medicine including the creation of immunologically compatible replacement organs. ESCs have been mooted as providing prospective cures for disorders such as diabetes, Alzheimer's disease, Parkinson's disease, Huntington's disease, motor-neurone disease and a range of cancers, treatments for spinal cord injuries through generation of neurological tissue and the creation of blood products for transfusion as well as transplant organs.

ASC, usually found in bone marrow, brain and fat tissue are termed multipotent⁹². Their potential for differentiation was initially understood to be limited to cell

91 Panter (2002) distinguishes between pluripotent cells which can differentiate into many different cell types and totipotent cells which can give rise to a completely new organism. ESC are pluripotent. An individual ESC can be used to create a stem cell lines which can reproduce indefinitely. The stem cells arising from a stem cell line are genetically identical to each other. Each stem cell in a human stem cell line is potentially able to differentiate into any one of around 220 different human cell types. A fertilised egg is totipotent. Also see Australian Stem Cell Centre website

http://www.stemcellcentre.edu.au/public-education_what-cells_types.aspx Accessed 20 July 2006

92 Jiang et al. (2002:41) reported pluripotency of adult stem cells derived from bone marrow in *Nature*.

lineages found within the tissue of origin however more recent research into ASC demonstrates a greater potential for plasticity than originally believed (Vats et al. 2005, 295, Panter 2002, 1). Stem-cell populations are also present in the foetus during gestation (NHMRC 2002) but research into the clinical applications of these stem cells has been limited due to potential harms to foetus and the pregnancy from intrauterine procedures (Vats et al. 2005, 294). Stem cells can be found in umbilical cord blood⁹³ (NHMRC 2002) and collection and banking of cord blood is available at both public and commercial facilities in Australia (Samuels et al. 2007, Sullivan 2008).

Basic research into both ASC and ESC science is an essential antecedent to any clinical or therapeutic applications of stem cell science. Basic research in the biomedical sciences is costly and proceeds slowly, with vaunted 'breakthroughs' often the result of years or even decades of scientific endeavour. Clinical trials⁹⁴ in humans typically occur in stages over lengthy time periods, following laboratory based research and trials in animal models, so that efficacy and safety can be evaluated. In stem cell science, ongoing basic research is necessary to assess stability, risks of genetic mutations, transfer of harmful pathogens and of forming unwanted tissues and cancers (Vats et al. 2005, 592). The growth of human ESC efficiently, reliably and in large enough numbers is the only first step in developing regeneration therapies (Robertson 1999, 110) and while research holds great promise, actual progress in terms of novel therapies has progressed slowly. By 2005 advancement had been made into understanding the mechanisms of differentiation and a wide variety of cell types were able to be produced from ESC but few had been used therapeutically (Vats et al.

93 A baby's cord blood has a 100% match for the baby, 50% chance of a match for siblings and father and a 95%+ chance of a match for mother. See www.Stemlife.com.au accessed 16 June 2009

94 see www.nlm.nih.gov/services/ctphases.html, / www.medicinesaustralia.com.au

Phase I: A new drug or treatment is tested in a small group of people, usually a healthy volunteers, for the first time to evaluate safety, determine a safe dosage range, and identify side effects.

Phase II: The drug or treatment is given to a larger group of people with the condition for which it was developed, to see if it is effective and to further evaluate its safety.

Phase III: The drug or treatment is tested on larger sample to confirm its effectiveness, monitor side effects, compare it to other treatments, and evaluate safety

Phase IV: Studies are done evaluate drug's effect in various populations and any side effects associated with long-term use

2005, 296). More recently, cautious but hopeful progress in stem cell applications for the treatment of heart disease has been reported (Zhang and Pasumarthi 2008, 361) as have developments for treatment for haematological, cardiovascular and central nervous system disorders in animal models (Tani and Umbas (2009, 30). In January 2009 the University of Glasgow and the ReNeuron Group⁹⁵ announced a clinical trial with stem cell therapy for stroke victims, the Geron Corporation⁹⁶ received Federal Drug Administration (FDA) approval for a world first clinical trial of ESC based therapy for acute spinal cord injury and TCA Cellular Therapy⁹⁷ expect Phase II trials of stem cell therapy for ischemic heart disease to commence in 2009. In Australia the Embryo Research Licensing Committee (NHMRC 2008) has issued a license for collaborative research between IVF Australia and the Diabetes Transplant Unit, Prince of Wales Hospital, to derive human embryonic stem cell lines for the treatment of diabetes and the Australian Stem Cell Centre⁹⁸ (ASCC) is currently focused on therapeutic stem cell technologies for the creation of blood products for treatment of human haematological diseases using both ESC and ASC.

While ongoing research into adult stem cells continues and is an important scientific endeavour with its own merits, it is ESC research which intrigues scientists and continued access to ESC underpins future research. Greber and Schöler (2008, 1005) and Yu et al. (2007, 1917) report advances in reprogramming somatic cells into ES like cell lines which have potential for clinical applications once safety issues are addressed. These induced pluripotent stem (IPS) cells resemble ESC in morphology, proliferation, surface antigens, gene expression and pluripotency so have similar potential for regenerative therapy as ESC without the attendant ethical dilemmas (Meyer 2008, 849). To date, however, human embryos still remain the most reliable source of ESCs for research and this presents policy makers with a significant ethical dilemma. ESCs are extracted from the embryo at the blastocyst⁹⁹ stage of growth, a process which destroys the embryo's capacity to develop further. By contrast the

95 See <http://www.reneuron.com/>, Accessed 12 April 2009

96 See <http://www.geron.com/>, Accessed 12 April 2009

97 See <http://clinicaltrials.gov/ct2/show/NCT00790764>, Accessed 12 April 2009

98 See http://www.stemcellcentre.edu.au/research-development_funding.aspx, Accessed 12 April 2009

99 5-7 days after fertilisation

extracted stem cells can be grown in culture and can replicate indefinitely in an embryonic stem cell line (Norberry 2002, 4). In essence they are immortal. Human embryonic stem cells, with the ability to proliferate apparently indefinitely in vitro and the capacity to differentiate into any somatic cell type¹⁰⁰, are therefore an important resource (Vats et al. 2005, 293).

ESCs for research are most commonly sourced from donated¹⁰¹ surplus ART embryos which would otherwise be allowed to 'succumb'. In theory, however, an endless supply of research embryos could be specifically created using ART or cloning technologies. As new discoveries are made and research progresses it is probable that scientists pursuing specific lines of research will require ESC from embryos with specific characteristics, for example, a particular genetic abnormality.

There are two inescapable factors which policy makers, researchers, clinicians and the public need to confront when discussing ESC research:

- The source material is a living human embryo which has the potential to develop into a human being;
- Present ESC extraction techniques result in the death of the host embryo.

This brings a distinct ethical consideration into this policy arena characterised by deeply held and conflicting beliefs about the nature and value of human life. In part these echo debates from other policy arenas namely abortion and ART. However ESC debates are not just about ethics. They are firmly situated in the discourses of science and technology, health and global economics. Biotechnology in general and ESC in particular is 'big science' in terms of competitiveness, financial investment¹⁰² and potential rewards for individuals, companies and nation states. How the state responds to the policy challenges of ESC has important ramifications not only for the

100 See Vats et al. (2005). ESC have been differentiated into neurons, (oligodendrocytes, and glia), cardiomyocytes, osteoblasts, hepatocytes, and haemopoietic progenitors to date.

101 Surplus embryos can be donated by their biological 'parents' for research or reproductive purposes.

102 Worldwide Markets and Emerging Technologies for Tissue Engineering and Regenerative Medicine, predicts the largely untapped global market potential for tissue engineering and regenerative medicine products will exceed \$118 billion by 2013.

public values it espouses at a national level but where it is positioned in the international arena of science and technology.

In the first part of this chapter I will examine the key issues which have confronted policy makers world wide in relation to human ESC research and the associated issue of cloning. In the second part I will discuss the Australian policy context and the Australian policy response.

4.1 Cloning and Somatic Nuclear Cell Transfer

Cloning is a separate but related issue for ESC research. The term 'clone' was first used in the early twentieth century to describe grafting techniques for plants but by has now become common language to mean 'reproductions or carbon copies' (Gogarty 2003,86). The Australian Academy of Science (AAS) (1999, 4) defines cloning as production of a cell or organism with the same nuclear genome as another cell or organism. Cloning describes a number of processes and techniques¹⁰³ which involve making a copy of biological material including a human embryo (Johnson 2001, 1) and in the case of Dolly, a complete live mammal¹⁰⁴ (Wilmut et al. 1997). Franklin (1999, 114) argues 'the term 'cloning' belongs less to scientific than to popular discourse, where it has increasingly come to be used as a condensed signifier for the potential of genetic science to produce unnatural kinds.'

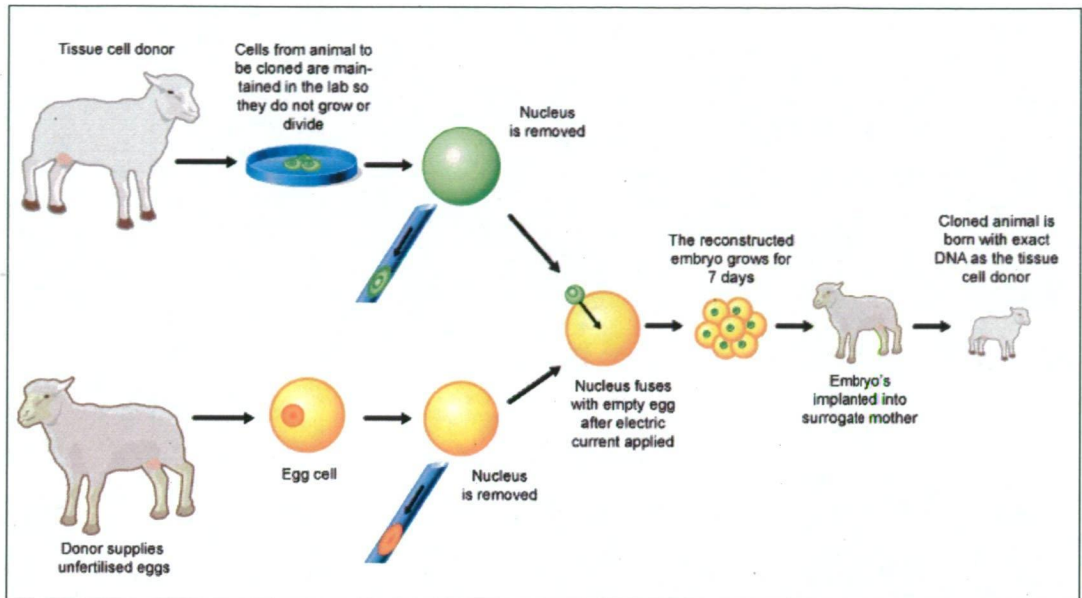
In this discussion cloning is taken to mean the scientific procedure of somatic cell nuclear transfer (SCNT). In this technique, the DNA from a somatic cell (usually skin or muscle cell) is removed and transferred through a microscopic glass tube into an enucleated unfertilized ovum. In a culture dish, the ovum is then coaxed into developing as if it had been fertilized (Mollard 2005). Under the correct conditions

103 See Franklin 1999. Cloning can refer to natural occurrences such as mitosis or asexual reproduction which occurs among micro-organisms and plants, some fish, reptiles and amphibians. Twinning which occurs both naturally and technologically induced by splitting an embryo, Somatic cell nuclear transfer and pathogenesis.

104 Wilmut did not use the term cloning in his 1997 publication (discussed in Franklin 1999).

the cells will continue to divide until an embryo is formed. The resultant embryo will be a genetic match for the donor of the original somatic cell as illustrated in Figure 4.

Figure 4 Somatic Cell Nuclear Transfer



Source: www.biotechnologyonline.gov.au

Cloning is related to ESC research in that a cloned embryo is *one* possible source of embryonic stem cells. A clear distinction needs to be made between ESCs and embryos. ESCs are not embryos. ESCs are pluripotent cells which are *incapable* of forming a new individual or being transplanted into a uterus to grow into a child, whereas an embryo is a totipotent¹⁰⁵ entity, which given the right conditions will develop into a complete human (Robertson 1999, 111).

A distinction is usually made between therapeutic and reproductive cloning on the grounds of intent. Therapeutic cloning involves cloning a human embryo for the purpose of extracting embryonic stem cells for therapeutic use in the individual from whom the clone originated (Norberry 2002, 4). The advantage being that the donor

¹⁰⁵ This distinction between the pluripotency of embryonic stem cells and the totipotency of the embryo was used by General Counsel Harriet Raab in the United States to allow ESC research under the then Federal law. She concluded that ESC did not have the status of embryos because they did not have the capacity to grow into an individual with all life functions. This ruling was described as 'disingenuous' and 'legalistic' by opponents of ESC research who argued that the derivation and use of ESC could not be legally or morally separated.

and the recipient are genetically the same persons which means there is no risk of rejection of a created replacement organ (Norberry 2002, 4) or rejection of transplanted somatic cells for regeneration of diseased organs and tissues in situ (Panter 2002, 9). Vats et al. (2005, 299) argue SCNT offers the greatest potential to revolutionise regenerative medicine through the potential for perfectly matched tissues and the development of experimental models to 'elucidate the pathogenesis and development of specific diseases'.

In 2001, Advanced Cell Technology (ACT) announced that it had created the world's first human embryos produced via cloning¹⁰⁶ but none of the embryos developed sufficiently to produce stem cells (Johnson 2001, 2). In 2004 Hwang and colleagues reported the significant breakthrough of a human ESC line from a cloned blastocyst (Hwang et al. 2004, 1669). In 2005 they received worldwide acclaim in the scientific and popular media¹⁰⁷ when they announced the creation of patient specific stems cells from a SCNT procedure (Hwang et al. 2005, 1777). In December 2006, following an investigation into alleged scientific fraud¹⁰⁸, the prestigious journal '*Science*' retracted both articles on the grounds that evidence had been fabricated (Kennedy 2006, 335). Hence, the current state of the science is that donated ART embryos are the most common source of ESC for research and the effective production of patient specific stem cells for clinical application is an ongoing endeavour.

Theoretically the cloned embryo could be implanted in a woman's uterus and gestated. That is, its *purpose* is reproductive. Reproductive cloning is widely opposed by the general community, policy makers and the majority of scientists (Hall, 2002, AAS, 1999^a, AHEC 1998, Annas 1998^b) however there are others who argue that reproductive cloning can be considered as another ART technology (Elsner 2006, Savulescu and Harris 2004, Robertson 1999) supportable in the name of procreative

106 See Johnson 2001. Using SCNT scientists created 19 clones of which seven began to divide. Two reached the four cells state and one embryo divided into six cells before division stopped. A further 22 clones were created using pathogenesis of which six matured into a larger mass of cells before division stopped.

107 See Vats et al. 2005; Kalb 2005; Magnus and Cho 2005.

108 See Investigation Committee Report, Seoul National University, 10 Jan. 2006 (Chairman Myung-Hee Chung, SNU)

liberty. Robertson (1998^a, 1372) argues that provided safety issues can be resolved, reproductive cloning

would appear to be part of one's fundamental right to have and rear children.

The key ethical, legal, and policy question then posed is whether the use of cloning to achieve these goals presents such special risks or problems that prohibition or close regulation is justified (Robertson 1998^a, 1372).

Further Robertson (1998^b, 119) argues that given the difficulties involved, a couple is unlikely to choose to reproduce through cloning if other viable options for a biologically¹⁰⁹ related child are available. Nonetheless, generally reproductive cloning is not supported on several grounds, foremost the absence of medical need and the potential risks to women and the cloned offspring (Gogarty 2003, Andrews Report 2002).

The safety aspect is a particular concern given the high failure rate of creating successful mammal clones to date and the health and developmental problems suffered by cloned animals (Bowring 2004, 403). For example, the Dolly experiment required 400 unfertilised eggs of which 277 had their nucleus replaced with a somatic cell and stimulated into developing embryos. 29 embryos were implanted into 13 ewes resulting in a number of miscarriages and deformed offspring. And only one lamb was born normally (NHMRC 2002, Attachment A). The attempt to clone a human being is thus thought to be inherently dangerous irrespective of any moral considerations (AAS 1999, NHMRC 2002, Annas, Andrews and Isasi 2002).

Further arguments against reproductive cloning include the threat to human diversity due to a diminishment of the gene pool (Gogarty 2003, 84) and the ever present spectre of eugenics (Shapiro 1997, Kass 1998) when any new technical intervention in the natural process of human reproduction is considered. Annas, Andrews and Isasi

109 Robertson 1998 suggests that a couple could choose cloning if they were infertile but wished for a child who was biologically related to one or both of them through using the father's DNA and the mother's donated oocyte. Other scenarios include couples at high risk of transmitting a genetic disease, or where the father has infertile sperm but does not wish to use a donor gamete.

(2002, 161) and Kass (2003, 11) argue that the combination of market forces and scientific capacity will create the demand for cloned and genetically altered humans; a 'neo eugenics' which could result in both superspecies and subspecies of humans.

Reproductive cloning it is argued, devalues the cloned person by depriving them of their uniqueness (McCormick 1994, Shapiro 1997, Annas 1998, Bowring 2004).

Given that other factors such as uterine environment, social interactions, and temporal differences will impact on any cloned individual, it is unlikely that such an individual would be identical to its donor. In this sense it is still a unique individual. Robertson (1998^b) suggest that the naturally occurring phenomena of monozygotic twins demonstrates that having the same genome as another human being is not in itself harmful, to the contrary twins often have a closeness which other siblings lack. Therefore there is no reason to believe that a 'twin' formed through cloning and born at a later date would be disadvantaged on the grounds of uniqueness.

Further, it is argued that human dignity is affronted by reproductive cloning which treats humans as means rather than ends in themselves. Highly valued social principles such as choice, agency and individuality are arguably violated in the act of cloning (Harvey 2005, 131). For other critics, the issue is not so much the genetic identity of the clone, but the act of control in creating the clone (Catholic Archdiocese of Melbourne, 2002¹¹⁰). The loss of autonomy and dignity arises from the clone being a 'predetermined product' ordered to fulfil the requirements of the donor (Bowring 2004, 405).

As demonstrated in the Hwang scandal¹¹¹, the issue of coercion of women has applications for therapeutic as well as reproductive cloning as long as human oocytes remain a vital part of the procedure. Exploitation and commodification of women, particularly the poor and uneducated (Beesom and Lipman 2006, Baylis and McLeod

110 Submission No 876 to Senate Community Affairs and Legislation Committee (SSCALC) 2002

111 See Holden 2005

2007, Meyer 2008) is an important feminist¹¹² issue for the wider ESC research debate. The arguments that ESC research reinforces patterns of oppression and domination in society and male-dominated medical / scientific practice appropriates their reproductive labour for research and commercial benefits (Rickard 2002^b, 5) echo those of the ART debates of previous decades. The arguments against reproductive cloning on the grounds of disruption of family relationships and kinships ties have been also debated widely in the ART literature as discussed in Chapter 3.

4.2 Demand for Embryonic Stem Cells

There are already a number of established stem cell based treatments for human diseases including some cancers, immune system deficiencies and Parkinson's disease. Stem cells for these treatments are sourced variously from bone marrow, umbilical cord blood and the brains of aborted foetuses. These sources of stem cells present a number difficulties for researchers including moral objections to the use of aborted foetuses, technical complexity in removing brain cells, limited supply and the probability that adult stem cells will age prematurely. ESC by contrast offers potentially unlimited supply and maximum flexibility in applications, particularly where specific cells are created through cloning technology (Panter 2002, 6-7). The possibility of using somatic-cell nuclear transfer to create autologous human embryonic stem cells for therapy has been a technical possibility since the creation of the first cloned animal. Thus along with the increased recognition of the potential of ESC has come an increased demand *by* science to conduct research in this field and an increased demand *for* access to ESC.

4.3 Contested Issues

As with ART, ESC research and cloning present public policy with deeply divisive value conflicts. The political struggle over the moral status of the embryo which informs both abortion and ART policy debates reaches its zenith in the ESC research

¹¹² See George 2008, Beeson and Lipman 2006, Rothman 1988, Dickenson 2002, Ettore et al. 2006 as discussed in Chapter 3

and cloning debates. As such, it is not a new value conflict but a constant feature which reemerges with each significant scientific breakthrough (Salter 2007, 271). The stem cell debates, yet again expose the conflicts between 'those who would privilege scientific progress and individual choice' (Green 2008, 840) over all other values. They bring into sharp focus '...competing visions of gender, family and society' constructed by shifting social and cultural discourses (Green 2008, 841). The ethical debate begins with an uncomfortable fact; extraction of embryonic stem cells results in the death of the host embryo. The morality or otherwise of this process is contingent on the moral status of that host.

4.3.1 Destructive Embryo Research

Destructive embryo research is an ethical dilemma because it brings two fundamental moral principles into conflict,

- Prevention or alleviation of suffering
- Respect for the value of human life.

The harvesting and culturing of embryonic stem cells has considerable potential to bring about health benefits thus fulfilling the first principle but the resultant destruction of embryo violates the second principle because a human life with value is destroyed (Rickard 2002^b, 2). Embryonic stem cell research calls for a judgment over which principle should take precedence. More simply put, do the potential benefits of ESC research ethically justify destroying embryos?

Devolder (2005, 366-7) identifies a number of principles which can be applied to ethically justify destructive ESC research. Firstly freedom of research claims restraints on scientific research are inherently offensive and unjustifiable and that we have a right to acquire new knowledge. Secondly the bioethical principles of beneficence and non-maleficence¹¹³ claim a moral compulsion to pursue actions which benefit people and protect against wrongs or harms. Thirdly the intention of

¹¹³ See Beauchamp and Childress 2001. The four pillars of classical bioethics are autonomy, beneficence, non maleficence and justice.

the research, increased health and wellbeing of fellow humans fulfils the principle of proportionality. Finally, the principle of waste avoidance is fulfilled when a valuable resource, which would otherwise be discarded, is put to good use (Devolder 2005, 366-7).

This in turn raises a number of other questions; what is the real value of ESC research, how is the value of an embryo determined and what if anything is morally wrong in destroying an embryo (Rickard 2002^b, 2)? The first question is easiest to answer given the consensus that the value of ESC research lies in its potential to alleviate human suffering through a multitude of possible therapeutic applications, which can only be realised through continuing research, basic and applied. However in emerging scientific areas, it is not easy to predict timelines, outcomes and breakthroughs and this uncertainty is a factor in evaluating the ethical consequences of embryonic stem cell research (Rickard 2002^b, 3).

The other questions are more demanding. Irrespective of the benefits, there is a moral cost. Embryos, whether created specifically through therapeutic cloning or surplus to ART requirements, are destroyed for their component parts. Whether this is acceptable depends on how the embryo is constituted and constructed in terms of moral, material and social worth. The central consideration is the moral status of the human embryo, which can be thought of as on a continuum from human being with full moral status to organic material with no more moral standing than any other body part (Rickard 2002 b, 6). This is not a question of fact but a question of value (Warnock cited Harris 1992, 31). And it is with such questions of value, that rational instrumental policy making struggles.

4.3.2 Moral Status of the Embryo

There is very little scientific disagreement that every embryo is a continuous human life. What is argued is the status of that life on a continuum from no moral status to the full moral status afforded any other living human (SCALC 2002, 42). As discussed in the previous chapter, at one end of the continuum, the potential of the

pre-implantation embryo to grow into an individual human being confers on it the full moral status of a human being¹¹⁴. This accords with the traditional Roman Catholic view, that from the moment of fertilisation, whether through natural or induced means, the embryo is a human being entitled to the rights and protections of any other human being (Cameron and Williamson 2005, 216). In this view any non-therapeutic research on the embryo which results in harm is immoral regardless of any benefits which may result. At the other extreme is the belief that such a rudimentary structure, without central nervous system or sentience has no moral status or interests. The latter view does, however, accord the embryo 'special respect'¹¹⁵ by virtue of its potentiality to become a human being (Robertson 1999, 117-8).

Denial of full moral status is based on the belief that embryos lack specific capacities, including consciousness, reasoning and sentience. The 1994 Human Embryo Research Panel (HERP) in the US found that the preimplantation human embryo 'warrants serious moral consideration as a developing form of human life' but 'does not have the same moral status as infants and children, because it lacks most qualities considered relevant to the moral status of persons' (Stith-Coleman 1998, 4). The embryo can be regarded as an important symbol of human life but its symbolic value and intrinsic value are separate. Its intrinsic value lies in its utility for legitimate scientific and medical endeavour thus the great potential to treat or prevent disease warrants destructive research of those embryos no longer wanted or needed for reproduction (Robertson 1999, 118-9).

Attributions of moral worth to embryos have typically been characterised by attempts to isolate an 'objective' point, through identification of biological markers, at which a morally relevant difference can be determined (SCALC 2002, 46). Thus the moral consideration given to the unborn human changes with specified milestone

114 See discussion in Cameron and Williamson 2005 of different religious and secular perspectives.

115 The 1984 Warnock Report found that legally the human pre-implantation embryo did not have the same status as a living child or adult but the pre embryo of the human species did have a 'special status'. Similarly in the United States, in 1979, an Ethics Advisory Board for the Department of Health Education and Welfare found the 'human pre embryo is entitled to profound respect but this does not necessarily encompass the full legal and moral rights attributed to persons' (Cited in Robertson 1999, 120)

developmental stages. For example the appearance of the primitive streak at 14 days post gestation¹¹⁶ is one such milestone, which recognizes the significant biological distinctions between the earliest human embryos and those which have begun to initiate organogenesis (Daley et al. 2007, 604). The transformation from embryo to foetus at the end of the eighth week after fertilisation is another developmental milestone (NHMRC 2005, 4). Cameron and Williamson (2005, 220) argue that respect is due an embryo once it has been successfully implanted in the uterus because this ‘gives a group of cells the ability to progress to a living human without further scientific intervention’. Respect increases as the pregnancy progresses and the prospect of a live birth increases. This reflects the scientific concept of a ‘multifactorial processes of development ... which combines recognition of observed events with potential for further development’ (NHMRC 2005, 4) and a concept of fertilisation and development as dynamic processes which can ‘only be defined by observation of specific markers’ (NHMRC 2005, 4). This focus on developmental stages sidesteps the issue of the moral status of the entity which is at the centre of controversy over the use of embryos. Such ‘empirical investigations’ are *interpretations* of moral status rather than an objective measure but they have become the prerequisite for workable policy. They help to establish both a timeframe (Parens 2001, 41) for which procedures can be lawfully performed on the nascent being and the range of acceptable practices including destruction.

Support for destructive ESC research is garnered from the fact the vast majority of embryos in question are surplus to reproductive requirements and will eventually be allowed to die. If they can be put to some good it is ‘...both crazy and wicked’ not to do so (Edwards cited Harris, 1992, 48). Even avowed social conservative, former Australian Prime Minister, John Howard agreed there was no qualitative moral difference between allowing an embryo to succumb and to be used for ESC research and a greater moral wrong occurred if valuable resource with the potential for so much beneficial research was wasted (Interview with Neil Mitchell April 2002).

116 The ‘14-day limit’ first articulated in 1984 by the Warnock committee of the U. K. Human Fertilisation and Embryology Authority. See www.hfea.gov.uk/cps/rde/xchg/hfea Accessed 16 September 2006

4.3.3 Creation of Embryos for Research

There are circumstances under which it may be optimal to create a specific embryo for a specific research or therapeutic purpose¹¹⁷ and this adds another layer of complexity to the ESC debate. Those who are opposed to all ESC research generally oppose creation of embryos specifically for research. There are differences, however, amongst those who agree that ESC is justifiable on surplus embryos. While they may agree that such embryos have no interests or rights they disagree with the creation of embryos where there is never any intent for implantation. The principal objection to the creation of research embryos is the use of 'a form of human life' as a means to an end which both instrumentalises and undermines respect for that life and violates its human dignity (Devolder 2005, 367). Opponents also fear that creation of research embryos will devalue the act of procreation and parenting as well as placing women at risk of exploitation as sources of ova from which they gain no benefits. These consequentialist concerns are based on fears that such production will undermine respect for other human research subjects, lead to a market for embryos for research and their use for trivial purposes (Robertson 1999, 123-4).

Arguments against embryo production can also be made from a deontological¹¹⁸ perspective. Robertson (1999, 127) argues that while one can acknowledge the important symbolism of the preimplantation embryos and that ordinarily they are created to bring that life to fruition, this in itself does not preclude them from being created specifically for research. Just as the discarded ART embryo can serve a greater good, so can the created for research embryo. He contends

The ethical acceptability of creating research embryos will turn on the symbolic/constructivist meanings associated with such a practice in light of

117 For example, to create genetically matched tissue for an individual or for research on specific diseases/conditions or for trialing patient specific drugs.

118 Deontology - an ethics based on acting according to duty or doing what is right, rather than on achieving virtue or on bringing about good consequences.

See www.filosofia.net/materiales/rec/glosaen.htm accessed 12 June 2009

the benefits that may be produced. Conclusions will depend upon perceptions of the importance of the research and the harm to respect for human life that creation of embryos is perceived to cause' (Robertson 1999, 128).

Devolder (2005, 366) argues there is an ethical inconsistency for supporting the 'creation and sacrifice of embryos to benefit infertile people with a child-wish' but condemning the 'creation and sacrifice of embryos to benefit ill and injured people.' In what she refers to as the Discarded Created Distinction, she claims it is inconsistent to believe the surplus ART embryo is not a person albeit has 'special moral worth' as a potential person and not believe the same of a created research embryo. If it is acceptable to use the former in destructive research than it is acceptable for the latter because they are the same entity with the same moral value therefore entitled to the same measure of human dignity. Thus, independent of people's intentions, there is no intrinsic moral difference between spare and research embryos (Devolder 2005, 368). The counterargument is that the act of creation of an embryo, for research purposes only, is an example *par excellence* of treating a human as a mere means which is morally wrong.

Savulescu (1999, 94) argues that it is not only reasonable to produce embryos as a source of stem cells but it is a moral requirement given the 'most justified use of human cloning is arguably to produce stem cells for the treatment of disease.'

Savulescu bases his case on a number of claims:

- The moral status of such an embryo is no different to the somatic cell from whence it emerged;
- No morally relevant difference exists between the foetus and the embryo until some critical point in brain development and function;
- The practice is consistent with existing practices of foetal tissue transplantation and conceiving humans as a source of tissue for transplantation;
- The practice fulfils the moral requirement of beneficence;

- In the interest of autonomy, individuals should be able to determine the fate of their own cells, including whether they change into other cell types (Savulescu 1999, 94).

These claims are in themselves open to challenge. Firstly, a somatic cell is demonstrably different to an embryo. The whole point of SCNT is to transform one thing into another; a somatic cell is stimulated so that it changes from a differentiated cell into a new entity capable of totipotent differentiation. The claim that two such different entities have the same moral worth is highly questionable. To equate embryo creation for stem cell harvest with existing practices of transplantation is problematic. In transplantation the host is not necessarily destroyed in the process. Further organs or other tissues are donated with the consent of the donor. The whole issue of saviour siblings stirs its own ethical controversies. The appeal to autonomy presents some difficulty. Human beings have no conscious control over what happens at a molecular level. They cannot direct cells to behave in specific ways. Irrespective of this, once the new entity is formed, it arguably has its own claims to autonomy. The issue of assigning moral worth contingent on developmental stage has been discussed elsewhere in this Chapter.

AusBiotech suggested the term 'Nuclear Transfer Progenitor', be used to describe the entity created through SCNT arguing this was more scientifically accurate and less likely to confuse or create unnecessary concern than the term human embryo clone (AusBiotech 2005, 6). In a similar vein, the Australian Stem Cell Centre (ASSC) suggested the embryos derived through SCNT technology, be labelled as a 'SCNT embryo' or 'human nuclear transfer embryo', thereby clearly identifying its lineage and method of being brought into existence' (ASSC 2005, 7) ostensibly to avoid any confusion.

In stem cell research, public policy has moral responsibilities for the welfare of the community, the donors of 'materials for the derivation of stem cells' and the recipients of stem cell technologies (Giacominia, Baylis and Robert 2007, 1491). The

issues affecting community welfare are similar to those of other health technologies including access and equity based on clinical imperatives, sustainability of the health system and the ethical imperative to use resources prudently. For donors of materials there are the potential harms to women resulting from invasive procedures, the self evident harms to embryos and the impacts of 'industrial' creation and destruction of embryos for routine clinical applications. Finally public policy has a responsibility to minimise risk and ensure the safety of those who receive stem cell interventions whether in a clinical trial or as the recipient of a novel treatment¹¹⁹ (Giacominia, Baylis and Robert 2007, 1492-3).

4.4 The Australian Policy Context

Within the Australian federal context, public policy has a distinct intergovernmental dimension lending to what Chapman (1990, 70) describes as 'legal, financial, and political complexity' to policy formulation, process and implementation. Within any federal system, national and constituent governments are both independent and interdependent, the degree of interdependence varying across different policy arenas (Chapman 1990, 71) and not all decisions involve more than one government. While there are number of different understandings of federalism¹²⁰, all federal systems have a core principle of divisions of power, function and responsibility between the component parts (Painter 1998, 62, Galligan, Hughes and Walsh 1991, 3) and they all require intergovernmental institutions and processes to manage this relationship. The Australian Constitution formally allocates specific and finite powers to the Commonwealth government but as the business of government becomes ever more complex, the lines between the formal jurisdictions of Commonwealth and State blur particularly in the social policy arenas (Galligan, Hughes and Walsh 1991, 3).

Mechanisms such as the Premiers Conferences, Council of Australian Governments (COAG) and Ministerial Councils in specific policy arenas are created to manage intergovernmental relations and these institutions evolve to meet new needs.

119 Giacominia, Baylis and Robert (2007) identify tissue rejection and disease transmission as risks to stem cell recipients.

120 Legal and constitutional, administrative and political, fiscal and executive variations in collaborative, cooperative or coordinated modes are all identified in the vast literature on federalism

COAG¹²¹ is the peak Australian inter-governmental forum, concerned with policy issues of national significance which require cooperative intergovernmental action.

ESC research and cloning research falls within the confines of health and medical research in the Australian policy context. Since 1937, the NHMRC has supported health and medical research¹²², aligning research objectives with public-health issues and the community's need for health advice. The precursor to the NHMRC was the Federal Health Council established in 1926 and consisting of the then Commonwealth Director General of Health and the Chief Health Officer of each State¹²³ making medical research an intergovernmental concern from its earliest days. In 2006, the NHMRC became an independent statutory agency under the National Health and Medical Research Council Act 1992, administered by the Australian Government Minister for Health and Ageing. In 2008, the Australian Government committed \$357 million to the NHMRC to support health and medical research (Roxon 2008).

As in other countries, stem cell research generated wide public discussion and media coverage in Australia. The Australian public were generally supportive of embryonic stem cell research if directed toward improving human health. They were much more sceptical however where the motive was corporate profit or scientific career advancement (Biotechnology Australia Report 2001). In 2002, 53% of Australians found it morally acceptable to derive human stem cells from embryos, 74% approved of the use of gene therapy to correct genetic disorders and 77% the use of gene therapy to cure genetic disease. Only 8% found human cloning morally acceptable. Acceptability for stem cell derivation and genetic therapies had increased slightly by 2003 but approval for cloning had decreased (Biotechnology Australia 2003). In other research 72% of Australians approved of research using excess embryos, in relation to developing therapies (SCALC 2002, 136). However it is unclear whether

121 COAG comprises the Prime Minister (Chair), State Premiers, Territory Chief Ministers and the President of the Australian Local Government Association.

122 The NHMRC administers a range of research support grants and capacity building grants on behalf of the Australian government. Grants are allocated on an open competitive

123 See <http://www.nhmrc.gov.au/about/org/history/index.htm>

the participants in any of this research, understood explicitly that embryonic stem cell derivation resulted in the destruction of the embryo and whether this would impact on approval. Further, Australians appeared perplexed about the moral status of the embryo, particularly whether it should be considered a human being from conception (SCALC 2002, 136-7).

The international developments in cloning and ESC research in the late 1990s generated an immediate response from the Australian Health Minister who instigated one of many subsequent reports and inquiries into the emergent science¹²⁴. The policy issue was also placed on the COAG agenda as early as 2001 (COAG communiqué 2001). State Premiers Bob Carr (NSW), Peter Beattie (QLD) and Steve Bracks (Vic) were strong advocates for ESC research, recognising the potential economic opportunities for their respective States (The Australian, 19 August, 2002). Carr and Beattie both declared they would introduce their own laws to facilitate ESC research if the Australian government failed to do so (Shanahan 2002).

4.5 The Australian Public Policy Response

There have been a multitude of reports, inquiries, public and expert consultations and submissions into the regulation of research on embryos, embryonic stem cell research and human cloning in Australia in the past two decades. Prior to 2002, there was no national regulation and State based regulation varied from reliance on NHMRC¹²⁵ guidelines and research ethics committee assessments to existing ART legislation¹²⁶ in a number of jurisdictions (Dodds and Ankeny 2006, 95-6). In 2002 the Australian Government enacted national legislation through the Research Involving Human Embryos Act 2002 (RIHE Act) and Prohibition of Human Cloning Act 2002 (PHC Act) which was amended in 2006 to implement the findings of the 2005 Lockhart Legislation Review.

124 Minister for Health and Ageing Michael Wooldridge instigated a report from the Australian Health Ethics Committee in 1998 as discussed later in this chapter.

125 The Council comprises nominees of Commonwealth, State and Territory health authorities, professional and scientific colleges and associations, unions, universities, business, consumer groups, welfare organisations, conservation groups and the Aboriginal and Torres Strait Islander Commission.

126 As discussed in Chapter 3.

In arriving at a national legislative and regulatory framework for Australia, a number of important political actors and institutions have engaged in the policy process. The NHMRC, the Australian Health Ethics Council (AHEC), the Council of Australian Governments (COAG), the House of Representatives Standing Committee on Legal and Constitutional Affairs (SCLCA) and the Senate Committee on Community Affairs (SCALC) have had a significant impact on eventual outcomes. Key processes such as the Andrews Inquiry (2001), the 2002 Senate inquiry into the Prohibition of Cloning and Regulation of Human Embryo Research Bill (2002) and the 2005 Lockhart legislative review process have engaged with complex and often contradictory science. In this contested policy arena, a number of powerful but conflicting interests have emerged and in the democratic state, it falls to public policy to navigate these conflicts, ultimately to serve the public interest. While embryonic stem cell research and cloning was propelled onto the Australian policy agenda by the events of the late 1990s, embryo research has been on the Australian policy agenda for more than two decades. During this period, the extrauterine embryo has undergone a transformation from valued potential child to valued resource. In the next section I will discuss how the Australian public policy process has responded to challenges of this complex policy domain.

4.6 Policy Responses 1986-1996

4.6.1 The Senate Select Committee (Tate) Report 1986

The issue of embryo research emerged onto the Australian national political agenda as early as 1985 when Senator Brian Harradine proposed the Commonwealth Human Embryo Experimentation Bill in response to concerns over embryo experimentation associated with ART. Subsequently a Senate Select Committee (SSC)¹²⁷ was formed and Chair Senator Michael Tate released the report, 'Human Embryo Experimentation in Australia' in 1986.

¹²⁷ The seven member committee comprised Michael Tate (Chair), Sir John Carrick, Brian Harradine, Michael Macklin, Shirley Walters, Rosemary Crowley and Alice Zakharov.

One of the first issues the SSC grappled with was the definition of a human embryo. It concluded that an embryo was the entity which results from the completion of fusion between human egg and sperm. Acknowledging it would not be possible to 'achieve agreement either amongst scientists or others on the complete set of attributes' (SSC 1986, 8) of this entity, the Committee believed general agreement was possible on a number of basic attributes. Namely, the entity has life, it is genetically human and most significantly it is a centrally organised unit with developmental potential (SSC 1986, 9). The SCC noted that in other jurisdictions, the term pre-embryo was used to describe the fertilized ovum up until the 14-16 day mark and concerns were raised that language such as this was not merely descriptive but operated as 'behaviour governing terms' (SCC 1986, 11).

The Committee also wrestled with the issue of respect due to the embryo, finding it impossible to separate the language of stages and development from a proper description of the embryo hence the respect due to it (SCC 1986, 12). Drawing on expert evidence¹²⁸, the Committee found that the formation of the new human entity was the significant event and its orientation to the future, the feature which demanded respect (SSC 1986, 25). They also found the new entity to be demonstrably different to its pre fertilisation component parts namely sperm and ovum (SSC 1986, 12).

The Committee also made the distinction between biomedical experimentation for diagnostic or therapeutic purposes and 'pure' experimentation, for the purpose of gaining knowledge, which was of no direct benefit to the subject (SSC 1986, 15).

The majority of the Committee (Senate Hansard 1986, 970) argued that for the purposes of biomedical ethics, the human embryo should be considered a human subject and the principles of international medical ethics and guardianship be employed to protect it. Drawing on the Helsinki Declaration's¹²⁹ basic principle that

128 See Tate report 1986 pages 12-13 citing evidence from Dr John Kerin, Head of Reproductive Medicine, Queen Elizabeth Hospital, SA, St Vincent's bioethics centre and Professor Roger Short, Australian academy of Science.

129 See Helsinki Declaration <http://www.cirp.org/library/ethics/helsinki/>

'concern for the interests of the subject must always prevail over the interests of science and society', the Committee recommended national regulation which prohibited non therapeutic and destructive embryo research whilst 'supporting the creative aspects of reproductive technology [and] acceptance of the need for research, including therapeutic experimentation on the human embryo' (SSC, 1986, 15). As such, a distinction was made between biomedical experimentation for diagnostic or therapeutic purposes on embryos and 'pure' experimentation, for the purpose of gaining knowledge, which was of no direct benefit to the embryo as a subject.

Fundamental to the Committee recommendations was the understanding that an embryo was a '...genetically new human life organised as a distinct entity oriented towards further development' which was not the property of the gamete donors but an entity entitled to protection until the '....onus of proving that it should not be treated as a human subject [was] successfully discharged' (SSC 1986). Further in the submissions to the SSC, evidence was received from scientists and medical experts, none of whom attempted to argue the embryo was other than a developing human being (Senate Hansard October 1986, 978). Arguments were presented that value, respect and protection for the embryo be contingent on its developmental stage, but the majority of the Committee rejected this position, concluding 'the human embryo deserved respect and protection according to its status as human' (SSC 1986). In a dissenting report, Senators Crowley (Senate Hansard October 1986, 980), and Zakharov (Senate Hansard October 1986, 981) argued that significant marker events do occur and these *are* relevant to treatment of embryo, the embryo cannot be equated with a child and that decisions about what happen to embryos correctly remain with zygote donors, which ironically they refer to as parents.

Ultimately the Harradine Bill, described as a 'prohibition model ...with its dependence on the criminal law and the obtaining of injunctions as the sole method of regulation and enforcement' (Senate Hansard 1986, 970) was rejected and the SCC

recommended a cooperative Federal/State national regulatory framework which was not enacted by the government of the day.

4.6.2 National Health and Medical Research Council Guidelines

The NHMRC first issued guidelines on ethical aspects of research related ART as Supplementary Note 4 (*In Vitro Fertilisation and Embryo Transfer*) to the then *Statement on Human Experimentation* (NHMRC 1992). AHEC developed a new edition of the guidelines during 1993–96, which were published in 1996 as *Ethical Guidelines on Assisted Reproductive Technology*.

In developing the guidelines, the NHMRC acknowledged

- Research involving early human embryos raised profound moral and ethical concerns.
- A range of opinions existed amongst Australians regarding the moral status of embryos which at the time were unable to be resolved.

The guidelines permitted therapeutic research on embryos and non-therapeutic destructive research in exceptional circumstances subject to approval by an institutional ethics committee (IEC). Caveats on permissible research included the likelihood of significant advances in knowledge, improvement in treatments, restrictions on the number of embryos involved and consent for specific form of research from gamete providers. The guidelines identified a number of practices deemed ethically unacceptable, including creating embryos for purposes other than ART and prohibition of human cloning (see Appendix 2).

4.7 Policy Responses 1998-2002

4.7.1 The Australian Health Ethics Committee Report 1998

The announcement of the successful cloning of Dolly the sheep in 1997 was the seminal event which placed the issue of human cloning onto the political agenda worldwide. The announcement some twelve months later, that human embryonic

stem cell line had been established was another such event (SCALC 2001, 31). In 1998, the Australian Health Minister, Michael Wooldridge asked AHEC to report on the issue of the human cloning. AHEC conducted limited consultations and in December 1998, presented the minister with the report, '*Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*' which was later rescinded¹³⁰.

The report, made a number of recommendations and resolutions (see Appendix 3). In summary, practices considered contrary to human dignity, such as reproductive human cloning should be prohibited. AHEC noted that different regulatory and legislative conditions were in operation in different States and Territories and recommended that all jurisdictions introduce legislation which prohibited human cloning and regulated embryo research in accordance with existing NHMRC guidelines. Informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques should be encouraged and promoted.

In discussing the embryo, AHEC (1998, 10) noted that given the technological advances, a more comprehensive definition than the 1986 SSC definition was required. They noted the US Congress definition of an 'entity derived by fertilisation, parthenogenesis, cloning or any other means from one or more human gametes or diploid cells' but in their own glossary defined an embryo as the 'developing organism from the time of fertilisation until significant cellular differentiation has occurred, when the organism becomes known as a foetus' (AHEC 1998, 51).

AHEC (1996, *ii*) advised that a distinction should be made between the cloning of whole humans and the cloning of human DNA or cells. The former being a prohibited practice under Article 11 of the Universal Declaration on the Human Genome and Human Rights (United Nations Educational Scientific and Cultural Organisation

¹³⁰ This report was rescinded in 2003. Rescinded publications no longer represent the Council's position on the matters contained therein and the Council no longer endorses, supports or approves these rescinded publications. See <http://www.nhmrc.gov.au/publications/pubstatus.htm>

1997) and the latter an established scientific practice. AHEC (1986, 12) also drew attention to the fact that embryonic stem cells were not the equivalent of an intact embryo.

The AHEC report (1998, 23-31) devoted a chapter to ethical concerns related to SCNT, production of embryonic stem cell lines and revisited the ethical distinction between therapeutic and non therapeutic experimentation on embryos. However it did not make explicit that the production of stem cell lines could only occur if ESC were harvested from the blastocyst, a procedure which leads to embryo death.

4.7.2 House of Representatives Standing Committee on Legal and Constitutional Affairs (Andrews) Report 2001

In August 1999, Minister Wooldridge asked the House of Representatives Standing Committee on Legal and Constitutional Affairs (SCLCA), Chaired by Kevin Andrews MP to review the AHEC Report. Submissions were invited from the public and from individuals and organisations with a known interest in the subject. 347 written submissions and 50 exhibits were received while a further 316 members of the public wrote requesting a ban on human cloning. Public forums were held to bring together members of the scientific community, ethicists, church, community groups, legal professionals and members of the public (SCLCA 2001, 6-7). The Andrews report '*Human cloning, scientific, ethical and regulatory aspects of human cloning and stem cell research*' was released in August 2001.

In conducting his review, Andrews, (SCLCA 2001, x) identified the core issues confronting the Committee:

- What, if any, were benefits of conducting stem cell research?
- What application of cloning technologies was relevant to human beings?
- What was permissible use of these technologies to achieve those benefits?

In framing these questions, Andrews identified the need for consideration of respect for human life, the appropriate limits of science, and the need for transparency and

accountability in any system of regulation. He also identified the importance of 'clear language in our public discussions' drawing attention to terms such as 'therapeutic' and 'reproductive' cloning which could be misleading and concealing (SCLCA 2001,x).

In all, the Andrews Committee (2001, xxix) made 16 recommendations (see Appendix 4). The majority of the Committee supported the establishment of a national legislative and licensing framework for the regulation of human cloning and stem cell research and prohibition of human reproductive cloning. Destructive research on surplus ART embryos could be permitted under strict licensing and ethics approval processes. The Committee also recommended a three year moratorium on the creation and use of embryos created by somatic cell nuclear transfer on the grounds that enough spare embryos existed, the therapeutic benefits were at best speculative and the method of production was inefficient. Further they argued the distinction between therapeutic clone and reproductive clone created through SCNT was arbitrary. Finally there were legal and ethical considerations over consent to the use of such embryos, which have no 'parents' thus could be considered as property, rather than the subjects of guardianship (SCLCA 2001, 122). A minority of Andrews Committee members opposed any research which involved the destruction of human embryos and expressed concerns about the continued use of embryonic stem cells derived from embryos, whether in Australia or overseas. (SCALC 2002, 7)

Again there were issues pertaining to definitions. The embryo was defined in terms of the completion of syngamy, a specific point in the process of fertilisation, following the fusion of ova and sperm nuclei when the chromosomes from each zygote align to form the new genetic entity (SCLCA 2001, 13). However 'confirmation of the organised embryo and its orientation' does not occur until around 14 days when the primitive streak develops (SCLCA 2001, 14). The report observed the 'many definitions' of cloning used with reference to plants and animals and reiterated the AHEC distinction between the cloning of a whole individual and the cloning of cells.

Noting the advances in technology, specifically SCNT, since the AHEC report, the Committee cited the Australian Academy of Science working definitions of cloning:

- The production of a cell or organism with the same nuclear genome as another cell or organism;
- Reproductive cloning, to produce a human foetus by nuclear replacement
- Therapeutic cloning, to produce human stem cells, tissues and organs (SCLCA 2001, 19).

The focus had shifted significantly in the short time period between the AHEC report and the Andrews report. Where AHEC were discussing therapeutic and non therapeutic *research on embryos*, the focus was now on the distinction between reproductive and therapeutic *cloning*, the latter directed usually toward embryo creation by SCNT for ESC harvest. In the previous context this would have constituted *non-therapeutic research on embryos*. Andrews also made it quite explicit that ESC harvest result in the death of the host embryo whether this embryo was surplus to ART requirements or created specifically for research purposes (SCLCA, 2001, 116).

The Andrews Committee also had to deal with the emerging issue of embryonic stem cell lines and the implications for stem cell based therapies. How the differentiation of the stem cells could be directed and controlled was still an area of relative scientific uncertainty¹³¹ but important because therein lay the promise of significant therapeutic breakthroughs and a number of eminent Australian scientists publicly supported ESC research using both SCNT and surplus ART embryos as sources of ESC.

Much of the evidence and discussion of embryonic stem cells recognised the value and the significant potential benefits of basic and strategic research on pluripotency of cells and the regulatory steps in cell lineage development.

¹³¹ See House of Representatives Official Committee Hansard 1.3.2000 and 29.3.2000

Research to find the cell signals and triggers that govern differentiation may provide alternatives to therapies using the cells, but the stem cell research has to be completed in order to find and characterise these factors. As this inquiry concludes, the pace of the research continues to increase (SCLCA 2001, 42).

The Committee also explicitly acknowledged the intense international competition amongst scientists to better understand the emerging science and the potential value of intellectual property associated with discoveries of the factors that determine cell differentiation (SCLCA 2001, 23). Further, Australia perceived as a leader in ART, was well placed to play a leading role in the related fields of ESC and cloning research and just as importantly benefit from the 'ultimate commercial applications of new therapies arising from this research' (SCLCA 2001, 57). In a similar vein, Prof Don Chalmers (AHEC chair) advised the Andrews Committee of 'an extraordinary investment internationally and nationally in the biotechnology area and those commercial interests are a very noticeable aspect of this work' (House of Representative Hansard 1/3/2000).

4.7.3 Council of Australian Governments (COAG) 2001 and 2002

Regulation of human cloning, nationally consistent regulation of ART technology and related emerging human technologies appeared on the COAG agenda in 2001(COAG 2001). The 8 June 2001 communiqué agreed to a need for nationally consistent legislation to prohibit human cloning and a need for nationally consistent regulation of ART and related emerging human technologies. To aid their consideration of the issues, a technical report, *Human Cloning, Assisted Reproductive Technology (ART) and Related Matters*, was prepared by the Commonwealth in consultation with officials from all jurisdictions and following expert consultation with experts in a range of fields including medical research, ART, ethics and law (SCALC, 2002, 6). The report was considered simultaneously by Health Ministers and by COAG at their respective meetings on April 5, 2002. Subsequently COAG issued a Communiqué, announcing the Commonwealth, States and Territories would

introduce nationally consistent legislation to ban human cloning and other unacceptable practices (COAG 2002).

The Council agreed that research involving the use of excess assisted reproductive technology (ART) embryos that would otherwise have been destroyed is a difficult area of public policy, involving complex and sensitive ethical and scientific issues. However they agreed that research should be allowed on existing excess ART embryos, under a strict regulatory regime, with the consent of donors and on condition that the embryos were already in existence at 5 April 2002 (COAG 2002). In June 2002, all States and Territories agreed to introduce nationally consistent legislation.

This research would be permitted so that Australia could remain at the forefront of research which may lead to medical breakthroughs in the treatment of disease.

4.7.4 Federal Funding for Research

In May 2002, the Prime Minister John Howard, announced federal funding of \$46.5 million, from the Backing Australia's Ability program, to the Australian Stem Cell Centre (then known as the Centre for Stem Cells and Tissue Repair) for a Biotechnology Centre of Excellence. The centre would conduct research on adult and embryonic stem cells with a focus on developing treatments for a range of diseases and conditions. Professor Alan Trounson was announced as the inaugural Chief Executive Officer. This funding aimed to cement Australia's 'reputation as a world leader in biotechnology' (McFarlane and Nelson 2002). Professor Trounson described the new centre as 'a not-for-profit institute with a commercial company attached ... that aimed to develop commercial potential from the intellectual property generated at the centre' (Doez and Wroe 2002).

There was some criticism of this funding decision in the Australian press, for pre-empting the Senate decision on stem cell legislation (Metherell and Smith, 2002). In

2004, a further \$55 million grant was awarded to the Australian Stem Cell Centre from the Backing Australia's Ability II program.

4.7.5 Senate Community Affairs Legislation Committee (SCALC) Inquiry 2002

The Research Involving Embryos and Prohibition of Human Cloning Bill 2002 was introduced into the House of Representatives on 27 June 2002. The Bill was debated in the House on 27 June and on 20, 21, 22 August and in the Main Committee of the House on 26, 27 and 28 August 2002 with 105 members participating in the debate. On 29 August 2002 the House agreed after a lengthy debate to a procedural motion that divided the provisions of the Bill into two separate bills, the Research Involving Human Embryos and the Prohibition of Human Cloning Bills (SCALC, 2002, 2). The original Bill was referred to the Senate Community Affairs Legislation Committee for report by 24 October 2002, prior to the splitting of the Bill.

The purpose of the referral was 'to consult widely with various stakeholders in the community to inform the Senate in its deliberations on the Bill' (SCALC 2002, 1). The purpose of the enquiry was information gathering to inform Senators' decision making rather than formulating conclusions or recommendations, which in the 'free vote' situation remained the prerogative of individual Senators.

The Committee received 1851 public submissions and public hearings were held in Canberra during August and September 2002 involving some 52 witnesses. The subsequent report of the inquiry devoted separate chapters to reviewing the scientific aspects of ESC research and cloning and the ethical aspects.

4.7.5.1 Scientific Issues

The inquiry sought to clarify important definitions such as embryonic stem cell, germ cell, adult stem cell, stem cell line and restated explicitly that embryos were destroyed in the process of extracting ESCs. The recent Trounson incident had highlighted the need for precision in definition and use of terms. In a presentation to

the Liberal/National parties and in a parliamentary briefing, Professor Trounson, Monash Institute of Reproduction and Development and CEO (Designate), National Stem Cell Centre, used an experiment on a paralysed rat, to demonstrate the treatment potential of ESC. Following treatment the animal was cured, its paralysis was reversed and control of bowel and bladder function regained. This demonstration was used as an illustration of the potential of such therapies to treat human Motor Neurone Disease, a devastating and incurable disease of the central nervous system (SCALC 2002, 12). There was considerable outcry and accusations from some quarters of deliberate deception when it was later revealed the rat had been treated with differentiated germ cells not ESC. Professor Trounson disputed any fundamental difference between the two types of cell and denied he had deliberately misled anyone¹³².

The Committee revisited the distinction between therapeutic and reproductive cloning drawing attention to potential of such language to obfuscate important issues. Citing evidence from the Chair of AHEC who said ‘...the term ‘therapeutic cloning’ collapses both (a) the distinction between therapeutic and non-therapeutic research on embryos and (b) the distinction between destructive and non-destructive experimentation on embryos’ (SCALC 2002, 18).

The Committee acknowledged the conflicting views of eminent Australian scientists¹³³ on the potential for therapies arising out of ESC research, particularly cures for degenerative diseases and manufacture of tissue and organs for transplantation. It highlighted the issue of unrealistic public expectations of imminent treatment breakthroughs in a field of research which was still in its infancy and where there was much scientific uncertainty (SCALC 2002, 20-23). There was extensive debate about the relative therapeutic merits of embryonic stem cell and adult stem

132 See Tony Jones interview with John Anderson

<http://www.abc.net.au/lateline/stories/s661371.htm>

Fran Kelly interview with Prof Trounson <http://www.abc.net.au/7.30/content/2002/s662263.htm>

The Age August 29, 2002 <http://www.theage.com.au/articles/2002/08/29/1030508098797.html>

133 See evidence to Andrews inquiry and to SSCALC from Prof Trounson, Dr Peter McCullagh, Prof Colin Masters, Prof Martin Pera.

cell research in evidence to the Committee. Citing the clinical and medical research literature, adult stem cell proponents pointed to successes in stroke and cancer treatment in humans and the treatment of conditions such as Diabetes, Parkinson's and spinal injury in animal models. Likewise, embryonic stem cell research advocates cited studies which indicated 'potential for treatment of a range of diseases including neurological, cardiac, cancer and other conditions' (SCALC, 2002, 27). The Committee also noted adult stem cell research and treatment applications were more established than those of ESC research (SCALC, 2002, 27). Again there was conflicting evidence from scientists and clinicians on the relative advantage of ESCs pluripotent properties. While on one hand pluripotency conferred maximum flexibility and potential to differentiate into any somatic cell, it also made ESC inherently unpredictable given, the mechanisms that control differentiation were neither fully understood or controllable in the clinical setting (SCALC, 2002, 2809). As referred to earlier in this Chapter 4, recent developments indicate adult stem cells have more plasticity than originally believed, making the access to ESC on the grounds of pluripotency perhaps less critical in absolute terms.

In summarising the state of the science, SCALC (2002, 37) concluded:

- Research involving stem cell and cloning technologies was in its infancy;
- There was insufficient experimental data to have certainty about the importance of stem cell research or the relative value of embryonic and adult stem cells;
- Therapies derived from stem cell research had at least the potential to ameliorate currently incurable conditions.

4.7.5.2 Ethical issues

In revisiting the ethical dimensions of the ESC and cloning debate, the Committee identified two main sets of issues, 'first, the ethics of human cloning and, second, the ethics of destructive research on human embryos' (SCALC 2002, 37). While there was little disagreement on the need to prohibit human reproductive cloning, the issue of destructive embryo research remained ethically contested. At the heart of matter

was the moral status of the embryo (SCALC, 2002, 37). The Committee considered a number of arguments in grappling with this vexed issue. At one extreme there was the no moral worth position due to absence of consciousness or sentience (SCALC 2002, 38). However, this line of reasoning leads to an analogy between embryos and comatose humans, who also lack consciousness, but who would not be subject to destructive experimentation. Ultimately the Committee decided the consciousness argument as insufficient to grant equal moral status between embryos and other humans (SCALC 2002, 41).

At the other end of the continuum was the 'full moral status' position grounded in the biological fact that new human life commences at fertilisation and 'this biologically related entity' enjoys full moral fellowship with born humans (SCALC 2002, 41). While there was little disagreement that the embryo is a human life, the contested issue was the meaning and significance of that life (SCALC 2002, 41). As with previous inquiries and reports, marker events were discussed as being relevant to the 'beingness' of the human entity, a position the Committee described as arbitrary given the 'essentially developmental nature of embryonic life' (SCALC 2002, 44) which is continuous not incremental. In grappling with these arguments, the Committee noted that 'the focus on biological markers is an attempt to isolate an *objective* point at which a morally relevant difference in the embryo's development can be recognised' (SCALC 2002, 46). Again this is not the point. If it is the human kinship shared with the embryo as a member of the human species that accords it full moral status, then an objective developmental point is irrelevant to this position.

The middle ground is the embryo has some moral status because the '...unborn belong in a sense to the human family' (SCALC 2002, 47) presents the problem of how to quantify that moral status. The use of term unborn is illuminating. It conjures up a sense of a *life* not actualized, more so than the technical term 'embryo'. The 'unborn' can constitute miscarried or stillborn infants or aborted foetuses; human lives that could have been and whose loss can be mourned. The Committee noted that the proposed Bill and its supporters implicitly adopt this third way (SCALC 2002,

47). Some moral status is accorded to embryos because restrictions are placed on what can be done to them and with them. For example, the age limitation of embryos to be used, the prohibition on the creation of embryos specifically for research, the specification that only serious research be undertaken with no unnecessary destruction of embryos; in essence a harm minimisation approach. The limitation of that moral status is revealed by the assumption inherent in the Bill that the interests of born human beings, as potential beneficiaries of ESC research, take precedence over the interests of the embryos (SCALC 2002, 47-8), now no longer considered unborn *humans*, merely unborn.

Proponents of destructive embryo research argued that surplus embryos were going to die anyway but antagonists argued there was a moral difference between dying a natural death, withdrawal of life support and the deliberate destruction of human entities (SCALC 2002, 41).

The Committee considered a number of arguments against research on embryos. The 'slippery slope' position claims destructive ESC research will lead to greater demand for embryos which the existing stockpile cannot meet leading to the creation of embryos specifically for research through therapeutic cloning. Once this becomes accepted practice, reproductive cloning will be inevitable. Just as IVF technologies transformed initial objectives of pregnancy into freezing embryos, selective implantation and PGD, so too cloning technologies will become normalised (SCALC 2002, 51-3). Other arguments spoke to the fear that permitting certain practices will lead to erosion of values, particularly respect for other human beings and protection of the vulnerable and the commodification or instrumentalisation of life (SCALC 2002, 53-4).

The issue of the embryo as the property of the gamete donors was also considered. Michael Tate (SCALC 2005, 55) argued that property rights of egg and sperm donors are extinguished once fertilisation takes place, because at this point guardianship arises, which would ordinarily be exercised by the intended social parents.

Arguments concerning the autonomy of embryo donors, the exploitation of people with disabilities to promote ESC research, and the level of community support for ESC research were also considered by the Committee (SCALC 2002, 55-61).

4.7.5.3 Scientific, Economic and Technological Impact

The Committee was advised that failure to pass this legislation would damage Australia's standing as a pioneer in ESC research and force research and associated business interests off shore to more liberal jurisdictions. As a result, Australia's long term economic interests were at risk. If Australian science was forced to source ESC from overseas they risked losing intellectual property (IP) rights arising from subsequent research and potential financial benefits from commercialisation of discoveries. However other evidence presented warned of potential conflicts of interest amongst pro ESC research scientists who had the 'potential for vast monetary gain' as well as the personal prestige that breakthroughs in ESC research could bring (SCALC 2002, 62-3).

Dr Chris Juttner, Executive Director, BresaGen Ltd told the Committee his company's present commercial activities would not be inhibited if ESC derivation was banned in Australia but it would mean that research and product development would be forced off shore to the United States where there was no prohibition on the derivation of new embryonic stem cell lines subject to meeting local ethical standards and legal requirements. He warned 'such an exodus....would represent a significant scientific and commercial disadvantage for Australia' (Senate Hansard 17 September, 2002)

The need for *national* legislation was perceived as crucial for unity and security for community, science and business investors. The prospect of piecemeal and contradictory State based legislation was perceived as harmful to Australia's position at the cutting edge of the new technologies (SCALC 2002, 63).

4.7.5.4 Qualifying Comments

Senators Guy Barnett (LIB), Bill Heffernan (LIB), Stephen Hutchins (ALP), Mark Bishop (ALP), Ron Boswell (NP), Jacinta Collins (ALP), Brian Harradine (IND) and John Hogg (ALP) provided a qualifying report to the SCALC Inquiry report. They identified a number of 'fundamental flaws in the Bill' and 'a failure to justify the need for the legislation with respect to destructive embryo research' (SCALC 2002, 115).

First and foremost they believed that the need for destructive embryo research had not been demonstrated, describing the evidence presented as 'conflicting and contradictory' (SCALC, 2002, 118). Further the Bill did not regulate the use of ESCs and its passage or otherwise would not impact greatly on that research in Australia as existing stem cell lines were adequate for current research and stem cell therapies were not imminent. Should future therapies be developed, it would require the creation and destruction of millions of embryos, not just the thousands which would be available if this legislation were passed (SCALC, 2002, 119).

The dissenting Senators believed the human embryo to be a human life entitled to protection, and it should not to be considered as a resource or as property. They reiterated the moral difference between an excess ART embryo dying and being destroyed deliberately in the research process, thus disputed the claim that such research was morally permissible because the embryos would end up dead anyway (SCALC 2002, 128-9).

4.7.6 National Legislation 2002

In December 2002, the Australian Parliament passed the Prohibition of Human Cloning Act (PHC) 2002 and the Research Involving Human Embryos (RIHE) Act 2002. The combined effect of the two Acts was to prohibit human cloning and other specified unacceptable practices, prohibit the creation of human embryos specifically for research purposes and to allow certain uses of excess human embryos created

through assisted reproductive technology (ART) under strict regulation and license (Legislative Review Committee (LRC) Issues Paper, 2005, 4).

In Section 8 of the PHC Act and Section 7 of the RIHE Act, the human embryo was defined as a ‘live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pronuclei or the initiation of its development by other means.’

The PHC Act 2002 prohibited the creation, import or export of a human clone. It also prohibited the placement of a clone in a human or animal body for the purposes of gestation irrespective of the survival or otherwise of the clone. The Act also prohibited therapeutic cloning through the ban on the creation of a human embryo by any process other than the fertilisation of a human egg by a human sperm, which included SCNT.

The Act specified a number of ‘prohibited’ embryos:

- Those created for purposes other than a pregnancy;
- Chimera embryos;
- Those with genetic material from more than two people, precursor cells from a human embryo or foetus or an altered genome inheritable by its descendants;
- Those developed outside the body of a woman for more than 14 days, excluding any period when development is suspended;
- Viable embryo extracted from the body of a woman (embryo flushing).

Import and export of prohibited embryos and placing such embryos into the body of a woman were prohibited as was placing a human embryo in the body of an animal or an animal embryo in the body of a human or placing a human embryo in the body of a human except in a woman’s reproductive tract. Commercial trading in human eggs, sperm or embryos was prohibited (PHC Act 2002).

The RIHE Act 2002 addressed 'concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos by regulating activities that involve the use of certain human embryos created by ART' [RIHE Act, Section 3].

It specified the use of excess ART embryos, defined as human embryos created by ART for use by a woman to become pregnant which are no longer required for this purpose. The Act (Section 3) required the woman for whom the embryo was created and her spouse (if any) at the time of creation to give written authority to declare an embryo as excess. A license issued by the Embryo Research Licensing (ERL) Committee of the NHMRC was required for all research on excess embryos with the consent of all 'responsible persons'. Specified 'exempt uses' of excess ART embryos were permitted without a licence, largely for the clinical practice of ART (LRC 2005, 16). Only those excess ART embryos created before 5 April 2002 were available for research.

4.7.7 Licensing and Statutory Arrangements

Minister Kevin Andrews announced the establishment of the Embryo Research Licensing (ERL) Committee¹³⁴, on 15 May 2003. As a principal committee of the NHMRC, it had regulatory authority to consider applications and grant licences for research on excess ART embryos. The Committee was granted the power to suspend or revoke a licence if it believed that the conditions of the licence have been breached and applicants were granted appeal rights to the Administrative Appeals Tribunal (LRC 2005, 18-19).

The ERL was required to maintain a public database of licence holders, descriptions of their projects, the number of research embryos authorised, date and period of licence. It had the authority to appoint inspectors for monitoring and compliance and to report annually on embryo research activities to the Australian Parliament. The

134 Licensing committee appointed by the Australian minister with portfolio responsibility for human cloning and embryo research. See <http://www.nhmrc.gov.au/about/committees/lc/index.htm> Accessed 17 February 2006.

ERL was forbidden to disclose confidential commercial information to anyone except those involved in the functions of the RIHE Act.

4.8 The Legislative Review Committee (Lockhart Review) 2005

On 17 June 2005, The Hon Julie Bishop, Minister for Ageing, Australian Government announced the appointment of a committee to conduct independent reviews of Australia's Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002.

The Legislation Review Committee (LRC) was chaired by retired Federal Court Judge, Justice John Lockhart AO QC and comprised clinical ethicist and haematologist, Associate Professor Ian Kerridge; scientist and community advocate, Professor Barry Marshall; lawyer and ethicist, Professor Loane Skene; neuroscientist, Professor Peter Schofield and clinical neurologist Associate Professor Pamela McCombe and was supported by an independent secretariat (Bishop 2005).

The review, which became known as the Lockhart Review, was charged to 'consider and report on the scope and operation of each of the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002' and to 'consult with the Australian, State and Territory governments and a broad range of people with expertise or experience in relevant disciplines.'¹³⁵

The review was completed and a report submitted to the Minister and to COAG in December 2005. In all, 1035 submissions were received, public hearings were held in all State and Territory capitals¹³⁶ and a series of facilitated consultation meetings were held in Sydney, Brisbane and Melbourne¹³⁷.

135 See Terms of Reference of Legislative Review (2005) Appendix 4

136 Tasmanian hearing was held by video conference.

137 See (www.lockhartreview.com , accessed 17 Feb 2006).

4.8.1 The Consultation Process

The LRC used a number of consultation techniques and strategies to facilitate their tasks. They established a website, prepared an issues paper, a web based 'key questions' document and engaged professional consultancy group Biotext Pty Ltd¹³⁸ to advise on models of stakeholder consultations and to assist the Committee draft its reports.

4.8.2 Key questions

The LRC identified a number of key questions they would be addressing during the review and invited input from the Australian public to assist them in their requirement to 'assess community standards' (LRC 2005^a, 1). This is standard consultation practice in Australian policy making which allows the reviewing body to determine and control the parameters of the debate and potentially to disregard any submissions which do not fall within the predetermined scope.

The Committee identified the main issues for consultation as:

- Scope and operation of the Acts in relation to developments in ART and developments in medical and scientific research;
- Potential benefits of such research for the treatment of human diseases;
- Establishment of a National Stem Cell Bank (LRC 2005^a, 2).

They also suggested that respondents read the prepared issues paper prior to making a submission as this would help write a response that would be 'be most useful to the Committee.' This issues paper, released in August 2005, was described as using 'plain language' to assist the community in its understanding of a complex scientific field' (LRC 2005^b, 5).

138 Biotext is a scientific consultancy based in Canberra, specialising in the areas of health, agriculture and the environment that provide a range of scientific consulting, writing and editorial services. www.biotext.com.au accessed 5 September 2005

The paper provided a brief history of the existing legislation and the events shaping previous decisions. It included a discussion on the need for uniform legislation across Australian States and Territories to regulate technology and research involving human embryos and cloning¹³⁹. It also identified the need for a common language and a shared understanding of terms used in the legislation. Thus the paper implicitly acknowledged that legal, scientific and public understanding of terms such as 'embryo' and 'clone' may differ (LHR 2005^b, 5).

Sections four and five of the Issues Paper dealt specifically with the RIHE Act 2002 and the PHC Act 2002 respectively. Each section followed a format of defining the purpose of the legislation, explaining scientific and legal terms in laymen's terms and identifying the issues the LRC perceived as important to address.

Again the issues paper was setting the legitimate scope of the review by clearly delimiting its purpose. Most significantly it endeavoured to limit the scope to a review of the Acts in the light of any changes in scientific or community understanding rather than revisiting the underpinning community debate and rationale for the Acts (LHR 2005^b, 3). The implication here was that debate was settled in the first round of legislation but a considerable number of respondents did not agree. The ethical issues were not settled in the public mind and attempts to stymie further debate were not successful.

The issues paper, however, did unpack the scientific and legal terminology used in the debate and sought to reveal important nuances. For example, differences between the legal definition and scientific understanding of the term 'embryo'. The latter understands the embryo as a series of stages in early human development rather than one finite entity (LHR 2005^b, 5-7). These distinctions became important in later discussions over what properly constitutes a live human embryo and what rights and protections it is entitled to. They were also important for the anti-embryo research lobby which feared that the scientific micro classifications were being used to conceal

139 See pages 1-2 LRC Issues Paper 2005

one of the central conflicts; should the human embryo enjoy the same rights and protections as any other human being irrespective of its stage of development?

In the case of 'human embryo clone', the issues paper distinguished between artificially created clones and those occurring naturally through egg splitting after fertilization (identical twins or triplets). It described the somatic nuclear transfer process which could be used to create a clone and differentiated between reproductive and 'non reproductive' clones in terms of intent (LHR 2005^b, 7-8). Again this is an important point because it repositions the moral dilemma from one of 'creating' a cloned embryo to the different morally contentious issue of intended use of the cloned embryo. It remains ethically unacceptable to create a clone for reproductive purposes but ethically acceptable to create a clone for therapeutic purposes, i.e. to harvest stems cells for research or treatment. The fact that the *same* type of entity is created, irrespective of its purpose, gets obscured in this discussion as does the key issue of the moral status of the entity.

This type of argument carried little weight with the anti cloning lobby which saw this as a sleight of hand to avoid confronting the real moral issues around creating human clones. In fact many see the deliberate creation of a human clone for the purpose of harvesting stem cells as more repugnant than implanting said clone and offering it a chance of life¹⁴⁰. Further, creating a human embryo clone for research is not morally different to creating an ART embryo specifically for research. It becomes sophistry to equate morality with method of creation when the end result is the same – a potentially viable human embryo who has no possibility of reaching its potential.

The LRC also introduced a number of alternative terms for therapeutic cloning including 'Non reproductive cloning', 'cloning for research purposes' and 'nuclear transfer' (LRC 2005^c, 55). These terms or similar replacements found some support in the pro-cloning lobby but were generally rejected by the anti cloning lobby, again as attempts to conceal the central issues through the use of scientific jargon.

140 See Submission 494 to Lockhart Review from Cardinal George Pell (2005).

The issues paper offered a concise introduction to the science of stem cells for the layperson. It clearly distinguished between concepts such as totipotency, pluripotency and multipotency and acknowledged the continuing controversy amongst researchers about stem cell classification and terminology as well as the relative therapeutic potential of adult and embryonic stem cells (LRC 2005^b, 10).

In summarising the arguments, the LRC found those who were pro ESC and cloning for research believed

It is acceptable to create and use preimplantation human embryos for research that may benefit human health and wellbeing by development of stem cell therapies to repair damaged and diseased tissues. It is not known at this stage whether embryonic or adult stem cell research will provide greater benefits (if any), so it is legitimate to progress both pathways until a clearer picture emerges (LRC 2005^c, 80).

while those who were against the technologies believed,

a human embryo clone is a human embryo (capable of becoming a human being), [thus] it is wrong to create one specifically to destroy it. Adult stem cells show similar potential for development of stem cell therapies as embryonic stem cells and their use does not involve the destruction of human embryos (LRC 2005^c, 80).

While the intent of the issues paper was ostensibly to provide a stem cell and cloning primer for the scientifically uninitiated, it subtly guides the reader to focus on the scientific 'facts'. The implication here is that this policy question is really about the content of an emerging science and the importance of nurturing that science for the common good rather than the struggle over the deeply conflicting values which drive the politics in this arena.

In guiding the readers as to what was appropriate for consideration, the issues paper used the strategy of directing specific questions to specific stakeholders. For example the 'community' was asked to consider whether the definitions of 'human embryo' and 'human embryo', appropriately reflect community standards. Whereas 'researchers, ART providers and people who use ART services', were asked specifically to consider ART issues and 'government' submissions were asked to consider implementation issues¹⁴¹. Researchers and patient advocacy groups were charged with addressing the effect of prohibitions on research in Australia while 'governments, special interest and community groups (including religious groups), and others, were directed to address issues 'about the overall scope of the prohibitions' (LRC 2005^b, 15). The implication here is that those different stakeholders have different legitimate concerns, particularly in matters of expertise and experience. This is rational instrumental policy making in practice; breaking down a complex question into constituent parts that properly belong to specified experts and stakeholders as a pre-emptive strike thus avoiding uncomfortable political fallout.

However as the submissions to the review revealed, this strategy was not wholly successful, particularly with the anti cloning and destructive ESC lobby.

4.8.3 Literature Review

Biotext Pty Ltd ¹⁴² undertook a literature review of advances in research on embryos, cloning and stem cell technologies since December 2001 and delivered their report to the LRC on 25th August 2005. The scope of the review was:

- Developments in reproductive technology;

141 See page 12 LRC Issues Paper for full list of issues.

142 Biotext, Science Information Consultants are Janet Salisbury PhD (experimental oncology), Hilary Cadman , MSc (science communication), PhD (biochemistry), Malini Devadas, PhD (Neuroscience), Ann Van den Borre , PhD (Botany) and Meg Heaslop who has post graduate qualifications science and social science. <http://www.biotext.com.au/> accessed 2 June 2009

- Stem cell technologies (embryonic, adult and foetal stem cells);
- Exchange and trade of human embryos and embryonic stem cells;
- International regulation of human cloning/embryo research.

In their report, Biotext (2005, xi) acknowledged that the short timeframe and large scope resulted in a focus on 'review articles that show trends, but, where appropriate, have included primary research articles that show significant breakthroughs', and this had limited their capacity to critically analyse all potentially relevant and useful research. Rather their review was to be used as 'broad overview of the status of human embryology, cloning and stem cell research in August 2005' (Biotext 2005, xi).

The literature review was specifically confined to scientific and regulatory aspects of ESC and cloning technology and placed no impost on Biotext to report on ethical or philosophical 'developments' in the arena. Again this could be seen as a strategy for placing the policy 'problem' firmly within the realm of science/technical thereby legitimately an issue for science to resolve and amenable to a rational objective policy process.

The literature review revealed a number of salient points (see Appendix 5).

Significant progress had been made on ART outcomes due to better techniques for embryo selection, including preimplantation diagnosis (PGD), culturing and transfer. Further alternative fertilisation strategies for patients unable to produce their own gametes were being developed. There were advances in animal cloning but SCNT had not yet proved reliable in producing live animals. Progress in animal cloning had led to advances in human embryonic cloning for the derivation of ESC but there was much work to be done on reprogramming and activation of genetic material. Developments in ESC research had led to animal free cultures but as yet there was no culturing method which allowed efficient clonal propagation of human ESC. In vitro cell differentiation was a high priority for research (Biotext, 2005, xii-xix).

Stem cells were being used to support three lines of research:

- Development of cellular therapies;
- Study of disease development and progression;
- A cellular model system for drug development (Biotext, 2005, xxi).

Development of stem cell therapies was a very active area of research but ESC research was still mainly confined to preclinical studies. Some therapies were already established using ASC and a number of new therapies had reached the preliminary clinical trial stage. No consensus had been reached on the plasticity of ASC but there were indications that some ASC may be pluripotent (Biotext, 2005, xx).

Internationally, there was no legislation to permit human reproductive cloning or implantation of chimeras but creation of human embryos specifically for research purposes was permitted in some jurisdictions, particularly those which invested heavily in stem cell research. Use of excess ART embryos for research, import and export of reproductive materials for human therapeutic use and exchange of stem cells and stem cell lines was widespread between countries. However import of products derived from prohibited practices was generally not permitted. Commercial trade was allowed in some countries; however trade was not covered by legislation in most countries. Stem cell registries and banks existed in a number of countries (Biotext, 2005, xxvi)

4.8.4 Public meetings and Fora

The Committee consulted with stakeholders and other interested parties through public hearings in all capital cities. The public was invited to attend most of these hearings as observers, except for a small number of sessions where stakeholders had requested a private meeting¹⁴³. The Committee also met privately with State and Australian Government ministers, officials from relevant State and Territory government departments, and the Embryo Research Licensing Committee of the NHMRC (LRC, 2005^c, 19).

143 Private hearings were held in Darwin and a videoconference in Hobart.

Individuals and organisations invited to address the Committee were selected on the basis of:

- The terms of reference (see Appendix 4);
- Advice to the Committee from relevant government agencies on stakeholders who had the greatest interest in the issues;
- The Committee members' own knowledge about relevant stakeholders;
- Expressions of interest from stakeholders in meeting with the Committee;
- Information contained in written submissions.

Additional facilitated discussion forums with invited attendees were held in Sydney, Melbourne and Brisbane. This allowed the Committee to hear the views of a larger number of stakeholders and to encourage discussion and debate among participants with opposing views. The discussion at each forum was structured around the two Acts and the Committee's terms of reference (LRC 2005c, 20).

4.8.5 Findings and Recommendations

The LRC (2005^c, 161) acknowledged there was a range of views on human embryo research and cloning in the pluralist Australian community, which made it impossible to identify a single set of standards or values with which to inform policy in this contentious arena because different communities attached different social and moral values to the embryo and to the treatment of disease. In grappling with the contested moral status of the embryo, they conceded that the conflict was irreconcilable, but it was necessary to make recommendations 'consistent with shared values and take into account the needs, beliefs and concerns of the whole community' (LRC 2005^c, 161).

In arriving at their decisions, the LRC argued that prohibition of an activity which promised great potential benefits required widely held and high level ethical objections. Concomitantly, where there were diverse ethical views, as in ESC research and therapeutic cloning, the case for making those activities illegal and

criminal was weak. This was not the case for reproductive cloning which enjoyed little support amongst any sector (LRC 2005^c, 162).

The LRC acknowledge that the therapeutic benefits of ESC were yet to be realised but argued that progress had been made in ‘understanding of stem cells and research directed to future therapeutic outcomes of stem cell research.’ They also acknowledged the progress in adult stem cell research and the need for continuing scientific inquiry into both modes given there was substantial potential for therapies to be developed and benefits to accrue (LRC 2005^c, 166).

In all the LRC (2005^c, xxii-xxvi), made 54 recommendations to the regulation of human embryo research and cloning (see Appendix 5) including retaining the national legislation and regulatory framework but with a number of noteworthy changes (LRC 2005c, 161)

Importantly Recommendation 28 proposed a change to the definition of a human embryo to incorporate new modes of production and facilitate ART focused embryology research. In keeping with NHMRC (2005, 27) advice, a human embryo was defined as

A discrete entity that has arisen from either,

(a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or

(b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears; and has not yet reached 8 weeks of development since the first mitotic division (LRC 2005^c, 174).

The recommendation to change the definition of the embryo to a ‘slightly later stage in the fertilisation process’(LRC 2005^c, 167) allowed ART research on fertilised eggs to proceed without fear of litigation. Further proposed changes aimed to remove

ambiguity surrounding access to fresh embryos, unsuitable for implantation¹⁴⁴, but useful for research into genetic disorders revealed by PGD. The Committee recommended that these embryos be reclassified as surplus to ART to allow researchers legitimate access (LRC 2005^c, 168-9). In making this recommendation, the LRC argued it was essential that the legislation used unambiguous and biologically accurate terminology which could be understood by all stakeholders. It accepted that 'definitional clarity will not, in itself, resolve moral concerns and it is likely that, whatever language is used, different moral interpretations will be made regarding the status of such entities and the obligations owed to them'(LRC 2005^c, 173).

The LRC proposed a number of recommendations to remove prohibitions on the creation of embryos through SCNT (Rec 23, 25); creation of animal human hybrids (Rec 24) and creation of embryos containing genetic material from more than two people (Rec 26) (LRC 2005^c, 162-3). Research on eggs fertilised by sperm could be permitted up until the first cell division, but creation of embryos in this manner specifically for research remained prohibited. Regulated research on excess ART embryos continued to be permitted (LRC 2005^c, 166).

Reasoning that the SCNT embryo, if only created for research purposes and with the intent never to be implanted or allowed to develop beyond 14 days, is no different to using an excess ART embryo for research purposes, the Committee recommended a lift on the ban on therapeutic cloning (LRC 2005^c, 171). In doing so the LRC rejected the three major objections to this technology; the 'slippery slope' from therapeutic cloning to reproductive cloning; the means ends argument and the risk to women resulting from the demand for donor eggs (LRC 2005^c, 170). The Committee believed the continued prohibition on reproductive cloning would ensure no development of cloned embryos beyond 14 days despite the fact that making something illegal does not necessarily prevent it happening. They reasoned that the moral significance of an

144 In Victoria, this ambiguity is removed because freezing embryos that are not suitable for implantation is prohibited under the Victorian Infertility Act 1995. However, this is not the case in other States and Territories (LRC 2005^c,169).

SCNT embryo is more correctly linked to the 'potential for research developments, including the development of treatments for serious medical conditions, than [its] potential as a human life' (LRC 2005^c, 170) thus it does not have the moral status of other humans.

Further they argued that production and destruction of an embryo clone is no different to creation and destruction of excess ART embryos making it a moral inconsistency to distinguish between the two entities (LRC 2005^c, 170). However this would appear to lead to an argument that would also allow the creation of research embryos through ART. If production of embryos via SCNT is not dissimilar to ART then production of embryos through ART is not dissimilar to SCNT. The issue is that an embryo is produced and the intent argument does not alter this 'fact'. The next issue is what is a permissible use of the embryo? If it is permissible to produce research embryos through SCNT, it should also be permissible to produce ART embryos specifically for research and to use disabled fresh embryos for research. The mode of production does not alter the entity.

In arriving at the SCNT decision the LRC rejected a number of counter claims;

- All ART embryos are created with the intent to be implanted and are only subject to destruction if classified as excess which is morally different to creating with intent of destruction;
- To allow to succumb or die of natural causes is ethically different to deliberate destruction;
- Cloning through SCNT offends human dignity (LRC 2005^c, 170).

The Committee proposed that appropriate and strict guidelines would prevent the exploitation of women as egg donors and the lifting the current prohibition on the creation of hybrids would decrease demand for human ova (LRC 2005^c, 171).

4.8.6 Education and Public awareness

The LRC found the public had limited knowledge of stem cell and ART research and were confused to the purpose of the existing legislation which they believed regulated ESC research rather than the use of excess ART embryos for research and clinical training. Further, both the scientific community and the public underestimated the timeframes for therapeutic outcomes of research, leading to disappointment and the risk of 'diminished public trust' (LRC 2005^c, 183). This is an important finding, given that policy legitimacy in this arena is to a large extent contingent on public support.

4.9 The Political Response to the Lockhart Review

Initial response to the Lockhart report was muted, perhaps influenced by the untimely death of Justice Lockhart in January 2006. In July 2006, the Prime Minister John Howard, announced that the existing legislation would not change, despite the Lockhart recommendations (Dudley, John and Clark 2006, 8).

The Lockhart report was an agenda item for the COAG 14 July meeting where it was noted that agreement had not yet been reached across jurisdictions on all the recommendations. The States and Territories reiterated their preference for nationally consistent regulation but if this was not possible, warned they would amend 'legislation within their own jurisdictions to the extent that is within their power' (COAG Communiqué July 2006).

Following his decision not to make changes to legislation covering research involving human embryos, John Howard, released a privately commissioned report by MPconsulting who had been engaged to report on any 'change in the state of play' in this policy arena which had arisen since 2002. The consultants interpreted this as evidence of new scientific developments, unintended consequences of the legislation or new ethical arguments.

The subsequent report focused on three main issues:

- The definition of human embryo;
- The creation and use of embryos for ART research;
- The creation of embryos for stem cell research;

and concluded there was NO significant change. (MPConsulting, 2006, iii)

With respect to the definition of a human embryo they noted 'there would not appear to have been significant movements in terms of the internationally recognised "scientifically correct" definition of human embryo. It appears that a person's definition of an embryo continues to be influenced by the moral, ethical and other perspectives of each individual' (MPConsulting 2006, 15).

The consultants claimed the LRC report did not provide any information regarding scientific developments which could justify the proposed changes to the legislation, commenting the 'Recommendations appear to be based on the Committee's assessment of the potential benefits of the suggested changes rather than the state of the science at a particular point in time' (MPConsulting 2006,4).

Private Members Bill 2006

Following a flurry of backbench activity and political lobbying Prime Minister Howard agreed to a conscience vote. Two separate Bills dealing with stem cell issues and the Lockhart recommendations were proposed. The first, sponsored by Senator Stott Despoja (Australian Democrats) and Senator Webber (Australian Labor Party) titled 'Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006' was released as an exposure draft on 14 September 2006. The second, sponsored by Senator Patterson (Liberal Party) the 'Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment (PHCR and RHER) Bill 2006' was released an exposure draft on 26 September 2006 and this bill was subsequently introduced to the chamber. The bill proposed amendments to the PHC Act 2002 and the RIHE Act 2002 to permit therapeutic

cloning (SCNT) of human embryos for research, training and clinical application and the creation of animal-human hybrids (Dudley, John and Clark 2006, 9).

The Patterson Bill repealed the definition of 'human embryo' in the existing Acts and replaced it with the NHMRC working party definition which in essence implements Lockhart recommendation 28:

Human embryo means a discrete entity that has arisen from either,
(a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
(b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears; and has not yet reached 8 weeks of development since the first mitotic division' (PHCR and RHER Bill 2006, Subsection 8.1).

Using this definition, the embryo comes into existence at the slightly later point of the first mitotic division which signals the completion of fertilisation rather than original definition of the appearance of two pro nuclei which indicated that fertilisation had been initiated. The new definition included embryos created through SCNT or other techniques which have the capacity to develop until the appearance of the primitive streak (Dudley et al., 2006, 38). This amendment allowed researchers to undertake experimental fertilisation studies, including maturation of oocytes and testing of sperm quality, which were prohibited by the original legislation which had required such research to stop prior to the appearance of the two pronuclei (Dudley, John and Clark 2006, 19).

The PHCR and RHER Bill proposed amendments to the RIHE Act Subsection 20(1) to permit previously banned research, involving the creation and use of embryos. The original PHC Act Section 9 made it a criminal offence to create a human embryo clone but no such provision exists in the revised Part 2 of the PHC Act. Section 20(1)

(b) of the RIHE Act permits the creation of human embryos other than by fertilisation of a human egg by a human sperm, and the use of such embryos under licence (Dudley, John and Clark 2006, 39). This implements the Lockhart Committee's recommendations to permit the creation of human embryo clones in specified circumstances.

Section 15 of the PHC Act 2002, made it a criminal offence to create or develop a human embryo containing genetic material provided by more than two people but the Patterson amendments allowed for the creation of human embryos through SCNT that contain genetic material provided by more than 2 persons, and the use of such embryos under licence (Dudley, John and Clark 2006, 41).

The PCH Act 2002 Subsection 20(2) also made the creation of a hybrid embryo a criminal offence, but the proposed amendments permitted licensing of 'the creation of hybrid embryos by the fertilisation of an animal egg by a human sperm, and use of such embryos up to, but not including, the first mitotic division, provided the creation or use is for the purposes of testing sperm quality, and the creation or use will occur in an accredited ART centre' (PHCR and RHER Bill 2006, Subsection 20(1)). However the creation of 'hybrid embryos by introducing the nucleus of a human cell into an animal egg, and the use of such embryos' was prohibited (Dudley, John and Clark 2006, 44).

Similarly Section 17 of the PHC Act 2002 made it a criminal offence to use precursor¹⁴⁵ cells from a human embryo or foetus with the intent to create or develop a human embryo but the new bill authorised these activities under licence (Dudley, John and Clark 2006, 43). The original ban on using precursor cells to create an embryo were based on concerns it might be possible to create a human who has never had a living genetic parent (LRC 2005^b, 14).

¹⁴⁵ A precursor cell is defined as a cell that has the potential to develop into a human egg or human sperm (Dudley, John and Clark 2006, 42)

In December 2006, the House of Representatives voted 82-62 in a conscience vote to pass Liberal Senator Kay Patterson's private member's bill despite opposition from the Prime Minister, Opposition Leader, Treasurer and Health Minister (Murphy 2006). The new Act amended the Prohibition of Human Cloning Act 2002, the Research Involving Human Embryos Act 2002 and the Customs (Prohibited Exports) Regulations 1958 to implement the majority of the Lockhart Committee recommendations including the most ethically contentious; permitting therapeutic cloning in Australia.

Table 2 summarises the major issues and public policy responses to research involving human embryos and cloning in Australia in the 20 year period 1986 to 2006. Over time, the policy process has engaged with these issues in an essentially instrumental manner focussing on facts and definitions in an attempt to manage the much more difficult contested political issues of meanings and values. In a relatively short time period, in public policy terms, the embryo has evolved from a human entity, whose purpose was reproductive and entitled to guardianship and protection to a resource valued for its utility in scientific research, potential therapies and commercial gain. In terms of experimentation, the embryo has moved from a status of human who can only be subject to therapeutic research to that of 'human entity' subject to destructive research under specified conditions.

Table 2 Embryo Research and Cloning Policy Responses 1986-2006

Year	Inquiry/Report	Major issues	Embryo definition and attributes	Key recommendations	Policy response
1986	'Human Embryo Experimentation in Australia' (Tate) Report	<ul style="list-style-type: none"> • Definition Human Embryo • Attributes of the Embryo (moral status) • Definition of therapeutic and non therapeutic (experimental) research 	<ul style="list-style-type: none"> • The entity which exists from the completion of the fusion of egg and sperm(9) • Fertilised ovum has 'life', is genetically human and has developmental potential (8-9) 	<ul style="list-style-type: none"> • For the purposes of biomedical ethics, the embryo is human • Embryo entitled to protection and guardianship • Interests of the subject (embryo) prevail over that of science and society • Cooperative Federal State regulatory framework 	<ul style="list-style-type: none"> • No national legislation implemented • Report 'buried' • NHMRC Guidelines amended 1992 –Supp note 4 • 1996 NHMRC ethical Guidelines on ART
1998	'Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings' Australian Health Ethics Committee (AHEC) report (rescinded)	<ul style="list-style-type: none"> • Definition Human Embryo • Distinction between cloning cells and whole humans • Distinction between therapeutic and non therapeutic research • Inconsistent legislation /regulation in Australia • Emergence of commercial interests in biotechnology (Chalmers Hansard 1 /3/00) 	<ul style="list-style-type: none"> • The developing organism from the time of fertilisation until significant cellular differentiation has occurred, when the organism becomes known as a foetus(at the 8th week of development) (p51) 	<ul style="list-style-type: none"> • Prohibition of human reproductive cloning • Regulatory framework consistent with NHMRC guidelines in all States and Territories • Establishment of a non Human primate research centre 	<ul style="list-style-type: none"> • AHEC report Referred to House of Representatives Standing Committee on Legal and Constitutional Affairs for review
2001	'Human cloning, scientific, ethical and regulatory aspects of human cloning and stem cell research'. Standing Committee on Legal and Constitutional Affairs (Andrews) Report	<ul style="list-style-type: none"> • Definition of embryo • Moral status of embryo • Reproductive and therapeutic cloning • Limits of science • Excess ART embryos 	<ul style="list-style-type: none"> • Embryo defined as the completion of syngamy • Andrews glossary uses AHEC definition 	<ul style="list-style-type: none"> • Prohibition of human reproductive cloning • National regulatory framework for human embryo research • Creation of licensing body • Destructive human embryo research permitted under licence • 3 years moratorium on SCNT 	<ul style="list-style-type: none"> • COAG Agreement • Research involving Human Embryos and Prohibition Cloning Bill drafted • Bill referred to Senate Community Affairs legislation Committee • \$ 46.5 million federal funding for stem cell research from Backing Australia's Ability, Biotechnology Centre of Excellence Program

Year	Inquiry/report	Major issues	Embryo definition and attributes	Key recommendations	Policy response
2002	'Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002' Senate Community Affairs Legislation Committee	<ul style="list-style-type: none"> • Reproductive and therapeutic cloning • Therapeutic potential of ESC and ASC • Scientific uncertainty • Destructive embryo research • Moral status of embryo • Commodification of human life • Economic impact 	<ul style="list-style-type: none"> • A live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means (as per Bill) • Embryo has some moral status but not full moral status 	<ul style="list-style-type: none"> • Purpose of document was to inform Senate in its deliberations • No formal recommendation made • Need for nationally consistent legislation recognised 	<ul style="list-style-type: none"> • RIHE Act 2002 and PHC Act 2002 passed on conscience vote • Australian Stem Cell Centre established 2002 • NHMRC Embryo Licensing Committee established 2003 • \$55 million federal funding from Backing Australia's Ability II, to the Australian Stem Cell Centre
2005	'Legislation Review, Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002 Report' (Lockhart Report Dec 2005)	<ul style="list-style-type: none"> • developments in ART and in medical and scientific research since 2002, • potential therapeutic benefits of such research • Establishment of a National Stem Cell Bank.' 	<ul style="list-style-type: none"> • a discrete entity arisen from the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears; and has not yet reached 8 weeks of development since the first mitotic division • moral significance of SCNT embryo linked to potential for research development 	<ul style="list-style-type: none"> • Retain ban on reproductive cloning • Continue research on surplus ART embryos • Permit research on embryos until first cell divisions • Permit creation of <ul style="list-style-type: none"> ➢ human embryo clones through SCNT ➢ Hybrid embryos ➢ Embryos with DNA of more than persons 	<ul style="list-style-type: none"> • Howard proposes no change to legislation (July 2006) • COAG Communiqué (July 2006) • Release of MP consulting report (2006)
2006	'Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006', 'Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006' (Patterson Private Member Bill)		As per Lockhart recommendation	Implement Lockhart recommendations as above	'Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006' passed on conscience vote.

4.10 Embryos, Politics and Policy

Advances in embryology and associated medical technologies have made defining the embryo in material terms straightforward. There is no argument that each embryo is part of a single physical continuity from fertilisation through to birth. It is accepted that fertilisation is not a finite point but a developmental process from which the new entity will continue to develop, into a fully fledged human being, given the appropriate environment. This is not altered by the capacity of technology to suspend development and store the embryo for months or even years. Whether that embryo shares another human's genome as a result of a natural phenomenon or deliberate technical intervention does not change this reality.

New technological developments allowed for new modes of production of the embryo which raised new political issues and the need for new policy responses. Breakthroughs in ART allowed for new techniques of fusing sperm with ova; SCNT makes 'cloning' a reality through the fusion of a somatic cell with an enucleated ovum. The result, if successful is an embryo. Public policy must engage with the question 'Are these embryos different because of their mode of production?' Thus the question of value lies not with *what* they are but *how* they were created. Does a different mode of production result in a different entity and justify different treatment?

Similarly public policy has confronted the changing issue of the *purpose* of embryos. ART embryos are created for the purpose of reproduction, but those considered excess to reproductive needs can be used for research purposes with the consent of their donors. Embryos created through SCNT have no reproductive purpose at present, so the only rationale for their creation is research. Again the policy process has moved away from consideration of what the embryo *is* and now deliberates on its *purpose* for being. Does different purpose result in a different entity and justify different treatment?

As the field of embryo research and cloning has developed, terminology which describes the practices and products has evolved. The distinction between reproductive and therapeutic cloning is one example. Therapeutic cloning results in destruction of the host embryo for potential therapeutic discoveries. Previous understandings of embryo as human subject would have termed this practice non therapeutic or experimental research as distinct from therapeutic research.

The rapid developments in biotechnology from the creation of the first in vitro embryo to the birth of the first IVF human to the birth of the first cloned mammal to the establishment of the first human embryo stem cell line have confronted publics and policy makers with issues that were previously unimaginable. The ethical debates surrounding embryos are unlikely to be resolved. Disaggregating embryos into developmental stages and ascertaining units of moral worth depending on that stage does not satisfy opponents of destructive ESC. If one believes a human life is a human being from the moment of conception, then its developmental stage is an irrelevance to its moral status. Similarly its mode of creation, whether sexual reproduction between male and female, ART or cloning technology is an irrelevance to its moral status once it comes into 'being', even if those modes of creation are themselves considered ethically suspect. Likewise, its purpose whether reproduction or research, becomes a moral irrelevance. To those who believe the embryo is fully human, that life once created is entitled to all the protections and rights of any other living human being including the right to life. If one does not agree with this position, then there are a multitude of possible ethical positions contingent on developmental stage, mode of creation and purpose of creation, all the way to no moral worth at all.

The ethical dimension of the ESC and cloning debate impacts on health, science and economic interests and the multiple ethical positions must be mediated by the policy process. However as Franklin (1999, 112) points out, official reports and the findings of parliamentary committees usually begin with a summary of the science as if it is 'neutral, objective, factual basis that constitutes a shared, undisputed territory'. This obscures the real policy debate which is about society and how it responds to new

technology, not the new technology itself. The real challenge is not about how to regulate technology but how to have a democratic and inclusive conversation about it (Franklin 1999, 119).

The essential conflict over the moral status of the embryo remains irresolvable by appeal to rational fact or for that matter rational objective policy processes. Policy decisions, however, are made and legislation and regulatory frameworks have been implemented. In the next chapter I will analyse the interests which have surfaced in the ART and ESC research and cloning policy arenas and the central role of discourse and narrative in the Australian policy outcomes.

5 Chapter 5 Interests, Narratives and Discourse Coalitions

In the days when an idea could be silenced by showing that it was contrary to religion, theology was the greatest single source of fallacies. Today, when any human thought can be discredited by branding it as unscientific, the power exercised previously by theology has passed over to science; hence, science has become the greatest single source of error (Polyani 1957, 480).

Fukuyama (2002, 5) claims the debate over biotechnology is essentially polarised. On one side sits the supporters of unconstrained technological development and on the other are those who have moral concerns over the impacts of biotechnology. The former comprises the scientists, researchers and biotechnology industries who stand to benefit most from technological advances while the latter is a 'more heterogeneous' group including conservative religious groups, people who belief in the sanctity of nature, 'Luddite opponents of new technology' and those with concerns over eugenics. Similarly, within the narrower specification of embryo research and cloning, Ankeny and Dodds (2006, 104) say the media have framed the debate in terms of 'science versus religion' or religious irrationality¹⁴⁶ versus scientific rationality.

As noted by Dodds and Ankeny (2006) such simplistic dichotomies have limited usefulness. There are multiple sectoral interests within both ART and ESC policy arenas and within the sectors there are competing policy positions. In both ART and ESC research and cloning, interests can be broadly categorized as ethical, scientific, health and welfare and those relating to industry. These are not mutually exclusive categories which make a policy analysis based on interests or even coalitions of interests¹⁴⁷ unsatisfactory.

In the first part of this chapter I will identify the key interests in ART and ESC research and cloning in Australia. In the second part, I will argue that interests are informed by a number of different discourses and the policy outcomes in both arenas can be explained through the storylines or narratives they create around

146 Professor Alan Trounson received wide media coverage after labeling the Catholic Church irrational hypocrites over their opposition to destructive ESC (AAP, 2 August 2002, Shanahan, The Australian 6 August, 2002)

147 See discussion on Sabatier (1088) in Chapter 2

embryos. These storylines allow fragmented sectoral interests to form Hajerian¹⁴⁸ type discourse coalitions which endorse particular policy outcomes as being in the public, and in the case of ESC and cloning, the national interest.

Finally I will compare policy outcomes in the two domains. I argue that in both domains, proponents of technologies are able to create storylines which construct the embryo as a resource rather than a fully moral agent. In the case of ART, the storyline which informs policy outcomes is one of hope. The discourse coalition which forms around this storyline constructs the embryo in terms of its capacity to accomplish a specific need; namely fulfilling the child wish and in this process the commodification of the embryo begins. In its reproductive context, the embryo is also the subject of purposeful research to improve ART outcomes. ART policy stays within the essentially private realm of reproductive health which in the Australian context results in a fragmented policy framework controlled by State and Territory governments rather than the national government. The national government exerts the same policy control in this health arena as it does in any other health arena through the national health insurance scheme Medicare and the bilateral Australian Health Care Agreements. When the ART embryo emerges from its reproductive context into a purely experimental context the storyline changes to one of saviour science (Goggin and Newell, 2004). The embryo, now fully commodified, is a valuable scientific, medical and economic resource fulfilling a number of needs. It moves out of the private world of reproduction and into the public world of international science. ESC and cloning policy is a national concern, demanding a national policy response. At stake is Australia's international status as a scientific innovator and her capacity to reap the economic benefits of the scientific breakthroughs which this research promises. Alternative storylines which construct the embryo as a human being with full moral status fail to create discourse coalitions strong enough to inform an alternate public policy in these arenas. The debate over the moral status of the embryo remains irresolvable but more importantly in terms of policy outcomes, I contend it is largely irrelevant.

148 See discussion in Chapter 2

5.1 The Public Interest?

As discussed in Chapter two there are multiple understandings of the public interest. In ART and ESC research and cloning, there are the usual claims that sectoral interests serve the public interest and community support for a particular policy is evidence the public interest is being served. Determining community support in contentious policy arenas often begins with an assessment of community attitudes toward those technologies. As discussed in Chapter 3, in Australia, the public is very supportive of ART for married infertile couples and increasingly supportive for single women and lesbians (Kovacs et al. 2003, 537). As discussed in Chapter 4, the Australian public is also supportive of embryonic stem cell research if directed toward improving human health. They are much more sceptical however if the motive is corporate profit or scientific career advancement (Biotechnology Australia Report 2001).

Where questions about human life are central to the policy issue, the public have intrinsic and deep seated ethical concerns (Cormick 2007). In Australia, as in Europe (Gaskell 2005, Critchley and Turney 2004) community attitudes towards emerging biotechnology appear to be context dependent. In Britain, the Wellcome Trust (1998, 4-5) found the 'uninformed public' had 'fearful perceptions of human cloning' and were 'shocked by the implications of cloning technology', especially reproductive cloning. Tellingly, being better informed did little to assuage these concerns. Therapeutic cloning, received more support in the context of beneficial health outcomes, but there were reservations and caveats on the type of research and the uses the public supported. For example, research directed toward curative medicine was supported more than basic research. The Wellcome Trust study (1998, 23-4) found that with more detailed information, apprehension toward therapeutic cloning increased and subjects became more critical of ideas they had initially accepted in their 'uninformed' state. In the USA, Nisbet (2005, 90) found that while increasing 'awareness' of controversial science and technology resulted in increased support for research; this was moderated by religious and ideological value predispositions. In the effort to win the ideological battle over stem cell research, science has worked on the assumption that increased knowledge would result in 'proper' public judgments. That is, a well informed public, after careful and deliberative consideration, will align

themselves with the scientific experts (Nisbet, 2005, 91). In Australia, public support, however, appears contingent on the context in which scientists work with those in the public sector perceived as more trustworthy and benevolent than their private counterparts (Critchley 2008, 324). Acceptance of new technology is more likely if the public trust the individuals and institutions which develop and regulate that technology (Critchley and Turney 2004, 87).

The public are also concerned over the control of biotechnology¹⁴⁹ (Cormack 2002, 6, Fukuyama, 2002, 8) and perceive society and government as powerless compared to international financial interests and the large multinationals which drive scientific innovation. The public are fearful that genetic technologies in corporate hands will not serve the public interest and the pursuit of profits and the patenting system will slow research thus further disadvantaging the public (Collins, 2003)¹⁵⁰. Sheehan (2002, 15) claims that products of scientists' endeavours are '...sure to be taken over and exploited by powerful economic forces...forces born of advances in technology that society endorsed earlier.' In Britain, the Wellcome Trust, (1998, 36-7) found there was little public confidence that regulation could effectively control research or that public opinion could affect the research agenda. Scientists were regarded with cynicism, as individuals driven by their own curiosity to take the next step without regard for the outcomes, driven by a need for recognition and personal accolade. Commercial pressures were perceived as responsible for research being manipulated to serve negative ends and for negative outcomes to be concealed. Similar concerns have been raised in Australia that scientists driven by their own intellectual satisfaction and quest for status and monetary gains, shape the policy debates, excluding the public in the process (SCALC 2002, 63).

The message of distrust is important in debates about scientific innovation, because it suggests that the problem is not new technology, but the social process of coming to terms with such developments which is compromised by the

149 In 1998, the Wellcome Trust found a low level of public trust in scientists and those perceived to be in control of scientific research in the UK. Researchers were believed to be driven by a technological imperative irrespective of wider community concerns. Gaskell et al. (2006, 47-48), however, found that trust in university and industry scientists had improved considerably between 1999 and 2005 throughout the European Union (EU) member states including the UK.

150 ABC 4 Corners Interview , Tuesday 9 July 2003

reproduction of persistent forms of inequality and exclusion (Franklin 1999, 119). Authoritative scientific facts, as presented by experts are privileged over lay opinion which reinforces the power relation between experts and the public which in turn influences the options for governing new technology (Franklin 1999, 119). The public are reliant on information from experts because they generally do not have the knowledge, ability or the time to understand the complexities of new or advanced technologies themselves (Critchley and Turney 2004, 87). This allows particular discourses of ethics, health, science and technology and economics to dominate policy making and more importantly silence alternative discourses.

Public opinion on biotechnology matters politically, because much is at stake for the nation state in terms of international research status and economic wellbeing (Peters 2005, 1-2). Politics has to navigate between retaining international competitiveness and responding to citizens concern over risks and values. Governments embrace commercially oriented science and technology policies in the interests of public health and the economic advantages resulting from commercialisation of innovative research (Bouchard 2007). However it is questionable whether these policies ultimately serve the public interest. Arguably the public interest is best served by a scientific commons which maintains an open, free intellectual exchange. This however is at odds with privatised science which seeks to control and restrict access in the interests of profit maximization. The public private partnership model of science is based on an assumption that private resources and infrastructure are necessary to convert basic research into viable products but this risks 'ghettoization of research lacking in commercial potential, including the possible demise of true public interest science' (Bouchard 2007).

In the era of globalisation, attempts to prevent development of new technologies by any one nation state have little overall impact. Research and development simply moves to jurisdictions with more permissive regulation. Fukuyama (2002, 9) argues that the only way to control technologies¹⁵¹ are through international

¹⁵¹Fukuyama (2002) cites regulation of nuclear weapons, nuclear power, ballistic missiles, biological and chemical warfare agents and human experimentation as evidence that political control is possible and the technological imperative need not prevail.

agreements which are difficult to negotiate and enforce. While such regulation may not be completely 'effective', it acts as a brake and allows powerful nation states¹⁵² to show leadership.

Claiming the public interest is an important rhetorical battle between competing interests. In areas of scientific complexity, where the public have low levels of scientific literacy (Critchley 2007), public opinion formation is heavily reliant on expert interpretation usually expressed through popular media. There is little opportunity for a genuine engagement between knowledge elites and the public or for any critical analysis of the scientific facts in a Habermasian public sphere, particularly in the face of conflicting expert evidence. As argued elsewhere, there is no singular knowledge elite in policy arenas characterised by emerging science *and* conflicting values and public interest is not able to be defined objectively in such debates. Nonetheless, public support, as evidence through opinion polls, is an important legitimating factor in policy makers' decisions and in their claims to represent the public interest.

In their analysis of public interest in ART, Johnson and Peterson (2008, 722) developed a four part typology. The concept was disaggregated into 'public health' and 'financial' aspects which are largely concerned with service provision and 'ethico legal' aspects which were concerned with autonomy. These three interests are primarily restricted to the ART stakeholders which are essentially a medical market with an additional actor, the extra uterine embryo. This brings into play the fourth aspect of public interest, the socio-political. Concerns about the embryo in ART are translated into a much wider concern about the abuse of embryo technology and its subsequent impact on humanity and society's wellbeing, because of the value attached to the embryo as a potential child. For Johnson and Peterson (2008, 722) this socio-political aspect only represents 'a tiny component of the total public interest in ART', therefore the public interest is mostly articulated in the provision of and access to fertility services and the role of public policy in facilitating this.

152 Fukuyama (2002) says the actions of a politically, economically, and culturally dominant country like the United States are important as other countries pay a great deal of attention to what the United States does in its domestic law. He claims an international consensus on the regulation of certain biotechnologies is unlikely in the absence of American action at the domestic level.

As discussed in Chapter 3, IVF polarised opinion when it first appeared on the public agenda. For some it was an obscene intrusion into the private and intimate realm of reproduction. For others the separation of the sexual act from reproduction was an affront to God. For others it was a dangerous interference in nature or the exploitation of women. The ART policy debates saw some of the old allies from the abortion debates realign to oppose ART on moral grounds while the proponents argued for the rights to parenthood and the right to access the technology which made it possible. As the debates matured, however simple dichotomies along moral grounds did not adequately explain policy positions. Radical feminists groups found themselves aligned with the Catholic bishops, pro-life groups and the socially conservative in opposition to ART while the infertile across social, class and gender divides, aligned with fertility advocates, other feminist groups, socially progressive politicians of all persuasions and the normally conservative medical professions to liberalise access to ART for single women and same sex couples as well as married or de facto heterosexual couples.

In a similar fashion the ESC debate has been described as being hijacked by two opposing groups with different interests. On the one side are the conservative 'pro-life' groups who oppose the violation of any human being's right to life, and on the other, are the patient groups, scientific organisations and biotechnology industries who predict restrictive policy on ESC research and cloning will return medical science to the dark ages (Holland, Lebacqz and Zoloth 2001). As with ART however, the ESC policy debate is much more complex and interests are heterogeneous with stakeholders *within* sectoral interests making competing claims to legitimacy in the policy process. In considering biotechnology generally and ESC and cloning particularly, the public interest appears to be contingent on a number of considerations; balancing societal concerns with commercial interests; assessment of potential harms and benefits; fair and equitable access to benefits; and responsibilities of the biotechnology sector to the wider community (Biotechnology Australia Information Sheet 2003).

In the next section I will examine the interests which have emerged in the ART and ESC research and cloning policy arenas and how they have impacted on policy outcomes. I argue that ethical, health and wellbeing, scientific and industry interests can be identified in both policy domains. Within these broad groupings, however, there are competing understandings of what constitutes the policy problem and the possible policy solutions. There are also competing constructions of the embryo. In ART, it is simultaneously a human entity with some claim to moral status, a treatment for infertility, a commodity in the fertility market, a social good which delivers recipients from the undesired social state of childlessness, and the ultimate private good situated in a family as the desired child, preferably biologically related. I will argue that in Australian ART policy making, the *intrinsic* interests of the embryo have minimal impact on policy outcomes despite it being a central actor in this policy arena.

5.2 Assisted Reproductive Technology Interests

5.2.1 The Ethical Dimension

There are four main areas of ethical contention in ART. The first centres on the moral status of the extra uterine embryo. Does it constitute a fully human entity or does it have only a degree of moral worth contingent on its potential to develop into a human being. The second is concerned with the ethics of a technology which separates the act of procreation from the act of sexual intercourse. Does this constitute an affront to human dignity? The third is the contention over whether ART changes understandings of procreational liberty. Namely does the right for the fertile to make decisions about procreation without external interference become the right for the infertile to access ART to fulfil a child wish? This creates a whole set of ethical conflicts over who has the right to be a parent. The fourth main ethical debate centres on the rights of children born as a result of ART. In the Australian context a number of different stakeholders can be identified who claim a legitimate interest in the ensuing policy contest.

The Catholic Church believes it and other religious organisations have an obligation to be a voice for the weak and vulnerable within society and to draw attention to the higher values which are often obscured in public policy debates

(Catholic Archdiocese of Melbourne (CAM) 2000, 8). As such the Catholic Church¹⁵³ is completely resolute on the moral status of the embryo, in their view the most vulnerable member of the human family and uncontrovertibly fully human from the moment of conception (Pullen 2000, 11, Australian Catholic Bishops Conference (ACBC) 2000, 30, CAM 1999, 9). The embryo is thus entitled to full human rights including the right to life, which 'grounded in divine origin is the basis of other rights and the basis of civilised society' (Pullen, 2000, 8). Thus any procedure or technology which treats embryos as a means to an end, and results in the deaths or disposal of thousands is profoundly wrong and morally offensive. As discussed in Chapter 3, the Catholic Church also considers the separation of the act of procreation from the physical act of intercourse as demeaning and disrespectful of human dignity even if the end result is a much desired child within the bounds of marriage. These views however have little bearing on present-day ART practice and policy and any policy position based on a total prohibition of ART is simply not viable in a pluralist polity. Rather, the contemporary ethical debate in ART policy is over access.

The contest over access to ART is a contest over the right to be a parent and the rights of ART conceived children. In its earliest inception ART was a new response to medical infertility but only within the specific social context of marriage or stable de facto relationships. Following the McBain¹⁵⁴ case, marital status was no longer a prerequisite but clinical infertility remained a criterion. The McBain case saw a number of powerful actors collide. The Catholic Church, having lost the battle over ART as an immoral act, sought to ensure access to ART services remained limited to traditional family arrangements for two main reasons. Firstly to protect the child's entitlement to a father and a mother; and secondly they disputed the claim that the creation of a new human being could be compared to any other medical service (Skene 2000). The Women's Electoral Lobby (WEL), concerned about the erosion of women's rights entered the fray. As discussed in Chapter 3, feminists were fractured over ART. To some it was another avenue for the exercise of patriarchal power and the replacement of

153 The more conservative factions within the Anglican Church also hold this position. See Pullen 2000

154 See Chapter 3 The McBain Case p 81

women centred reproduction with technology centred reproduction, while for others it represented a new reproductive choice (McCormack 1991). Post modern feminist readings of ART see it more positively as an instrument with the potential to transform 'patriarchal reproductive hegemony' (Michelle, 2008, 9) forcing new understandings of parent and family. Importantly WEL's concern was not so much about access to ART services than about the implications of a policy response that sought to amend the Sex Discrimination Act in a way that would permit discrimination in specific circumstances.

With the way clear to allow access to ART irrespective of marital status, the next battle was over access to ART on infertility grounds. Same sex couples also had unfulfilled child wishes and lesbians could access ART services due to clinical infertility but not social infertility. Same sex female couples already self inseminated with privately procured sperm which posed health risks. Same sex male couples could become parents through informal surrogacy arrangements, using donated sperm from one male partner, but the birth mother remained a legal parent. ART for social infertility, whether same sex couples or single people evoked strong resistance from socially conservative politicians of all political persuasions and groups such as the Australian Family Association, Women's Action Alliance, Right to Life,¹⁵⁵ again the old allies from the abortion debates. Again protecting the welfare of children was the often cited reason behind their stance. Dower (2001) however, argued the reluctance to extend ART to non traditional family arrangements had little to do with children's welfare but arose from '... a deep-rooted fear of undermining the traditional heterosexual nuclear family'. Groups such as the Australian Coalition for Equality (ACE) an action group for lesbian, gay, bisexual, transgender and intersex (LGBTI) lobbied extensively for recognition of same sex families and equality of treatment under the law including access to ART. One submission¹⁵⁶ to the Victorian Law reform commission (VLRC) succinctly captured the argument saying

155 See list of Submissions VLRC Assisted Reproductive Technology and Adoption: Final Report

156 See ART and Adoption - Submissions Snapshot

<http://www.lawreform.vic.gov.au/wps/wcm/connect/Law+Reform/Home/Completed+Projects/ART+and+Adoption/LAWREFORM+-+ART+and+Adoption+-+Submissions+Snapshot>

The legislative criteria for access to ART and adoption in Victoria excludes and treats differently same-sex couples and single women without any 'reasonable and objective' basis. Whilst some members of the community have particular views of what a family is, and do not approve of either single-parent families, or same-sex-couple families, the nature of a pluralistic and diverse democratic society allows us all to have competing views without any one being able to oppress those in the minority (VLRC 2008).

The Australian policy response to this issue is somewhat ambiguous. The legislation in Victoria (2008) and NSW (2007) clearly legitimises ART services for the socially infertile, while the South Australian and Western Australian legislation retain the medically infertile requirement. Ultimately treatment can only be obtained through a licensed medical practitioner, a transaction which takes place between doctor and client generally in a private medical setting where the doctor makes the final decision whether or not to treat. Likewise the Commonwealth decision to limit Medicare rebates to the medically infertile sends a very strong policy message about what is a legitimate use of public funding and reasserts the idea of clinically diagnosed infertility as the legitimate basis for treatment.

The contemporary policy response to protecting the rights of ART conceived children, particularly in the case of donated gametes, focuses primarily on the rights of children to knowledge of their genetic heritage. The various State based legislation has generally been informed by the NHMRC guidelines¹⁵⁷. All states which have enacted specific legislation now make donation of gametes contingent on agreement to disclosure of identifying information about the donor to any future children. ART conceived children are also entitled to access information about any biologically related siblings. The relevant jurisdictions have created mechanisms to store and manage this information. Where donations occurred prior to enactment of legislation, donors are encouraged to place themselves on voluntary registers. Legislation, however, has no control over whether parents inform their children of the circumstances of their conception. The wellbeing of

¹⁵⁷ See Chapter 3

ART conceived children is further protected through limiting the use of any one donor's gametes therefore minimising the probability that ART born persons might unwittingly form a sexual relationship with a sibling. NSW has controversially extended the notion of protection of ART children through allowing donors to specify criteria for access to their gametes. They reasoned that if children were born into families the biological parent(s) disapproved of, this could affect the child's sense of wellbeing.

Victoria is the only state to protect future children's wellbeing through the use of selection criteria for prospective ART clients based on any history of violent or sex crime or prior removal of a child from their care¹⁵⁸.

The arguments that children's interests are best served by traditionalist heterosexual family structures seem to carry little weight in contemporary ART policy making in Australia. Family structure is increasingly flexible, with growth in single parent, same sex and blended families over the past three decades. Many children live with only one biological parent or share time with both biological parents and their new partners in different living arrangements (VLRC 2007, 24). Although same sex couples constitute only a small proportion of relationships¹⁵⁹, 20% percent of lesbian couples have children living with them (VLRC 2007, 24).

5.2.2 Health and Welfare Dimension

Australian policy responses situate ART firmly in the medical context. Heitman (1999, 24) argues infertility was a prime candidate for medicalisation when early researchers offered the possibility of technologic solution to the personal responsibility for the 'deviance of childlessness'. By the early 1980s, the availability of IVF had placed infertility firmly into the medical model that stressed clinical diagnosis and a range of treatment options (Heitman 1999, 23). By concentrating efforts on technological solutions to infertility, O'Donnell (2000, 138) claims '...the extent to which infertility is socially constructed as an

¹⁵⁸ *ibid*

¹⁵⁹ ABS (2009) data reveal the number of people living in a same-sex couple relationship increased from 0.2% of all adults in 1996 to 0.4% in 2006, or around 50,000 people. However this is possibly underreported due to reluctance to identify as same sex or lack of knowledge about what the census includes in its definition of couple.

illness, the causes of infertility, and other means of dealing with infertility' are largely left unexplored. Medicalisation of infertility also delivered rewards to medical researchers, clinicians and pharmaceutical companies (Heitman 1999, 25), turning ART into a lucrative industry.

Australian ART legislation sits with the relevant State Health Ministers and Medicare is the policy responsibility of the Australian Health Minister. While guidelines and legislation identify the need for support and counselling for people undergoing ART services, there is little question that ART is medical treatment which attempts to cure infertility through the production of a living child. Even if the infertility is social in origin, ART situates women as patients requiring tests and medical procedures in the clinical setting.

The health and welfare interests in ART are multiple and sometimes contradictory. As with any other expensive, high technology medical services, there is a tension between demand and supply which is played out mainly between funders of services on one hand and the providers, consumers and advocates of ART, on the other. As discussed in Chapter 3 the particular form of health service provision in Australia is a complicated mix of Federal and State jurisdiction, government funding and private/public provision, with most ART services delivered in the private setting but substantially subsidised by Medicare¹⁶⁰. In the context of ART, the funder is predominantly the public purse administered through state and federal health programs while the providers are predominantly

¹⁶⁰ It is beyond the scope of this thesis to discuss the complexities of health delivery in Australia. There are however a number of structural tensions in the system. One such tension is the concept of private patient for specialist treatment. A patient is private in the sense of being referred from one doctor to another for professional consultation. However for out of hospital services, Medicare still pays the rebate for the specialist scheduled fee (generally 85%). The consultant can set their own fee which is generally higher than the Medicare scheduled fee meaning the patient must pay the gap between the Medicare rebate and scheduled fee *and* the gap between the scheduled fee and the actual fee charged. This is usually referred to as 'out of pocket expenses' incurred by the patient and for some services can be quite large. If services are provided in hospital, in some cases, private health insurance will pay the gap. Doctors' fees are not regulated and in theory the doctor can set any price for their service. The AMA has a List of Medical Services and Fees which may be used as a guide.

In Australia, specialist medical services are essentially private businesses sometimes with one practitioner but often with groups of doctors, other health professionals and support staff. The fees charged must cover the cost of premises, staff wages, insurance, supplies and all the other costs of running a business as well as providing an income for the doctor.

privately owned IVF clinics¹⁶¹. The key actors on the supply side are the IVF specialists, the Australian National Infertility network ACCESS, the Fertility Society of Australia, the IVF Directors Group and in specific contexts gay and lesbian advocacy groups and women's advocacy organisations such as WEL. In addition the Australian Medical Association (AMA) 'supports the right of every woman to make her own decisions about reproduction and about her use of available and appropriate reproductive technology as long as she is fully informed of the risks and potential outcomes' (AMA 2005).

The health professionals involved in the provision of ART services also have a major interest in ensuring quality of services. This is done in part through FSA sanctioned accreditation and through credentialing by professional bodies such as the Royal Australian & New Zealand College of Obstetricians and Gynaecologists (RANZCOG). Reproductive Endocrinology & Infertility is a subspecialty within the specialty of Obstetrics and Gynaecology and the College offers the Certificate of Reproductive Endocrinology and Infertility (CREI) as an additional qualification to its Fellows. While the CREI is not a prerequisite to treat infertility, it is an expectation of the College that leaders in the field and directors of assisted conception units will hold this qualification¹⁶². ACCESS Australian National Infertility Network advises prospective clients to consult with 'an infertility specialist with CREI qualifications'¹⁶³. In Australia ART, like most specialist health services is essentially self regulated (Saunders Senate Hansard 24 September 2002, 188).

The restriction of ART services to medically infertile women by some state legislatures could be interpreted as an attempt to control demand for an expensive, non essential medical service with relatively poor success rates when State governments are under extreme budgetary pressure to provide a whole range of health services. Likewise the restriction on Medicare rebates for the clinically infertile and the proposed changes to the EMSN can be seen as a federal

161 See Fertility Society of Australia accredited treatment centres

162 See RANZCOG website http://www.ranzcog.edu.au/fellows/sub_crei.shtml Accessed 12 September 2009

163 See ACCESS website http://www.access.org.au/about_infertility Accessed 12 September 2009

government attempt to control demand. However compared to similar countries, Australia has very generous public funding provisions for ART (Smith 2006, 3), placing no age restrictions or limits on the number of treatment cycles funded despite firm evidence that ART is significantly less successful for older women and with each subsequent treatment cycle (ARTRC, 2006, 67). Following the review of assisted reproductive technologies in 2005, the Australian Health Minister flagged a number of changes to Medicare including limiting the number of ART treatment cycles funded by Medicare to three per year for women aged 42 and under and to three cycles in total for women over this age due to low success rates and rising Medicare expenditure, a policy measure estimated to save approximately \$7 million per year (Smith 2006). Following public challenge from the IVF lobby, these changes were never made (Gordon, 2009). The AMA also came out in support of the status quo calling the proposed budget cuts 'a callous attack on the dreams of hopeful women and families' (AMA 2005). Similarly with the recent proposed changes to the EMSN the AMA again lobbied the government claiming that the changes will substantially increase out of pocket expenses for patients using ART services (AMA 2009) thus limiting access to treatment. ACCESS estimate increase in out-of pocket costs of around \$3,000 per treatment cycle (ACCESS, 2009) a claim refuted by the Department of Health and Ageing (DoHA, 2009, 38).

A review of the EMSN commissioned by the Australian Government Department of Health and Ageing (DoHA) found ART services to be an area of concern. EMSN funding of ART services increased from \$29 million in 2004 to \$72 million in 2007 and ART accounted for 22% of EMSN expenditure (Centre for Health Economic Research and Evaluation (CHERE) 2009, 46). From 2003 to 2007, the amount of public funding for assisted reproductive services increased from \$55.5 million to \$158.7 million, with 70% of this increase attributable to the EMSN (CHERE 2009, 49). Of further concern, was the overall rise in fees since the introduction of the EMSN by around 4.2%, around 70% of the rise attributable to the EMSN resulting in a 'considerable leakage of government benefits towards providers' incomes, rather than reduced costs for patients' (CHERE 2007, vi). The review found the EMSN had made some services, including ART, more affordable for some people but had little impact for those in lower socioeconomic

groups. Given that the MBS items with high out of pocket expenses, allow patients to qualify more quickly for benefits, there was an incentive for providers to bill these high cost items placing fewer competitive constraints on their fees (CHERE 2009, vii).

The implication that IVF specialists were deliberately increasing fees to take advantage of this situation was refuted by the AMA and the IVF Directors Group who retaliated with claims that the methodology used by CHERE was questionable and the research had failed to consider the rapidly increasing costs in the sector (AMA 2009, Metherell and Miller, 2009, Metherell 2009).

5.2.3 The Science and Research Dimension

ART has always had a dual nature; it is a clinical practice and a field of continuing scientific research. Contemporary ART is the result of extensive research and experimentation on human gametes and embryos. Improvement in success rates, and development of successful techniques such as single embryo transfer result from a body of knowledge built up over many years. As such research interests in ART sit in a tradition of biomedical research for a purposive good (O'Hear, 1989, 11).

The NHMRC guidelines grappled with the duality of ART, specifying the conditions under which research on embryos was permissible, acknowledging their potential humanity therefore the special consideration due to them. In short, destructive embryo research was only permissible if it led to significant gains in knowledge and developments in ART practice. When embryo research moved out of the specific ART context, into the wider biotechnology context, there was a seismic shift in understanding of what constitute significant advance in knowledge and permissible use of embryos in research as discussed in Chapter 4.

Scientists and clinicians in the ART field have a particular interest in human embryos for research and training in pursuit of successful fertility outcomes. Thus they have legitimate interest in any legislation or regulatory framework which impacts on access to embryos despite a quite different research focus to that of

ESC research per se. Scientists in Reproductive Technologies (SIRT), a special interest group representing the scientific membership of The Fertility Society of Australia, is the recognised advocate for scientists working in the field of assisted reproduction and fertility.

IVF researchers and clinicians had concerns that the 2002 Research Involving Human Embryos legislation would curtail existing ART research resulting in impaired clinical outcomes. The IVF industry relied on access to embryos, both fresh and frozen for embryology training programs, laboratory quality assurance processes and embryo culture system improvements and techniques. Further because there was no distinction in the legislation between ‘normal’ embryos and those with no capacity to develop normally, which were routinely used for training purposes, they feared a valuable resource could no longer be used without licence (Monash IVF, 2002). There was also some trepidation that the proposed licensing system would make embryology research and development work more difficult because each project, no matter how small would require ‘a protracted submission’ (Bowman, 2002). The Lockhart review heard that licence application process had at times been slow and complicated (SIRT 2005). Sydney IVF (2005, 21) criticised the Licensing Committee for its micromanagement of embryo research projects, and duplication of HREC activities. They also claimed excess embryos were ‘inappropriately’ treated as human research subjects which caused long delays while ‘...relatively minor technicalities are resolved.’

There was a perceived risk from some quarters that the licence committee would be structured so as to effectively ban further research work which in turn could impinge on IVF success rates¹⁶⁴ and a belief that the RIHE legislation would in effect restrict IVF research and practice (Bowman 2002). Describing the 2002 legislation as proceeding from ‘a denominational, faith-based, minority moral position on Australian society’, Sydney IVF, (2005) were highly critical of its impact on ART research and practice. They claimed the legislation had made fertilisation of a human egg for research illegal in Australia which hindered

164 Dr Saunders told the SSCALC Inquiry Australia, as a country led the world in IVF success rates Senate Hansard 24 September 2002, 202

research into oocyte maturation and factors affecting infertility in older women and the ban on therapeutic cloning made research into human fertilisation and early embryonic development illegal. Further, the safety of novel fertilisation procedures could not be examined prior to implantation and any abnormality in the subsequent child would remain undetected until after birth, an unsatisfactory outcome for clinicians, parents and the child. As discussed in Chapter 4, the 2006 amendments to the national legislation dealt with these issues.

5.2.4 The Assisted Reproductive Technology Industry

In Australia, as in most of the developed world, ART is not just a medical service- it is an industry. As discussed above, the majority of ART services are provided in the private sector and demand for ART services in Australia has grown by almost 10% per annum since 2004 (DHA 2009, 32). ART has become an attractive proposition for private investment due to its continued growth and the fact it is heavily supported by taxpayer funding (Williams 2008). Public expenditure through Medicare grew from \$39.3 million in the calendar year 2000, to \$202.2 million in calendar year 2008, with the greatest increases following the introduction of the EMSN (DHA 2009, 32).

Continuing investment in the sector by large financial corporations, including the Macquarie Bank, ABN Amro and Quadrant Private Equity, demonstrates the profitability of ART as an industry (DHA 2009, 35, Williams 2008). In 2008 'IVF Australia' acquired 'Melbourne IVF' in a corporate deal and the combined company now supplies 30% of IVF services in Australia making it the market leader (Vantage Private Equity Growth (VPEG) 2009). IVF Australia reported a \$5 million net profit on \$26.9 million revenue for the 2006-07 financial year and Sydney IVF made a \$3.8 million net profit on \$45.9 million revenue in 2007, a substantial increase from the previous year (Williams 2008).

IVF specialists are highly paid, the top 10% receiving \$4.5 million each from Medicare alone in 2008 (DHA, 2009, 33). The total remuneration increases further when patient contributions are included. The AMA (2009) argues these figures are not a valid proxy for doctors' incomes as the fees generated must also

cover the costs of running a practice. In the case of ART this includes a significant labour component for nurses, scientists, technicians and counsellors as well as practice infrastructure costs which vary considerably depending upon the size, nature and geographical location of the practice.

Australian ART companies already have international affiliations and offer scientific and clinical training products and consultancy services to the international market¹⁶⁵ as well as providing treatment in Australia to international clients¹⁶⁶. Despite these very considerable profits, gamete and embryo donation are largely altruistic and commercial surrogacy is prohibited in Australia. When relinquished by their donors, with no further instructions, ART clinics retain ownership of gametes and embryos.

As discussed in Chapter 4, with the advent of ESC research and cloning, the embryo became a very valuable commodity. The policy debate moved out of the reproductive context and into the much broader biotechnology context reigniting some old ethical debates and bringing new debates onto the policy agenda. Again the embryo is a central actor and again it has multiple constructions. As discussed in Chapter 4, the controversy over the moral status of embryo takes on a new urgency in the context of ESC research. The ethical debate shifts ground as the scientific and clinical potential of the embryo is realised bringing new and powerful stakeholders to the fore.

5.3 Embryonic Stem Cell Research and Cloning Interests

5.3.1 The Ethical Dimension

In the Australian stem cell and cloning policy debates, traditional Christian churches, affiliated organisations and conservative family groups, have articulated the main ethical arguments against embryonic stem cell research and cloning. In laying claim to a legitimate voice in public policy, the Anglican Church claims that many of Australia's moral attitudes, ethical values and laws are embedded in

165 See Monash IVF website <http://www.monashivf.com/default.asp?action=article&ID=21605> also Sydney IVF <http://www.sydneyivf.com/AboutUs/Worldwideservices/tabid/81/Default.aspx>

166 see IVF Australia website <http://www.ivf.com.au/IVF-International-Patients.aspx> also Sydney IVF <http://www.sydneyivf.com/Howwecanhelp/Internationalenquiries/tabid/135/Default.aspx>

the Judeo-Christian tradition conferring on the church a leadership responsibility to identify and articulate serious moral concerns (Pullen 2000, 3). Likewise, the Catholic Church, while recognizing the plurality of the Australian society believes that the Church speaks for a 'sizeable proportion' of the community when it reasserts common morality and adds its own particular 'spiritual perspective'.

Christian opposition to cloning and embryonic stem cell research is based on the perceived violation of a number of basic Christian principles:

- The sanctity of human life;
- The status of the human embryo and the beginnings of human life at conception¹⁶⁷;
- The dignity of humanity ('imago dei');
- The legitimacy of scientific enquiry and the limits and boundaries of our knowledge;
- The accountability of science to society and its use for the good of all;
- The need to ensure justice for those who are most vulnerable;
- The role and function of the family in society (Pullen 2000, 9).

As discussed above, in both Anglican and Catholic traditions, the 'sanctity of human life' is a fundamental premise derived from the doctrine of God as creator. While acknowledging other moral responsibilities such as the relief of suffering and the eradication of disease, if it occurs at the expense of another human being, regardless of its developmental stage, it is unethical. To base moral worth on developmental stage is simply another form of discrimination which reverses the moral imperative to protect the most vulnerable (Knights of the Southern Cross 2000). The consideration of the relative 'value' of the embryo as compared with some other outcome is not legitimate if the end can only be achieved by the destruction of the embryo. To devalue some human lives in such a way is to devalue all human existence (Russell 2006, 4).

167 In Australia there is a range of positions within the Anglican Church. For some, destructive experimentation on embryos up until 14 days post fertilisation is ethically permissible whilst others are opposed to any destructive ESC research. See <http://www.anglican.org.au/docs/SICloningNewell.pdf>

Neither Anglicans nor Catholics accept the distinction between reproductive and therapeutic cloning. They argue that such a distinction is misleading and sound policy requires 'absolute frankness on this point' (CAM 1999, 2). While there are different outcomes, the deliberate manipulation of the human being in a utilitarian fashion is ethically problematic, whether the result is a cloned child or a replacement organ (SRC 2000, 12). Further the Anglican Church considers non reproductive cloning as ethically more controversial arguing that to clone with full intent of destroying for spare parts is even more morally repugnant (SRC 2000, 22).

The mainstream churches affirm the 'rightness of scientific investigation' but take a strong normative stance regarding scientific endeavour at all costs , arguing it should be ethically justified and measured against the moral standards of the society and directed towards societal goals and justice. Ethical research aimed at furthering knowledge of human genetics, fertility, health and therapeutic interventions aimed at preventing or correcting diseases or disabilities are supported. However, activities which might be harmful to embryos or fetuses including freezing and procurement of tissues or organs are both immoral and unethical (CAM 1999, 9). Further, intellectual curiosity, potential for profit and availability of suitable materials are not in themselves a justification for the pursuit of a particular scientific goal or knowledge (truth). Society has the responsibility for the use and direction of science, scientific truth and discovery; it is not the sole remit of scientists, doctors and private companies. Scientific progress is a societal choice and public policy and law should serve the values of the community rather than scientific and technological imperatives (SRC, 2000, ACBC 2000, CAM 1999).

Other Australian Christian churches including Baptists (LHR Sub 280, 2005), Presbyterians (LHR Subs 531, 540, 2005) and the Uniting Church of Australia (LHR sub 486, 2005), give added voice to the issues which concern the Catholic and Anglican hierarchy. They reiterate the positions of the dignity of human life, full moral status from conception and the ethical paucity of any scientific research which allows any human to be used as a means to an end.

Christian ethics groups (Centre for Applied Christian Ethics (CACE) 2002, Southern Cross Bioethics Institute (2000, 2005), Queensland Bioethics (2005), and Right to Life groups¹⁶⁸ concur with the traditional Christian perspective; reproductive cloning should be prohibited, destructive embryo research should be prohibited and the distinction between reproductive and therapeutic cloning is a convenient construct by those who wish to pursue the latter. The continuity of the human entity from conception to birth confers in it full human rights and to make moral status contingent on developmental stage is ethical sophistry.

During the Andrews inquiry and the subsequent SCALC review in 2002, a number of submissions¹⁶⁹ from churches, bioethical organisations and individual ethicists emphasised their support for stem cell research using adult stem cells, which did not involve destruction of embryos or any requirement to produce embryos specifically for research, therefore circumventing the main ethical stumbling block. This theme was strongly reiterated during the legislative review process in 2005 particularly in light of lack of progress in developing therapeutics from embryonic stem cell research¹⁷⁰.

Traditional Christian moral concerns do not represent the entire gamut of ethical issues in ESC and cloning. For feminists, the moral status of the embryo or Kantian 'means ends' debates are not the issue; rather they raise concerns over commodification of and appropriation of women's bodies in the interest of scientific knowledge and economic gain. As discussed in Chapters 3 and 4, feminists are suspicious of technologies, such as ART and ESC research and cloning, which they believe reinforce patriarchal relationships of power. Ankeny

168 Queensland RTL, Victoria Pro Life. See also submissions to SCALC 2002; Subs 1028, 1031 Right to Life NSW; Sub 1003 RTL Victoria; and Sub 1502 Salt Shakers.

169 See submissions to Andrews Inquiry; Sub 17 Centre for Applied Christian Ethics; Sub 82 QLD Right to Life; Sub 221 Catholic Archdiocese of Melbourne; Sub 233 Southern Cross Bioethics Institute; Sub 277 Australian Catholic Bishops Conference and Submissions to SSCALC 2002; Sub 667 Human Life International (AUS); Sub 86 Dr. Nicholas Tonti-Filippini; Sub 211 Do No Harm; Sub 282 National Civic Council; Sub 672 Anglican Diocese of Sydney; Sub 892 Southern Cross Bioethics Institute; Sub 898 Newell; Sub 981 Australian Catholic Bishops Conference.

170 See LRC submissions: Sub 482 Catholic Bishops; Sub 246, Civic Council; Sub 248 Catholic Women's League; Sub 361 and 259 Australian Family Association; Sub 360 Endeavour Forum; Sub 376 Right To Life QLD; Sub 406 Christian Adult Institute; 4 Sub 51 Southern Cross Bioethics institute; Sub 540 Lutheran Church; Sub 780 Anglican Church; Sub 505 Australian Christian Lobby; Sub 531 Presbyterian Church.

et al. (2005) have no moral objections to creating embryos specifically for research, but argue that the donation of oocytes and other tissues must be conducted in a manner which is 'fair and respectful but non paternalistic'. Central to this is full and informed consent, explicit acknowledgement of potential health risks involved and voluntary donation, free from coercive pressures, financial or otherwise. Further there should be full disclosure of the 'likely use of their donation, including details about likelihood of production of patentable products and profits, and whether profits will accrue to the public or private sector (Ankeny et al. 2005).

Feminist International Network of Resistance to Reproductive and Genetic Engineering (FINRRAGE 2002) argue that ESC research is driven by the scientific imperative but the ethical premise of this research is the manufacture of hope. To attempt to place the interests of women as a gender above the interests of the potential beneficiaries of ESC research is to challenge this hope. Nevertheless, all embryo research is founded in women's reproductive labour. Without oocytes, embryo research cannot proceed but women are dehumanised in the process just as they are in other reproductive technologies. In ESC research women are reduced to breeding stock, 'as suitcases for exquisitely screened products in the ultimate triumph of eugenics' (FINRRAGE 2002). Drawing parallels with the IVF industry and its hyped up promises, feminists are concerned the ESC and cloning debates are driven by the research and biotechnology interests who are 'intolerant of voices from other communities' (FINRRAGE 2002).

In Australia, other ethical concerns, focused on tampering with nature, particularly in the cloning and germ line engineering contexts (Fukuyama 2002, 5, Shepherd et al. 2007, 382) have had little impact in public deliberations.

While much of the ethical debate on ESC research and cloning has been promoted by groups and individuals opposed to the technology, a different ethical position is forwarded by some proponents of the research. Savulescu (2000, 2005^a) argues for a moral imperative to engage in this research because of the enormous potential for good in the form of life saving treatments for common diseases as well as the promises of breakthroughs in regenerative medicine. Further the use

of excess ART embryos is respectful because it gives some meaning to their existence through the opportunity to contribute to scientific knowledge which in turn will ease human suffering (ACCESS, 2005). Savulescu and Foddy (2005) argued it is morally wrong not to engage in beneficial acts within our reach and it is deeply wrong to prohibit research 'unless the reasons to impede the research are as strong and as certain as the benefits'. They agreed the moral status of the embryo, was an irresolvable controversy but 'policy on stem-cell research should not be dictated by the controversial beliefs of a vocal minority, especially when the research seems likely to save so many lives' (Savulescu and Foddy 2005).

Devolder (2005, 369) and Parker (2005) contend that one cannot morally defend the creation and sacrifice of embryos to fulfil a child wish through ART but condemn the creation and sacrifice of embryos for the benefit of the ill and injured who might benefit from stem cell therapies. This would appear to refute arguments there is a substantive moral difference due to intent. In drawing analogies between ART and ESC research cloning, one should consider that the outcomes of the former are already tangible whilst the latter is yet to deliver on any substantial therapeutic level. The benefits that have accrued from ESC research and cloning can be thought of in terms of professional prestige to individual researchers, the patenting of discoveries which have the potential to deliver future financial rewards to them and their partners in the biotechnology industry.

At the most extreme end, Swanton (2005, 3) makes an ethical case for reproductive cloning and embryo research based on three principles:

1. That the same weight should be given to the interests of others as one gives to one's own interests;
2. Genetic discrimination is unacceptable;
3. Scientifically, human embryos are collections of cells, not rational conscious human beings.

He claimed the PHC Act 2002 violated the first principle in forcing a religious perspective of cloning on those who may wish to clone a human for reproductive purposes, arguing that reproductive choices are the domain of prospective parents.

Further the Act is discriminatory because it classifies people according to their mode of conception; the implication being that a cloned person is different (and lesser) than those conceived through more regular means. The third principle is self explanatory in that embryos have no legal status as human persons. On this basis Swanton concludes that human cloning should be permitted, as long as it is safe and the life of the clone not be adversely affected once it is born and research should be permitted on human embryos as long as it 'is justified and acceptable under usual research guidelines' (Swanton, 2005, 4).

5.3.2 The Health and Wellbeing Dimension

In the ESC cell research and cloning policy debates, the promise of these new technologies to revolutionise treatment of disease and disability has been the consistent message (Martin 2005, CAMRA 2005). ESC research and therapeutic cloning is supported by peak professional bodies such the Australian Medical Association (AMA, 1999) and the Royal College of Nursing¹⁷¹ (RCN 1999). Generally, individual disability organisations and disease advocacy groups support this view. The emphasis is on the moral compulsion to use otherwise wasted excess embryos for good use and the promise that ESC will eventually deliver treatments and cures. The organisations quote the extent and financial cost to the community of the diseases they represent and the impact on individual sufferers. They frequently align themselves with saviour science (Goggin and Newell, 2004), reinforcing arguments from the science lobby that restrictive legislation will force Australian research and scientists offshore to the detriment of Australian citizens (Motor Neurone Disease Association 2002, Australasian Spinal Research Trust 2002). Further, a number of disability organisations actively fund biomedical research including ESC research¹⁷². In submissions to the Legislative Review Committee, disease advocacy groups clearly articulated the distinction between therapeutic and reproductive cloning, the need for continual support for both ESC and ASC research and cited the significant breakthroughs in jurisdictions with more liberal regulatory frameworks including

¹⁷¹ RCN supports scientific endeavour with caveats regarding effective control of revolutionary technologies and the capacity for the community to engage in the relevant debates.

¹⁷² See Juvenile Diabetes Foundation SSCALC Sub 896 2002; Diabetes Australia NSW LRC Sub 536, 2005; Retina Australia LRC Sub 578, 2005

the now discredited Hwang research (Spinal Cure Australia 2005, Movement Disorder Society of Australia 2005).

However there are competing viewpoints, particularly within the disability sector. The Australian Federation of Disability Organisations (AFDO) (2005) and the Physical Disability Council of Australia Ltd (PDCA) (2005), peak bodies for people with disabilities, voice concerns over the hype surrounding imminent cures. They question the altruism of ESC research scientists and whether trivial research goals will be pursued at the expense of the more worthy. Further, the National Caucus of Disability Consumer Organisations¹⁷³ (NCDCO 2000) argue the perspectives of health care consumers, specifically people with disabilities, are largely excluded from both the ethical debates and the way in which their bodies are perceived as the 'sites for intended therapy'; therapies which are experimental and potentially pose risks of further damage or disability. In a similar vein, the Disability Action Group (2002) points to the exploitation of images of people with disabilities to promote research on ESC when they as a group do not support destructive ESR and claim they would not avail themselves of treatments based on such research.

Leipoldt (2002) says the use of disability as a lobbying tool for the biotechnology industry is offensive. People with disabilities are portrayed as tragic; awaiting rescue in the form of miracle cures from ESC research. He questions the altruism of a research lobby that is the recipient of government funding and the potential beneficiary of enormous private profits from their research. Newell (2000) says 'the embryonic stem cell debate talks *about*, rather listening *to* Australians with disabilities' (emphasis added). As a result, people with disabilities who support ESC research have their lives painted as tragedy whilst those who oppose it, largely don't get heard.

Goggin and Newell (2004, 51) claim the narrative of the social tragedy of disability and the need for delivery from this catastrophe is underpinned by a number of contentious assumptions:

¹⁷³ Provides policy advice and facilitate the appointment of consumer representatives to government, business and community working groups (NCDCO 2000)

- Disability is an individualized experience as opposed to being created and perpetuated by society;
- People with disabilities are to be acted upon by technology;
- Voices supportive of the technology are heard, magnified and appropriated;
- Heroic delivery from disability is the moral trump card played in debates regarding biotechnology.

Thus, disability is appropriated to secure specific ends, in this case support for ESC research and cloning technology. The technology delivers the victim from disability, provided that society legalises, funds, or embraces such a solution and disability as a political issue retreats until its needed again in the 'powerful politics of media representation' (Goggin and Newell 2004, 51).

5.3.3 The Science and Research Dimension

As with ethical and health and wellbeing interests, in the Australian ESC and cloning policy debate, science interests are neither homogeneous nor mutually exclusive particularly where they form new alliances with industrial and commercial interests.

The Australian Government receives policy advice on scientific matters from peak bodies such as the AAS, the NHMRC and individual experts in the field. The AAS has had significant stakeholder input into the ESC and cloning policy process for more than a decade in the form of reports, forums, papers, media releases and formal submissions (AAS 1999^a, 1999^b, 2001, 2005, 2006) and claims legitimacy in the stem cell policy arena based on 'the knowledge and skills to offer unbiased *and accurate* advice to the Government on the scientific aspects of stem cell science, and on relevant legislative issues' (AAS, 2005, 2) (emphasis added).

In 1999, the AAS identified two potential inhibitors to progress in biotechnology research in Australia:

- Unduly restrictive legislation based on misunderstanding of the benefits and risks;
- The possibility of a public backlash against science if sensitive cultural issues are ignored by private or public scientific work (AAS, 1999^a, 16).

Arguing that policy makers, scientists and the broader community all have a responsibility to facilitate progress in regenerative research, the AAS recognised that public support would be an essential factor in securing public funding, allowing the research to be directed toward serious therapeutic goals rather than trivial cosmetic ends (AAS, 1999^b, 2-4). The AAS also identified the need for national, uniform legislation to fulfil public demand for accountability in this controversial research arena (AAS, 2001, 5).

Since the beginning of the policy debate in the late 1990's, the AAS strongly supported a liberal regulatory framework toward embryonic stem cell research and cloning on two main grounds; the potential therapeutic benefits and maintaining Australia's reputation as a leader in medical research (AAS 1999, 6, 2001, 7). Since 1999, they have maintained the policy position that '...human cells, whether derived from cloning techniques, from ES cell lines or from primordial germ cells should not be precluded from use in approved research activities in cellular and developmental biology' (AAS 1999^a, 2005, 2006). The Academy continued their opposition to reproductive cloning and the creation of embryos, with specific genotypes for disease, for research purposes from egg and sperm donors on the grounds there were adequate surplus ART embryos and embryos unfit for transfer to meet research requirements in Australia (AAS 2006, 5). The AAS were a strong advocate for the distinction between reproductive and therapeutic cloning arguing that only the former should be prohibited. As long as there was no attempt to convert pluripotent cells into a viable embryo in utero there should be no proscription on the creation of such cells. The unlawful act was in the implantation, not the creation (AAS 2005, 4).

Given its peak body status, it is hardly surprising that the AAS policy position reflects mainstream science interests¹⁷⁴ in this field. The Human Genetics Society (2000) supported research including the use of cloning techniques in the quest for novel therapeutics, while opposing reproductive cloning. Nonetheless it acknowledged a diversity of views amongst its membership regarding destructive embryo research as a source of ESC. Monash Institute of Reproduction and Development (2002,1) believed both ASC and ESC research were important lines of inquiry into potential cures for disease, but claimed it could be many years before clinical applications were developed from the latter. Eminent scientists Alan Trounson¹⁷⁵ and Martin Pera¹⁷⁶ believed ESC research held great clinical promise despite being an evolving science (Senate Hansard 24 September 2002) but Pera cautioned 'it would be very wrong for anyone in the scientific community to promise cures in a certain time frame' despite encouraging results in animal models using mouse embryonic stem cells in a number of diseases (Senate Hansard 24 September 2002).

By 2005, the support for ESC research and therapeutic cloning amongst high profile scientists and research organisations was very significant. The Australian Society for Medical Research (ASMR) (2005) supported the AAS position as did BIO 21 Australia¹⁷⁷ (2006). The NHMRC (2005,18) recommended continued access 'to excess ART embryos' in the interests of 'medical advances that will greatly improve the health and quality of life of Australians'. Individuals such as Paul Simmons (2005), Program Head, Stem Cell Biology at the Peter MacCallum Cancer Centre argued Australian scientists, bound by restrictive legislation, were unable to compete on equal terms with their overseas colleagues and were

174 Also see support Professor RV Short (Andrews submissions 335, 2000) Prof. Rathjen (Andrews Sub 280, 2000) Australian Research Council (SSCALC Sub 1239, 2002), Australia & New Zealand Society for Cell and Developmental Biology (SSCALC sub 1219, 2002) The Murdoch Institute for Research into Birth Defects (Andrews Sub 97, 2000)

175 Trounson was deputy director of the Monash Institute of Reproduction and Development at this stage (see SCALC Sub 477, 2002). He was also a founder of the start-up biotechnology company ES Cell International along with fellow scientists Martin Pera, Reubinoff (Israel), and Prof Bongso (Singapore).

176 Pera was Associate Professor and Codirector of the Centre for Early Human Development at the Monash Institute of Reproduction and Development at this time.

177 Bio21 is a biomedical, biotechnology research cluster supporting collaborative projects, shared technology platforms, business development and education programs. The twenty-one members encompass Universities, Tertiary Health Services, Medical Research Institutes, CSIRO and other member-based organisations providing international strengths in biomedical research, education and healthcare See http://www.bio21.com.au/splash_flash.asp accessed May 2009

constrained to be 'followers rather than leaders'. As a consequence Australian science which would have:

- At best derivative contributions to SCNT as scientists and as a nation;
- Poor capacity to secure IP from SCNT technology;
- Lost opportunities for development and commercialisation of new biotechnologies, reducing Australia to customer status;
- Diminished capacity to retain key stem cell scientists or attract overseas scientist in this field (Simmons 2005).

In a similar vein, the AAS was concerned that Australia, as one of the few developed countries who still prohibited SCNT, had lost its leading edge in stem cell science (AAS, 2005, 4). Monash Immunology and Stem Cell Laboratories (MISCL) (2005) and students from the Australian Stem Cell Centre (ASCC) echoed these sentiments, invoking the detrimental effects of the loss of home-grown technologies and potential treatments on the public as well as lost opportunities for career development within Australia.

Monash University colleagues, Pera, Trounson, Jenkin, Boyd, Wilson, Elefanty, Stanley, Bernard, Ban-Hock Toh and Ricardo argued eloquently for continued research in both ASC and ESC to 'determine the efficacy and safety of new medical treatments based on cell therapy and associated discoveries' (Pera et al. 2005, 6). They believed that on available evidence it was unlikely enough ASC could be harvested to be of therapeutic value whereas ESC posed 'a unique potential for research and therapy.' Further, there was a need for embryonic stem cell lines with diagnosed genetic abnormalities which would lead to better understanding of specific diseases and development of new treatment strategies. Claiming SCNT was now a relatively efficient method of deriving specific stem cells and was 'critical to study the causation and treatment of the genetic predisposition to many common diseases' they argued denying access to this technology would impact negatively on Australian medical research (Pera et al. 2005, 6).

Even in the absence of applications for regenerative medicine, there was much to be gained in knowledge about the reprogramming of adult cells following SCNT with 'far reaching implications for biology and medicine' (Pera et al., 2005, 11). Scientific research, being inherently unpredictable, risked missing 'discovery' if therapeutic cloning was not permitted (Finkel ¹⁷⁸ 2005). Prof Phil Waite¹⁷⁹ (2005) argued that until it could be determined whether ASC had the same potential as ESC, scientists and clinicians had a moral responsibility to patients to pursue appropriately regulated ESC research.

Australia established expertise¹⁸⁰ early in ESC and cloning research and recognised the great potential for a new form of medicine and a new biotechnology industry of enormous value (Rathjen 2000). However there was considerable disagreement amongst the scientific elite on a number of issues. Most significantly, scientists were divided over the potential for differentiation of ASC and the therapeutic potential of ESC. Further, there were accusations of self interest and conflicts of interest between the pursuit of science as knowledge and science for commercial advantage.

In 2002, Martin¹⁸¹ (2002), had argued that the therapeutic benefits of ESC were seriously misrepresented, adding there was little evidence to support claims that research using ESC was 'essential and urgent' to the development of therapies for previously untreatable chronic conditions such as Alzheimer's, Parkinson's and diabetes. He believed unrealistic expectations had been created in the community regarding the imminence and scope of ESC therapy for serious disease, effectively restricting genuine community participation in this debate. Further, he claimed there was insufficient evidence from animal models regarding sustained therapeutic benefits of ESC as well as serious and unresolved problems with immune rejection and the propensity of ESC to form tumours following

¹⁷⁸ Former research scientist and science writer

¹⁷⁹ Waite is now Head of Neural Injury Research Unit, School of Medical Sciences, University of NSW. Research interest includes stem cells in spinal cord injury.

See <http://www.brainsciences.unsw.edu.au/BrainSciWeb.nsf/page/SOMS>

¹⁸⁰ Research into primate ES cells, ES cell maintenance and ES cell isolation and differentiation established at a number of different sites throughout the nation by 1999 (See Rathjen Sub 289 to Andrews Inquiry)

¹⁸¹ T.John.Martin, Emeritus Professor of Medicine, University of Melbourne. Martin reiterated this position in a 2006 lecture in the parliamentary library series.

implantation. Without such evidence and given the ethical complexities surrounding destructive embryo research, there was no compelling imperative to pursue this research. In summary there were many milestones to be reached before the community could 'decide whether the potential benefits of human ES cell research are sufficiently great that they warrant its approval' (Martin, 2002)¹⁸². McCullagh¹⁸³ along with Martin (2002), Masters¹⁸⁴ (2002), Pender¹⁸⁵ (2002) and Prentice¹⁸⁶ (2002) concurred, also refuting the much vaunted promise of potential ESC generated cures for Alzheimer's, spinal cord injuries and diabetes and raised the significant clinical dangers associated with stem cell transplants from any source.

Scientists also voiced concerns that members of parliament had been captured by 'scientist/lobbyists' who seriously misrepresented the scientific evidence on which their subsequent conscience vote decisions were made. McCullagh (2002) claimed assertions were made which could not be scientifically substantiated or were at a minimum open to academic challenge. He observed that reference to embryos as 'resources' had become the norm, situating them in a commercial and private context rather than in the public domain; the implication being that goods resulting from such research would be private not public. However public support for this and other medical research relied on an implicit assumption that any goods thus derived would be available to those in the community who need them (McCullagh 2002).

In 2005, Martin (2005) and McCullagh (2005) reiterated their positions that the therapeutic benefits of ESC research had been overstated; insufficient proof of principle had been demonstrated using animal models and SCNT to generate immuno-compatible cells for individual patients was costly, difficult and unlikely

182 See SSCALC Submission 162, 2002

183 Holds a medical degree and was a senior scientist at the John Curtin school of Medical Research, ANU for 34 years.

184 Professor of Pathology, University of Melbourne with expertise in the study of brain diseases, Alzheimer's and other neurodegenerative disorders. (See SSCALC Sub 87)

185 Director of the Neuroimmunology Research Centre at Queensland University with research interest in Multiple Sclerosis.

186 Professor of Life Sciences, Indiana State University, Adjunct Professor of Medical and Molecular Genetics, Indiana University School of Medicine

to form the basis of treatments. MacKay-Sim¹⁸⁷ (2005) argued that ASC appeared to offer many advantages over ESC in both ‘transplantation therapies and cellular study of disease’ and his published work (Murrel et al. 2005, Feron et al. 2005) on the success of nasal stem cells transplants for neural regeneration in humans was cited by many submissions¹⁸⁸. Again the LRC heard evidence from eminent Australian scientists that much work was required in animal models to evaluate the safety concerns of SCNT before the technique be used for creating human ESC lines and in the interim, research should focus on ASC (Ward¹⁸⁹ 2005, Good, 2005) which McKay-Sims’ work indicated were much more versatile than previously thought. Meanwhile Vats et al. (2005, 592) published a review in *Lancet* which concluded much more research was required before ESC or ASC became commonplace in clinical applications.

Originally, support for ESC research had been based on three broad goals; potential therapeutic applications; increased scientific knowledge; and the development of commercial products (McCullagh 2005). By the time of the legislation review in 2005, the first goal had not been realised and no treatments had reached clinical trial status. The pro ESC research scientists now switched their course slightly to promote the importance of *basic* research as a necessary precursor to the new therapies, which in itself necessitated further embryo experiments and production of embryos with specific diseases using SCNT. Martin (2005, 4) described this ‘blue sky’ research in the pursuit of knowledge as ‘interesting, fun to engage in, and publishable... but no more likely to yield practical benefits than other cell/molecular biology approaches’. McCullagh (LRC, 630, 2005) agreed there were alternate avenues to gaining this knowledge and the real issue for the pro ESC lobby was whether the ‘technological

187 Director, National Adult Stem Cell Research Centre, Eskitis Institute for Cell and Molecular Therapies. Professor, School of Biomolecular and Physical Sciences, Griffiths University with research interest in stem cells from the adult nervous system, neurogenesis and regeneration of the nervous system, repair of the nervous system via cell transplantation therapies, patient-derived stem cells to investigate neurological diseases.

See <http://www.griffith.edu.au/professional-page/professor-alan-mackay-sim>

188 See LRC submissions: Sub 315 Dr Gail Tulloch PhD; Sub 457 Dr June Westwood MD; Sub 494 Archbishop George Pell; Sub 547 Lutheran Church; Sub 616 Drs E and J Billing MD; Sub 624 alt Shakers; Sub 1007 Sophie Panopoulos MP and Sub 1010 Ron Boswell MP.

189 Retired CSIRO scientist and pioneer of domestic animal cloning in Australia

imperative' should prevail. In other words this was science for science sake and investigation driven by scientific curiosity because it was possible.

With therapeutic products based on individualised histocompatible stem cell lines or 'off-the-shelf' stem cell lines, modified to counteract immune rejection¹⁹⁰ still on a distant horizon, the most lucrative commercial benefits of stem cell research lay in the development of ESC lines for testing new pharmaceutical agents (McCullagh 2005). Any assessment, however, of the commercial potential was made difficult by the prevailing discourse of 'commercial-in-confidence' whereby data was withheld as a condition of contracts between industry and science partners. This practice was contrary to the traditional discourse of science which involved formulating a hypothesis, testing it through experiment and subjecting the results to peer scrutiny through publication. As McCullagh (2005) noted 'a hypothesis incorporated in a prospectus' was unlikely to be found wanting.

In 2005, the deep divisions identified in the early ESC and cloning debates were still present. There was vigorous support for permissive regulation in the name of developing novel therapies, maintaining Australia's position as a pioneer in biomedical research and retaining the intellectual property and any commercial benefits which proceed from research. By contrast there was also support from within the science community for retaining the restrictions imposed by the 2002 legislation. There was a major disagreement over the potential of ESC to ever deliver therapies, the need for embryo research at all and whether SCNT was an efficient and effective method of producing stem cell lines. There was a major unresolved conflict over the properties of ASC and whether they constitute a viable alternative source of stem cells for research and therapeutics.

5.3.4 The Biotechnology Industry

Biotechnology is a broad term for technological applications that use biological organisms and as such cover a wide range of activities in agriculture, environment, animal and human health. A specific 'biotechnology' sector emerged in the 1970s and 80s as small science based firms (Gilding 2007, 24)

¹⁹⁰ McCullagh is highly sceptical that this is possible (LRC Sub 630, 2005)

straddling 'the historical divide between for-profit and not-for-profit research' (Cockburn 2005). These new firms retained their 'for profit' orientation but had closer more explicit links to non profit research institutes, universities and government.

Benner and Lofgren (2007, 84) say

Bio-industries are characterized by strong linkages between the public research system and corporate technological developments, tight connections between dedicated biotechnology firms and larger corporations (particularly pharmaceutical firms), and the centrality of intellectual property rights due to the importance of codified knowledge for innovation.

The bio-economy is characterised by an interconnectedness between different stakeholders; large pharmaceuticals reliant on smaller biotechnology firms which are reliant on the public science base and public funding as well as investment from venture capital (Benner and Lofgren 2007, 94, Fukuyama 2002,19). The state has two main roles; first it fosters 'knowledge policies' through its funding of universities, R&D systems, training and education, support for entrepreneurship and the commercialisation of science and tax incentives and second it engages in a dialogue with stakeholders, including the community, over the risks and benefits of biotechnology (Benner and Lofgren 2007, 82). In Australia this dialogue was institutionalised to a certain degree through the creation of the federal agency Biotechnology Australia¹⁹¹.

Cockburn (2005) claims this interdependency represents a shift from the essentially binary relationship which existed between science and the biomedical industries prior to the 1990s, characterised by a clear distinction between 'upstream not for profits' curiosity driven science and 'downstream for profit' research and development focused industry. The former was driven by the social norms of 'open' science as practiced in universities and public research institutes and the latter by those of commercial business. Where the former attracted funding on the basis of reputation and publication in peer reviewed journals, and

191 See <http://www.biotechnology.gov.au/>

was concerned chiefly with basic science, the latter was more concerned with market advantage and protection of profits largely facilitated by the patent system (Cockburn 2005). However the new 'partnering' mode of research in biotechnology has blurred the distinction between for profit and not for profit scientific research. The extension of exclusion based intellectual property rights into basic science through the patent system results in 'market-based competition based on proprietary rights over biomedical knowledge [which] now plays a very significant role in determining the overall rate and direction of technological progress' (Cockburn 2005). Industry has become more involved in basic research while universities and other not for profit organisations have begun to patent their intellectual property. Joint ventures and strategic partnering became more common. Academic scientists have played a significant role in the founding of biotechnology firms, including spin offs from established university research centres and a new actor, the 'entrepreneurial' scientist has emerged, who operates in both public and private capacities (Cockburn 2005).

The new models raise some important issues for science including the impact of the profit motive on science. Industry typically wants a return on its investment. As Saunders and Savulescu (2008, 216) observe 'funding directs, if not dictates, science, because without funding, research cannot occur' and more frequently funding comes from industry and business partnered with universities and not for profit research institutes. The concerns are that science will be directed toward those ventures which hold the greatest promise of financial returns but there is a risk of conflicts of interest which threaten integrity, prohibit knowledge sharing and restrict access to benefits. The counter argument is private investment in science increases productivity, expedites generation of knowledge and production of beneficial products (Critchley 2008, 310).

From its inception, the new biotechnology sector has had a distinctly 'international' perspective. In the USA and UK, biotechs are typically concentrated geographically forming major hubs but they also form 'out of hub' relationships in order to harness resources and capacities not available locally (Gilding 2007, 24-5). In the USA, large scale research collaborations between universities and major pharmaceutical companies have become a feature of

therapeutics oriented biomedical research. In 2008, GlaxoSmithKline (GSK) and Harvard University entered into \$25 million dollar alliance in stem cell research. GSK retained the rights to intellectual property and patents, including those generated by university scientists, as well as first rights to a non-exclusive license for any discoveries made on campus. Pfizer formed a three year, \$14 million collaboration with four research universities to study diabetes and the University of Washington at St. Louis has entered into an agreement with AstraZeneca¹⁹².

Since the 1980s, Australian and State governments have actively promoted the bio-economy. The Australian biotechnology sector like its overseas counterparts comprises a range of companies, from start-ups to the more mature, operating in health, industrial processing, agriculture and the environmental fields. It is characterised by a large number of research intensive small to medium enterprises (SME) including many spin-offs from universities and other publicly funded research organisations. The sector's major exports continue to be IP, through licensing arrangements with large, international pharmaceutical and biotechnology companies. Australia's strengths include '...well trained but not highly paid [science] graduates, high quality science, good and improving linkages between public sector research and industry, low costs and high quality of life, and a supportive regulatory environment' (Benner and Lofgren 2007, 87). As with the industry internationally, major pharmaceutical companies are perceived as key partners. However linkages between the public research sector and such companies are still relatively immature in Australia. State governments working with the commonwealth have been keen to establish biotech clusters in their jurisdictions (Benner and Lofgren 2007, 88).

The federal agency Biotechnology Australia (BA) was established in 1999, to facilitate development of the biotechnology industry and 'encourage the advancement and uptake of biotechnology applications by Australian industry', with consequent benefits both in economic development and in the large number of jobs being created (Benner and Lofgren 2007, 90). The Australian government recognised the importance of the biotechnology sector through the National

192 see <http://www.cspinet.org/integrity/watch/200809081.html#2>

Biotechnology Strategy launched in 2000 and in 2002 established the first Biotechnology Centre of Excellence, the Centre for Stem Cells and Tissue Repair, which became known as the Australian Stem Cell Centre (ASSC). The ASSC has a number of academic and research partners¹⁹³ as well as collaborative agreements for commercialisation and product development with industry partners Cell International Pte Ltd (ESI), LifeCell Corp and Millipore Corporation. By the time of the legislative review process in 2005, the ASSC had filed a 'number of patents and created a valuable portfolio of intellectual property' which it believed would ultimately benefit the Australian community and individuals suffering from disease worldwide (ASSC, 2005, 11).

In 2002, Australia was already established as a world leader in biotechnology. It had an international reputation for quality medical research and excellence in bioscience research and development, and was considered an attractive option for overseas investors but it needed a policy framework which allowed the industry freedom to operate, to innovate and to remain internationally competitive (BA 2002, 3-4). BA argued in favour of destructive embryo research so that derivation of stem cell lines could proceed locally and the associated IP and investment remain in Australia rather flow overseas (BA 2002, 15).

The Australian biotechnology sector has matured significantly in recent years despite the impact of the global financial crisis which resulted in a reduction in venture capital, an increase in mergers and cost cutting measures to conserve cash flow. At the end of 2008, the Australian Stock Exchange (ASX) listed 75 biotech companies with a combined market capitalisation of A\$22.4 billion, most of which belongs to CSL (\$20.3bn). The majority of these firms are involved in product development, diagnostics and therapeutics in the human health market while a smaller number focus in environment, agribusiness and veterinary products. Overall the sector has doubled its wealth since 2004, however that

193 University of Adelaide, Monash University, University of Queensland, Howard Florey Institute, Peter MacCallum Cancer Institute, Victor Chang Cardiac Research Institute, Murdoch Childrens Research Institute, Baker Heart Research Institute, Mater Medical Research Institute. See http://www.stemcellcentre.edu.au/centre_partnerships.aspx

wealth is now concentrated in fewer companies¹⁹⁴. At the end of 2006, approximately 14,189 people were employed in 449 biotech companies in Australia (Department of Innovation, Industry, Science and Research 2009).

In the Australian policy debates, the potential commercial benefits of stem cell research came to the fore during the 2002 Senate SCALC inquiry. It was argued that Australian science and technology and long term economic interests would suffer if embryonic stem cell research was not permitted. Prohibition would force research off shore to jurisdictions with more progressive laws, risking international investment opportunities and intellectual property (SCALC 2002, 61-2). AusBiotech, the peak biotechnology industry organization supported the 2002 legislation in the interests of 'important and potentially life-altering medical research ... to the potential benefit of individuals in Australia, and throughout the world' (2002). Biotechnology companies Bresagen (2002, 2). ES Cell International (ESI) (2002) and Stem Cell Sciences Limited (2002) all focused on the therapeutic potential of ESC research and maintaining Australia's place in the international biotechnology market and made it clear that future investment and economic benefits depended on the 'right' legislative results.

BresaGen (2002, 2) said

Passage of this legislation is essential in BresaGen retaining a significant presence in this country...failure of this legislation to pass will...force BresaGen to consider its Australian presence.

Bresagen was placed in the hands of administrators in 2004 following the resignation of three of six directors over a failure to secure funding¹⁹⁵ (Greenblat, 2004). As of October 2006, BresaGen Ltd. operates as a subsidiary of US based

194 At the end of Q4 2008 the market cap of ASX-listed biotechnology companies excluding CSL was A\$2.1bn, compared to A\$4.1bn at the end of Q4 2004. At the end of Q4 2008, excluding CSL, there were five ASX-listed biotech companies with a market cap in excess of A\$100 million (combined market cap of A\$0.8bn), compared with 9 companies valued at over \$100 million in Q1 2008 (combined market cap was A\$1.8bn) See <http://www.innovation.gov.au/Section/AboutDIISR/FactSheets/Pages/AustralianBiotechnologySectorFactSheet.aspx>

195 See <http://investing.businessweek.com/research/stocks/private/snapshot.asp?privcapId=344916>

Hospira Inc., a global pharmaceutical company, and is no longer listed as separate company on the ASX.

ES Cell international (ESCI) established in 2000, as a spin off from the Monash Institute, is a Singapore registered company. It has 'been at the forefront of developing new and novel human embryonic stem cell technology.' It holds several patents for embryonic stem cell technology and has a number of academic and industry partners. In 2008, ESCI entered into a partnership with a 'prominent international Pharmaceutical company' to evaluate propriety stem cell lines for stem cell applications. The identity and terms of the agreement were not disclosed (ESCI Press Release Sept 2008).

Stem Cell Sciences (SCS) was one of the earliest Australian biotechnology companies established in 1994, to deliver 'safe and effective cell-based therapy to global markets' (SCS 2002). They supported unencumbered access to human embryonic stem cells for basic and applied research and believed that products derived from such research should be available to all qualified researchers, unfettered by commercial constraints. They opposed commercial control and exploitation of such an important biological resource as human stem cells (SCS 2002). By 2009 SCS, however, held exclusive patents on genetic engineering technologies developed to optimise gene discovery and validation, gene therapy, and the production of genetically engineered and tissue-specific Embryonic or Adult Stem cell lines research or cell therapy. It has research and licensing agreements with major international biopharmaceutical companies, including Aventis, BioTransplant Inc., Genentech and Glaxo SmithKline and research projects with Merck & Co. and the philanthropic Myelin Research Foundation.

During the 2005, legislative review, AusBiotech (2005, 6-8) argued the prohibition of SCNT for stem cell derivation was no longer appropriate and placed Australian scientists at a disadvantage to their international colleagues. This impacted negatively on the quality of the science as well as potential investment and timely access to the clinical trials process. Similarly the Australian Stem Cell Centre (ASSC) (2005, 2) and Stem Cell Sciences Ltd (2005, 3) argued for the use of SCNT as a means of deriving disease specific stem cells for

research purposes and for the import and export of SCNT derived cell lines.

ASSC claimed that a continued ban on SCNT Australia would limit the potential for stem cell research, resulting in reduced benefits for Australians suffering from certain diseases. By contrast the *unlimited* potential of stem cells would be fully explored, understood and harnessed elsewhere risking the defection of some of Australia's most valuable and highly regarded human capital whilst reducing the country to consumer rather than producer status (ASSC 2005,6).

The promises of contemporary biomedical research are seductive; the alleviation of human suffering on an unsurpassed scale and the creation of wealth in the process (Cockburn, 2005). The extension of the patent system into basic science is now fundamental to progress because it encourages and rewards entrepreneurs and risk taking in commercial science, with potentially very significant benefits to society once the technology reaches end-users. Along with the benefits come the risks; exclusionary property rights applied to scientific knowledge may in the long run generate inefficiencies, waste, and misallocation of resources (Cockburn 2005).

Within a democratic society there exists an 'irreversible contract' between science, technology and economics (Meith 2001, 1). This began innocently enough with ideas that publicly funded scientific research should be directed toward goals that would result in economic growth (Kerin 2006). As the costs of scientific research grow, new partnerships with industry are sought which are mutually beneficial. As Wilsden et al., (2005, 2) say, science must deliver economic success but at the expense of a '...growing disquiet among university scientists that the drive for ever closer ties with business [is] distorting research priorities'. The prospect of corporate funding may tempt researchers away from high risk, novel areas of research towards more readily marketable applications. The global market is shaped by powerful corporate interests who direct capital, labour, production and consumption in the desire for greater profits. For States this has implications for 'competitiveness' of the national economy and imperatives to strategically support industries that both attract investment of transnational capital and produce new sources of economic growth (Barry and Patterson, 2004, 779). Biotechnology is one such an industry. It is informed by

discourses of the national interest underpinned by international competitiveness for both discovery and for market share.

I have argued above that interests in both ART and the ESC research policy domains can be conceptualised as falling into four main categories or sectors; ethical, health and well being, scientific and industry. Within these interest sectors however, there are multiple policy positions which make an analysis based on a dichotomous alignment of interests limited. That is, interests do not line up in Sabatier¹⁹⁶ type coalitions of ethical versus scientific or health and wellbeing versus industry based on an assumption that these sectors share a set of beliefs or values which will inform their policy position. Rather I will argue that the different policy positions are informed by different discourses which compete with each other for policy ascendancy within the sectors. In the next section I will identify the discourses and their power to shape policy outcomes.

5.4 Competing Discourses

As discussed in Chapter 2, a discourse can be understood as a ‘...set of linguistic practices and rhetorical strategies embedded in a network of social relations’ (Litfen 1994, 3). Discourses operate to frame our understanding of the policy problem and the possible policy solutions. Discourses also define legitimacy in policy debates. For example, if a policy issue is framed by a particular understanding or discourse of health and wellbeing then a particular set of stakeholders can claim policy legitimacy over their competitors. In ART and ESC research and cloning policy domains, there are a number of different discourses all making legitimacy claims. These competing discourses not only construct the policy issues in different ways but allow actors to operate in multiple contexts. A discourse analysis allows a single actor to be a researcher, advocate, an entrepreneur and company director. This allows actors to move in and out of discourses, taking on different roles in different contexts whilst promoting their policy preferences.

196 See chapter 2

5.4.1 Ethical Discourses

The different ethical positions in both ART and ESC and cloning policy arenas can be understood as situated in different ethical discourses. Different ethical discourses allow for different understandings of the embryo and what is permissible behaviour towards it.

In medicine, the traditional bioethical discourse was concerned with the relationship between a health practitioner and a 'patient' and is guided by the four normative principles of autonomy, non-maleficence, beneficence and justice as they apply to the patient (Beauchamp and Childress, 1974). However contemporary bioethics is concerned with more complex issues, as it attempts to apply ethical theory to new dilemmas created by emerging biotechnologies (Hedgecoe 2004, 122). As these dilemmas become more complex, they move beyond the professional practice and expertise of medical practitioners and into the realm of bioethics which encompasses law, theology, social science and philosophy (Campbell (2005, 88). As biotechnology continues to unlock knowledge about the human biological entity it forces a re-examination of values and understandings of what it means to be human and how this positions us in the social and political world of rights and responsibilities.

As discussed in Chapter 4, biological 'fact' shows that the individual human being forms a continuum from fertilisation through implantation through blastocyst to embryo to foetus to neonate. Even if the sequence is interrupted through technological innovations like IVF or the suspended animation of the frozen embryo, there is little argument against the notion of a continuum of individual being. The contestation arises from moral status of the being. As previously discussed this falls on a spectrum of no intrinsic moral status at all, incrementally increasing moral status contingent on developmental stage through to full moral status from the moment of conception (Beyleveld 200, 59). At one end of the spectrum the embryo constitutes 'human life' and at the other the 'human person', a distinction which allows for the category of 'human non-person' who is not a member of the moral community therefore not entitled to its privileges (Meith 2000, 5).

In ART, the question of the moral status of the embryo is complicated further by the deliberate creation of the embryo as a 'cure' for infertility. Its right to life does not hinge on its intrinsic moral worth but on its viability. Only the viable proceed to implantation and the hoped for successful pregnancy. Viability being a decision made in the laboratory based on objective criteria of 'fitness' for reproductive purposes. The result is an ambiguity around the ART embryo which is both the desired child and a product to be discarded if it does not pass the quality criterion. As such its value lies in its capacity to fulfil others' needs. It is not 'the patient' in a traditional bioethical sense, but a treatment for the infertile woman or couple. Thus compromising the autonomy of the embryo is not an ethical consideration in ART practice. Ironically, in other branches of reproductive and neonatal medicine, the embryo and the developing foetus do constitute the patient and are the recipients of sometimes heroic and costly medical interventions aimed at saving their lives.

The moral status of the embryo is one ethical dilemma in ART, but there are other moral contestations over appropriate family structures and the rights of the socially infertile to become parents. When the capacity to reproduce is separated from the sexual act of reproduction, it allows for the possibility of whole range of non traditional families including single and same sex parents. In the democratic state where ART services are publicly funded this becomes a political issues of access and distributive justice for the 'involuntary childless' (Nordgren 2000, 27). To deny access to publicly funded services based on age, gender, sexual orientation or marital status is discriminatory. Arguments centred on the moral obligation to provide children with two parents in a traditional family structure are subservient in policy terms to the right to become a parent through ART. A discourse of procreational liberty underpins ART where the focus is on the freedom of the already human to access the embryonic human to fulfil the parent wish.

As with ART, the ESC/cloning policy debate begins over the moral status of the embryo. The fact that extraction of ESC results in the death of the embryo is inescapable and to many repugnant but it is morally defensible if this destruction

results in a greater good; the relief of existing human suffering at the small expense of the non sentient, non conscious human embryo who was going to die anyway. This is the essential promise of ESC/cloning research. In policy terms, when the choice is between protection of an entity whose moral status remains irresolvable and the moral imperative to aid the sick and suffering through the use a valuable resource, the former loses. As such the commodification of the human embryo begun in ART is complete. The ethical conflict over the moral status of the embryo is not resolved but in policy terms, the value attributed to the embryo is decided. Again as with ART it has no intrinsic moral value; the value of the embryo lies in its capacity to fulfil the needs of others.

5.4.2 Health and Wellbeing Discourses

Multiple understandings or constructions of health, sickness, disease and disability are possible. Traditional discourses of health and well being conceive disease and disability as conditions to be treated and cured. Within a traditional health model there is a wide power differential between the experts who are the keepers and interpreters of medical knowledge and the recipients of this expertise, the patients. Health policy in this perspective is about the provision of and access to effective services. Good health policy is informed by expert knowledge and 'scientific' evidence of effective practice. With advances in biotechnology and genetics, the legitimacy of technological scientific discourse of health becomes even more pronounced (Habermas 2003, 46).

Social health models constitute an alternative discourse¹⁹⁷. The social health discourse, understands health as multi causal and the result of interaction between biological and genetic factors, environmental, social and economic factors (AIHW 2002, 4). The concept of wellness or positive health replaces the disease/disability perspective of the medical model. Further the idea of patient is replaced by that of active partner in health actions and choices, disaggregating power and allowing a wider range of actors a legitimate voice in policy making. The women's health

197 United Nations Alma Ata declaration of the principles of Primary Health Care (1978)

http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf

Ottawa Charter for health promotion which emphasized the need for health consumers to be part of the policy making process (1986)

movement (WHM) can be understood as a discursive variable of the social health model. It developed both consciously and unconsciously as a branch of the broader women's movement, based on the belief women could not control their lives until they had power and control over their own bodies (Wass 1992, Pringle 1998). The WHM argues traditional medical health discourses reinforce traditional stereotyped power relationships between men and women with decision making largely in the hands of predominantly male doctors (Victoria Women's Health Program Working Party (VWHPWP) 1985). Fertility control and reproduction are primary interests for the WHM not just as health issues, but as political issues (Dowse 1983). Despite this, it is not a social model let alone a women's health model of health and welfare which dominates assisted reproductive technology policy in Australia. Rather it is a virulent restatement of a medical model. Policy statements and policy instruments support ART as treatment for clinically demonstrated medical infertility diagnosed by a physician. The object of treatment is a healthy, biologically related child. ART services advertise not only their capacity to fulfil these hopes but their 'state of the art' science and technology capabilities¹⁹⁸.

IVF technologies have clinical applications other than treating infertility. In combination with the technique of pre-implantation genetic diagnosis (PGD), couples at risk of producing a child with genetic defects, can be treated by screening out defective embryos prior to implantation. Implicit in the decision to undergo PGD is the parental decision to implant or discard an embryo subject to diagnosis, to spare the child from the burden of a life encumbered by profound disability and the woman the trauma of an abortion if the abnormality was detected during pregnancy. To Habermas (2003, 97) this freedom to dispose on the basis of scientific prognosis leads to an unavoidable instrumentalisation of the 'prepersonal' human. It also has implications for understandings of disability and what constitutes a life worth living. Medical models of health see disability in terms of amenability to treatment and likelihood of cure for an *individual* whereas social models are more likely to focus on enhancing the capabilities of the disabled by dismantling social and cultural barriers to wellness.

198 See websites for Australian ART service providers

In the ESC research and cloning policy arena the concept of health and wellbeing is not just medicalised but potentially thoroughly 'scientised'. The eventual cures will emerge from sophisticated molecular science. This science offers the ultimate in proactive health care (Habermas 2003, 17); screening for genetic disadvantage at the earliest possible stage in a human life and with it the choice of whether that life progresses. Just as chorionic villi sampling (CVS), amniocentesis and ultrasound examinations are a routine component of good ante natal care in Australia, it is likely that new diagnostic procedures such as PGD and genetic screening will normalise into clinical care. That is diagnostic procedures currently used to investigate 'at risk' embryo will become accepted clinical practice for screening first the quality of all embryos and perhaps eventually for 'preferred' genetic attributes of embryos. When molecular science informs the discourse of health and wellbeing, the result is surely genetic reductionism, the antithesis of any holistic understanding human health and welfare.

5.4.3 Science Discourses

One of the issues that came to light during the embryo debates was the shifting discourse of science in the biotechnology era. Traditional science operates in a discourse of open exchange driven by the norms and values of intellectual integrity, investigator initiated research, peer review and reciprocal sharing of data (Cockburn 2005, 14). In Australia, science is traditionally funded through the public purse with researchers looking to publication in prestigious journals to bolster their chances of securing competitive grants (Saunders and Savulescu 2008, 216). Open science is driven largely by priority and reputation based incentives as opposed to the profit motive, patents and commercial concerns of the business world (Cockburn, 2005, 14) but in the era of biotechnology, the boundaries between science and business have blurred. Corporations increasingly underwrite university research and have their own legitimate interests in gaining a return on investment through commercial applications which creates potential for conflicts of interest which in turn threaten to erode the trust placed in universities (Cahill 2001, 222). The scientists who advise governments as experts are also the recipients of government funding and have private financial interest in biotech

companies. Science as a singular 'interest group' with a set of shared values and understanding of the world no longer exists in this particular policy arena.

Biomedical science traditionally sits within a discourse of science for purposive good; its great contribution the expansion of human life expectancy through the application of science based medicine (O'Hear, 1989, 11). Belief in the power of science to improve human life remains '...a quintessential hallmark of modernity' (Litfen 1994, 29). In contrast is the discourse of science as technological imperative. The dilemma for science is the competition between the desire for knowledge itself and wanting the knowledge to be socially useful. In fulfilling the second requirement, science enters into a 'covenant with society' thus the direction of research and the application of new knowledge generated by science are social issues (Meith (2000, 1). They are 'bound up with social questions of trust, governance, democracy and public value' (Wilsden et al. 2005, 22) placing a responsibility on scientists to serve as guides in separating out scientific and technological solutions which are truly life enhancing from those which are merely the 'disinterested pursuit of truth' (Cavalieri, 1981, 230). The 'technological imperative', asserts the pre-eminence of objective scientific knowledge over 'the ordinary person's sense of power over his own life' (Packard, cited Koski 2005, 268). What is needed is a critical faculty for assessing and accepting innovation (O'Hear, 1989, 223) or, as Cavalieri (1981, 22) argues demystification of science and revaluation of social goals by those exposed to their consequences.

In ART, embryo research is only part of the research agenda. ART scientists pursue many different research avenues in the pursuit of improved fertility outcomes in the interests of improving the human condition. They are also engage in basic research to gain knowledge about the early embryo and the phenomenon of fertilisation, some of which will have fertility treatment applications. Prior to the 2002 legislation, ART research operated within the framework of NHMRC Guidelines, institutional ethics approval and relevant State based legislation, where it existed. In the policy process leading up to the RIHE Act 2002, ART scientists were deeply concerned their existing research agenda would be curtailed by new regulations which impacted on access to embryos and permissible

practices. The IVF industry relied on access to embryos to improve their product and feared a licensing system would interfere with this (Monash IVF 2002).

In the ESC and cloning domain, the discourse of science for the public good also dominated the public debate. However as discussed above, when those goods fail to materialise, the underpinning scientific imperative is reasserted but not explicitly acknowledged by the pro ESC research lobby. In the new biotechnology, science operates according to new rules and along with its commercial partners creates a 'Biotechnology-Industrial complex' which is hungry for unfettered access to ESC, specific to research needs. Habermas (2003, 18) says the 'system dynamics of science, technology and economics create a *fait accompli* which can outstrip any normative framework'. Because biotechnology research is bound up with investors' interests and perceived national interests, it has the capacity to steamroller the 'inherently slow paced processes of an ethicopolitical opinion and will formation in the public sphere' (Habermas 2003, 18).

5.4.4 Industry Discourses

Parallels can be recognised in the discourses that inform ethics, health and science interests in both ART and ESC and cloning policy domains. It is more difficult to identify such parallels in the discourses which inform the biotechnology industry interests. The domains are linked by the entity called the embryo. ESC and cloning research is elemental to the biotechnology industry and embryo research has its beginnings in the ART sector. At this point they diverge. Research in ART is essentially directed forward better ART outcomes therefore is of commercial value to the fertility industry. Discovery in ART research may inform ESC research which may inform product development in the biotechnology industry. Such is the serendipity of science. There are obvious commercial interests in ART both in clinical practice and the science which supports it and there is certainly an international market for fertility products/services. However in the Australian context, the national interest is rarely invoked when discussing the fertility industry. Rather the fertility industry in Australia remains localised and regional and firmly within a context of health service provision.

By contrast, in ESC and cloning, the importance of maintaining Australia's position as an international science innovator and amassing any financial benefits which proceed from such research is appealed to constantly. International competitiveness and prestige in science and wealth accumulation are invoked in the national interest. This is a policy arena that is too important to be managed piecemeal by State governments and run the risk of different legislation in different jurisdictions creating confusion and incoherence particularly for investors. ESC and Cloning research is situated firmly in a context of science, technology and industry policy not health policy despite the appeals of the pro research lobby to health and wellbeing interests.

In both policy domains, discourse plays a vital role in defining the parameters of debate but this does not explain what links actors with different beliefs and values, to form coalitions around policy positions. What is missing from the analysis is the narrative or storyline that binds powerful but separate interests together in their pursuit of common goal.

5.5 Interests, Discourses and Narratives

'Ideas enter into social reality via the idealizing presuppositions innate in everyday practices and inconspicuously acquire the quality of stubborn social facts' (Habermas 2006, 411).

Traditional policy analysis presupposes a rational solution to conflicts in need of 'normative regulation' (Habermas 2003, 38) but the contested ethical dimensions of both ART and ESC research and cloning policy arenas make a predominantly rational analysis unsatisfactory. Or as Habermas (2003, 38) would say

No such rational acceptability may be expected if the description of the conflictual situation as well as the justification of the pertinent norms are themselves shaped by a preferred way of life and existential understanding of the individual or a group of citizens, that is, by their identity forming beliefs.

I have argued that interests in both ART (Chapter 3) and ESC research and cloning (Chapter 4) are complex and fragmented within the broad sectoral interests of ethics, health, science and industry. Simple dichotomies of science versus religion, fact versus values, or cleavages along conservative/liberal or gendered lines do not inform the coalitions that form around pro and anti positions in either policy arena. Rather the interests are informed by multiple discourses some of which operate explicitly while others are subliminal. These discourses form coalitions *across* interest groups to promote a particular policy stance. Table 3 below summarises the different discourses which inform interests in the two policy domains.

Table 3 Competing Discourses

	ART	ESC and cloning
Interests	discourses	
Ethical	Embryo as moral agent Feminism Reproductive liberty	Embryo as moral agent Feminism Alleviation of suffering
Health and Wellbeing	Women’s Health Movement Social Medical	Social Medical Molecular
Science	Biomedical research Traditional science	Biomedical research Traditional science
		Entrepreneurial science
Industry	Private business	National interest International competitiveness Global economics

In both policy domains, ethical interests are informed by discourses of the embryo as a full moral agent and feminist perspectives on the commodification of women’s reproductive labour. In ART there is an additional discourse which is grounded in the notion of reproductive liberty. The first two discourses speak to the opponents of ART but for different reasons. If the embryo were fully human in a moral sense it would not be permissible to create it and destroy in solely in the interests of others, even in fulfilling the child wish. Similarly feminists arguments against the objectification of women’s bodies as the sites for medical

and scientific intrusion do not carry much clout, particularly when single women and lesbians avail themselves of treatment for their social infertility to fulfil their own child wish. The third discourse supports ART and places the interests and desires of the prospective parent over the intrinsic right of the embryo as a full human being. The discourse of procreational liberty in the era of ART confers a right to parenthood because the technology exists.

In ESC and cloning there is also a third discourse but this time it is grounded in the imperative to alleviate human suffering. Again the first two discourses speak to opponents of ESC and cloning and again they lose the rhetorical battle. The intrinsic rights of the embryo as a moral agent cannot compete with the moral imperative to cure sufferings, particularly when the embryo in question is surplus to ART and is going to die anyway or was produced through SCNT with no option ever to be implanted. It has no opportunity for a fully realised life of its own thus it serves some moral purpose by serving others' needs. Similarly an argument that places women's reproductive labour above the needs of the sick and dying has little power (Dodds and Ankeny 2006). Feminist views are all but missing from public policy debate despite the fact that SCNT relies on women's reproductive tissue-the lady has vanished (Dickenson 2006, 43). The ethical responsibility to the living trumps any ethical responsibility to the unborn or women as a political class.

In terms of health and wellbeing interests, in ART the medical discourse of health reasserts its power in the policy argument to support treatment of the infertile through reproductive technology. Infertility is a primarily a deficit which can be medically treated and cured through the delivery of a live child. The competing social discourse of health which has the potential to embrace the socially infertile is only a minor player. The socially infertile can and do access infertility services but they must carry the full burden of cost. Medicare restricts its support to those who fulfil specific access criteria. Women's health arguments against ART have little impact. The dangers to, exploitation of women's bodies and low success rates of the reproductive technologies pale in comparison to fulfilling the child wish as do feminist arguments of women ceding control of their reproductive labour (again) to male dominated science and medicine.

Similarly with ESC and cloning, the entire health discourse is one of rescue from the tragedy of disease and disability. The medical model is restated through the potential of a new 'molecular medicine'. The fact that the treatments have yet to materialize has little relevance as it is the promise that has the rhetorical power. Any voices which appeal to a discourse of social health are silenced or derided. As discussed above, medical discourses of health individualise disability rather than looking at the social construction of disability which places limits on how disabled people interact with the world.

Discourses of science and technology are relatively small players in ART policy making, however science is essential to ART. The science that underpins ART operates in a discourse of traditional biomedical research in the pursuit of human good – improved ART outcomes which more efficiently deliver on the child wish. ART scientists' fears that the proposed RIHE legislation would restrict their access to the embryo as a scientific resource were couched in terms of the effect it would have on fertility outcomes rather than compromising basic research although it is the discovery in the latter which uniform the former.

By contrast, discourses of science and technology are quintessential to ESC and cloning policy. First the discourse of traditional biomedical research for the good of mankind is articulated by proponents of research. It has been a leitmotif of the ESC and cloning debates. When opposing science interests critique ESC research and cloning as failing to adhere to the principles of biomedical research they go largely unheeded. As the policy debate matured, proponents switched to a discourse of biomedical research underpinned by basic research which may or may not deliver therapeutic applications. Critics suggested they were really driven by the scientific imperative or research for its own sake. Finally in ESC and cloning there is the development of a new discourse of science, one that is informed by IP and ideas of commercial-in-confidence. This new discourse is the antithesis of open science which operates on a free exchange of knowledge, public scrutiny and peer review. This discourse sits in the space between science as medical research in the pursuit of public good and science as technology directed toward commercialisation and production in the pursuit of private gain.

Finally the discourses which inform the biotechnology industry in this analysis apply primarily to the ESC and cloning policy domain. Proponents of permissive ESC and cloning policy invoke the discourse of the national interest. This is served by a regulatory framework which maintains Australia's position as a producer of science and scientists and owner of IP allowing retention of any wealth generated by any commercial therapeutic products. The public interest is served because Australians will have access to the therapeutic products of home grown science. If Australia is to compete successfully in the global biotechnology industry, then her policies on ESC research and cloning must support that aim.

In ART, policy outcomes emerge from the private world of reproduction. In Australia, legislation and regulation remain under the jurisdictions of State and Territory governments despite attempts to implement national regulation. ART practice is subject to accreditation and professional guidelines as for any other health service and research is primarily clinical, focused on achieving better success rates in achieving pregnancy and live births. In the case of ESC research and cloning, policy outcomes are situated primarily in the public world of scientific research and competition for new biotechnology products, governed primarily by discourses of science and economics, which invite a national policy response. Bioethical and health and welfare discourses are viewed as political resources in this arena, a necessary condition for delivering the policy outcomes which support national scientific and economic goals.

It is clear that interests are influential in shaping policy outcomes in both ART and ESC and cloning policy domains. It is also clear that the interests are fragmented within their sector and inform different policy positions within debates. I have argued that these different positions are framed by different discourses simultaneously operating within the interest sector. So in promoting a particular policy position the interests do not form coalitions around a shared set of values and beliefs in a Sabatier typology but particular discourses form coalitions around a shared storyline in a Hajerian sense as discussed in Chapter 2.

5.6 Assisted Reproductive Technology Narratives

The narrative of hope (Parry 2006, 2357) dominates the ART policy arena. This narrative is based on the desire for a child and the capacity of medical science to deliver. The narrative of hope brings together discourses of procreational liberty, biomedical science in the pursuit of human advancement, and medical models of health which view infertility as a condition which needs a cure. The ART industry continuously promotes this message through advertising success rates and state of the art facilities and their advocacy for continuing generous public funding. A more cynical analysis might suggest that the ART industry is primarily concerned with expanding its client base and fostering demand for its services.

The narrative of hope says very little about the embryo itself because it is a means to an end and is only truly valued when it fulfils its destiny as a live child. To consider the pre-implantation embryo as fully human contradicts the narrative of hope because this would require full acknowledgement of the failure rates and subsequent loss of life in ART.

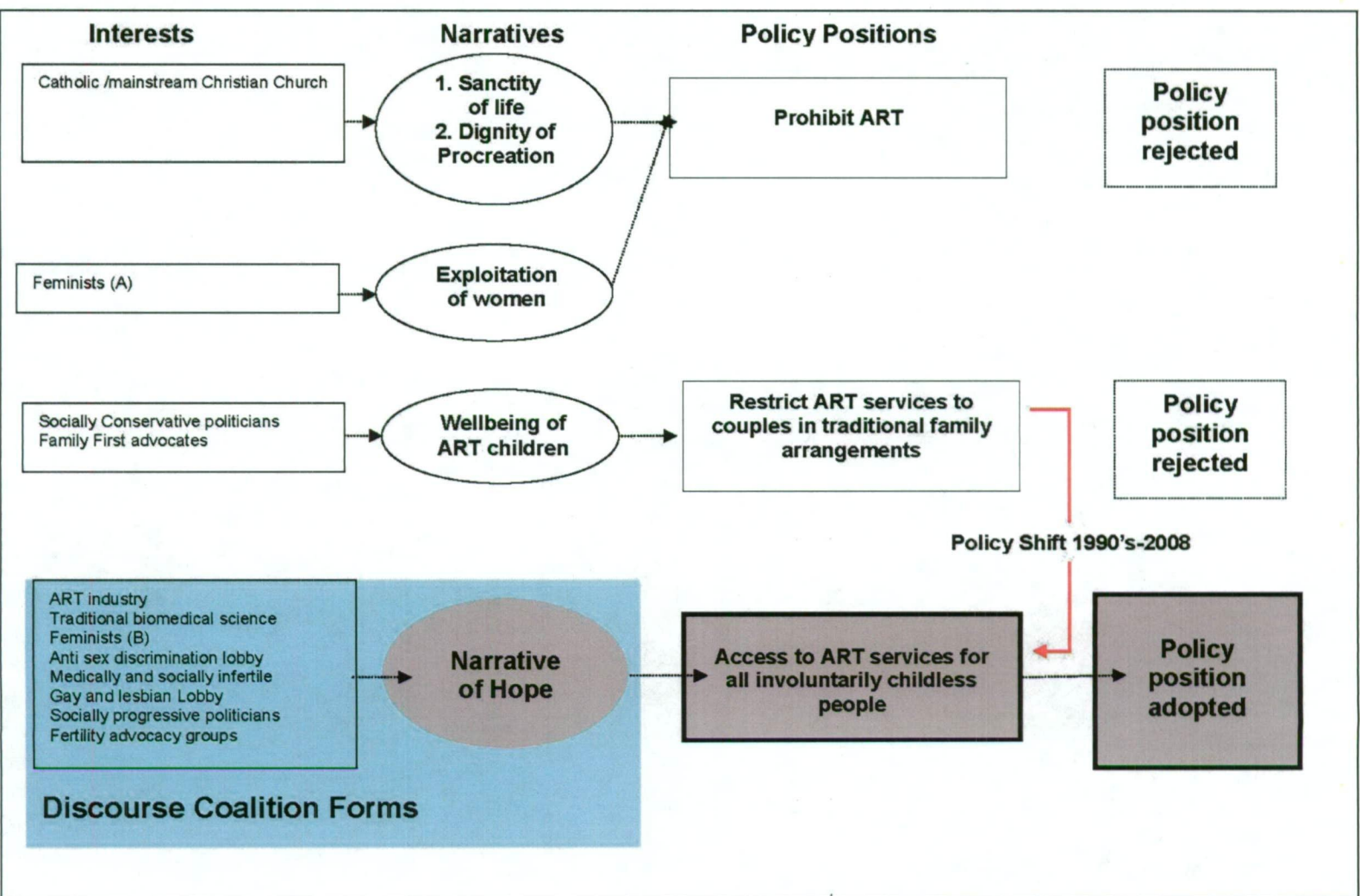
There were a number of challenges to the dominant narrative, none of which had much impact on eventual policy outcomes. The conservative Christian (predominantly the Catholic Church) narrative that embryonic life is fully human and ART contravened both the sanctity of life and the dignity of procreation found few supporters. Similarly, the feminist narratives of exploitation of women and patriarchal dominance over women's reproductive labour had little support in spite of high failure rates and repeated disappointment as embryos were revealed as unviable or unable to sustain a full term pregnancy.

The social conservative narrative of the rights of a child to a traditional family of mother and father garnered support for many years, but ultimately was insufficient to overcome the proponents of procreational liberty who successfully argued for a right to children for anyone with a child wish and the resources to realise that objective.

Three distinct policy positions can be identified in the ART policy domain. At one extreme prohibition of ART is proposed, promoted by the Catholic Church and

some feminist groups. The second position promotes ART as a service only for couples living in traditional family arrangements and is supported by socially conservative politicians, conservative pro family advocates and mainstream religious groups predominantly on the grounds that this is in the best interests of children. The final position is liberal access to ART to all who are involuntarily childless, including the socially infertile and those living in non traditional families. This policy stance is supported by a broad coalition of actors including the ART industry, post modern feminists, medical practitioners, gay and lesbian advocates and socially progressive politicians. In this final position, the quality of family relationships is understood to be more important than family structure in ensuring the wellbeing of children. The best interests of children are understood to be served by knowledge of their genetic heritage. Policy outcome in contemporary Australia favours the third policy stance but is somewhat ambiguous in that Medicare funding is currently restricted to those who are clinically infertile. Figure 5 represents the discourse coalition which forms and the competing narratives active in contemporary ART policy making in Australia.

Figure 5 Discourse Coalition Formation in Assisted Reproductive Technology Policy



5.7 Embryonic Stem Cell Research Narratives

In ESC research and cloning the narrative of 'Saviour Science' (Goggin and Newell, 2004, 56) dominates. This narrative speaks to both health and well being interests and to entrepreneurial scientific interests but the interests of the embryo qua embryo become irrelevant. The ethical argument has moved away from contestations over the moral status of the embryo to the moral prerogative of treating the diseased and disabled. Saviour science provides the ethical basis for biomedical research based on the promise of regenerative therapeutics irrespective of the ethical deficit due to destructive embryo research. It serves both the pecuniary and intellectual interests of entrepreneurial science and biotechnology industry which are constructed as being in the public and national interests. Ultimately the narrative operates as a political device which allows governments to circumvent the irresolvable problem of the moral status of the embryo which at one stage threatened to undermine the progress of embryonic stem cell and cloning research.

The pro-ESC triumphs because the narrative of saviour science allows interests, which do not share values or beliefs systems to form a powerful discourse coalition. Those ethical interests which claim the moral imperative to use a valuable resource for the good of alleviating human suffering trump those moral interests which proclaim full human status for the pre implantation embryo. Allies are found in the peak disability organisations and the advocacy groups which grow around specific diseases. These groups bring the face of individual human suffering into the debate defying any claim that the interest of non sentient, non conscious cells should take precedence. Similarly entrepreneurial science can invoke this narrative. Their research is directed toward therapeutics which will rescue the sick and disabled from the tragedy of their existence. They do this in concert with the biotechnology industry that has the resources and the infrastructure to transform breakthrough scientific discoveries into therapeutic products which will benefit the public, the economy and the national interest. The majority of the public are willing collaborators based on an implicit understanding that the benefits of research will be non trivial and will be equitably distributed. Political actors are protecting the public interest by keeping the benefits of the

research in Australia. They are protecting the national interest by maintaining Australia's position as a global leader in biomedical research as well as the financial benefits which flow from commercialised discoveries.

A second narrative of 'cautious science' can also be identified. This represents the interests of the traditional biomedical scientists who promote a more measured approach. They refute the claims of saviour science due to the lack of existing evidence and question the need for embryo creation or SCNT. These scientists are willing to acknowledge ASC as a safer, more effective, less contentious *alternative* to ESC based on scientific evidence. A third narrative of science is that of unimpeded scientific progress which advocates for unrestricted ESC research and reproductive cloning if it can be demonstrated to be safe. Neither of these alternative science narratives creates successful coalitions.

As the ESC and cloning science and policy debates have matured, the promised therapies have not materialised and this comes as no surprise to the scientific and medical research community or the biotechnology industries. However the truths of basic research driven by scientific imperatives, time consuming clinical trials, discoveries protected by IP and private ownership of therapeutics does not serve the interests of entrepreneurial science and the biotechnology industry nor do they attract support from political actors, the disability and disease groups or the general public. This is in spite of the very public links between universities, industry and individual star scientists and the discourse of 'commercial in confidence' which underpins their relationships. The narrative of saviour science prevails irrespective of competing evidence.

The narratives of the anti ESC research and cloning lobby are multiple and fragmented and unable to form a strong singular coalition to challenge saviour science. Ethical narratives such as the sanctity of human life or the feminist perspectives on the commodification and appropriation of women's bodies in the interest of science and profit do not garner the same support. Likewise dissenting health and welfare voices which challenge the idea that disability is a tragedy and protest against exploitation of the disabled, do not form strong coalitions.

Again there is a continuum of policy positions from, prohibition of ESC research and cloning, to unrestricted use of embryos for research and no restrictions on human cloning. Between these extremes are two other significant policy positions; one speaks to a conservative and restrictive policy regime with limited access to surplus ART embryos and prohibition of therapeutic cloning as per the 2002 national regulation while the other promotes a more liberal approach which includes therapeutic cloning and the creation of specific research embryos under strictly regulated conditions exemplified by the 2006 legislative amendments.

Figure 6 represents the discourse coalition which forms and the competing narratives active in contemporary ESC research and cloning policy making in Australia.

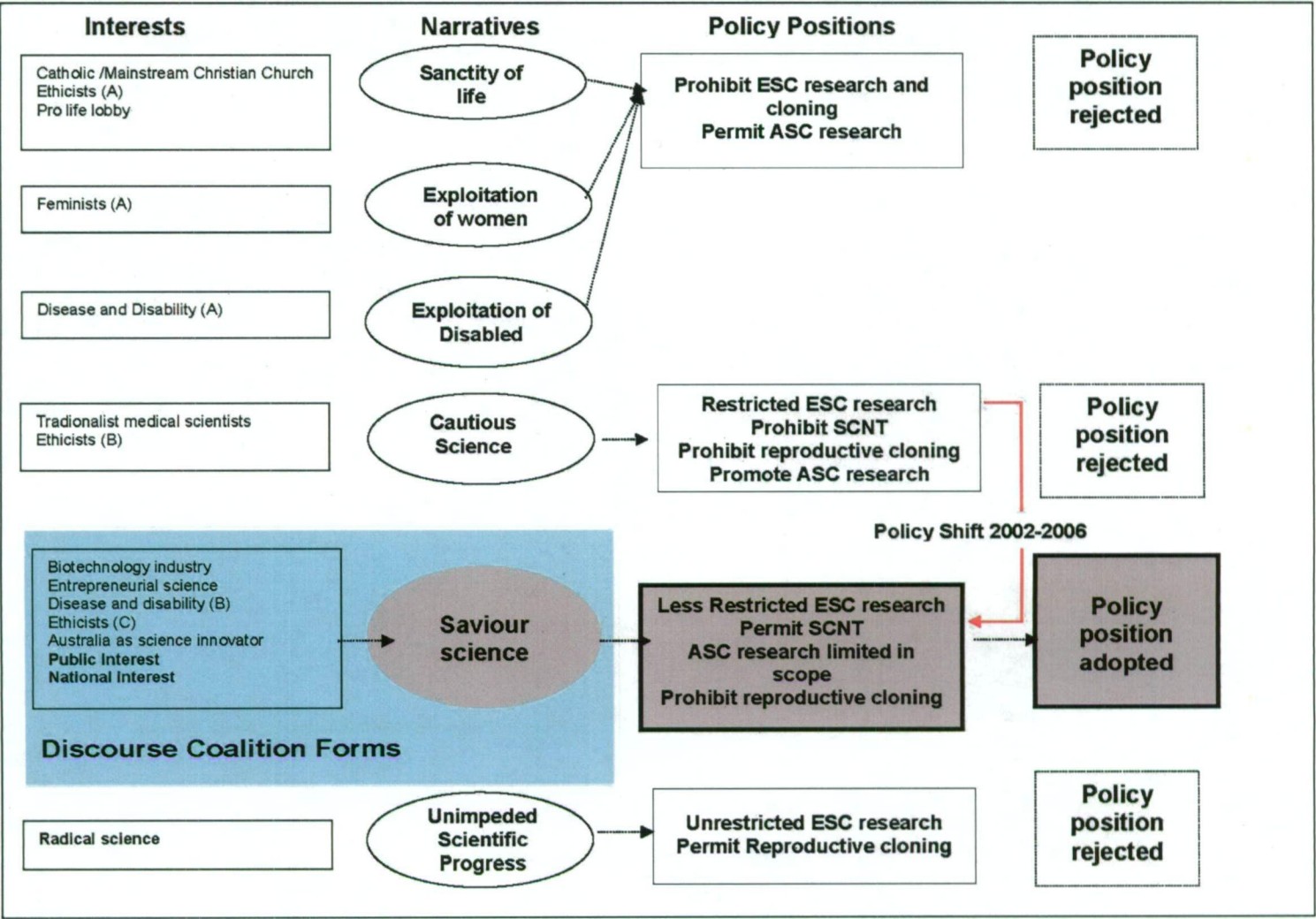


Figure 6 Discourse Coalition Formation in ESC Research and Cloning Policy

5.8 The Triumph of Rhetoric

In both cases, public policy could be said to come out on the side of protagonists. The proponents of ART and the proponents of ESC and cloning both won their respective day. They told the story that allowed successful discourse coalitions to form. Alternate stories put forward by opponents of both technologies could not garner the same support.

Wolpe and McGee (2001, 185) say 'public policy debates are exercises in rhetoric' with the first battle over definitions. The winner is the one most able 'to capture rhetorical primacy by having its definitions accepted as 'natural', setting the context and rules by which the game will be played out'. Within any public policy debate, there are multiple claims to legitimacy with each contender struggling to ensure their perspective becomes the one which ultimately informs policy. When the very substance of the policy debate is contested, then the truth claims become even more complicated.

In the ART debates, there are a number of rhetorical battles; over infertility, family, children's rights and procreational liberty. Infertility is both medical and social. Family is both traditional and non conventional. Children's rights include the rights to particular family arrangements and rights to knowledge of their genetic heritage. Procreational liberty is both the right to non interference in reproductive decisions and the right to have a child. These alternative positions are informed by competing discourses on health, family and parenthood. These battles form the parameters of the public policy debate about access to and funding of ART. They inform the political debate over who has the right to a child.

I have argued that invoking the 'narrative of hope' is an important strategy in achieving policy preferences in ART. This narrative was once the domain of interests seeking to limit ART services to medically infertile couples living in traditional family arrangements but has now been appropriated by a diverse range of interests who understand family and infertility much more broadly. The embryo

is an important symbol of that hope but only in so far as it delivers on the promise of a living healthy baby.

In the ESC and cloning debates, there are also a number of rhetorical battles. The overarching battle is over the status of the embryo. Is it a human being or is it a form of human life? This informs the policy debate about the permissible uses of the human embryo for research. It informs the political debate over human rights; the right to protection as a human subject in medical research, autonomy and ultimately the right to life.

The debate over definitions of the embryo is an important aspect of the policy process. The linking of human status to developmental stage is a particularly important strategy of the pro SCNT lobby. If the debate can be moved away from the biological fact of the continuum of human life from conception through to birth, toward a debate which accords different levels of human status to different stages in that continuum then there is less disquiet over destruction of that entity. If the entity can be renamed in terms which further reduce any claims to shared humanity then the level of public discomfort with its destruction is also reduced.

Destructive embryo research is predicated on the rhetoric of imminent clinical breakthroughs which will deliver humanity from suffering and disease. The failure of ESC research to deliver the anticipated clinical applications was used unsuccessfully as a tactic by the anti ESC lobby to promote an alternative research agenda for ASC. The entrepreneurial science agenda, however, needs ESC to pursue basic research, which has less public appeal but is a prerequisite for therapeutic developments. Thus they acknowledged only a limited potential for ASC research whilst continuing to promote the unlimited potential of ESC research.

I argued that the 'narrative of saviour science' was successfully invoked by those interests seeking a liberal approach to ESC research and cloning. The embryo is an important material resource for scientific and industry interests, who seek to ensure access to this resource. The political debate over the status of the embryo is a potential impediment to access so the debate is reframed in terms of saviour

science. The otherwise wasted entity is put to a useful purpose for the good of humanity. The nascent human thus serves the interest of the fully human. Any reticence regarding creation and destruction of an embryo to harvest its cells is appeased by the knowledge that this is for a therapeutic purposes.

In both policy arenas, public opinion is commandeered by the dominant storylines which underpin the policy outcomes. In ESC and cloning research the narrative of saviour science taps directly into public support for medical science which serves the good of mankind, at the expense of the human embryo whose moral status cannot be resolved. In ART, the narrative of hope appropriates the widespread public support for access to technology to fulfil the child wish, in the context of multiple interpretations of family.

6 Chapter 6 Conclusion

This thesis began with reflection on the new era of biotechnology and the complex challenges it presents for policy makers. When the content of a policy arena is of a highly technical nature, there is an obvious appeal to refer policy problems to the relevant scientific elite. When the policy outcomes impact on a diverse range of stakeholders across a number of dimensions; scientific, health and industry, there are multiple elites who can make a claim to policy legitimacy. When the policy content speaks to the very definition of what it means to be human, a specific ethical context comes into play and public engagement becomes a significant factor in policy making. When the science is evolving at a rapid pace, the decisions made with the knowledge of today, might have unanticipated and undesirable consequences for future generations.

I argued that biotechnology raises a number of significant questions for public policy. First, how does policy emerge in arenas characterised by deep ethical conflicts and continuously evolving and uncertain science? Secondly, what models of policy analysis are best equipped to deal with policy which is complex, contested and engaged across multiple dimensions? Thirdly are there policy arenas with similar characteristics which can serve as a guide for navigating the future?

In an endeavour to answer these questions, two contemporary policy case studies, Assisted Reproductive Technology (ART) and Embryonic Stem Cell (ESC) research and Cloning, were chosen as having relevant features which made them analytically comparable to each other *and* to the broader question of how to traverse the policy challenges of the new biotechnology. Each instance is characterised by irresolvable ethical conflicts. Each has multiple stakeholders across multiple policy dimensions with claims to policy expertise. In each case there are a continuum of possible policy positions from the fervently antagonistic to the fervently protagonist with policy actors forming alliances to promote their policy preferences. The cases are linked by the novel entity, the extra uterine

human embryo, which elicits reappraisal of existing understandings of kinship, family and ultimately what it means to be human. They are also linked through shared stakeholders and shared policy dimensions; policy issues in both cases informed by multiple discourses of health and wellbeing, science, ethics and commercial enterprise. Despite these similarities, Australian policy outcomes in these two domains are different along a number of criteria. ART policy remains domestic, embedded in the private world of reproduction under State and Territory jurisdiction while ESC research and cloning is international, embedded in the world of biomedical research and the subject to a national legislation and regulation.

6.1 Frameworks of Analysis

In Chapter 2, I reviewed frameworks of analysis and their utility in policy arenas characterised by deep moral conflicts. Policy community and networks approaches were considered first, focussing mainly on Pross' policy community model. This approach allows the key interests and institutions to be identified. The model also emphasises the importance of functional responsibility, specialist knowledge and vested interests in policy making (Pross, 1986, 98) and indeed these are identifiable in both cases. The model's orientation toward stability and consensus through negotiation, however does not deal fully with the irresolvable ethical conflicts over the status of the human embryo which continuously resurface in these policy domains. The multiplicity of actors and institutions across different spheres of interests is also problematic for this model. There are a number of actors with claims of specialist knowledge or vested interest who could therefore make a claim to subgovernment status but because these actors inhabit different dimensions, they may have very different constructions of the policy issue and the possible policy solutions. For those actors who construct embryos as human beings, the policy issue is one of protection of human rights while for those who see embryos as human tissue, the policy issues are completely different. They include issues of ownership, regulation of valuable resources and tensions between private and public goods. Further, the policy community approach doesn't explain how the policy issue was constructed in one way rather than another.

The Advocacy Coalition Framework (ACF) (Jenkins-Smith and Sabatier, 1992) was also considered and the basic premise of coalitions forming around particularly policy positions has immediate appeal for these two case studies. The model explicitly embraces the importance of beliefs and values to competing policy stances. The model however conceptualises coalitions as forming around shared beliefs and values which is not the case for either ART or ESC research and cloning. In ART, at least three key policy positions can be identified along the continuum; at one end is prohibition of ART, further along is limitation of ART to the medically infertile in traditional family arrangements and at the other extreme is open access to ART for anyone in the state of undesired childlessness. The stakeholders who promote policies at the extremes of the continuum do not necessarily share values or beliefs. The Catholic Church and some feminists are anti ART but for completely different reasons informed by completely different value systems. For the former it is a question of morality while the latter a question of exploitation of women's bodies as an expression of patriarchal oppression. At the other end of the spectrum are gay and lesbian advocates, socially progressive politicians of different political persuasions, other feminists, human rights advocates, fertility advocates, the ART industry, research scientists and medical practitioners who are not bound together by an overarching sets of beliefs, values and causal explanations in the ACF context.

In the ESC research and cloning debates, the ACF is even less useful. Coalitions form around essentially pro and anti ESC research and cloning positions. Few proponents argue for total deregulation and most for a regulatory framework which allows research to proceed relatively unimpeded whilst prohibiting currently unacceptable practices such as reproductive cloning. In this arena we see some unusual alliances form, but more importantly we see fragmentation within knowledge elites particularly amongst scientists and bioethicists. Further fragmentation occurs within the disability sector despite popular media representations of this group as the recipients of future miracle cures.

The Epistemic Communities (EC) approach of Haas (1992) also offers some useful analytic tools. ECs have authoritative knowledge which lends them policy

legitimacy. The strength of the model is the recognition that knowledge is interpreted by experts and this has subsequent impacts on how interests are articulated, policy issues are framed and policy solutions postulated. A weakness is the privileging of expertise over other forms of knowledge and the implications this has for the democratic polity. The multidimensional nature of the ESC and ART policy domains is also problematic for the EC approach because there are multiple knowledge elites claiming policy primacy. Depending on the construction of the problem, appeal can be made to the expertise of science or ethics or medicine. Further the EC cannot accommodate the wider public who have a stake in the policy outcomes but lack the relevant expertise to participate in the policy process.

Finally, discourse analysis was considered. Discourse analysis rescues policy analysis from the deceit of instrumental rationality by admitting both the irrationality of politics and the impossibility of separating policy from politics (Stone, 1997). It is interpretative and critical in its orientation. Discursive approaches recognise that political problems are socially constructed and that language is a medium which actors use to *create* the world and not simply describe it (Hajer, 1993, 44). The actors who attain rhetorical supremacy also exert power because in claiming the linguistic representation of the phenomenon they also shape the political response, namely 'who is responsible, what can be done and what should be done' (Hajer 1993, 45). Hajer's Discourse Coalition (DC) model operationalises discourse analysis as policy analysis. It allows actors from multiple traditions and disciplines, with different belief systems to form coalitions around a narrative or storyline to promote the policy outcomes that serves their own interests. The storyline is a social construct set in a particular social and historical context and subject to change and is subject to many interpretations. It is a device which can be used to promote both overt and covert interests. Multiple narratives are possible and compete with each other to form coalitions. The narrative around which the strongest coalition forms wins the policy battle. The DC approach accommodates the multidimensional nature of ART and ESC research and cloning debates. It explains the role of narratives in binding together disparate interests to promote policy outcomes that serve those disparate interests.

6.2 Assisted Reproductive Technology Policy in Australia

Chapter 3 discussed the dilemmas posed by Assisted Reproductive Technology and the Australian policy response from the advent of IVF in the late 1970s until the present. Initial controversies over ART as dangerous to women and children were quickly dispelled despite poor overall success rates. The Catholic Church morally condemned ART on the grounds of violation of human dignity. Along with Pro-Life groups and other mainstream Christian institutions, the Catholic Church also took moral issue with the high loss of embryonic life inherent in ART which it perceived as violating the sanctity of life. Despite this, ART enjoyed wide public support and quickly became the treatment of choice for infertility.

ART separated the act of procreation from the sexual act and offered the promise of children to the clinically infertile. What began, however, as a treatment for a specific physical dysfunction, transformed into a wider debate over the meaning of family, kinship and infertility. The subsequent public policy debates which emerged were concerned with access to ART services, funding of services, rights to parenthood and the rights of children born as a result of reproductive technologies. In the Australian context these policy issues remained primarily within the jurisdiction of States and Territories as a health policy issue leading to a fragmented policy response.

Initial legalisation, where it existed, limited ART services to the medically infertile living in traditional family arrangements. This policy stance was supported through the Australian Government policy lever of Medicare which restricted medical rebates to the clinically infertile. Following a successful challenge to State based legislation on the grounds of sex discrimination in Victoria, restrictions to services based on marital status were no longer permitted although the requirement for medical infertility remained.

Gamete donation and surrogacy aspects of ART removed procreation from a solely heterosexual context. Single women and same sex couples, infertile through social circumstances also claimed a right to parenthood which refocussed policy

debate onto constructions of family and the wellbeing of children born into non traditional family arrangements. Championed by social progressives and resisted by social conservatives, new legislation in New South Wales and Victoria effectively removed restrictions to ART services for the socially infertile. At present, Medicare rebates remain applicable only to the clinically infertile.

Embryo research for the purposes of improved clinical outcomes was always a component of ART with the loss of embryonic life an unavoidable consequence of research activity. Regulation of such research was again fragmented, covered by State based legislation or adherence to NHMRC guidelines. Concerns over ART related embryo research initiated the Tate inquiry in 1985 which had recommended that the embryo be considered a human subject in the context of research, but the report was never acted upon. Debates over the embryo itself did not fully flourish until the seminal scientific events of the late 1990's, the successful cloning of Dolly and the establishment of the first human embryonic stem cell lines. With this, the embryo emerged onto the national policy agenda as a political actor in its own right.

6.3 Embryonic Stem Cell Research and Cloning Policy in Australia

Chapter 4 discussed the challenges presented by embryonic stem cell research and cloning and the policy responses in Australia between 1985 and 2006. Key events in the policy process were the Andrews Inquiry 2001, the Senate Community Affairs Legislation Committee Inquiry 2002, the subsequent Research Involving Human Embryos and Prohibition of Human Cloning legislation of 2002, the Lockhart Legislation Review of 2005 and the amendments to the national legislation in 2006.

The policy debates played out on the national platform centred on the status of the human embryo, the creation of embryos for research, the potential of ESC research for curative treatments, the importance of research for Australia's status as a scientific innovator and the potential for economic benefits.

From the beginning, ESC research and cloning was portrayed as an issue of national importance and the focus of intergovernmental attention in the Australian context. The need for a consistent national approach to regulation was a constant refrain and the major institution in intergovernmental relations in Australia, the Council of Australian Governments (COAG) facilitated agreement on this point.

Following extensive public consultation, commissioning of scientific reports, expert consultation with eminent Australian scientists, medical specialists, ethicists, disability and disease advocates, legislation regulating embryo research and cloning was passed by the Australian Government in 2002 on a conscience vote. Research on surplus ART embryos was permitted under licence and within prescribed limits but human cloning was banned. Creation of embryos for research, cloning using somatic cell nuclear transfer (SCNT) for research purposes, creation of hybrids and chimeras were all prohibited by the legislation as was the use of any surplus ART embryos created after a specified date. By international standards, this policy response was perceived as conservative and restrictive by many in the research community and the fledgling local biotechnology industry, leading to dire predictions of Australia becoming a scientific backwater with a subsequent loss of intellectual capital and the much anticipated intellectual property which would proceed from ESC research. Cognisant of the rapid developments in this research field, a review process was written into the legislation. The anti ESC research lobby who had pitched their case largely on ethical grounds retreated and regrouped for Round 2.

Three years later the Lockhart review, following another round of public and expert consultation, recommended a number of significant amendments to the legislation, most importantly lifting the date restriction on access to surplus ART embryos and the restrictions on SCNT and creation of chimeras and hybrids. This would in effect permit therapeutic cloning and creation of specific embryos for research purposes alone. They recommended that reproductive cloning remained prohibited. These recommendations were welcomed by the ESC research protagonists but condemned by the anti research lobby.

The Liberal Howard government initially chose not to act on the Lockhart recommendations, arguing that the policy landscape had not changed enough in the intervening years to warrant any changes in the legislation. Following a party room backlash, however, Liberal Senator Kay Patterson introduced a Private Members Bill to facilitate implementation of the Lockhart recommendations. This bill was passed on a conscience vote in 2006.

In a twenty year period, the human embryo had transformed from an entity to be considered as a human subject for the purposes of research to a resource whose value lay in its research potential rather than its being.

6.4 Discourse Coalitions in Practice

Chapter 5 identified the interests which emerged in the ART and ESC research and cloning arenas in Australia across four dimensions, ethics, health and wellbeing, science and industry. Using Hajer's model, policy outcomes were analysed in terms of discourse coalitions forming around dominant narratives to promote a particular policy stance.

6.4.1 Assisted Reproductive Technology

The Discourse Coalition model provides some useful insights into ART policy making in contemporary Australia. Three distinct policy positions were identified. At one extreme prohibition of ART was proposed, promoted by the Catholic Church and some feminist groups. The second position promoted ART as a service only for couples living in traditional family arrangements and is supported by socially conservative politicians and conservative pro family advocates predominantly on the grounds that this is in the best interests of children. The final position was access to ART for all who are involuntarily childless, including the socially infertile and those living in non traditional families. This policy stance is supported by a broad coalition of actors including the ART industry, post modern feminists, medical practitioners, gay and lesbian advocates and socially progressive politicians. In this final position, the quality of family relationships is understood to be more important than family structure in ensuring the wellbeing of children. The best interests of children are understood to be served by

knowledge of their genetic heritage. Policy outcomes in contemporary Australia favour the third policy stance but are somewhat ambiguous in that Medicare funding is currently restricted to those who are clinically infertile.

There are two distinct narratives which inform the prohibition of ART policy position; the sanctity of life and dignity of procreation narrative of the Catholic Church and the exploitation of women position of anti ART feminists. Neither of these narratives attracts enough members to form a coalition and this policy position is rejected.

The traditional family narrative of the second position held sway in the early days of ART but has lost saliency in contemporary Australia. The narrative of Hope dominates the third policy position around which the strongest coalition forms. The major interests in ART policy can all interpret this narrative as serving their specific interests. The ART practitioners, mostly in private practice, are interested in securing their market share which they do through advertising their technical capabilities, their supportive clinical environment and range of services and their success rates. Single women, same sex couples and others who are socially infertile are interested in fulfilling their own child wishes as are the medically infertile. Feminists have a number of interests; protecting against incursions into existing anti discrimination rights and challenging patriarchal oppression embodied in traditional structures of family. Fertility advocacy groups have an interest in maintaining current generous public funding for ART services and as wide as possible access to ART services.

The narrative of hope is a claim to a right to parenthood. In this process procreational liberty is transformed from a negative right of non interference in the private decisions of reproduction to a positive right to parenthood for anyone with an unfulfilled child wish, courtesy of technology. The embryo is a symbol of this hope, valued for its potential to fulfil the child wish rather than any intrinsic value. When defective or surplus to reproductive requirement, the embryo's value lies in its capacity to further knowledge in ART research or other research. In either case it is a means to an end.

6.4.2 Embryonic Stem Cell Research and Cloning

As with ART, there is a continuum of policy positions in ESC research and cloning ranging from prohibition to unrestricted use of embryos for research and no restrictions on human cloning. Between these extremes are two other policy positions; one speaks to a conservative and restrictive policy regime with limited access to surplus ART embryos and prohibition of therapeutic cloning as per the 2002 national regulation while the other promotes a more liberal approach which includes therapeutic cloning and the creation of specific research embryos under strictly regulated conditions exemplified by the 2006 legislative amendments.

The prohibition of ESC research and cloning position is illuminated by three distinct narratives. Firstly the 'sanctity of life' narrative which informs the Catholic Church, other conservative Christian religious interests, the pro-life lobby, some ethicists and a cohort of conservative Christian politicians from across the political spectrum. The second narrative is the 'exploitation of women' endorsed by particular feminist interests. The third narrative is 'exploitation of the disabled' endorsed by some disability advocates. This narrative emerges from a discourse of social health which promotes policies of inclusion and support for people with disabilities rather than rescue from the self evident tragedy of their lives. None of these narratives are strong enough to form winning coalitions. At the other end of the spectrum is a narrative of unimpeded scientific progress. This is endorsed by a limited number of scientists and again does not attract much support. A narrative of 'cautionary science' informs the restricted ESC research position. This narrative attracts mainly traditional biomedical scientists who favour the classical open science model of inquiry, validation through peer review, open exchange of information and measured claims to potential benefits. It is a narrative that holds some appeal to classical bioethicists informed by traditions of non maleficence.

The narrative of saviour science, however dominates contemporary policy formation. A strong and powerful coalition forms around saviour science. It serves the interests of

- Entrepreneurial science and the domestic biotechnology industry,
- People with untreatable diseases, profound disabilities and their advocates
- Bioethicists who promote the moral responsibility to ease suffering
- Australia as an international scientific innovator

Importantly saviour science captures the public interest and is seen to promote the national interest. Public support of ESC research and cloning however is contingent on that science being used for public good not private profit or individual prestige. Disease and disability interests and bioethical interests lie in development of novel treatments AND access to those. By contrast entrepreneurial science focusses on the development of for profit products, with little interest in equitable distribution of those goods. The social construct 'Saviour Science' is appropriated by different actors to promote their preferred policy stance but for different reasons.

The discourses around the moral status of the embryo and the health and welfare of the sick and disabled can be understood as political devices in the ESC research and cloning policy domain. They are necessary conditions to garner public support for biotechnology and public investment in science. The commodification of embryos which began in ART now fully flowers. The distinction between human life and human being is stretched to its fullest extent and the ties between the existential human and the suspended human life of embryo begin to disintegrate.

Where more traditional policy analysis would look to institutional actors, interests and power relations to explain policy decisions and outcomes, I have argued that rhetoric, narrative and discourse are themselves important actors in the policy process. The framing of the policy problem is of particular importance because this in turn frames the possible policy responses. The discourse which shapes the policy issue determines which actors can claim legitimacy in policy formulation. The rhetoric(s) invoked by key interests must resonate with both the public and policy makers to advance their policy preferences. In the case studies under examination, where multiple discourses were operating concurrently, the policy

issues were constantly shape shifting. The very ambiguity over what constituted the policy problem; simultaneously science, ethics, health and economic requires a policy response that is interpretative and responsive to the shifts. A shared storyline allowed the otherwise disparate actors to press for their policy preferences to policy makers invoking both public and national interest along the way.

6.5 Implications for Future Research

This research highlights the importance of narrative in contentious policy arenas. First it invites the policy analyst to investigate competing truth claims (facts) from a critical perspective. This means deconstructing the policy issue to the discourses which shape that particular story and the interests these discourses represent. This offers the opportunity to identify alternative readings, alternative narratives, alternative interests and alternative policy solutions. In this process, power relations hitherto hidden may be exposed and strategising by key actors revealed. Secondly, narrative can be used as a strategic device to promote one's own policy agenda in the face of known competing agendas. In this perspective the narrative shapes the parameters of the policy debate and secures support from key actors who are able to interpret the story to promote their own interests even in the absence of shared values, ontologies and epistemologies.

These case studies illustrate that the biological fact of possessing a human genome does not automatically confer upon an entity, the status of human being with its attendant rights. A discourse analysis reveals that interpretation of such facts is an important feature of policy analysis and this I believe has profound ramifications for how public policy deals with the new biotechnology. Future developments in biotechnology hold great promise and potentially great risks for humans.

Customised drugs matched to one's own genetic makeup, replacements for diseased or aged organs, genetic treatments for embryos with devastating inheritable diseases are all possibilities. As knowledge of the human genome continues to unfold and the subtle differences between humans at a molecular level, are greater understood, then policy makers will need to deal with the new problems of genetic reductionism, determinism and ultimately discrimination. Just

as race and gender formed the basis of racism and sexism, genetic differences posited as '...real, biological, and neutral grounds for different treatment' posits a new geneticism (Wolf 1995, 346). Scientists and researchers engage in rhetoric and metaphor as they deliberate over the new genetics and invoke the 'imagery of inexorable progress which limits science's control over what happens next' (Miller et al. 2006). But just as 'the cloning debate' was about society and not technological systems (Franklin 1999, 119) then so is the new biotechnology. Thus it falls to society to determine the ends for science and technology in the interests of our common future. Will narratives of social responsibility be used to promote the birth of only the healthiest and most intelligent children or perhaps narratives of overpopulation and diminishing natural resources to limit birth rates in specific populations? For policy makers and policy analysis, this is the importance of discourse; in revealing what is hidden by the stories that are told and suppressed by the ones that are not.

Discourse analysis has a critical orientation that alerts the analyst to how different social constructs are used to form coalitions which privilege particular policy preferences. It can expose covert interests of coalition actors. Storylines can be used as a device to move policy formulation beyond value deadlocks. Ambiguity is the key. The storyline must be open to wide enough interpretation so that actors with disparate belief system can form a coalition to promote the policy preference which serves their multiple interests. As in both ART and ESC research and cloning policymaking, irresolvable controversies over the moral status of the embryo do not disappear; they are merely hidden from view, subsumed by other less controversial debates such as the right to parenthood and the obligation to relieve suffering.

If public policy is truly a reflection of a society's values, then contemporary Australian values would suggest that human status therefore human rights are contingent on stage of development, permitting certain classes of human entity to be used as means to an end. It is acceptable that embryos are created for reproductive purposes but if surplus to requirement can be used for research. It is acceptable that embryos can be created solely for research. It is acceptable that they can be disposed of or kept in perpetual suspended life. The needs and desires

of the fully human have already trumped the rights of the nascent human. That is the truth obscured behind the narratives of hope and saviour science.

'The true value of a human being is determined by the measure, and the sense in which they have obtained liberation from the self. We shall require a substantially new manner of thinking if humanity is to survive.' (Albert Einstein, 1954)

7 Appendices

7.1 Appendix 1 Assisted Reproductive Treatment Act 2008 (Victoria)

Part 10, s100

Powers, functions, duties and consultation requirements

(1)The Authority has the following functions—

- (a) to administer the registration system under this Act;
- (b) to undertake public education about treatment procedures and the best interests of children born as a result of treatment procedures;
- (c) to undertake community consultation about matters relevant to this Act;
- (d) to monitor—
 - (i) programs and activities carried out under this Act; and
 - (ii) programs and activities carried out relating to the causes and prevention of I infertility; and
 - (iii) programs and procedures relating to treatment procedures carried out outside Victoria;
- (e) to keep under regular review and, if it thinks fit, to make recommendations to the Minister about its functions, operation or composition;
- (f) to promote research into the causes and prevention of infertility;
- (g) to approve the bringing of donor gametes or an embryo formed from donor gametes into or the taking of them from Victoria, and to provide for the exemption from particular provisions of this Act in accordance with section 37;
- (h) any other functions conferred on the Authority by or under this or any other Act.

(2)The Authority must, without delay, advise the Minister of any of the following matters that come to its notice—

- (a) a contravention of this Act or the regulations;
- (b) a contravention of a registered ART provider's registration;
- (c) a development in relation to the following, whether in Victoria or elsewhere, that the Authority considers of major importance or views with concern—
 - (i) research relating to infertility;
 - (ii) treatment for infertility.

(3)The Authority has all the powers necessary to enable it to perform its functions.

(4)The Authority must have regard to the Minister's advice in carrying out its functions and exercising its powers.

Section 40

(1) The Patient Review Panel may approve a surrogacy arrangement if the Panel is satisfied of the following—

- (a) that a doctor has formed an opinion that—
 - (i) in the circumstances, the commissioning parent is unlikely to become pregnant, be able to carry a pregnancy or give birth; or

- (ii) if the commissioning parent is a woman, the woman is likely to place her life or health, or that of the baby, at risk if she becomes pregnant, carries a pregnancy or gives birth;
 - (ab) that the surrogate mother's oocyte will not be used in the conception of the child;
 - (ac) that the surrogate mother has previously carried a pregnancy and given birth to a live child;
 - (b) that the surrogate mother is at least 25 years of age;
 - (c) that the commissioning parent, the surrogate mother and the surrogate mother's partner, if any, have received counselling and legal advice as required under section
 - (d) that the parties to the surrogacy arrangement are aware of and understand the personal and legal consequences of the arrangement;
 - (e) that the parties to the surrogacy arrangement are prepared for the consequences if the arrangement does not proceed in accordance with the parties' intentions, including—
 - (i) the consequences if the commissioning parent decides not to accept the child once born; and
 - (ii) the consequences if the surrogate mother refuses to relinquish the child to the commissioning parent.
 - (f) that the parties to the surrogacy arrangement are able to make informed decisions about proceeding with the arrangement.
- (2) In making its decision under subsection (1), the Patient Review Panel must have regard to the following—
- (a) a report from a counsellor who provided counselling under section 43 to the parties;
 - (b) an acknowledgment by the parties that the parties have undergone counselling and obtained legal advice as required by section 43.

Section 85 ART Act 2008 functions of Patient Review Panel

- (a) to consider applications for surrogacy arrangements; and
- (b) to consider whether there is a barrier to treatment if a presumption against treatment applies; and
- (c) to consider applications for posthumous use of gametes and embryos; and
- (d) to consider applications for treatment in circumstances in which a registered ART provider or doctor is concerned about the risk of abuse or neglect of a child that may be born as a result of the treatment; and
- (e) to consider applications for treatment in circumstances in which the applicant does not meet the criteria for treatment; and
- (f) to consider applications for extended storage periods of gametes or embryos or removal of embryos from storage; and
- (g) any other functions given to the Panel by this Act or by the Minister.

Section 40 ART Act 2008

- (1) The Patient Review Panel may approve a surrogacy arrangement if the Panel is satisfied of the following—
- (a) that a doctor has formed an opinion that—

- (i) in the circumstances, the commissioning parent is unlikely to become pregnant, be able to carry a pregnancy or give birth; or
 - (ii) if the commissioning parent is a woman, the woman is likely to place her life or health, or that of the baby, at risk if she becomes pregnant, carries a pregnancy or gives birth;
 - (ab) that the surrogate mother's oocyte will not be used in the conception of the child;
 - (ac) that the surrogate mother has previously carried a pregnancy and given birth to a live child;
 - (b) that the surrogate mother is at least 25 years of age;
 - (c) that the commissioning parent, the surrogate mother and the surrogate mother's partner, if any, have received counselling and legal advice as required under section
 - (d) that the parties to the surrogacy arrangement are aware of and understand the personal and legal consequences of the arrangement;
 - (e) that the parties to the surrogacy arrangement are prepared for the consequences if the arrangement does not proceed in accordance with the parties' intentions, including—
 - (i) the consequences if the commissioning parent decides not to accept the child once born; and
 - (ii) the consequences if the surrogate mother refuses to relinquish the child to the commissioning parent.
 - (f) that the parties to the surrogacy arrangement are able to make informed decisions about proceeding with the arrangement.
- (2) In making its decision under subsection (1), the Patient Review Panel must have regard to the following—
- (a) a report from a counsellor who provided counselling under section 43 to the parties;
 - (b) an acknowledgment by the parties that the parties have undergone counselling and obtained legal advice as required by section 43.

Section 85 Functions of Patient Review Panel

- (a) to consider applications for surrogacy arrangements; and
- (b) to consider whether there is a barrier to treatment if a presumption against treatment applies; and
- (c) to consider applications for posthumous use of gametes and embryos; and
- (d) to consider applications for treatment in circumstances in which a registered ART provider or doctor is concerned about the risk of abuse or neglect of a child that may be born as a result of the treatment; and
- (e) to consider applications for treatment in circumstances in which the applicant does not meet the criteria for treatment; and
- (f) to consider applications for extended storage periods of gametes or embryos or removal of embryos from storage; and
- (g) any other functions given to the Panel by this Act or by the Minister.

7.2 Appendix 2 NHMRC guidelines Section 11

1. Developing embryos for purposes other than for their use in an approved ART treatment program.
2. Culturing of an embryo in vitro for more than 14 days.
3. Experimentation with the intent to produce two or more genetically identical individuals, including development of human embryonic stem cell lines with the aim of producing a clone of individuals.
4. Using foetal gametes for fertilisation.
5. Mixing of human and animal gametes to produce hybrid embryos.
6. Mixing of gametes or embryos of different parental origin so as to confuse the biological parentage of the conceptus.
7. Placing an embryo in a body cavity other than in the human female reproductive tract.
8. Embryo flushing.
9. Commercial trading in gametes or embryos.
10. Paying donors of gametes or embryos beyond reasonable expenses.
11. The use in ART treatment programs of gametes or embryos harvested from cadavers.

7.3 Appendix 3 AHEC Recommendations

Recommendation 1

The Commonwealth Government, through the Minister for Health and Aged Care, should reaffirm its support for the UNESCO Declaration on the Human Genome and Human Rights, in particular Article 11, which states that, Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.

Recommendation 2

Noting that Victoria, South Australia and Western Australia have legislation Regulating embryo research and prohibiting the cloning of human beings, the Minister for Health and Aged Care should urge the other States and Territories to introduce legislation to limit research on human embryos according to the principles set out in Sections 6 and 11 of the NHMRC Ethical guidelines on assisted reproductive technology.

Recommendation 3

Noting that there are statutory authorities established in Victoria, South Australia and Western Australia which consider and may approve human embryo research under strict conditions, the Minister for Health and Aged Care should urge the remaining States and Territories to establish similar statutory authorities with power to regulate research on human embryos according to the principles set out in Sections 6 and 11 of the NHMRC Ethical guidelines on assisted reproductive technology.

Recommendation 4

The Minister for Health and Aged Care should encourage and promote informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques.

Resolution 1

The AHEC proposes that, until legislation is introduced in the remaining States and Territories, the AHEC will collect information from institutional ethics Committees (IECs) in these States and Territories on IEC research approvals of projects involving the application of current cloning techniques to human embryos. This information will be obtained in the course of the IEC annual compliance reporting system that is currently in place.

Resolution 2

The AHEC proposes that, until legislation is introduced in the remaining States and Territories, the NHMRC should consider the establishment of an expert advisory Committee to assist IECs

7.4 Appendix 4 Andrews Committee Recommendations

Recommendation 1, the enactment of legislation by the Commonwealth to regulate human cloning and stem cell research.

Recommendation 2, that legislation regulating human cloning and stem cell research cover all research in this area, both publicly and privately funded.

Recommendation 3, that the regulation of research involving the use of cloning technology should be separate from that governing assisted reproductive technologies.

Recommendation 4, that the legislation regulating human cloning and stem cell research contain a ban on cloning for reproductive purposes. Any attempt to undertake cloning for reproductive purposes should result in a criminal penalty and the withdrawal of a licence to undertake research in this area for the individual concerned.

Recommendation 5, that the Commonwealth regulates human cloning and stem cell research within the strict parameters outlined in paragraphs 12.41-12.43.

Recommendation 6, that a national licensing body be established to regulate any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 7, that a licence issued by the national licensing body should be required to undertake any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 8, that the national licensing body has the responsibilities listed in paragraph 12.55.

Recommendation 9, that AHEC be responsible for monitoring scientific developments in this area, analysing their potential impact and providing advice to Commonwealth, State and Territory governments on these matters.

Recommendation 10, that individuals and organisations be licensed for each research activity involving the isolation, creation and use of embryonic stem cells they intend to undertake.

Recommendation 11, that the matters listed in paragraph 12.63 be prohibited. Such a prohibition would mean that the licensing body would not have the authority to issue a licence for research involving any of the items listed in paragraph 12.63.xxx

Recommendation 12, that research using cloning technologies and involving the use of embryos may only be undertaken pursuant to a licence.

Recommendation 13, that a licence for research using cloning technologies and involving the use of embryos only be granted if the licensing body is satisfied of the matters listed in paragraph 12.43 and that informed consent has been granted by all relevant persons.

Recommendation 14, that the licensing body develop detailed guidelines specifying the requirements for informed consent and take into account the matters discussed in paragraphs 12.69-12.77 in developing these guidelines.

Recommendation 15, that the government establish an independent review of the institutional ethics Committee system in Australia.

Recommendation 16, that all Commonwealth departments refer to the licensing body for guidance where a matter arises that involves the use of human reproductive material, embryonic stem cell research or cloning research

7.5 Appendix 5 Terms of Reference –Legislative Review Committee

1. The Legislation Review Committee - *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* is required to consider and report on the scope and operation of each of the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* taking into account,
 - (I) the following statutory requirements,
 - a) developments in technology in relation to assisted reproductive technology;
 - b) developments in medical research and scientific research and the potential therapeutic applications of such research;
 - c) community standards;
 - d) the applicability of establishing a National Stem Cell Bank; and
 - (ii) the following additional matters in relation to the national legislative scheme,
 - a) consideration of relevant aspects of State and Territory legislation corresponding to the *Research Involving Human Embryos Act 2002*.
 - b) the role played by State and Territory statutory bodies that regulate assisted reproductive technology (ART) treatment as well as the role of national organisations including, but not necessarily limited to, the Fertility Society of Australia and its Reproductive Technology Accreditation Committee (RTAC);
 - c) the effectiveness of monitoring and compliance under the *Research Involving Human Embryos Act 2002* in particular, but also in relation to the *Prohibition of Human Cloning Act 2002* to the extent that issues may arise in relation to the latter Act;
 - d) the ongoing appropriateness and effectiveness of changes to the Customs regulations to regulate the export of human embryos derived through ART and the import of viable materials derived from human embryo clones;
 - e) options for regulation of the import and export of human embryonic stem cells;
 - f) the implications of cost recovery; and
 - g) implications for Australian science and economic activity.
2. The Legislation Review Committee is required to consult the Commonwealth, the States, the Australian Capital Territory and the Northern Territory and a broad range of persons with expertise in or experience of relevant disciplines.
3. The reports must, to the extent that it is reasonably practicable, set out the views of the Commonwealth, the States and Territories and those other persons consulted.
4. Each report must contain recommendations about amendments, if any, that should be made to the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*, whichever is applicable.
5. The Legislation Review Committee is required to give a written report to the Council of Australian Governments and both Houses of the Parliament on the independent review of the operation of the *Prohibition of Human Cloning Act 2002* no later than Monday 19 December 2005. The Legislation Review Committee is required to give a written report to the Council of Australian Governments and both Houses of the Parliament on the independent review of the operation of the *Research Involving Human Embryos Act 2002* as an

accompanying report to the report on the review of the operation of the
Prohibition of Human Cloning Act 2002.

7.6 Appendix 6 Biotext Literature Review Key points

ART outcomes

- ART outcomes are being improved by improving the ability to select the 'best' single embryo for transfer, reducing the risks associated with multiple births.
- This is being achieved by identifying embryos with genetic defects as well as improving the in vitro conditions during culture and optimising the timing of embryo transfer. (xiii)
- Alternative fertilisation strategies are being investigated to treat patients who cannot produce oocytes or sperm. These investigations involve novel cell fusions but are still at the preliminary stage. (xiv)

Cloning in animals

- Cloning by nuclear transfer in animals cannot be used to reliably produce live animals.
- Techniques such as embryo splitting and parthenogenesis have not been successful as an alternative to cloning by nuclear transfer. However, they may be useful as techniques to create embryonic stem cells.(xv)

Developments in nuclear transfer

- Embryological studies in animals and humans have given scientists new understanding of normal developmental processes, helping to define the processes that appear to fail during cloning by nuclear transfer.
- Technical improvements in cloning methods are refining the process of nuclear transfer. (xv)

Recent developments in cloning animals

- Increased understanding of embryology and cloning technology has improved cloning outcomes in animals.
- Interspecies cloning in animals has further helped to understand processes and improve techniques.
- Interspecies cloning using human material is banned in Australia and most other countries. (xvi)

Cloning human embryos

- Improved cloning techniques in animals have led to the cloning of human embryos to derive embryonic stem cells.
- Embryological processes leading to reprogramming and activation of the genetic material involved are not yet fully understood.
- If human embryo clones are used to develop stem cell therapies, the consequences of developmental problems in the embryos will need to be determined and minimised in the resulting stem cells.(xvii)

Embryonic stem cells

- Culture conditions for ES cells that are free of animal products and serum have been developed, but are less efficient and support lower growth rates than culture conditions with serum/feeder cells.

- Many growth factors have been identified and trialled with different ES stem cell populations but there is currently no culture method that allows the high efficiency clonal propagation of human ES cells.
- In vivo differentiation of ES cells leads to the development of teratomas.
- For clinical use, cells must be differentiated in vitro. This is now a high priority for research.
- Various methods of differentiation and cell selection are being developed for different cell types.(xix)

Adult stem cells

- AS cells are present in many tissues and most differentiate into cell types from within their 'home' tissue (unipotent/multipotent).
 - Some AS cells have been shown to differentiate into cell types of different tissues ('transdifferentiation') and such cells are described as having high levels of plasticity.
- Some AS cells may be pluripotent.
- However, mechanisms of transdifferentiation are not well understood and some claims have been disputed on the basis that the origin of the different cell types may be due to cell fusion rather than differentiation.
 - Development of culture conditions for AS cells that are free of animal products and serum are being developed as for ES cells.(xx)

Research with stem cells

- Stem cells are being used to support three lines of research,
development of cellular therapies
study of disease development and progression
a cellular model system for drug development.(xxi)
- Development of stem cell therapies
- Development of stem cell therapies is a very active area of research covering many diseases, conditions and injuries.
 - ES cell research is mainly confined to preclinical (animal) studies because the cells are not yet characterised well enough for use in clinical trials. However, preclinical research is providing encouraging results.
 - The scope of AS cell research is very broad and many cell types are being studied.
 - Some AS cell therapies are well established and some others have progressed to the preliminary clinical trial stage.
 - Development of potential therapies using AS cells with greater plasticity (such as bone marrow stromal cells) faces similar challenges to development of potential ES cell therapies.(xxiv)

Legislation

- No country has legislation that permits reproductive cloning.
- Most countries reviewed permit the use of excess human embryos from IVF.
- Only a small number of countries reviewed have legislation permitting the creation of human embryos specifically for research purposes. These are also countries in which there is considerable investment in stem cell research.
- In general, those countries that prohibit the creation of human embryos for research purposes also prohibit the creation of human embryo clones for research.

- Where legislation explicitly refers to the possibility of creating, developing or implanting human–animal hybrid embryos or chimeras, those practices are banned.

- Legislation in some countries includes a restriction or ban on the commercial trading of gametes and embryos.

- Some countries have a ban on germline genetic modification. (xxvi)

Trade and exchange of human embryos and stem cells

- Many countries have arrangements for import and export of reproductive materials (embryos and gametes) for human therapeutic use (such as in IVF).

- Embryos that would not be permitted to be created within a country (e.g. by nuclear transfer), or their products (e.g. stem cell lines), are usually not allowed to be imported.

- Exchange of stem cells and stem cell lines occurs between countries and between laboratories, but the extent of this is difficult to assess.

- Commercial trade in human embryos (and human sperm and eggs) is prohibited in some countries (e.g. Australia) but allowed in others (e.g. United States).

- Trade in cell lines is not covered by legislation in most countries; donors of material from which stem cell lines are derived do not usually benefit financially from their donation.

- Views differ about the appropriateness of patenting ES cell lines. (xxviii)

Stem cell registries and banks

- A number of stem cell registries have been set up to record information about stem cell lines.

- Stem cell banks have also been set up in several countries to store ethically derived and quality controlled human stem cell lines.

7.7 Appendix 7 Lockhart Review 2006 Recommendations

National legislation

1 Clinical practice and scientific research involving assisted reproductive technologies (ART) and the creation and use of human embryos for research purposes should continue to be subject to specific national legislation.

Reproductive cloning

2 Reproductive cloning should continue to be prohibited.

Prohibitions on developing and implanting embryos

3 Implantation into the reproductive tract of a woman of a human embryo created by any means other than fertilisation of an egg by a sperm should continue to be prohibited.

4 Development of a human embryo created by any means beyond 14 days gestation in any external culture or device should continue to be prohibited.

5 Implantation into the reproductive tract of a woman of a human-animal hybrid or chimeric embryo should continue to be prohibited.

6 Development of a human-animal hybrid or chimeric embryo should continue to be prohibited, except as indicated in Recommendation 17.

7 Placing a human embryo into an animal or into the body of a human apart from into a woman's reproductive tract, or placing an animal embryo into the body of a human, for any period of gestation, should all remain prohibited.

8 Implantation into the reproductive tract of a woman of an embryo created with genetic material provided by more than two people should continue to be prohibited.

9 Implantation into the reproductive tract of a woman of an embryo created using precursor cells from a human embryo or a human foetus should continue to be prohibited.

10 Implantation into the reproductive tract of a woman of an embryo carrying heritable alterations to the genome should continue to be prohibited.

11 Collection of a viable human embryo from the body of a woman should continue to be prohibited.

Creation of human embryos by fertilisation

12 Creation of human embryos by fertilisation of human eggs by human sperm should remain restricted to ART treatment for the purposes of reproduction.

13 Creation of human embryos by fertilisation of human eggs by human sperm to create embryos for the purposes of research should continue to be prohibited except in the situation described in Recommendation 15.

Use of excess ART embryos in research

14 Use of excess ART embryos in research should continue to be permitted, under licence, as under current legislation.

ART clinical practice and ART research

15 Research involving fertilisation of human eggs by human sperm up to, but not including, the first cell division should be permitted for research, training and improvements in clinical practice of ART.

16 Testing of human oocytes for maturity by fertilisation up to, but not including, the first cell division or by parthenogenetic activation should be permitted for research, training and improvements in clinical practice of ART.

17 Certain interspecies fertilisation and development up to, but not including, the first cell division should be permitted for testing gamete viability to assist ART training and practice.

18 The Licensing Committee should develop a simple proforma application for licences to undertake training and quality assurance activities for ART clinics.

19 Consideration should be given to the use of cytoplasmic transfer (including transfer of

mitochondrial DNA), under licence, for research on mitochondrial disease and other uses to improve ART treatment.

Use of fresh ART embryos

20 An expert body should formulate objective criteria to define those embryos that are unsuitable for implantation.

21 Fresh ART embryos that are unsuitable for implantation, as defined by the objective criteria, should be permitted to be used, under licence, for research, training and improvements in clinical practice.

22 Fresh ART embryos that are diagnosed by preimplantation genetic diagnosis (according to the ART guidelines) as being unsuitable for implantation should be permitted to be used, under licence, for research, training and improvements in clinical practice.

Use of human embryos created by somatic cell nuclear transfer

23 Human somatic cell nuclear transfer should be permitted, under licence, to create and use human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

24 In order to reduce the need for human oocytes, transfer of human somatic cell nuclei into animal oocytes should be allowed, under licence, for the creation and use of human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

Use of human embryos created by activation methods not involving fertilisation of a human egg by a human sperm or somatic cell nuclear transfer

25 Creation of human embryos and human embryo clones by means other than fertilisation of an egg by a sperm (such as nuclear or pronuclear transfer and parthenogenesis) should be permitted, under licence, for research, training and clinical applications, including production amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

26 Creation of human embryos using the genetic material from more than two people, or including heritable genetic alterations, should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

27 Creation of embryos using precursor cells from a human embryo or a human foetus should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

Definition of a human embryo

28 The definition of a 'human embryo' in both Acts should be changed to, 'A human embryo is a discrete living entity that has a human genome or an altered human genome and that has arisen from either,

- (i) the first mitotic cell division when fertilisation of a human oocyte by a human sperm is complete; or
- (ii) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, 14 days and has not yet reached eight weeks of development.'

Consent arrangements for the donation of embryos

29 The National Health and Medical Research Council (NHMRC) should review its guidelines in relation to consent to research on excess ART embryos, in order to clarify the consent process in relation to the following issues,

- the circumstances, if any, where those who choose to donate excess ART embryos to

research may be able to choose not to be contacted at some later stage to give consent

to a particular research proposal

- the circumstances, if any, where a human research ethics Committee can determine that

the researcher need not ask for further consent to use embryos already declared 'excess'

- the development of an appropriate form of consent that could be completed by the responsible persons for excess ART embryos shortly after the declaration that the embryos are excess

- the manner in which those who donate embryos or gametes for the creation of ART embryos may express any preference for the type of research for which the tissue will be used, once the embryo is declared excess.

30 The NHMRC should develop ethical guidelines for the use of embryos that are unsuitable for implantation for research, training and improvements in clinical practice (see Recommendations 20–22).

Egg donation

31 The current principles of consent for participation in medical research must apply to sperm, egg and embryo donors, so as to ensure that decisions are freely made.

32 The NHMRC should develop guidelines for egg donation.

33 The present prohibition of the sale of sperm, eggs and embryos should continue, but the reimbursement of reasonable expenses should continue to be permitted.

Licensing arrangements

34 The Embryo Research Licensing Committee of the NHMRC (the Licensing Committee) should continue to be the regulatory body responsible for assessing

licence applications, issuing licences and monitoring compliance, as under current arrangements.

35 The role of the Licensing Committee should be extended to include assessment of licensing applications and issuing licences for any additional activities permitted, under licence (see Recommendations 14–27).

36 The Australian Parliament and the Council of Australian Governments should give urgent attention to the problem of delays in the filling of vacancies on the Licensing Committee.

37 There should be no attempt to recover the cost of administration, licensing, monitoring and inspection activities associated with the legislation from researchers at this point in time.

Monitoring powers

38 The Licensing Committee should continue to perform its functions in relation to licences and databases for research permitted by licences under the Research Involving Human Embryos Act.

39 Licensing Committee inspectors should be given powers, under the Prohibition of Human Cloning Act and the Research Involving Human Embryos Act, of entry, inspection and enforcement in relation to non-licensed facilities in the same manner and by the observance of the same procedures as applicable to search warrants under Commonwealth legislation, if such powers do not clearly exist.

Oversight of ART clinical practice and research

40 There should be a continuation of the role of the Reproductive Technology Accreditation Committee in the regulation of ART.

Import and export of human reproductive materials for personal use

41 The import or export of a patient's reproductive material, including ART embryos, for the purpose of that person's ongoing ART treatment should not require any regulation other than that required under existing quarantine regulation.

Trade and international exchange of human reproductive materials and stem cells

42 The import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority.

The existing requirements for the import and export of human biological materials are

satisfactory and, for ethically derived human embryonic stem cells, no further restrictions are necessary.

Biotechnology and commercialisation

44 Trade in human gametes or embryos, or any commodification of these items, should continue to be prohibited.

45 Donors of tissue that is going to result in an immortal stem cell line should be informed by means of processes monitored by human research ethics Committees about the potential use of that stem cell line, including the potential for commercial gain and the fact that they may not have any rights in potential stem cell developments.

46 The development of biotechnology and pharmaceutical products arising from stem cell research should be supported.

National stem cell bank

47 A national stem cell bank should be established.

48 Consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem cell bank.

49 A national register of donated excess ART embryos should be established.

Regulatory approach to legislation

50 The Licensing Committee should be authorised under the Prohibition of Human Cloning Act to give binding rulings on the interpretation of that Act, or the regulations made under that Act, on condition that it reports immediately and in detail to the NHMRC and to parliament on such rulings.

51 The Licensing Committee should be authorised by the Research Involving Human Embryos Act to give binding rulings and to grant licences on the basis of those rulings for research that is not within the literal wording of the Act, or the regulations made under the Act, but is within their tenor, on condition that the Committee reports immediately and in detail to the NHMRC and to parliament on any rulings it gives, or any licences it grants, in that way.

52 A researcher who conducts research on the basis of a ruling or a licence should be protected from liability under the legislation, provided that they act in accordance with the relevant ruling or licence.

53 In view of the fast-moving developments in the field, and the range of amendments proposed herein, the two Acts should be subject to a further review either six years after royal assent of the current Acts or three years after royal assent to any amended legislation.

Public education

54 There should be ongoing public education and consultation programs in the areas of science that are relevant to the Acts.

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