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THE REGULATION OF STEM CELL RESEARCH IN IRELAND

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School of Law.

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ABSTRACT

This thesis explores the regulation of stem cell research internationally with a view to providing a suitable regulatory framework for Ireland. It examines the ethical, legal and economic issues which can be raised by stem cell research. Due to the uncertain status of embryos *in vitro*, this study focuses almost exclusively on embryonic stem cell research (ESCR). However, this study offers recommendations that apply equally to all forms of stem cell research. The impact that the ethical discourse on the status of the embryo should have on public policy is also explored. While this thesis does not seek to defend a particular ethical viewpoint on the moral status of the embryo, it does provide recommendations on how public policy may be formulated in light of this debate. It then assesses the differing approaches to regulation, including traditional “command-and-control” methods such as legislation and independent regulatory authorities, and reliance on economic instruments such as the patenting system and public funding. This feeds into the discussion of ESCR in Ireland and the thesis ends with a series of recommendations as regards the development of a suitable regulatory framework for ESCR in Ireland.

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Embryonic Stem Cell Research: Between Promises and Controversies

“The blood of those who will die if biomedical research is not pursued will be upon the hands of those who don't do it.”¹

1. Introduction

Today, people across the world are dying from Parkinson's disease, heart disease, from a failure to access organs necessary for transplantation, as well as suffering from spinal cord injuries and diabetes, to name but a few. Developments in embryology have led to the discovery of the “ultimate cell” or the “mother of all cells”: the embryonic stem cell.² This cell has the potential to develop into any cell type in the body, and can be engineered to produce new tissues or organs, and brings hope to those suffering from regenerative illness as well as incurable diseases.³

Despite these potential benefits, the research has faced much opposition. This is largely due to the fact that the creation of an embryonic stem cell results in the destruction of an embryo.⁴ For many, embryonic stem cell research (ESCR) can never be justified as an embryo is a human life and, as such, ESCR results in the destruction of human life.⁵ Yet many disagree with this contention that an embryo is life, arguing that defining human life has become much more difficult due to our increasing level of scientific information.⁶ Others still argue that the embryo is nothing more than a clump of cells, with the renowned scientist, Prof Lawrence Goldstein, stating

“I am a basic biomedical scientist who is interested in understanding and treating human disease. I have, to the best of my ability, thought through the ethics of these issues. At the end of that process, I have concluded that my commitment in trying to help people who have the terrible diseases I want to treat outweighs our social and ethical responsibility to an early human embryo. Part of my view comes from the obvious fact that the embryos in question are simple clusters or balls of cells that have been generated in a dish in the lab, have never been in a woman's body, and are thus not pregnancies or foetuses.”⁷

¹ Nobel Laureate Joshua Ledetberg in personal conversation with Daniel Callahan. D Callahan, ‘Promises, Promises. Is embryonic Stem Cell Research Sound Public Policy?’ (2005) *Commonweal* 12, 12.

² Singapore National Bioethics Advisory Committee, *Human Embryonic Stem Cells: Science and Ethics* para 2.

³ For more on the potential of the research see Editorial, ‘The Promise of Stem Cells’ (2004) 7 *Nature Neuroscience* 1013.

⁴ For a description on the creation of an embryonic stem cell, see J Thompson, J Itskovitz-Eldor, S Shapiro, M Waknitz, J Swiergiel, V Marshall & J Jones, ‘Embryonic Stem Cell Lines Derived from Human Blastocysts’ (1998) 282 *Science* 1145.

⁵ For example see Congregation for the Doctrine of the Faith, *Instruction Dignitas Personae on Certain Biological Questions* (2008).

⁶ K Fitzgerald, ‘Human Embryonic Stem Cell Research: Ethics in the Face of Uncertainty’ in N Snow, *Stem Cell Research: New Frontiers in Ethics and Science* (Notre Dame Press 2003) 30.

⁷ L Goldstein, ‘Political Issues in the Stem Cell Debate: The View from California’ in K Renwick Monroe, R Miller & J Tobis, *Fundamental of the Stem Cell Debate* (University of California Press 2008) 95.

In the face of such differing opinions on the status of the embryo, what are policy makers to do? Should they err on the side of caution and decide that as the embryo *could* be human life, they should prohibit ESCR? Should the potential value of the research be so persuasive that the research should be permitted? Or due to the lack of consensus on the status of the embryo, should policy makers do nothing?

These are issues which policy makers across the world have recently considered and there appears to be a growing trend internationally to introduce some regulations governing ESCR. Yet, to date, the Irish legislature has failed to address these issues, leaving scientists operating in a legal vacuum in Ireland. This thesis aims to address this vacuum and through an examination of the issues that have impacted upon ESCR regulations internationally, it will propose recommendations on the regulation of ESCR in Ireland. This introduction will provide a background to ESCR. This will include a brief overview of the differing types of stem cells as well as their potential benefits. The importance of this study will be highlighted before an overview of this thesis is offered.

2. Background to this Thesis

2.1 Stem Cell Research

Although embryo research has been on-going for some time, ESCR hit the headlines in 1998 with the announcement that Dr James Thomson had successfully derived the first human embryonic stem cell.⁸ The embryos used in that study had been created through *in vitro* fertilisation (IVF) and had been donated after informed consent from the individuals involved as well as institutional review board approval.⁹ Yet embryonic stem cells are not the only cells that can be used in research, with research on adult stem cells and induced pluripotent stem (IPS) cells also currently underway.

An adult stem cell is a cell type which is found in all tissues or organs in the body. The role of the adult stem cell is to repair and replace the tissue in which it is found. It can only replace that cell type in which it is found and in this way its use is limited. Thus an adult stem cell found in the liver can only replace another liver cell. If these stem cells can be isolated in a laboratory, they could potentially be used to grow new tissues or organs. Adult stem cell research has already had clinical application, with blood-forming stem cells used in bone marrow transplants for over 40 years,¹⁰ as well as over one hundred ailments being treated by adult stem cells.¹¹

An embryonic stem cell is a cell found in an early-stage embryo. It has the ability to develop into any cell in the body and thus has the potential to be used in the development of many

⁸ Thompson, Itskovitz-Eldor, Shapiro, Waknitz, Swiergiel, Marshall & Jones (n 4).

⁹ Ibid.

¹⁰ National Institutes of Health, 'Stem Cell Information' <<http://stemcells.nih.gov/info/basics/pages/basics4.aspx>> accessed 5 February 2013.

¹¹ UK Stem Cell Foundation, 'Stem Cell Research: Benefits and Future Hopes' <http://www.ukscf.org/research/benefitsandhopes.html> accessed 5 February 2013.

therapies. It is also one of the easiest cell types to grow.¹² In particular it is thought that ESCR may potentially benefit the following:

1. Transplantation therapy: Today, the only possible therapy for organ failure is organ transplantation. The rise in chronic diseases, as well as an increasing aging population has led to increased demand for transplantation but the number of available donors has decreased.¹³ As embryonic stem cells can produce unlimited quantities of any cell in the body, they have the potential to create any organ required for transplantation. Furthermore, organs may be grown using somatic cell nuclear transfer (SCNT), which will prevent organ rejection as they will be genetically identical to the patient. This will mean that patients can avoid a lifetime of immunosuppressant drugs.¹⁴ Embryos created through SCNT are cloned embryos and it is often referred to as “therapeutic cloning” as they are cloned for research purposes and not reproduction.¹⁵
2. Human Development Biology: As embryonic stem cells can be developed (or differentiated) into any cell in the body, they offer the possibility to further understand the early developmental process of the human body. Research on embryonic stem cells may not only provide the opportunity to understand fertility problems, premature pregnancy and birth defects, but may also eliminate the need to use foetuses for this research.
3. Pharmaceutical development: It is possible that embryonic stem cells can be grown into certain cell types that can be used for drug screening and testing. In particular, it may be possible to screen for drugs that can cause birth defects.¹⁶

However the controversy surrounding ESCR is that, in deriving an embryonic stem cell, the embryo is destroyed.

IPS cells are adult stem cells that have been reprogrammed to act like embryonic stem cells.¹⁷ In this sense, the science is "turning back the clock".¹⁸ While they act like embryonic stem cells they are not such cells. Although the research is very much in its infancy and it is unclear whether it will be successful, it does raise the possibility that it may be feasible to obtain stem cells with the same properties as embryonic stem cells without the need to destroy an embryo. Following this, it has been argued that ESCR should not be permitted if it is possible to get the same benefits from other sources of stem cells.¹⁹ However, many scientists disagree, with the European Science Foundation arguing that all types of stem cell

¹² R Lovell-Badge, 'The Future for Stem Cell Research' (2001) 414 *Nature* 88, 89.

¹³ European Science Foundation, *Human Stem Cell Research and Regenerative Medicine European Perspective on Scientific, Ethical and Legal Issues* (2010) 2.

¹⁴ H Semb, 'Human Embryonic Stem Cells: Origins, Properties and Applications' (2005) 113 *APMIS* 743, 747.

¹⁵ The Ethics Committee of the American Society for Reproductive Medicine, 'Human Somatic Cell Nuclear Transfer and Cloning' (2012) 98 *Fertility and Sterility* 804, 804.

¹⁶ Singapore National Bioethics Advisory Committee (n 2) para 10.

¹⁷ K Takahashi & S Yamanaka, 'Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors' (2006) 126 *Cell* 663.

¹⁸ European Science Foundation (n 13) 5.

¹⁹ S Holm 'Going to the Roots of the Stem Cell Controversy' (2002) 16 *Bioethics* 493, 503.

research should be encouraged.²⁰ In particular, it has been submitted both that ESCR and IPS cell research shall continue concurrently, as IPS cells and ESCR complements each other, and the risks and benefits of either research is not sufficiently known.²¹ Further complications to this debate arise when one considers that it is unclear whether embryonic stem cells will ever realise their potential in terms of clinical application.²²

In the face of such uncertainty, what are policy makers to do? Do the benefits of ESCR outweigh the harm it causes the embryo,²³ or should ESCR be prohibited in favour of adult stem cell research and IPS cell research?

2.2 The Development of ESCR Policy Internationally

The Warnock Report was one of the first reports in the world to consider embryo research. It recommended that while the embryo *in vitro* (the embryo outside of the womb) should be afforded some respect in law, this respect should be balanced against the benefits of the research.²⁴ Arising from this report, the Human Fertilisation and Embryology Act 1990 set out to regulate embryo research with the Human Fertilisation and Embryology Authority now regulating ESCR within the UK.²⁵ Since then, the majority of European and Asian countries, as well as Canada and the US, have adopted ESCR policies. These have ranged from very restrictive policies, such as the German Stem Cell Law of 2002 which only permits research on imported stem cell lines,²⁶ to much more permissive policies, such as the Australian Research Involving Human Embryos Act 2002. The regulatory frameworks have also ranged from the introduction of legislation and independent regulatory authorities²⁷ to the adoption of economic policies to encourage or restrict the research.²⁸

2.3 The Legal Vacuum in Ireland

Unlike its international counterparts, no policy on ESCR has been forthcoming in Ireland. As will be discussed later,²⁹ the embryo *in vitro* in Ireland currently has no legal protection. Thus scientists can arguably engage in any type of research using the embryo, even if it leads to the destruction of the embryo. There have been repeated calls for the introduction of regulations on ESCR to resolve this legal vacuum.³⁰ Despite the regulation of ESCR appearing on the current Programme for Government for the Fine Gael/Labour coalition, none has been

²⁰ European Science Foundation (n 13) 10.

²¹ Ibid.

²² Holm (n 19) 505-506.

²³ Commission on Assisted Human Reproduction *Report of the Commission on Assisted Human Reproduction* (2005) at paragraph 8.2.

²⁴ Department of Health and Security, *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (Cm 9314 1984) para 11.1.5. (Hereinafter the *Warnock Report*)

²⁵ For more on the Human Fertilisation and Embryology Act 1990 and the Human Fertilisation and Embryology Authority see Chapter 4.

²⁶ For more on this law see Chapter 1.

²⁷ See Chapter 4.

²⁸ See Chapter 5.

²⁹ See Chapter 6.

³⁰ See Commission on Assisted Human Reproduction, *Report of the Commission on Assisted Human Reproduction* (2005) and Irish Council for Bioethics, *Ethical, Scientific and Legal Issues Concerning Stem Cell Research* (2008).

forthcoming. Trinity College Dublin and University College Cork have introduced guidelines on ESCR,³¹ yet due to the ban on the public funding of ESCR in Ireland, it is unclear whether any ESCR is taking place in Ireland.³²

It is thus open to question whether ESCR is permitted in Ireland, what legal status and legal protection can be accorded to the embryo *in vitro*, and also whether there should be any ethical oversight of the research. To address these issues, this study will examine the international experience with regulating ESCR. It will then apply this to Ireland to first discuss the legal status of ESCR and, second, to recommend the formation of public policy on ESCR in Ireland.

3. Outline of this thesis

Part I of this thesis will consider the impact that the ethical discussion should have on the formation of public policy.

Chapter 1 focuses on the ethical debate surrounding the status of the embryo. While this thesis will not involve a discussion on the differing ethical arguments used to justify a particular viewpoint on the status of the embryo, it is important to acknowledge that there is an ethical debate and that it remains unresolved. The focus here will rather be on the influence that this debate should have on the formation of public policy and in particular, how policy makers should accommodate competing moral claims when determining the legal status of the embryo.

Differing moral views on the status of the embryo can lead to the adoption of restrictive, intermediate, or permissive ESCR regulatory frameworks. In the face of ethical disagreement, policy makers may consider taking the “do nothing” approach or attempt to reach consensus on the issue. Adopting a “do nothing” approach whereby policy makers fail to engage with the issues and introduce policy means that policy makers can avoid engaging with the ethical issues involved in ESCR. However, as will be illustrated, a decision will often still be made as, at times, the courts have been forced to consider the issues. It is submitted that policy makers should instead engage with the contentious ethical debate and provide legal clarity on the status of the embryo and ESCR. Democratic deliberation is an approach which policy makers can and should adopt, as it encourages a reasoned debate in the hope that consensus between all stakeholders can be achieved. It is submitted that from this debate, sound policy on ESCR may begin to emerge.

Part II of this thesis will focus on the regulation of ESCR internationally.

Chapter 2 will provide an overview of the regulation of ESCR. The concept of regulation is introduced and the rise of the regulatory state will be explored. Focus is given to the

³¹ See Trinity College Dublin, *Policy on Good Research Practice* (2009) and University College Cork, *Code of Practice for research Using Embryonic Stem Cell Lines* (2008), available at: <<http://www.ucc.ie/en/mandc/news/newsarchive/2008PressReleases/fullstory-63377-en.html>> accessed 13 March 2012.

³² <<http://www.sfi.ie/funding/grant-policies/research-using-human-embryonic-stem-cells/>> accessed 13 March 2012.

principles of “Better Regulation” which are used to analyse the differing regulatory frameworks to determine their suitability in regulating ESCR.

Chapter 3 puts forward the concept of the ethical precautionary principle. While the precautionary principle, which urges the restriction of a technology or activity if there is the potential for environmental damage, has been a part of environmental public policy for the past twenty years, the *ethical* precautionary principle is slightly different. This principle suggests that if the ethical status of a new technology or research is unclear, attention must be given to the potential restriction of that research.

Consideration is, however, given to the precautionary principle as it is traditionally understood, and its status internationally. Particular attention is given to the problems inherent in the principle, such as the difficulty in assessing risk in the face of insufficient scientific information. Despite such problems, the precautionary principle can be used to justify a particular policy decision. In much the same way, the ethical precautionary principle may explain whether a restrictive, intermediate or permissive regulatory regime is adopted.

Chapter 4 will examine the regulation of ESCR through so-called “command-and-control” regulation, i.e. legally-binding rules by public authorities. In exploring the use of legal rules, Chapter 4 analyses the Human Fertilisation and Embryology Act 1990 as a case study in regulation through legislation. It explores the benefits and pitfalls of such a model of regulation and examines the legislation in light of the principles of Better Regulation.

One particular problem with legislation is that developments in science may often render it outdated. To resolve this issue, independent regulatory authorities may be established. Regulatory agencies are generally independent of the government and staffed with experts in the areas they seek to govern. The input of scientific, legal and ethical experts can be integral to the successful regulation of ESCR and as such consideration is given to the formation of regulatory authorities. The UK Human Fertilisation and Embryology Authority will be analysed as a case study. The Authority will be analysed under the principles of Better Regulation to determine the suitability of an authority in regulating ESCR. As the principles of Better Regulation have become a hallmark of good regulation, it is essential that the use of both legislation and regulatory authorities in ESCR regulation conform to these principles.

Chapter 5 will examine the impact that economic policies can have in regulating ESCR, in particular the impact of the public funding of the research and the patent system. Despite a lack of detail analysis on this area, decisions on whether to fund ESCR can have a profound impact on its regulation, particularly if national guidelines only apply to the recipients of the funding. This can result in a system whereby some researchers will remain outside of the regulatory control. To assess such a model, the funding policies of the US and the EU are explored and these systems will be analysed under the Better Regulation principles. The patenting policies of the US and EU are discussed, as well as the consequences a particular patenting policy can have on the development of research. The patent system will also be analysed under the Better Regulation principles.

Part II will illustrate that a coherent regulatory framework, which includes legislation, regulatory authorities as well as economic policies that reflect the overall policy, is essential for ESCR.

In **Part III** the focus moves to the regulation of ESCR in Ireland.

Chapter 6 attempts to decipher the legal status of ESCR in Ireland. An understanding of the abortion debate in Ireland is necessary as it led to the enshrinement of a provision into the Constitution of Ireland whereby the “unborn” is protected. Until recently, it was not known whether the embryo *in vitro* came under the definition of the unborn. Despite many calls for clarification on the status of the unborn, none has been forthcoming from the legislature. The history of the insertion of this amendment and the jurisprudence of the Irish and European courts are discussed in order to decipher the status of the embryo, and thus ESCR, in Irish law.

Chapter 7 will recall the key findings of this thesis before making a series of recommendations for the development of a coherent stem cell policy for Ireland. The focus here is on the process that policy makers should follow and the issues they should consider. In this way, this thesis will provide a template for the introduction of a suitable regulatory framework for ESCR in Ireland.

Part I Ethics, Public Policy and Embryonic Stem Cell Research

Chapter 1 Ethics and Embryonic Stem Cell Research

1. Introduction

Developments in human biotechnology often bring fresh ethical concerns. Just as the early years of organ transplant technology brought about a change in our concept of death, developments in embryology are challenging our concept of what it is to be human life. Progress in medical science has now made it possible to not only create an embryo in a laboratory, but to destroy that same embryo for medical research. While there is great potential for the research in regenerative medicine, the fact that the embryo must be destroyed has resulted in embryonic stem cell research (ESCR) being described as the most contentious bioethical issue of recent times.³³

This debate surrounding ESCR is not new and revives the centuries old debate on the moral status of the embryo. If the moral status of the embryo is such that it cannot be destroyed for research purposes, there will be deep opposition to permissive ESCR policy. It would not reflect the values of society thus, the lack of consensus on the moral status of the embryo leads to difficulty in regulating ESCR.

The purpose of this chapter is to discuss the moral status of the embryo and, more importantly, the impact that the ethical discourse should have in framing a public policy. A number of differing approaches will be assessed from the point of view of ethics. The justifications for arriving at any particular position will be explored, noting that the decision on the status of the embryo may have more to do with political compromise than any concrete ethical principles. Finally, a process through which policy makers can regulate ethically controversial practices such as ESCR will be proposed, with a particular focus on democratic deliberation as part of that process.

2. Moral Status of the Embryo

Although the debate on the moral status of the embryo has been ongoing for centuries in relation to abortion, a consensus has failed to materialise. Disagreement lies in whether the embryo has the same moral status as that of a person, whether it is nothing more than a clump of cells and thus has no moral status, or whether it occupies some intermediate moral status. This section will first discuss the link between morality and the law and the issues the law has at times in enforcing morality. The varying positions policy makers may take will subsequently be outlined.

³³ H Varmus, *The Art and Politics of Science* (Norton & Co, 2010) 197.

2.1 Moral Principles and the Law

The importance of establishing the moral status of the embryo lies in the fact that morality has long guided the law. It is argued that the law is only followed because it consists of morally-binding principles which represent the ideals of society.³⁴ In a sense, moral and legal principles have a symbiotic relationship as moral principles are a quest for the ideal, for what society should be,³⁵ while the law attempts to ensure that these ideals are implemented through sanctions if they are not followed. Thus while ethics can promote good behaviour, the power of the law lies in its ability to punish undesirable behaviour.³⁶ Indeed natural law theorists would argue that the law cannot be neutral but must be guided by a sense of morality.³⁷

Differences, however, begin to emerge in the application of the moral and legal principles in society. First, moral principles can be quite aspirational in nature, with little guidance on how to ensure that the principles are followed. For example, the principle of respect for human dignity often appears on human rights treaties³⁸ yet it is hard to define, with the concept likely to have different meanings for different people. Indeed the vagueness of the principle has been criticised for lacking in content and has been argued that it should not appear in any legislation or policy statements without qualification.³⁹ The law can ill afford any such uncertainty but must instead be clear and precise so that individuals know their rights and duties and the protections guaranteed by law.

Second, the law may be called upon to decide between competing rights and interests that may impinge upon a person's moral beliefs. For example, a person is entitled to the freedom to practise their religion and the refusal of a blood transfusion may be an expression of their religious beliefs. Yet this may be limited in certain situations, such as in the case of a pregnant woman.⁴⁰ A conflict of rights may also manifest itself where the rights of an individual are in conflict with the beliefs of society. This can occur in the case of euthanasia where a person with a terminal illness may believe that their right to dignity includes the right

³⁴ N St John-Steva, *Law and Morals* (Hawthorn 1964) 18.

³⁵ E Petit, "An Ethics Committee for Patent Offices?" in A Plomer & P Torremans (eds), *Embryonic Stem Cell Patents: European Patent Law and Ethics* (OUP 2010) 306.

³⁶ D Steinberg (ed), *Biomedical Ethics: A Multidisciplinary Approach to Moral Issues in Biomedicine and Biology* (University Press of New England 2007) 279.

³⁷ O Doyle, 'Legal Positivism, Natural Law and the Constitution' (2009) 31 *Dublin University Law Journal* 206, 206.

³⁸ Article 1 of the Charter of the Fundamental Rights of the European Union states "Human dignity is inviolable. It must be respected and protected".

³⁹ J Burley, 'An Abstract Approach to the Regulation of Human Genetics: Law, Morality and Social Policy' in H Somsen, *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents* (Edward Elgar Publishing Ltd 2007) 83.

⁴⁰ *See Re T* where the court stated

"An adult patient who, like Miss T., suffers from no mental incapacity has an absolute right to choose whether to consent to medical treatment, to refuse it or to choose one rather than another of the treatments being offered. The only possible qualification is a case in which the choice may lead to the death of a viable foetus." [1993] Fam 95 at 102.

In *Re S(adult: refusal of medical treatment)* the court ordered that a caesarean section be carried out despite the objections of the pregnant woman as it was deemed necessary to preserve her life and her unborn child. [1992] 4 All ER 671. *See also Fitzpatrick v FK* [2009] 2 IR 7.

to die in dignity and on their terms, which may necessitate them dying with the assistance of another. Yet society in the past has generally believed that it is contrary to the right to life to allow a person to be intentionally killed, irrespective of the situation. Thus euthanasia is generally prohibited internationally, with The Netherlands and Switzerland being among some of the limited exceptions.⁴¹

Problems arise, however, when society cannot agree on moral principles, and policy makers must accommodate these differing moral beliefs while providing for a coherent set of legally binding rules or principles. This difficulty is compounded by the increasingly pluralistic nature of society in recent years, which has made reaching a consensus much more difficult on issues ranging from immigration to health care. Rawls has argued that these differing views are also a result of the democratic process:

“The political culture of a democratic society is always marked by a diversity of opposing and irreconcilable religious, philosophical, and moral doctrines. Some of these are perfectly reasonable, and this diversity among reasonable doctrines of political liberalism sees as the inevitable long-run result of the powers of human reason at work within the background of enduring free institutions.”⁴²

Brownsword on the other hand argues that “the more technologically sophisticated societies become, the more likely it is that value pluralism will abound”.⁴³ In other words, developments in embryology and ESCR have brought an increased awareness of the developmental process of the embryo coupled with knowledge of the potential benefits that ESCR may bring. The potential benefits of the technology may impact upon society’s view of the moral status of the embryo and perhaps persuade many that ESCR should be permitted in some circumstances.

Yet whether society’s differing views are an expression of democracy or are a reflection of the advances in technology in the stem cell context, the challenge for policy makers is to respect each of these differing views while not “being held hostage to any single view of embryonic life”.⁴⁴ Policy makers must consider the differing moral positions but resist opting for one moral position that does not have consensus approval as to do so would risk alienating large portions of society.

This task is not made any easier by the reactionary nature of the law to developments in science. As science develops, the law must quickly react to these technological advances to ensure that certain practices fall under government regulation or are prohibited. The difficulty is that there may be insufficient time to consider the relevant issues, which may result in poorly drafted legislation. A pattern appears to have emerged with developments in science being followed by a moral discussion of the technology, which is in turn followed by a legal

⁴¹ On the legal framework in Switzerland, see S Hurst & A Mauron, ‘Assisted suicide and euthanasia in Switzerland: allowing a role for non-physicians’ (2003) 326 *BMJ* 271.

⁴² J Rawls, *Political Liberalism* (Columbia University Press, 1993) 3.

⁴³ R Brownsword, “Regulating Human Genetics: New Dilemmas for a New Millennium” [2004] *Medical Law Review* 14, 30.

⁴⁴ J Childress, ‘An Ethical Defence of Federal Funding for Human Embryonic Stem Cell Research’ (2001-2002) 2 *Yale Journal of Health Law and Policy* 157, 161.

reaction that may have to be rushed through parliament.⁴⁵ As Beauchamp and Childress note “morality exists before we are instructed in its relevant rules”.⁴⁶ For example whether it is possible to clone a person is a scientific issue, whether it is right or wrong is an ethical issue⁴⁷ and how it should be permitted or prohibited is a matter for the law. By following this path, the law attempts to enforce a common morality which society holds; however as technology tends to develop rapidly and continuously, and society has become increasingly pluralistic, the common morality is less obvious and at times non-existent.

The challenge for the law is how to apprehend and regulate scientific developments in the absence of this common morality. While undoubtedly the task of policy makers is much more difficult as the emerging ethical challenges threaten the ability of public policy to respond,⁴⁸ they must nevertheless provide clarity as to the legal status of stem cell research. It is of importance that policy makers do not confuse their role of clarifying the legal status of stem cell research with making a decision on the moral status of the embryo.⁴⁹ The issue then is not for legislators to resolve the moral dilemma but to ensure that there is clarity as to the permitted boundaries of research within some ethical framework if possible. This point was eloquently put by Denham J in *Roche v Roche* when she stated:

“This case is not about the wonder and mystery of human life. This is a court of law which has been requested to make a legal decision on the construction of an article of the Constitution of Ireland. The question raised is whether the term “unborn” in the Constitution includes the three frozen embryos in issue in this case. It is a matter of construing the word in the Constitution to determine its constitutional meaning.”⁵⁰

However, while policy makers are not expected to resolve the status of the embryo debate, public policy should be informed by ethics, particularly if there is a common morality or a consensus amongst the community. Indeed it has been argued that the greater the consensus on issues, the more “powerful” the law is.⁵¹ If there is a common morality that the embryo has moral status, then a good justification is necessary to destroy them for research purposes. Furthermore, the greater the moral status that society affords the embryo, the greater the justification required before the embryo can be destroyed for ESCR.⁵² Otherwise the law may permit an activity which is contrary to the moral conscience of society.

⁴⁵ This may take the form of either legislation such as the Human Fertilisation and Embryology Act 1990 or a court case such as *Roche v Roche* [2010] 2 ILRM 1 which had to decide an issue in a legal vacuum as policy makers had failed to regulate the issue.

⁴⁶ T Beauchamp & L Walters (ed) *Contemporary Issues in Bioethics* (4th ed) (California, Wadsworth Publishing Company, 1994) 1.

⁴⁷ D Steinberg (ed), *Biomedical Ethics: A Multidisciplinary Approach to Moral Issues in Biomedicine and Biology* (University Press of New England, 2007), 3.

⁴⁸ B Frist, ‘The Promise and Peril of Embryonic Stem Cell Research: A Call for Vigilant Oversight’ (2001-2002) 2 *Yale Journal of Health Policy, Law and Ethics* 167, 170.

⁴⁹ The NIH has stated that it is not the role of policy makers to decide which view of the moral status of the embryo is correct. National Institute of Health, *Report of the Human Embryo Research Panel* (September 1994) 39.

⁵⁰ *Roche v Roche* [2010] 2 ILRM 1, 24. For the facts and a discussion of *Roche v Roche* see Chapter 6.

⁵¹ A Morgan Capron, ‘Morality and the State, Law and Legalism’ (1996) 26 *The Hastings Center Report* 35, 35.

⁵² S Holm “Going to the Roots of the Stem Cell Controversy” (2002) 16 *Bioethics* 493 at 503.

Based on a consideration of the moral status of the embryo, policy makers may adopt a liberal, conservative or intermediate approach to regulating ESCR.

2.2 Restrictive Approach

The restrictive position states that the embryo is a human being from fertilisation. The embryo thus has the same moral status as that of a living person from the moment of fertilisation and destroying any embryo for research purposes would contravene the sanctity of life. Such an approach is taken by some religions, notably the Catholic Church.⁵³ Religions that oppose ESCR believe that man is made in God's image and this extends to the embryo. It is irrelevant that an increased understanding of the developmental process of an embryo has shown that the embryo does not in fact resemble a human being as it is believed that "no amount of embryological investigation could conceivably crack what is held to be an awesome mystery".⁵⁴

However, the principle of the sanctity of life often comes in conflict with other rights and the courts have held that the sanctity of life does not always prevail. The English case of *Airedale NHS Trust v Bland* concerned the removal of artificial nutrition and hydration from a man who was in a persistent vegetative state.⁵⁵ The removal of nutrition and hydration would result in the starving of the man to death. It was argued that this was contrary to the sanctity of life, while Bland's family argued that he would have wished to have all treatment ceased and that a refusal to do so was contrary to his right to self-determination. In permitting the withdrawal of artificial nutrition and hydration, the House of Lords noted that, at times, the principle of the sanctity of life must accommodate other principles and is not absolute.⁵⁶

Others who favour the restrictive approach argue that an embryo has the same moral status as a human being, due to its potential to develop into a person. In some respects this potential is recognised by society as pregnant women are advised to take care of their health from the beginning of (and often prior to) their pregnancy. It is now also common for health warnings to appear on alcoholic drinks and cigarette packaging, advising women of the dangers of the product for their unborn child.⁵⁷

A problem with ascribing moral status based on potential is that it is a potential only, a potential which may not be realised.⁵⁸ In this sense, the oft-quoted comparison between the acorn and the tree has value: while the acorn has the potential to become a tree, it is not yet a

⁵³ In 2008, the Congregation for the Doctrine of the Faith stated that the embryo must be protected from conception. Congregation for the Doctrine of the Faith, *Instruction Dignitas Personae on Certain Biological Questions* (2008).

⁵⁴ D Evans (ed), *Conceiving the Embryo: Ethics, Law and Practice in Human Embryology* (Martinus Nijhoff Publishers 1996), 31.

⁵⁵ [1993] 2 WLR.

⁵⁶ *Ibid* 352.

⁵⁷ I would like to thank Daniel Callahan, Senior Research Scholar and co-founder of the Hastings Center, for a discussion on this point.

⁵⁸ Harris has stated that the only thing that is certain is that a fertilised egg is live human tissue. J Harris, *The Value of Life: An Introduction to Medical Ethics* (Routledge & Kegan, 1985) 12.

tree and should not be treated as such.⁵⁹ Similarly, in its opinion on the *Ethical, Scientific and Legal Issues Concerning Stem Cell Research*, the Irish Council for Bioethics noted that every person has the potential to become a criminal but they are not treated as such until they do in fact commit the crime.⁶⁰ While the Council did refute this argument as the type of potential a person has is much more basic, these examples do question why we must treat A as being B when it is clearly still A.

It is important to note the possibility that an embryo may never become a person: it may become a hydatiform mole,⁶¹ it may never implant due to a contraceptive barrier such as that of the intrauterine system (IUS), it may be frozen indefinitely in an IVF clinic,⁶² or, if implanted, the foetus may spontaneously abort. Furthermore it is highly unlikely that an embryo will ever become a person as up to 80% of all embryos never implant due to “natural wastage”.⁶³ Thus Watt’s argument that an increase in the likelihood of developing into another form is not a reason for conferring moral status has some credence as while an embryo’s chances of surviving increases as it develops, it is not guaranteed.⁶⁴

A further look at accepted health policy also indicates that society does not generally protect the embryo from the point of fertilisation. The “morning after” pill which is designed to prevent pregnancy by precluding implantation after fertilisation, is widely available. Turning back to the example of pregnant women, while society may encourage pregnant women to take care of their health through the provision of free health care, pregnant women are rarely legally prohibited from engaging in certain activities or consuming certain products due to their pregnancy.

Furthermore Cohen argues that this potential to become a person exists in the reproductive context only and thus is not an issue in regenerative medicine such as embryonic stem cell research. Cohen argues that an embryo only has moral status due to its potential to provide medical assistance to those already living.⁶⁵ According to this theory, full moral status cannot be afforded to every embryo as it was not intended that a live birth would result. This argument raises issues such as whether certain sources of embryos should be used beyond the purpose for which they were created; however, that is beyond the scope of this thesis.

⁵⁹ In contrast, in the House of Commons during the debates on the Human Fertilisation and Embryology Act 1990, one MP stated: “A rose is a rose not only by any other name, but no matter where it is or at what stage of its development”. HC Deb 2 April 1990, col 941.

⁶⁰ Irish Council for Bioethics, *Ethical, Scientific and Legal Issues Concerning Stem Cell Research* (2008) 39.

⁶¹ A hydatiform mole is when an embryo becomes a tumour which will endanger the life of the mother if it is not removed.

⁶² Singer and Dawson have queried whether the potentiality theory can be applied to embryos frozen indefinitely or whether the embryo *in vitro* has some other type of potential. P Singer & K Dawson, ‘IVF technology and the argument from potential’ (1988) 17 *Philosophy and Public Affairs* 87, 88.

⁶³ Natural wastage is the term given to the disposal of embryos naturally by the body. G Teklenburg, M Salker, C Heijnen, N Macklon & J Brosens, ‘The Molecular Basis of Recurrent Pregnancy Loss: Impaired Natural Embryo Selection’ (2010) 16 *Molecular Human Reproduction* 886, 886.

⁶⁴ H Watt, ‘Potential and the early human (1996) 22 *Journal of Medical Ethics* 222, 222.

⁶⁵ C Cohen, *Renewing the Stuff of Lie: Stem Cells, Ethics, and Public Policy* (OUP 2007) 86.

2.3 Permissive Approach

A much more liberal or permissive approach to embryonic stem cell research may consider that only human beings should have moral status. To be considered a person, an entity must have the capacity to be rational, have the capacity to be self-conscious or aware of themselves and the capacity to react to stimuli.⁶⁶ The first criterion (i.e. the capacity for self-consciousness) requires that a person ought to be aware of themselves and their interaction with others⁶⁷ and this recognition of self must be more than the presence of the ability to communicate⁶⁸ but include an ability to perceive others.⁶⁹ The criterion of rationality states that personhood is limited to entities which have the capacity to think rationally or, as Locke defines it, to an entity which is a “thinking intelligent being”.⁷⁰ The final criterion requires that entities react to stimuli such as pain or pleasure, warmth or cold.

For Lockwood, it is only when an organism has a brain that it should have moral status. Prior to the formation of the brain the entity has the potential to become a human being, but for Lockwood, this potential is irrelevant.⁷¹ Lockwood is of the opinion that the notion of a “brain life” is what should be used to determine the beginning of a human life as this is consistent with the concept of brain death, the time when a human being is thought to no longer exist.⁷² Thus Lockwood argues that unless another human being’s interests are affected, it is morally permissible to engage in research on an embryo or developing foetus up to the point of brain development.⁷³

The problem with both approaches is that there is the danger that they will exclude certain members of society. For example, in considering the criteria to be a person, the first two criteria potentially removes newborns, people with a disability or those in a coma from being a person, as they may not have the ability to both interact with others or rationalise. Such a move would also be contrary to disability rights conventions.⁷⁴ It is also unclear what level of self-awareness or rationality is required. On the other hand, the third criterion (reaction to stimuli) has the ability to expand the definition of person to both plants and animals. Animal will react to extreme heat much in the same way as a person does and plants react to sunlight by growing towards it.⁷⁵

⁶⁶ For more on this theory see N Ford, *When Did I begin?* (Cambridge University Press 1988).

⁶⁷ As Harris states, they must be aware that they are aware. Harris (n 42) 18.

⁶⁸ C Grobstein, *From Chance to Purpose* (Addison-Wesley Publishing Company 1981) 85.

⁶⁹ J Locke, *An Essay Concerning Human Understanding* Vol I, Bk II Ch 27, collated and annotated by A C Fraser (Dover Publications 1959) 448.

⁷⁰ Ibid 448.

⁷¹ M Lockwood, ‘When Does Life Begin?’ in M Lockwood (ed), *Moral Dilemmas in Modern Medicine* (OUP 1985) 19.

⁷² Ibid 20.

⁷³ Ibid 24.

⁷⁴ See UN Convention on the Rights of Persons with Disabilities.

⁷⁵ In this context Harris has queried the moral status of animals as he is of the opinion that to assess the moral value of a person we must know what makes them different from other animals that makes their lives valuable. He asks what features humans possess that if we were to meet creatures from another world could lead us to think of them as persons. J Harris (n 1) 14. The personhood theory fails to answer this and would grant moral status to animals while denying moral status to some human beings. This theory thus fails to explain why human beings have moral status.

Under these criteria and Lockwood's concept of brain life, the embryo would have no moral status and thus no protection. Even in the most liberal of embryonic stem cell regimes, there is some protection afforded to the embryo. This is often expressed through the limits on the research and the particular sources of embryos that can be used. While the ethical principles underpinning such an approach can be questioned, it arguably more accurately reflects public opinion, which, while it may be uncertain as to the status of the embryo, does consider that the embryo should have some degree of protection from the law.

2.4 Intermediate Position

While many positions can broadly be broken up into the restrictive and liberal position, there is a continuum of ethical opinion that does not neatly fit into either category. Rather these positions occupy some form of intermediate status that is somewhere between a restrictive and permissive position and can vary according to jurisdictions. According to this position, the embryo is deserving of "respect" or some form of moral status, but it does not have the same moral status as that of a human being.

Many who adopt this intermediate status subscribe to the gradualist theory, which states that an embryo gradually acquires status as it develops. The theory acknowledges that no single stage of the development of the embryo is more important than the others, but rather each stage is important as the embryo cannot develop without all stages. While acknowledging that there is no point at which the embryo can be said to be a person,⁷⁶ as the embryo develops and becomes closer to being a person, the moral status of the embryo increases.⁷⁷

Following this theory, it would appear that the embryo has the lowest level of moral status at the one cell stage when the embryo is initially formed after fertilisation, and has the highest level of moral status prior to birth. As the embryo's chances of becoming a person increase upon implantation, the implanted embryo would have a higher moral status than that of the embryo *in vitro* or the unimplanted embryo *in vivo*. One could also assume that following this theory, the embryo prior to implantation has the lowest moral status that the embryo could have. Thus if a choice had to be made between research on an eight cell, unimplanted embryo and a 30 week foetus, research should be carried out on it over the 30 week foetus. Similarly, when faced with the option of using a 16-cell stage embryo or a 14-day old embryo, the guidance from the gradualist theory is clear that the 16-cell stage embryo should be used.

While it is clear that under this theory an embryo *in vitro* would have a low level of moral status, it fails to indicate whether the embryo has such a low level of moral status that destructive research may be carried out in the first place. It also fails to indicate what moral status the embryo has at a particular point in its development, as opposed to its *relative* moral status. The theory provides guidance when faced with the choice of carrying out embryo-

⁷⁶ A "person" in this context is a human being who has full moral status. A discussion of what it is to be a person will be discussed below.

⁷⁷ The theory has been likened to that of the colour spectrum. Just as it is unclear at which point a colour changes into another colour, it is unclear at which point an embryo changes from one stage of development to the next. N Poplawski & G Gillett, 'Ethics and Embryos' (1991) 17 *Journal of Medical Ethics* 62, 63.

destructive research on embryos which are at different points in their development but not when faced with the question of whether ESCR should be permitted, or the question of what the moral status of the early embryo is.

Despite the lack of definitive guidance from this theory, it has been adopted, for example, by the Warnock Committee⁷⁸ and the Singapore Bioethics Advisory Commission.⁷⁹ It has also become associated with the notion of “respect” whereby the respect afforded to the embryo gradually increases as it grows. Thus an implanted embryo would have more respect than an unimplanted embryo. In this way, respect is granted according to the stage of development of the embryo. The embryo may also be respected by ensuring that it is only used for essential research such as for life-saving therapies and not for cosmetic research. Thus, while the embryo may have substantial moral status, this may be outweighed by the potential of the research, provided only necessary research is carried out.⁸⁰

While “respecting” the embryo is consistent with permitting some, albeit limited, research on the embryo,⁸¹ there is generally seen to be a cut-off point at which embryonic research is prohibited due to the increasing moral status of the embryo. This cut off point is often the formation of the primitive streak, which occurs around day 14. This point is seen as important as the primitive streak is necessary for brain function and also the formation of the central nervous system.

Although this intermediate position may be influenced by some ethical values, its legal counterpart is in reality often a political compromise, with due deference to the competing moral arguments as to the status of the embryo.⁸² Such a compromise could state that ESCR is only permitted for research into very serious illnesses. In a commissioned paper by the US National Bioethics Advisory Commission the following was put forward as a position, that both liberal and conservatives could agree upon:

⁷⁸ Department of Health and Security, *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (Cm 9314 1984) para 11.1.5. (Hereinafter the *Warnock Report*)

⁷⁹ Singapore Bioethics Advisory Commission, *Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning* (June 2002) 25.

⁸⁰ R Latham, ‘The Once and Future Debate on Human Embryonic Stem Cell Research’ (2009) 9 *Yale Journal of Health Law and Policy* 483,487.

⁸¹ E Parens, ‘What has the President Asked of NBAC? On the Ethics and Politics of Embryonic Stem Cell Research’ in National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research* Volume II Commissioned Papers (Maryland, January 2000) para I-7 (hereinafter NBAC Report). Similarly Myers and Nelson argue that the embryo can be respected if the embryo is used for legitimate research purposes. M Meyer & L Nelson, ‘Respecting What we Destroy: Reflections on Human Embryo Research’ (2001) 31 *The Hastings Centre Report* 18, 18 a point which has found agreement amongst many. See H Johnson Kukla, ‘Embryonic Stem Cell Research: An Ethical Justification’ (2001-2002) 90 *Georgetown Law Journal* 503, 543 and J Robertson, ‘Ethics and Policy in Embryonic Stem Cell Research’ (1999) 9 *Kennedy Institute of Ethics Journal* 116, 131.

⁸² Arguably it also reflects the uncertainty of the situation; that the status of the embryo is in fact uncertain. D Smith, ‘Stuck in the Middle’ (2006) 36 *The Hastings Centre Report* 32, 32. This position however ignores the fact that many on both sides of the debate do not think that the status of the embryo is uncertain. Michael Lockwood’s point that debates on the moral status of the embryo rarely achieve much as they are usually inconclusive and rarely clarify much is valid and perhaps much more accurately reflects the problem with the embryo debate. Lockwood (n 51) 9-10.

“Research that involves the destruction of embryos is permissible where there is good reason to believe that it is necessary to cure life-threatening or severely debilitating diseases.”⁸³

President Bush’s decision on permitting federal funding on certain limited embryonic stem cell lines, while restrictive, still was a political compromise. Indeed it has been argued that there was no ethical reason for his cut-off date; rather it was simply a political decision designed to satisfy the electorate and not grounded in any ethical principles.⁸⁴ Pro-life proponents were opposed to the decision as they view embryonic life as equivalent to that of a child, and it was opposed by researchers who were of the view that the decision represented an implicit position that embryonic life cannot be used for research in the future. Furthermore, it was opposed by certain sections of the academic community who saw the decision as being both ethically flawed and inconsistent. Yet many praised it as being a good political compromise between the opposing liberal and conservative views on ESCR.⁸⁵

The difficulty with pursuing a policy that arises out of a political compromise is that it is difficult at times to ethically justify the position. If, for example, research is permitted up to a certain point in the developmental process of the embryo and on certain embryos only, it can at times be difficult to justify the cut-off point. Taking President Bush’s decision as an example, if embryonic life has such a high moral status that it cannot be sacrificed for research, it should be prohibited irrespective of whether the embryonic stem cell lines have already been derived. To hold otherwise would suggest that the research is morally tainted.

Yet with controversial research such as ESCR, any decision is likely to be a political compromise with the policy lying somewhere along the conservative-liberal spectrum. The moral status, while perhaps not expressly stated, is likely to be expressed through policies on the cut-off date for research on embryos, the sources of embryos in which ESCR is permitted to be used and also the purpose for which ESCR may be carried out.

The problem thus becomes how best to achieve this political compromise as there are three competing moral viewpoints which policy makers must contend with: the liberal position, the conservative position and the intermediate position. Although the decision is likely to be as a result of a political compromise, good public policy should be motivated by and incorporate moral considerations,⁸⁶ thus policy makers will need to address and access the competing moral considerations of each group.⁸⁷

⁸³ A Siegel, ‘Locating Convergence: Ethics, Public Policy and Human Stem Cell Research’ in NBAC Report, Volume I (Maryland, September 1999) para J-10.

⁸⁴ D Wertz, ‘Embryo and Stem Cell Research in the United States: History and Politics’ (2002) 9 *Gene Therapy* 674, 677.

⁸⁵ R Charo, ‘Bush’s Stem Cell Compromise: A Few Mirrors?’ (2001) 34 *The Hastings Center Report* 6, 6. For more on President Bush’s decision see Chapter 5.

⁸⁶ Beauchamp & Walters (n 46) at 29.

⁸⁷ For example, HERP stated

“Public policy employs reasoning that is understandable in terms that are independent of a particular religious, theological or philosophical perspective, and it requires a weighing of arguments in light of the best available information and scientific knowledge.” National Institute of Health, *Report of the Human Embryo Research Panel* (September 1994) 39.

In light of the moral debate, a consensus may not be obvious but policy makers must work to achieve a compromise which puts societal interests at the heart of the discussion. Despite the opposing views present in the stem cell debate, it is possible that there is some consensus on these issues. This may form the basis of a discussion through which legal status may be afforded to the embryo which nonetheless permits some research on the embryo. It is the role of the policy makers to establish such a consensus.

3. From Moral Principles to Public Policy

Although a discussion of the moral status of the embryo is likely to form the basis of a discussion on public policy, there is the danger that the debate will descend into a bitter and divisive debate as occurred with the abortion debate in both Ireland and the US. Debates on bioethical issues have become increasingly divisive in the US and these debates have their beginnings in what is termed the “culture wars”. While these debates began in the 1990s, their origins can be traced to the early days of bioethics when it was discovered that bioethical issues had political as well as ethical consequences.⁸⁸ The culture wars have focused on the role of government in public and private life, with the issues ranging from the welfare state, to feminism, to gay rights. The debates have been characterised by both sides accusing the other of being too liberal or too conservative rather than focusing on the actual issues.⁸⁹ Callahan has argued that this has led to the words “liberal” or “conservative” having nasty overtones and has enabled others to question the motives of the opposing side in issues that have no impact on the debate at hand.⁹⁰ Indeed neither side is willing to fully explore its stance on any issue lest it lead to the revelation of “nasty skeletons in their ethical cupboard”.⁹¹

The culture wars in the US are probably enabled by the two party-political system. Party positions on issues are labelled as inherently liberal or conservative rather than facilitating any attempt to adequately discuss the issues so as to determine the reasoning behind their views.⁹² However the labelling of “conservative” or “liberal” on stem cell research should not be the focus of the debate but rather the debate should be concerned with determining what is a State’s policy on ESCR.

This section will consider the options available to policy makers. First, due to the potential political repercussions associated with engaging with the issues involved in the debate, policy makers may opt to do nothing. The problems associated with this approach will be discussed, along with the evidence that such an approach results in bad policy. The consensus approach,

⁸⁸ D Callahan, ‘Bioethics and the Culture Wars’ (2005) 14 *Cambridge Quarterly of Healthcare Ethics* 424, 424.

⁸⁹ Ibid, 424-425. It has been argued that there is unlikely to ever be a consensus on abortion in the US due to politicised climate around the issue. M Leinhos *The Logic and Legitimacy of American Bioethics* (Cambria Press 2008) 175.

⁹⁰ Callahan (n 88) 428.

⁹¹ Holm (52) 377.

⁹² Callahan has noted:

“Unlike Europe, the United States does not have a green party, or for that matter any significant groups on the left who any longer raise critical, troublesome questions about medical technologies. That fact means that the debates get pushed in either a liberal or conservative direction, with little room for nuanced maneuver.” Callahan (n 88) 428-9.

whereby policy makers attempt to formulate policy based on the deliberations of the public and which generally has agreement across society, will be considered. As will be shown, central to this approach is the concept of democratic deliberation.

3.1. “Do nothing” approach

Despite the need for a debate on the issue, due to the divisiveness of the debate and potential political fallout, policy makers may opt to do nothing. Such an approach enables policy makers to avoid the legal, political and ethical debates surrounding the moral status of the embryo. This approach obviously implies a lack of legislation or ethical guidance on ESCR and as the International Bioethics Committee has noted, leaves the matter of whether to engage in the research up to the individual conscience of the person concerned.⁹³

Ireland is one jurisdiction that has pursued this policy. Public inaction as public policy is particularly prevalent in debates relating to the abortion debate and the definition of the “unborn”. As a result of the bitter abortion debate,⁹⁴ Irish policy makers not only have sought to avoid being drawn into debates on the status of the embryo, but have also sought to avoid legislating even when it is required. With regard to the need for abortion legislation, both the High Court and Supreme Court have stated that guidance is necessary to assist medical professionals, the courts and lawyers in deciding when it is permissible for a woman to have an abortion in Ireland. Yet rather than discussing this ethically contentious issue and introduce legislation, the government continued to ignore the courts’ advice until the European Court of Human Rights (ECtHR) held in 2010 that in order for Ireland to comply with the European Convention on Human Rights (ECHR), guidance on the boundaries of permissible abortion must be introduced.⁹⁵ The net result of this “do nothing” policy adopted by the government has resulted in a lack of clarity as to the boundaries of a legal abortion in Ireland. It has also forced many women to travel abroad for medically recommended abortions due to the refusal of doctors to perform an abortion in Ireland for fear of legal proceedings.⁹⁶

The Irish government has also adopted this approach in relation to both assisted reproduction and ESCR. In 1982 the Attorney General questioned whether the word “unborn” in the proposed Article 40.3.3 included embryos *in vitro*;⁹⁷ in 1996 the Constitutional Review Group noted that it was unclear whether Article 40.3.3 protected the embryo *in vitro*;⁹⁸ and in 2005 the Commission on Assisted Human Reproduction was of the view that the embryo *in vitro* was not protected by Article 40.3.3⁹⁹ and thus had no protection under Irish law. Despite the uncertainty of the legal status of the embryo *in vitro*, no government has been willing to regulate assisted reproduction or ESCR, or to introduce legislation outlining the status of the

⁹³ International Bioethics Committee, *The Use of Human Embryonic Stem Cells in Therapeutic Research* 40.

⁹⁴ The history of abortion legislation in Ireland will be explored in Part III.

⁹⁵ (2011) 53 EHRR 2032.

⁹⁶ C O’Brien, ‘Woman with Cancer Tells of her Abortion Ordeal’ *Irish Times* (Dublin, 21 December 2010).

⁹⁷ The proposed amendment was ultimately passed and is now Article 43.3.3.

⁹⁸ Constitutional Review Group, *Report of the Constitutional Review Group* (1996) 275.

⁹⁹ Commission on Assisted Human Reproduction, *Report of the Commission on Assisted Human Reproduction* (2005).

embryo *in vitro*. Once again the courts were forced to address the issue in *Roche v Roche* where both the High Court and Supreme Court held that the embryo *in vitro* is not protected by Article 40.3.3 of the Irish Constitution.¹⁰⁰

Clearly the justification for taking such an approach was to avoid the ethically divisive debate of the status of the embryo, which may be politically damaging. Politically it was a wise decision as no party in the history of the Irish state has entered government on the back of a promise to liberalise abortion or to regulate assisted human reproduction and ESCR.¹⁰¹ However, this policy has no basis on ethical principles.¹⁰² In stark contrast to the full legal status of the embryo *in vivo*, by refusing to confront the moral debate on the status of the embryo *in vitro*, successive Irish governments have offered the embryo *in vitro* no protection. Thus the status of the embryo depends on its environment, which is an ethically flawed policy. For example the theory of potentiality would argue that the embryo *in vivo* has a greater potential for developing into a human being than the embryo *in vitro*. Yet the theory would still give the embryo *in vitro* some moral status irrespective of its location as it has the potential to develop into a human being. Similarly while the gradualist theory would give a greater moral status to the embryo *in vivo*, it would still give some moral status to the embryo *in vitro*.

Although it is unlikely that affording status based on environment is the intention of a majority of Irish citizens, the “do nothing” approach has resulted in an implicit decision to not protect the embryo *in vitro*. Thus despite the avoidance of a debate on the status of the embryo, an implicit decision has still been made. Indeed it is argued that policy makers “cannot *not* determine the moral status of embryos” as any decision they make will either implicitly or explicitly make a determination as to the moral status of the embryo.¹⁰³

Finally it is important to emphasise that many of the ethical issues discussed in this debate concern issues such as who belongs in our community,¹⁰⁴ or who has moral status worthy of legal protection. Such fundamental issues are not something on which the law should be silent, otherwise counter-majoritarian institutions such as the courts will have to decide on them. This has occurred in the United States where federal abortion policy has been dictated by the courts and not by the democratically elected Congress. The case of *Roe v Wade* established that a woman’s right to privacy permitted her to have an abortion if she so wished, subject to certain conditions.¹⁰⁵ Despite criticisms of the *Roe* decision,¹⁰⁶ Congress

¹⁰⁰ [2010] 2 ILRM 1, [2006] IEHC 221, [2006] IEHC 359. For a detailed analysis of the Roche case see Chapter 6.

¹⁰¹ In the 2011 Irish general election, the main political party did state that they would ensure that measures were introduced to comply with the ECtHR decision. Interestingly, while no political party which entered government has promised to liberalise abortion, in 1982 Fianna Fail entered government supported by the pro-life groups on foot of a promise to constitutionally prohibit abortion. That electoral promise resulted in Article 40.3.3.

¹⁰² In the context of abortion, the ECtHR also considered that the failure to provide guidance as to when an abortion is permissible in Ireland to be contrary to Article 8 of the ECHR. *ABC v Ireland* (2011) 53 EHRR 2032 para 268.

¹⁰³ Prens (n 81) para I-5. It has also been argued that the question of “who belongs” in our society is ultimately a political question and the law should not be silent on this. G Meilaender, ‘Less Law? Or Different Law?’ (1996) 26 *The Hastings Center Report* 39, 39.

¹⁰⁴ *Ibid.*

¹⁰⁵ (1973) 410 US 113, 162-163.

has refused to intervene and provide clarity with a federal abortion statute. Similarly in Ireland, there has been a continued lack of legislative guidance and the courts have found it difficult to decide cases in such a vacuum.¹⁰⁷ Yet despite repeated calls for clarity on the status of the embryo *in vitro*¹⁰⁸ and a clear need for legislation on the issues, the Irish courts have been forced to determine whether the embryo *in vitro* is constitutionally protected.¹⁰⁹ Furthermore judges are theoretically required to interpret the law and not create it, but when presented with cases on abortion or the status of the embryo *in vitro*, judges are forced to make a decision with little or no guidance from an elected legislature which may have the effect of creating policy that does not reflect the will of the people.¹¹⁰

The central problem with the “do nothing” approach is that an implicit choice is being made¹¹¹ and it is often left to judges to decide on legal issues, which should arguably be the role of Parliament; thus legislators are arguably not fulfilling their constitutional role.¹¹² Decisions are made on a case-by-case basis and dictated by the particular set of facts before the Court, rather than on the basis of principles that should apply generally, and without taking into account broader public policy questions. The arguably politically wise decision from the view of the political parties not to engage in an ethical debate therefore often results in legal uncertainties in the future which the courts are forced to attempt to resolve.

3.2 Consensus Approach

As illustrated, the “do nothing” approach will not only result in an implicit decision being made but also result in policy gaps as the legislature fails to address public policy needs. With such an unsatisfactory outcome, it is submitted that policy makers should proactively engage with the issues and clarify the regulatory framework in which ESCR must operate. However, as there is no clear consensus on the moral status of the embryo within society, it is

¹⁰⁶ See *Akron v Akron Centre for Reproductive Health* (1983) 462 US 416, *Webster v Reproductive Health Services* (1989) 492 US 490, *Planned Parenthood of Southeastern Pennsylvania v Casey* (1992) 505 US 833, A Lotierzo, ‘The Unborn Child, a Forgotten Interest: Reexamining *Roe* in Light of Increased Recognition of Fetal Rights’ (2006) 79 *Temple Law Review* 279. For more on *Roe v Wade* and subsequent decisions see L Tribe, *Abortion: The Clash of Absolutes* (W.W. Norton & Company 1992) 31.

¹⁰⁷ McCarthy J in *AG v X* stated:

“In the context of the eight years that have passed since the Amendment was adopted and the two years since *Grogan's* case the failure by the legislature to enact the appropriate legislation is no longer just unfortunate; it is inexcusable. What are pregnant women to do? What are the parents of a pregnant girl under age to do? What are the medical profession to do? They have no guidelines save what may be gleaned from the judgments in this case. What additional considerations are there? Is the victim of rape, statutory or otherwise, or the victim of incest, finding herself pregnant, to be assessed in a manner different from others? The Amendment, born of public disquiet, historically divisive of our people, guaranteeing in its laws to respect and by its laws to defend the right to life of the unborn, remains bare of legislative direction.” [1992] 1 IR 1, 82.

¹⁰⁸ Constitutional Review Group (n 98) 275.

¹⁰⁹ *Roche v Roche* [2010] 2 IR 321.

¹¹⁰ In his decision, Murray CJ stated that the issue before the Court in *Roche v Roche* was not justiciable as the Court did not have any objective criteria through which it could consider at what point an unborn life should be protected. He considered this an issue for the Oireachtas to determine with due regard to the Constitution. Ibid 351-352.

¹¹¹ Although discussing advisory commissions, Parens has argued that despite a decision being potentially divisive and controversial, an advisory commission “cannot choose not to choose an interpretation”. The same can equally be said for policy makers. Parens (n 81) para I-6.

¹¹² See generally A Bickel, *The Least Dangerous Branch* (Yale University Press 1962).

likely that there is no correct answer to the moral status of the embryo¹¹³ and that the debate is unlikely to “resolve itself into a broadly shared consensus”.¹¹⁴ Thus the question becomes whether policy makers can and should act in the absence of a consensus.

While new technologies undoubtedly bring new challenges for the law, legislators should not hide behind ethical uncertainty, but must respond to the developing technologies as they emerge. Indeed there are areas where policy has adapted to changes in technology which question our concept of life, notably in relation to organ transplants. Advances in technology made it possible for an organ from a recently deceased person to be transplanted into a living person, bringing with it a raft of legal, ethical and policy issues. As continued blood circulation is necessary to ensure the further use of organs, the heart must continue to beat while the organ is removed. This necessitated a change in a definition of death.¹¹⁵ While the medical profession took the lead in devising a new definition of death based on brain functioning, social and moral perspectives were also sought with the aim of achieving a consensus. While the process was not without controversy, it resulted in a definition that has been adopted and accepted by most stakeholders.¹¹⁶ Part of the reason for the success was that no attempt was made to resolve the ethical issues associated with taking organs from a person whose heart was still beating. Rather the focus was on responding to a legal vacuum which the new technology brought.

Thus it is possible for policy makers to engage with the relevant stakeholders and formulate a policy based on some consensus. Key to building a consensus is ensuring that the relevant issues, groups and processes are considered. This can be done first by examining the history of the particular jurisdiction and how it has responded to developments in embryology; second, by ensuring that the relevant stakeholders and interest groups, such as the religions, are consulted; third, by ensuring that the debate is correctly framed; and fourth, by ensuring that the appropriate deliberative process is followed to ensure that there is a consensus on policy.

3.2.1 History of the jurisdiction

While policy makers should be willing to change their approach to policy issues concerning embryology according to changes in technology as well as changing societal attitudes, historical factors peculiar to a jurisdiction may indicate the direction policy is likely to take. The history of Germany, for example, may be taken into account when seeking to make sense of its ESCR legislation. Arguably, without understanding the crimes of Nazi Germany, it

¹¹³ E Parens (n 81) para I-5. Charo argues that there is no shame in admitting that the embryo raises certain moral issues which a government cannot answer. A Charo ‘The Hunting of the Shark: The Moral Status of Embryos, Right-to-Lifers, and Third World Women’ (1995) 6 *Stanford Law Review* 11, 19.

¹¹⁴ K Fitzgerald, ‘Human Embryonic Stem Cell Research: Ethics in the Face of Uncertainty’ in N Snow, *Stem Cell Research: New Frontiers in Ethics and Science* (Notre Dame Press 2003) 42. The opposing sides of the stem cell debate have even been likened to the opposing sides of the peace process in the Middle East. Wertz (n 84) 677.

¹¹⁵ J Kahn, ‘Organ and Stem Cells: Policy Lessons and Cautionary Tales’ (2007) 37 *The Hastings Centre Report* 11, 11.

¹¹⁶ *Ibid.*

would be impossible to appreciate Germany's ESCR policy.¹¹⁷ The eugenic policies central to Nazi Germany have had a lasting impact on the regulation of biotechnology. Article 1 of the German Basic Law adopted in 1949 states that human dignity is inviolable and it is the duty of the state authorities to ensure that human dignity is protected. While it can be argued that the destruction of the embryo is not the destruction of a human and thus not contrary to Article 1, for many the destruction of the embryo, which represents the earliest forms of life, in pursuit of scientific research would be "to repeat the sins of the past".¹¹⁸ As a result, the German Embryo Protection Act of 1990 prohibits the fertilisation of an egg for any purpose other than for reproductive purposes.¹¹⁹

However, in early 2002, the Deutsche Forschungsgemeinschaft (DFG), Germany's research funding agency, proposed that ESCR be permitted on imported stem cell lines as the research would be on the stem cell lines and not embryos and thus the Embryo Protection Act would not be violated.¹²⁰ A Study Commission on Law and Ethics in Modern Medicine was convened in March 2001 to examine this issue. In the meantime Chancellor Gerhard Schroder established the National Ethics Commission in May 2001 to also report on the importation issue. The Study Commission recommended against a policy change while the National Ethics Commission recommended that embryonic stem cell lines be imported for research purposes.¹²¹

The debate pitted Chancellor Schroder, who was in favour of ESCR on imported lines, against President Rau, who argued that events which took place during World War II should not be forgotten where "an uncontrolled scientific community did research for the sake of research aims, without any moral scruples".¹²² While Schroder did defend ESCR, pointing out the benefits in healing those in need of research, he did not get much support in the Bundestag and it is likely that this was due to the fear that a liberalising of stem cell policy¹²³ could be seen as being reminiscent of Nazi policy. Despite these fears, the German Stem Cell Law was eventually passed in 2002. It permits the importation of embryonic stem cell lines that were derived prior to 2002¹²⁴ thus allowing some limited ESCR in Germany.

German policy thus remains highly restrictive. The UK legislature on the other hand is not constrained by historical precedents and has traditionally been quite permissive in its approach to medical advances. While the introduction of the Human Fertilisation and Embryology Act 1990 was not without controversy, it had a relatively easy passage into law in comparison to experiences elsewhere. This passage was likely aided by the relative lack of public controversy in the UK regarding bioethical issues and also by the fact that the UK has

¹¹⁷ K Bayert, 'Struggling for Consensus and Living Without It: The Construction of a Common European Bioethics' in T Engelhardt, *Global Bioethics: The Collapse of Consensus* (M & M Scrivener Press 2006) 222.

¹¹⁸ Cohen (n 65) 147.

¹¹⁹ Embryo Protection Act 1990, s1(1) & s2(1).

¹²⁰ Cohen (n 65) 150.

¹²¹ German National Ethics Council, *The Import of Embryonic Stem Cells* (2001).

¹²² Cohen (n 65) 151.

¹²³ Ibid.

¹²⁴ This was amended in 2008 and the cut-off point is now the 1st May 2007.

generally taken a pragmatic approach to such issues, while Germany has tended to be more principled for mostly historical reasons.¹²⁵

3.2.2 Religion

Religious beliefs have been central to the shaping of moral principles and thus have had an impact on public policy.¹²⁶ Indeed the moral principles of Western civilisation are generally those of Christianity.¹²⁷ The Catholic Church in Ireland in particular has historically been quite influential in formulating policy, particularly in relation to issues such as family life, sexuality and contraception.¹²⁸ While the Church's influence has waned in Ireland and across the world, religious beliefs continue to have a role in shaping both moral principles and public policy.¹²⁹ Callahan has argued that if religion is excluded from public debate, the accumulated knowledge of the religions on moral thinking will be ignored.¹³⁰ However, it should be noted that the Catholic Church's views on abortion, for example, have changed with developments in medical science. It was not until the nineteenth century when the process of fertilisation was discovered, that the Church came out against abortion from the moment of conception.¹³¹

The issue for policy makers is to ensure that while religious beliefs are considered, they do not take over the debate, particularly in a multi-cultural society where differing religious beliefs are in play. Furthermore, policy makers should be aware that there are such deep divisions on the stem cell issue that great care is required to ensure that one religious view is not favoured over another.¹³² While there may be fears that a "fundamental stem cell theology"¹³³ could emerge in consultations with the religions, this should not be a reason for preventing the religions from contributing to the debate, particularly as many people would describe themselves as belonging to a particular faith. The opinions of the various religious groups should be both sought and welcomed. Importantly, Article 17(3) of the Treaty on the Functioning of the EU requires the Union to "maintain an open, transparent and regular dialogue" with the churches and religious associations of the Member States, thus

¹²⁵ K Bayert (n 117) 221.

¹²⁶ Cohen states:

"For example, when religious believers speak out about treating humans as ends in themselves, about the potential for the abuse of power by those in legislative and regulatory positions, or about the need to provide medical treatment in fair and just ways to those who are marginalised, they bring to public attention core values that have shed and continue to shape our republic." Cohen (n 65) 90.

See also Brody "Religion and Bioethics" in H Kuhse and P Singer *A Companion to Bioethics* (Blackwell Publishing, 1998) at 41.

¹²⁷ P Devlin, *The Enforcement of Morals* (OUP 1965) 4.

¹²⁸ On the other hand religion in China does not play a large role when it comes to regulating ESCR. D McMahon, H Thorsteinsdottir, P Singer & A Daar, 'Cultivating regenerative medicine innovation in China' (2010) 5 *Regenerative Medicine* 35, 39.

¹²⁹ Rawls has argued that the religious doctrines which formed the basis of society in previous years have given way to principles of constitutional government which all citizens irrespective of their religion can endorse. J Rawls, *Political Liberalism* (Columbia University Press 1993) 10.

¹³⁰ D Callahan, 'Religion and the Secularization of Bioethics' (1990) 20 *The Hastings Center Report* 2, 3.

¹³¹ Tribe (n 106) 31.

¹³² Robertson (n 81) 131.

¹³³ G Heine, 'Theological Arguments in the Human Stem Cell Debate: A Critical Evaluation' in L Ostnor (ed), *Stem Cells, Human Embryos and Ethics: Interdisciplinary Perspectives* (Springer 2008) 223.

recognising the important influence of the various churches.¹³⁴ However, it is important that all religions are invited to contribute and that the views of one particular faith are not chosen as the basis for a stem cell policy.¹³⁵

In framing his stem cell policy, President Bush provided a classic example of how the views of one religion can dominate over the others. The President's Council for Bioethics appointed by President Bush was criticised for only inviting Christian commentators to hearings,¹³⁶ whereas the National Bioethics Advisory Commission heard from a variety of faiths. It is alleged that this is contrary to a secular society, in which all religious views must be heard.¹³⁷ A preferred approach would be to invite all religions to speak in a public forum where they are given the opportunity to explain their beliefs and allow them to be challenged and debated and, just as must be done for ethical divergence, a compromise between the various religious views can be sought.¹³⁸

However, not all are in agreement with the criticisms levied at the Council and it has been argued that these attacks are in fact a symptom of the culture wars in the US.¹³⁹ The previous Presidential Commissions were quite liberal in outlook and received very little criticism,¹⁴⁰ thus suggesting that there is a move against Commissions that are deemed to be conservative. While it is not inconceivable that President Bush would have appointed a Commission that would be likely to support his own political or religious views, the focus should not be on conservative or liberal views of the Commission but rather the issues at hand.

However, President Bush's first address to the nation reflected his personal beliefs on ESCR and his reasoning was heavily based on his Christian faith.¹⁴¹ It is because of this that his policy has been described as inappropriate for favouring one religious view over another in banning the federal funding of ESCR.¹⁴² In August 2001, President Bush announced that the federal funding of stem cell research would be restricted to lines that had been created before 9 August 2001, a decision which has been criticised as being too strongly based on his faith and thus failing to adequately consider the benefits of ESCR.¹⁴³ It is argued that rather than

¹³⁴ Treaty on the Functioning of the European Union, Article 17 states:

1. "The Union respects and does not prejudice the status under national law of churches and religious associations or communities in the Member States.
2. The Union equally respects the status under national law of philosophical and non-confessional organisations.
3. Recognising their identity and their specific contribution, the Union shall maintain an open, transparent and regular dialogue with these churches and organisations."

¹³⁵ Robertson argues that it is "because people differ so deeply over personal spiritual and value commitments, one group should not erect its own view of the matter into public policy". Robertson (n 65) 131.

¹³⁶ Cohen (n 65) 90-91.

¹³⁷ Ibid 108.

¹³⁸ Ibid 108-109.

¹³⁹ D Callahan, 'Bioethics and the Culture Wars' (2005) 14 *Cambridge Quarterly of Healthcare Ethics* 424, 425.

¹⁴⁰ Ibid, 428.

¹⁴¹ See 'President Bush Discusses Stem Cell Research' <http://georgewbushwhitehouse.archives.gov/news/releases/2001/08/20010809-2.html> accessed 19 January 2013.

¹⁴² R McGough, 'A Case for Federal Funding of Human Embryonic Stem Cell Research: The Interplay of Moral Absolutism and Scientific Research' (2001-2002) 18 *Journal of Contemporary Health Law and Policy* 147, 191.

¹⁴³ H Fowler, Federal Stem Cell Mandates Lack Global Focus and Market Foresight, (2003-2004) 36 *Cornell Journal of International Law* 521, 541-2.

allowing religion to cloud his view, President Bush should have relied more on scientific opinion and government reports and research developments in other jurisdictions.¹⁴⁴ That said, President Bush did note the potential of the research and acknowledged that embryonic stem cells have “unique potential”.¹⁴⁵ The President also acknowledged that the science may not live up to its potential. The problem with the President’s address is that he stated his belief that human life is a unique gift from “our creator” and that as the research destroys potential life it could result in a devaluation of life. His reliance on “our creator” or God as a justification for his decision imposes a religious angle on the United States policy which is not shared by all citizens.

3.2.3 The Promise of Science

It is important that policy makers engage with members of the scientific community. This will ensure that scientific facts and not ideology frame the debate. It will also ensure that the potential of the research is understood. Brownsword has argued that in a representative democracy, decision making needs to be properly informed and this includes understanding the relevant science.¹⁴⁶ On the issue of scientific fact, the scientific community can outline the developmental process of the embryo and state that while this process is intimately understood, science cannot pin-point the beginning of life, as life is much more than simply a scientific issue.

The potential of the research is likely to have an impact on public policy. If a jurisdiction opts for an intermediate approach to regulating ESCR such that research is permitted on the embryo in certain situations, policy makers may decide that embryo-destructive research may be used to cure life threatening or severely debilitating diseases.¹⁴⁷ On the other hand, it would not be suitable for curing less serious ailments, such as finding a cure for baldness.

The potential for other forms of research may have an impact on public policy. Policy makers may thus consider scientific developments in adult stem cell research and IPS cells. As adult or IPS cells do not require the destruction of the embryo, policy makers may opt to permit the use of IPS and adult stem cells, but prohibit ESCR. While the opinions of scientists will differ as to whether IPS cells or adults cells hold the same potential as embryonic stem cells, through engaging with scientists, policy makers can educate themselves to ensure that they are fully informed and make a decision based on the best scientific information.

Two final issues must however be considered when engaging with the scientific community. First, embryonic stem cell research is still at the experimental stage, with its potential yet to be realised. If policy makers opt to permit some degree of research based on its potential,

¹⁴⁴ Ibid 544.

¹⁴⁵ The President stated: “Based on preliminary work that has been privately funded, scientists believe further research using stem cells offers great promise that could help improve the lives of those who suffer from many terrible diseases, from juvenile diabetes to Alzheimer’s, from Parkinson’s to spinal cord injuries. And while scientists admit they are not yet certain, they believe stem cells derived from embryos have unique potential.”

¹⁴⁶ R Brownsword, *Rights, Regulation and the Technological Revolution* (OUP 2008) 127. Beauchamps and Childress have also noted that many moral problems could be resolved by accessing accurate information Beauchamp & Walters (n 46) 4.

¹⁴⁷ Siegel (n 83) para J-10.

they should consider that the potential may in fact never be realised and whether a time frame should be put on the research. Callahan has argued that if it is decided to permit embryo-destructive research based on a proportionality analysis, the scientific potential should not be assumed but proven.¹⁴⁸ While such a policy would all but stop medical research,¹⁴⁹ Callahan has a point that while the potential of the research should be considered, it should not be the sole focus.

Second, policy makers should consider that the scientific community's opinions are not value-free and are likely to reflect a particular agenda, which is either in favour of or against ESCR.¹⁵⁰ Furthermore it is not uncommon for the scientific community to exaggerate the promise of controversial research. Gene therapy, for example, faced ethical criticisms but was permitted due to the scientific promise of the research.¹⁵¹ While the promise of gene therapy is great, progress has been slow.¹⁵² Despite clinical trials beginning in 1990, gene therapy has yet to be approved for commercial use, illustrating that caution must be exercised when exaggerating the potential of a new science.¹⁵³ ESCR scientists have equally exaggerated its potential with promise of stem cell therapies in five years,¹⁵⁴ and therapies for age related diseases which will both improve the quality of life for older people and also reduce the cost of treating older people.¹⁵⁵ Yet over ten years later there has been no such breakthrough. Scientific promises must not therefore be taken at face value.¹⁵⁶

Finally it must be remembered that the scientific community itself is divided as to whether ESCR should occur at all. While it is true that the potential of ESCR may never be realised, opponents of ESCR are quick to exaggerate the potential of adult stem cell research and suggest that ESCR is not necessary. Both William May and Elizabeth Blackburn, who are two former member of President Bush's President Council on Bioethics, were in fact critical

¹⁴⁸ D Callahan, 'The Puzzle of Profound Respect' (1995) 25 *The Hastings Center Report* 39, 39.

¹⁴⁹ As Steinbrook has noted "[r]esearch...is still research" and the consequences of the research are unknown and often unexpected. R Steinbrook, 'The Gelsinger Case' in E Emanuel, C Grady, R Crouch, R Lie, F Miller & D Wendler (ed), *The Oxford Textbook of Clinical Research Ethics* (OUP 2008) 119.

¹⁵⁰ For example, adult stem cell scientists took the case of *Shelby v Shelbius* in the US trying to stop the US government from funding ESCR. Thus not all scientists are in favour of ESCR. For more on this case, see Chapter 5.

¹⁵¹ It was stated that gene therapy was the only cure for people with genetic diseases, which helped to overcome public and political resistance to the research. Holm (n 52) 502.

¹⁵² Steinbrook (n 149) 110. There have been some recent developments in gene therapy however and in April 2008 researchers from the UK announced the success of the first clinical trial for the treatment of a type of inherited blindness: http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml

¹⁵³ Gene therapy faced a major setback with the death of Jesse Gelsinger in September 1999 during clinical trials. For more on the Gelsinger case, see Steinbrook (n149).

¹⁵⁴ Holm (n 52) 502.

¹⁵⁵ In 2000 it was estimated that age-related illnesses cost the United States an additional \$26bn annually. As the population of people over 65 is expected to double and the population over 85 is set to quadruple by 2020, that cost will also rise. D Perry, 'Patients' Voices: The Powerful Sound in the Stem Cell Debate' (2000) 287 *Science* 1423, 1423.

¹⁵⁶ Callahan argues that there is a "research imperative" at force which attaches too much attention to the importance of research and that unless this force is neutralised embryos are likely to be sacrificed for this research. D Callahan, 'Promises, Promises. Is Embryonic Stem Cell Research Sound Public Policy?' (2005) *Commonweal* 12, 14.

of the Council's underestimation of ESCR and overestimation of adult stem cell research.¹⁵⁷ Thus while the input of the scientific community is important, policy makers must remember that scientists are likely to have an agenda, which could be the promotion of ESCR friendly regulations or a prohibition on ESCR so that investment is directed solely at adult or IPS cell research.

3.2.4 Bioethics Commissions

It has become increasingly common for policy makers to appoint bioethics commissions. Indeed the majority of European countries have an established national bioethics commission whose role it is to consider such issues. Such commissions are generally interdisciplinary and their membership includes experts in law, ethics and science. These commissions have the necessary expertise and time to engage with the issues associated with developments in biotechnology and can attempt to balance the interests of human rights, science and public policy in an environment that should be free from political influence.¹⁵⁸ These commissions generally examine the issues and prepare a report with recommendations as to the best regulatory system for that particular jurisdiction.

Successive commissions have deliberated on the moral status of the embryo and some have explicitly recommended an approach to regulating ESCR. For instance, the Singapore Bioethics Advisory Commission recommended that the embryo have an intermediate status, which would permit some research on the embryo.¹⁵⁹ In the UK, the Warnock Committee explicitly sought a decision that society could accept irrespective of the personal objections of members of the committee, as their personal views were not to be used as a basis for recommendations.¹⁶⁰ They attempted to reach a decision grounded in ethical principles on "how it is right to treat the embryo".¹⁶¹

However, bioethics commissions have, at times, been criticised for not being apolitical. In particular, President Bush's President's Council for Bioethics was criticised due to the appointment of Leon Kass as its chair. Leon Kass is generally viewed as one of the world's leading conservative bioethicists¹⁶² and his appointment as the chair of President Bush's President's Council for Bioethics led to the expectation of a conservative report in line with President Bush's views. This view was reinforced when two prominent dissenters of the report, Elizabeth Blackburn and William May, were not reinstated at the conclusion of their

¹⁵⁷ R. Charo, 'Passing on the Right: Conservative Bioethics is Closer Than it Appears' (2004) 32 *Journal of Law, Medicine & Ethics* 307, 307.

¹⁵⁸ Petit (n 35) 309.

¹⁵⁹ Singapore Bioethics Advisory Commission (n 79) 25.

¹⁶⁰ See foreword Warnock Report (n 78).

¹⁶¹ Ibid para 11.9

¹⁶² R. Macklin, 'The New Conservatives in Bioethics: Who are they and What do they Seek?' (2006) 36 *The Hastings Center Report* 34, 35.

two-year term.¹⁶³ Thus it has been argued that the appointment of certain members to the Commission was to ensure that a particular political philosophy was followed.¹⁶⁴

In such a case the Commission is not fulfilling its role of considering the legal, ethical and scientific issues and recommending a framework in light of the legal and social considerations of that particular jurisdiction. Rather, its recommendations are based on its own particular moral principles or political philosophy. Arguably this occurred in Ireland when Gerry Whyte dissented from the Commission on Assisted Human Reproduction and opposed any activity that would lead to the destruction of the human embryo. While on the face of it, a reasoned expression of dissent should be welcomed as further informing the public debate, Whyte's reasons appear to be solely based on his personal views as to the status of the embryo and whether it should have a right to life. In giving reasons for his dissent, Whyte went so far as to state "turning to my own position on this issue...";¹⁶⁵ thus he grounded his decisions in his personal opinion only and failed to consider whether his personal opinion resonates with Irish society. The Commission's terms of reference was to consider the "social, ethical and legal factors to be taken into account in determining public policy" for assisted reproduction.¹⁶⁶ Thus Whyte was not asked to formulate recommendations based on his own opinions but rather to consider the issues that should influence Irish public policy.

Bioethics commissions have been criticised for enabling politicians to avoid making a decision on a politically-charged issue and thus transferring the decision making power to the commissions.¹⁶⁷ Although reports such as the Warnock Report have proved to be central to the framing of policy on assisted reproduction and ESCR,¹⁶⁸ policy makers are under no obligation to follow these reports. The decision on whether the recommendations from the Commission are followed rests with the policy makers; the report simply ensures that policy makers make an informed decision. Therefore while bioethics commissions can be a valuable tool for policy makers, care should be taken to carefully consider and dissect reports to ensure that the recommendations of the report are unbiased and based on considerations of the ethical issues in light of society rather than a member's personal views.¹⁶⁹ Only if the members of a commission are fully independent and willing to put their personal opinions aside in the interests of society as a whole can a bioethics report truly contribute to the wider debate.¹⁷⁰

¹⁶³ Charo (n 157) 307.

¹⁶⁴ Ibid 308. Callahan has argued that bioethicists should be wary of serving on Commissions where "there is a reasonable certainty that its political aim is to legitimate a controverted research or policy proposal". D Callahan 'Bioethics, Our Crowd and Ideology' (1996) 26 *The Hastings Center Report* 3, 3.

¹⁶⁵ See Commission on Assisted Human Reproduction (n 84) 73.

¹⁶⁶ Ibid Appendix I.

¹⁶⁷ Petit (n 35) 312.

¹⁶⁸ Indeed the Warnock Report has been influential in the framing of the debate around the world. Cohen (n 65) 146.

¹⁶⁹ It should also be borne in mind that a person's own views may not be what they think is best for the nation. Dworkin has noted that while many believe that abortion can never be morally permissible, they do not think that the law should force one particular view on women. R Dworkin, *Life's Dominion: An Argument about Abortion and Euthanasia* (Harper Collins Publishers 1993) 31.

¹⁷⁰ Capurro sums up the purpose of bioethics commissions:

4. Towards a Consensus on ESCR Policy

Due to the pluralistic nature of the issues involved with ESCR, there is a view that a consensus will never be reached.¹⁷¹ This should not be taken to mean that it is not possible to achieve consensus on public policy or a regulatory framework. The historical approach to ethical issues and in particular embryology may indicate where a jurisdiction will lie on the liberal/conservative spectrum. Bioethics Commissions, if apolitical and interdisciplinary, can provide the expert opinion on the issue, while the religious groups, scientists and other interest groups can provide input into the debate. It is policy makers, however, who must strive to define a consensus on the issues.

Policy makers must therefore be clear about what their role is. They are not expected to determine the moral status of the embryo or indeed the legal status of the embryo; their role is to determine the status of the embryo in the context of ESCR. Policy makers should aim to achieve complete agreement on the issues. Not only will this benefit them politically,¹⁷² but it will also result in social policy that has been reached through a consensus and thus reflective of society. One way in which this may be achieved is through democratic deliberation.

4.1 Democratic Deliberation

Democratic deliberation is a collaborative decision-making process that encourages individuals to put societal interests over their own personal interests. It promotes an environment for debate and decision-making that focuses on common ground while ensuring mutual respect where differences remain.¹⁷³ While acknowledging that there are times when no consensus may emerge, by encouraging respectful debate coupled with a desire to achieve some common ground, a decision which all parties can agree on should emerge.

There are a number of features to this policy: first, policy makers are required to give reasons for their decisions; second, this reasoning should be accessible and understood by all; third, the process results in a decision which is binding for some period of time and finally the process must be dynamic.¹⁷⁴

Providing a reasoned decision is the most important aspect of democratic deliberation, as it is through the discussion of opinions and explanation of the reasons for holding beliefs that

“They are supposed to provide a sound and independent argumentation and to facilitate judgement that should help politicians and society to get a more transparent view of the intricacies of scientific, technical, and legal issues as seen from an ethical viewpoint.” R Capurro “Ethics and Public Policy Within a Digital Environment” in General Report on the Activities of the European Group on Ethics in Science and New Technologies to the European Commission 2000 – 2005 at 23.

¹⁷¹ HC 2 April 1990, Column 914.

¹⁷² It has been argued that policy makers do not always strive to achieve consensus but rather at times reinforce divisions to ensure electoral gain:

“But arguments in favour of the political process neglect the fact that many elected officials are not interested in finding common ground on divisive social issues like abortion. Indeed, candidates and public officials often prefer to exploit such controversies for electoral gain.” D Orentlicher, ‘The Legislative Process is Not Fit for the Abortion Debate’ (2011) 41 *The Hastings Center Report* 13, 13.

¹⁷³ A Gutmann, ‘The Ethics of Synthetic Biology’ (2011) 41 *The Hastings Center Report* 17, 19.

¹⁷⁴ A Guttman & D Thompson, *Why Deliberate Democracy?* (Princeton University Press 2004) 3-6.

common ground may be found¹⁷⁵ and mutual respect can be ensured. Habermas has argued that despite the differing moral opinions amongst society, citizens are expected to respect one another, and when confronted with a contentious issue, they are expected to look for agreement.¹⁷⁶ In reaching this agreement, Habermas argues that “they owe one another good reasons”.¹⁷⁷ By deliberating and justifying their position, others can begin to see the “moral merit” in their arguments.¹⁷⁸ Respecting one another in the debate will ensure that it does not descend into a culture war and importantly it recognises that often there are no right or wrong answers but rather a series of differing moral opinions. Focusing on the reasons will also ensure that the attacks do not become personal but rather that the debate remains focused on the issues.¹⁷⁹ This approach has been affirmed by the US National Bioethics Advisory Commission, which recommended a policy that would

“demonstrate respect for all reasonable alternative points of view and that focus, when possible, on the shared fundamental values that these divergent opinions, in their own ways, seek to affirm”.¹⁸⁰

It must be noted that while the purpose of this process is to focus on shared values and areas of agreement so that a consensus begins to emerge, its aim is not to rid the political process of moral differences. Guttman and Thompson argue that if, in a pluralist society certain moral differences are so deep that they can never be reconciled, these differences can only disappear through repression.¹⁸¹ Thus, while looking for shared values and common ground, this process should also acknowledge that there are differing moral values in any democratic society.

This policy of reasoned argument has also received recent support from the Presidential Commission for the Study of Bioethical Issues. In its 2010 report on synthetic biology the Commission highlighted “the importance of robust public participation in both the development and implementation of specific policies”.¹⁸² It also recommended that scientific, religious, civic engagement scientists, policy makers, and religious, secular, and civil society groups maintain an on-going dialogue about synthetic biology with policy makers.¹⁸³ Looking to Europe, Article 11 of the TEU requires that the EU institutions maintain a regular dialogue with the citizens of the EU and representative organisations, and that the

¹⁷⁵ Ibid 7.

¹⁷⁶ It has been argued that it is the role of policy makers to ensure that focus is on areas of agreement rather than disagreement between those with differing viewpoints as to the moral status of the embryo. Siegel (n 83) para J-19.

¹⁷⁷ J Habermas ‘Religion in the Public Sphere’ (2006) 14 *European Journal of Philosophy* 1, 5.

¹⁷⁸ Guttman & Thompson (n 174) 11.

¹⁷⁹ Fitzgerald has noted that there is “no straight line from mistaken moral judgment to radical defects of character”. Rather the views of others should be engaged with both scientifically and professionally. K Fitzgerald, ‘Human Embryonic Stem Cell Research: Ethics in the Face of Uncertainty’ in N Snow, *Stem Cell Research: New Frontiers in Ethics and Science* (Notre Dame Press 2003) 44.

¹⁸⁰ NBAC Report (n 81), 51.

¹⁸¹ Guttman & Thompson (n 174) 28.

¹⁸² Presidential Commission for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies* (2010) 151.

¹⁸³ Ibid 154.

Commission carry out consultations with parties concerned “in order to ensure that the Union's actions are coherent and transparent”.

In the stem cell context, a reasoned debate should focus on the justifications each side has for their views. Proponents of ESCR are likely to be in favour of the research due to its potential for advancing medical science. Opponents of ESCR may indicate that while they are not anti-science or anti-research, they are not in favour of research that devalues human life, which they believe is one implication of embryo destructive research. While both sides are unlikely to resolve their core differences, they will at least understand the other’s viewpoint. This echoes what Brownsword has noted when he states that “if society is to get away from trench warfare between the rival constituencies” both sides of the debate must get away from their entrenched and at times extreme views and begin a discussion towards a reasoned outcome.¹⁸⁴

Following this understanding the debate can move to the core issue of determining the status of the embryo and the legal status of ESCR. Despite having opposing views on ESCR, both sides of the debate are likely to agree that the embryo is deserving of some level of protection. For some it should be absolute protection, equivalent to that of a human being while for others protecting or respecting the embryo may mean that the embryo may only be used for research for the most serious diseases. The issue thus becomes the level of protection that the law should afford the embryo.¹⁸⁵ Indeed the National Bioethics Advisory Commission has stated that the debate should not be set as being between those who believe that the embryo has a right to life against those who believe that the embryo has little or no moral status as if it is framed in this particular way there will be no resolution.¹⁸⁶

A final point to note is that while the focus is on common ground, during the debate and reasoning process, it is likely that more areas of agreement will begin to emerge. For instance during the debate on the Human Fertilisation and Embryology Act 1990, it was found that the prolonged period of debate from the Warnock Report to the debates in Parliament resulted in an increasing amount of common ground.¹⁸⁷

4.2 From Consensus to Compromise

Democratic deliberation recognises that there are differences that cannot be eliminated irrespective of deliberations. These differences can involve disagreements when it is not clear which side is clearly right or wrong, and furthermore, involve arguments that cannot reasonably be rejected.¹⁸⁸ In such a situation each side must attempt to discuss their position with a view to minimising differences but accept differences if they persist. Guttman and Thompson give the example of the debate on gay marriage and the resulting decision as to

¹⁸⁴ Brownsword (n 146), 129.

¹⁸⁵ The National Bioethics Advisory Commission similarly stated that “there may be a sufficiently broad consensus regarding the respect to be accorded to embryos to justify, under certain conditions, not only the research use of stem cells but also the use of embryos remaining after infertility treatments to generate ES cells”. NBAC Report (n 81) 51

¹⁸⁶ Ibid.

¹⁸⁷ HC 2 April 1990, Column 914-915.

¹⁸⁸ Guttman & Thompson (n 151) 28.

how the process may be carried out. In acknowledging that both heterosexual and homosexual couples should have the option of entering into marriage should they wish to do so, states do not force religions to permit homosexual unions.¹⁸⁹ Thus any legislation on same sex marriage will apply to civil unions only.

The problem for policy makers is what they should do in the event that a consensus on all issues does not emerge. While Guttman and Thompson dislike the political bargaining process, there is likely no other mechanism in which the dispute can be politically resolved and legislators should acknowledge this.¹⁹⁰ In discussing the work of the US Human Embryo Research Panel, Charo was critical of the Panel's failure to acknowledge that it is not possible for a government to decide the status of the embryo. He believes that if the Panel had accepted this and stated that part of its work was an attempt at a compromise to the differing views of the status of the embryo, the Report would have received less criticism.¹⁹¹

Due to the differing views on ESCR, it is unlikely that any decision on the status of the embryo will not be without its critics. However, the public acknowledgment by legislators that they are seeking a compromise to any issues which have not yet received agreement is the correct path to take. This makes it clear that rather than taking a moral stance on what they believe to be the status of the embryo, they are making a decision which the majority of the public is most likely to accept. While the public may not appreciate the difference between ethics and politics, legislators must make it clear that they have made a decision based on what emerged through the process of democratic deliberation; any issues which could not be resolved came as a result of political bargaining between the differing groups. Indeed, Chowcat argues that the public has the right to know the basis on which such decisions are made.¹⁹²

In the stem cell context, it is possible that there is a point at which political bargaining becomes a feature with one, or both, sides agreeing to compromise some of their views. Thus while policy makers should aim to achieve a consensus among the stakeholders of the debate, this consensus does not mean complete agreement on every issue and may involve some compromise.¹⁹³ For example in the abortion context, many who are morally opposed to abortion did not wish it to be prohibited in law.¹⁹⁴

¹⁸⁹ Ibid 28-9.

¹⁹⁰ The Irish Civil Partnership and Certain Rights and Obligations Act 2010 did not entitle homosexual couples to marry but permits civil partnership. In passing the Act, Deputy Ciaran Cuffe (who was a member of the Green Party which was the junior coalition partner) stated that while the legislation did not go as far as the Green Party had hoped, it was a step in the right direction for equal rights which would take years to achieve. "Civil Partnership Bill passes through Dáil" Thursday 1 July 2010 <<http://www.rte.ie/news/2010/0701/gay.html>> accessed 19 June 2012. Thus while the Green Party may have wished to go further in the drafting of legislation, they were limited by a desire to ensure that the public would approve of the legislation generally, they also had to balance their beliefs with those of their coalition partners.

¹⁹¹ Charo (n 157) 12.

¹⁹² I Chowcat, 'Moral Pluralism, Political Justification and Deliberative Democracy' (2000) 48 *Political Studies* 745, 756.

¹⁹³ Petit (n 35) 308.

¹⁹⁴ Beauchamp & Walters (n 46) 31.

However, while this process may go some way to achieving a consensus either through the collaborative decision-making process or political bargaining, it is likely that some stakeholders in the stem cell debate will be unwilling to compromise. They may explain their views, respect alternative views and engage in the debate; yet their views may be so strongly held that they are unwilling to accept anything other than a recognition of full moral status of an embryo in law (for example). It is at this point that policy makers must act and implement legislation based on the discussions arising from the deliberations. It is possible that there is a consensus amongst the majority of stakeholders, and policy makers are likely to proceed based on this majority as this is politically expedient and will ensure that the majority of the population is in agreement with its policy. For those not in agreement with the policy, it must be borne in mind that the process is dynamic, the law can be revisited in future when the potential of the research is fully understood and thus both sides have the opportunity to once again put forward their viewpoints.¹⁹⁵

5. Conclusion

It is clear from the foregoing discussion that ethical consensus on the status of the embryo is not possible. Differing ethical viewpoints ascribe differing levels of moral status to the embryo and at differing times in its developmental process. The debate is further hindered by the uncertainty surrounding the science. The only certainty based on current scientific knowledge is that the embryo will be destroyed in the research; the potential of the research is potential only and may never be realised.

The concept of the moral status of the embryo will vary across society and may depend on competing interests such as religious teachings and moral values, as well as other issues such as the value placed on scientific progress. Should policy makers adopt one ethical viewpoint, they risk alienating other members of the public who do not agree with their ethical justification and furthermore, they risk grounding their decision in a theory that can easily be discarded.

The value of a discussion on the moral status of the embryo lies in identifying whether society is liberal or conservative in its approach to ESCR. Once this is identified, policy makers should not concern themselves with this debate, but rather focus on the legal status of the embryo and ESCR. To achieve this end, the process of democratic deliberation should be adopted to ensure that the debate is reasoned and focuses on common ground. As the National Bioethics Advisory Commission stated:

¹⁹⁵ Childress has argued that the ESCR debate should be revisited as the science develops and the ethical implications become clearer. J Childress, 'An Ethical Defence of Federal Funding for Human Embryonic Stem Cell Research' (2001-2002) 2 *Yale Journal of Health Law and Policy* 157,163. The European Group on Ethics also proceeds on the basis that its analyses are not permanent but can change according to developments in society and science. General Report on the Activities of the European Group on Ethics in Science and New Technologies to the European Commission 2000 – 2005 at vi.

“Although many of the issues remain contested on moral grounds, they co-exist within a broad area of consensus upon which public policy can, at least in part, be constructed.”¹⁹⁶

This process acknowledges that at times a consensus may not be achieved, but by focusing on areas of agreement and justifying a decision, it is more likely that a decision will be acceptable to those who do not necessarily disagree with the decision. Furthermore this process seeks, although does not necessarily achieve, consensus without requiring those involved in the process to abandon their philosophical, moral or religious beliefs.¹⁹⁷ While those engaged in debates surrounding abortion or ESCR may have very polarised views, this process attempts to reconcile both sides of the debate with one another so that they at least respect one another’s viewpoints and also create an environment in which active debate is encouraged. It is a process that, at its core, seeks to get all sides of the debate to reach a collaborative decision on policy.

¹⁹⁶ NBAC Report (n 81) at ii.

¹⁹⁷ F Ankersmith, ‘Representational Democracy An Aesthetic Approach to Conflict and Compromise’ (2002) 8 *Common Knowledge* 24, 40.

Part II: The International Regulation of Embryonic Stem Cell Research

Chapter 2: The Regulation of Embryonic Stem Cell Research: An Overview

1. Introduction

Having established the necessity of regulating ESCR, and a process by which the legal status of the embryo and thus ESCR can be agreed, policy makers must next consider the regulatory regime for ESCR. The process of consulting with stakeholders through democratic deliberation will assist policy makers in establishing a regulatory framework, as the boundaries of the research will likely have been agreed. The role for policy makers is now to formulate a regulatory regime that reflects this discussion and that also conforms to the principles of “Better Regulation” and “smart regulation” as espoused by the European Commission.

European governance has evolved from a period of considerable regulation to the beginning of mass deregulation, as initiated by the Thatcher and Regan administrations.¹⁹⁸ While the tide has turned on deregulation, there is a refocus on the need for regulation and whether policy outcomes can be achieved through other means. Where state regulation is deemed to be necessary, policy makers are increasingly following the Principles of “Better Regulation”, or its successor “smart regulation”, as encouraged by the OECD and the European Commission.¹⁹⁹ By adopting these principles, policy makers ensure that regulations achieve the desired policy outcomes and also that state regulation only intervenes where necessary. Policy makers may thus look to other regulatory options such as market controls, self-regulation and co-regulation. Analysing these various forms of regulation under the principles of Better Regulation can aid policy makers in determining their suitability to form part of the regulatory structure for ESCR.

Part II of this thesis will analyse the various structures which are used to regulate ESCR internationally. In particular, it will focus on direct state intervention, such as legislation and regulatory authorities, and economic measures, such as the use of the patent system and the public funding of ESCR to regulate the industry. Each will be analysed under the principles of Better Regulation. To provide some context, this chapter will provide an overview of regulation and the factors that must be considered when regulating ESCR. In discussing the purpose of regulation it will discuss the origin and evolution of the principles of Better Regulation. Furthermore the importance of regulatory impact statements will be highlighted and the impact that regulatory impact reports may have on ESCR will be outlined. Finally,

¹⁹⁸ C Brown & C Scott, ‘Regulation, Public Law and Better Regulation’ (2011) 17 *European Public Law* 467, 468.

¹⁹⁹ *Ibid.*

there will a discussion of the regulatory tilt and the regulatory mix and the need to establish both as part of the ESCR regulatory framework.

2. Main purpose of Regulation

While definitions of regulation may differ, at its core, regulation is concerned with controlling behaviour. A House of Lords Select Committee report has argued that regulation can be broadly divided into three categories: “economic regulation aimed at controlling the abuse of monopoly power; regulation of public goods and external effects, such as environmental pollution; and social regulation”.²⁰⁰ Whether one agrees with this break-down, common to all three types of regulation is the need to control certain activities or behaviour. This control may manifest itself through either the prohibition or permitting of certain activities, but irrespective of its purpose, regulations will seek to manipulate a particular aspect of social behaviour. In the stem cell context, the purpose of regulation may be to prohibit or permit the research within certain boundaries. A particular challenge for policy makers seeking to permit the research is balancing the legal, social and ethical concerns with their desire to encourage innovation.²⁰¹

A narrow conception of regulation focuses solely on state-sanctioned actions to influence behaviour, be it through the adoption of legislation or the enforcement of legal rules.²⁰² As Galligan describes it, regulation “means simply the use of law and legal techniques to supervise an area of activity”.²⁰³ Thus, for example, if the government sought to increase the use of seat belts, criminal sanctions could be imposed for a failure to wear seatbelts. A narrow definition of regulation may therefore be any deliberate attempt by the state to influence social behaviour which may have potential negative side-effects by monitoring, establishing and enforcing legal rules.

On the other hand, a broad view of regulation encompasses all forms of social control, regardless of whether it is imposed by a state actor or some other social institution.²⁰⁴ It may cover “any form of controlling or channelling strategy”²⁰⁵ irrespective of whether this attempt to control is initiated by the government or some other group. As Scott has stated, “governments do not and cannot regulate everything”.²⁰⁶ Similarly Braithwaite argues that

²⁰⁰ House of Lords, Select Committee on the Constitution, *The Regulatory State: Ensuring its Accountability*, 6th Report of Session 2003-04 at 12. Similarly the European Commission has stated that “public authorities can take regulatory action by setting standards, by levying taxes and charges, by financing specific actions and groups, or by providing information and advice”. European Commission <http://ec.europa.eu/governance/better_regulation/instruments_en.htm> accessed 20 January 2013.

²⁰¹ A Naimark, ‘Biotechnology, Innovation and Health’ (2006) 32 *Canada-United States Law Journal* 220, 221.

²⁰² B Morgan & K Yeung, *An Introduction to Law and Regulation: Text and Materials* (Cambridge University Press 2007) 3.

²⁰³ D Galligan, ‘Citizens’ Rights and Participation in the Regulation of Biotechnology’ in F Francoini *Biotechnologies and International Human Rights* (Hart Publishing 2007) 336.

²⁰⁴ Morgan & Young (n 187) 3. Koops *et al* describe regulation as “controlling human or societal behaviour by rules or restrictions. It can have many different forms: government regulation (laws and decrees), co-regulation, self-regulation and market regulation, or social regulation, etc.” B Koops, M Lips, C Prins & M Schellekens, *Starting Points for ICT Regulation* (Asser Press, 2006) 81.

²⁰⁵ R Brownsword, *Rights, Regulation and the Technological Revolution* (OUP 2008) 8.

²⁰⁶ C Scott, ‘Regulating Everything’ *UCD Geary Discussion Paper* (2008), 7.

the regulation overseen by government is “but the tip of the iceberg”²⁰⁷ as social norms and market forces, such as the price of goods or services, can control behaviour without the need for legal rules. It is thus unsurprising that it has been noted that a lack of regulation by public authorities does not necessarily result in a regulatory void.²⁰⁸ Returning to the seatbelt example, under a broader view of regulation a public education campaign highlighting the risks of not wearing seatbelts, or charging those injured in a car accident for their medical expenses if they did not wear their seatbelt, could be considered as alternatives to criminal sanctions.²⁰⁹

Further regulation can also include not only controlling individuals behaviour, but also the effect of individual’s behaviour on society.²¹⁰ For example, a law will not prevent you from breaking your own vase but may prevent you from breaking someone else’s vase.²¹¹ In the stem cell context, this is of importance as governmental regulation of the technology may be to influence the moral beliefs of the public. Thus the purpose of regulating ESCR may be to ensure that the moral principles of society are preserved.

For the purposes of this thesis, the broader view of regulation will be adopted. This recognises, as Grabosky has stated, that public policy can no longer be understood as originating from either solely private or public institutions, but should be understood as being a blend of public and private frameworks.²¹² While the view of regulation adopted here will consider the traditional command and control regulation, it will also consider social norms and the role of the market in regulating ESCR. This is due to the important impact that ESCR public funding policies and also both national and international patenting policies have had on the regulation of ESCR globally. Furthermore, such an approach is consistent with Scott’s concept of a regulatory regime, which he defines as “the aggregation of the activities of those whose actions shape behaviour within a particular set of activities”.²¹³ This involves an examination of an issue, in this case embryonic stem cell research, and the factors that will influence that research, rather than merely an examination of the rules.²¹⁴ Thus, for Scott, the importance of regulation lies not only in the rules that govern the behaviour of relevant social actors but how regulation occurs.²¹⁵ Taking such an approach will ensure a deeper understanding of how regulatory regimes evolved internationally.

²⁰⁷ V Braithwaite, ‘Ten Things You Need to Know about Regulation and Never Wanted to Ask’ (2006) RegNet Occasional Paper No. 10, available at <<http://ctsi.anu.edu.au/publications/occasionalpapers.htm>> accessed 29 November 2012.

²⁰⁸ J Blundell & C Robinson, *Regulation Without the State* (The Institute of Economic Affairs 1999) 13.

²⁰⁹ This seatbelt example has been provided by Brownsword. Brownsword (n 190) 8

²¹⁰ Koops, Lips, Prins & Schellekens (n 204) 83.

²¹¹ Ibid.

²¹² P Grabosky, ‘Using Non-governmental Resources to Foster Regulatory Compliance’ (1995) 8(4) *Governance* 527, 529.

²¹³ Scott (n 206) 7.

²¹⁴ Scott notes that in Ireland, for example, there is a regime regulating the safety of food, smoking in public places and also the quality of teaching and research in universities. These regimes are only partly shaped by legal rules and involve other forms of control. Ibid 1-2.

²¹⁵ Ibid 7.

2.1 Principles of Good Regulation

In the past, there has been a perceived notion that the solution to any crisis is the introduction of state regulation. This attitude muted any potential voluntary response.²¹⁶ Since the late 1990s, there has been a move within the EU and its Member States towards reducing bureaucracy and improving the regulatory process.²¹⁷ This movement has also sought to reduce the burden on businesses,²¹⁸ which should lead to a reduction in the costs for businesses. To achieve this end, the EU has begun to devote time to improving its legal proposals, reducing unnecessary or over-lapping rules and making its laws more understandable.²¹⁹ This is part of an attempt to improve European governance, and the reform of European governance was identified as a strategic objective by the European Commission in 2000.²²⁰ It has also become a feature of many international organisations such as the OECD, the World Bank, the International Labour Organisation (ILO) and the IMF.²²¹ This improved governance focuses on participation and power sharing, multi-level integration, diversity and decentralisation, flexibility and revisability, deliberation and experimentation and knowledge creation.²²² It has emerged due to, amongst other issues, the increasing complexity and uncertainty of issues, irreducible diversity, legitimacy concerns and new approaches to public administration and law.²²³

This drive towards good governance has become known as “Better Regulation” and it covers the entire process from the initial conception, to implementation and enforcement.²²⁴ It describes the desire of governments to ensure that government policies are created using the correct tools and that they achieve the desired outcomes.²²⁵ The Commission is of the opinion that this has led to improvements in how it makes policies and proposals to regulate.²²⁶

The concept of Better Regulation has emerged from combining the American tool of regulatory impact assessments (RIA) with European initiatives of simplification and

²¹⁶ Blundell & Robinson (n 208) 13.

²¹⁷ The Better Regulation movement began in the UK with the publication of the White Paper, *Lifting the Burden*. R Baldwin, ‘Is Better Regulation Smarter Regulation?’ [2005] *Public Law* 485, 485.

²¹⁸ C Brown & C Scott, ‘Regulation, Public Law and Better Regulation’ (2011) 17 *European Public Law* 467, 469.

²¹⁹ Commission, ‘Better Regulation-Simply Explained’ (2006) 3.

²²⁰ Commission, ‘European Governance: A White Paper’ COM (2001) 428 final, 3.

²²¹ C Harlow, ‘Law and Public Administration: Convergence and Symbiosis’ (2005) 71 *International Review of Administration Sciences* 279, 288. For example, see The OECD Reference Checklist for Regulatory Decision-Making.

²²² J Scott & D Trubek, ‘Mind the Gap: Law and New Approaches to Governance in the European Union’ (2002) 8 *European Law Journal* 1, 5-6.

²²³ *Ibid* 6-8.

²²⁴ Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, ‘A Strategic Review of Better Regulation in the European Union’ COM (2006) 690 final, COM (2006) 691 final.

²²⁵ Commission (n 204) 3.

²²⁶ Commission communication, ‘Smart Regulation in the European Union’ COM (2010) 543.

standardisation.²²⁷ Its purpose is to ensure that there is good governance within the regulatory state²²⁸ and to reduce the perceived growth in regulatory burdens on businesses.²²⁹

In the 2001 Mandelkern Report on Better Regulation, which forms the basis of better regulation within the EU, the seven common principles for better regulation were set out. They are: necessity, proportionality, subsidiarity, transparency, accountability, accessibility and simplicity.²³⁰

(i) Principle of Necessity

The principle of necessity requires that prior to the introduction of a new policy, it must be determined whether the regulations are in fact necessary. This will involve an examination of the various forms of public actions, other than legislation, that may achieve the desired aims.²³¹ The UK Better Regulation Task Force (BTRF) has noted that, too often, the response is that we need to regulate, rather than determining whether this is in fact the best way to resolve a problem.²³²

(ii) Principle of Proportionality

The regulations must be proportional to their aims and a balance must be struck between the advantages of the regulations versus the constraints that they impose. In considering the various regulatory instruments, the Commission and the Member States must opt for the regulatory instrument that is most proportional to their aims; or as the House of Lords Select Committee has stated, regulation must achieve “the desired outcome in the most effective and least burdensome way”.²³³ To achieve this end, there must be consideration of the various instruments such as primary and secondary regulation, framework directives and co-regulation.²³⁴

(iii) Principle of Subsidiarity

The principle of subsidiarity ensures that decisions are taken at the level closest to the citizen. Thus, if the objectives of the regulations can be better met by action at a Member State level, this must be opted for over EU action.²³⁵

(iv) Principle of Transparency

The regulations must be transparent and all interested stakeholders must be given the opportunity to participate in the process prior to the introduction of the regulations.²³⁶ This

²²⁷ J Wiener, ‘Better Regulation in Europe’ (2006) 59 *Current Legal Problems* 447, 452.

²²⁸ *Ibid* 458.

²²⁹ Brown & Scott (n 218) 468.

²³⁰ Mandelkern Report on Better Regulation (2001) i.

²³¹ *Ibid* 9.

²³² Better Regulation Taskforce, *Imaginative Thinking for Better Regulation* (2003) para 4.1.

²³³ House of Lords (n 200) 15.

²³⁴ Mandelkern (n 230) 9.

²³⁵ *Ibid*.

²³⁶ *Ibid* 10.

not only conforms to the principles of democratic deliberation,²³⁷ but it also ensures that potential side-effects of regulations, which may be unforeseen to policy makers, may be raised and addressed at an early stage. The importance of transparency in regulating biotechnology was stressed in the 2002 strategy on life sciences and biotechnology where the European Commission stated that more transparency was required in how regulators dealt with risk.²³⁸ Thus the Commission is advocating for transparency throughout the regulatory process and not only in the drafting of regulations.

(v) Principle of Accountability

The principle of accountability requires that the policies and the parties which the policies are intended to affect are clearly identified. Where there is difficulty in implementing the regulations, the party overseeing the regulations must be informed so that they may be amended.²³⁹ It has been noted that one risk of delegating regulation to private groups is the potential loss of accountability, as these groups are not accountable to the public and the democratic process.²⁴⁰

(vi) Principle of Accessibility

The regulations must be accessible and understood by those they intend to regulate. This is important to ensure that the regulations are implemented and complied with. This may involve additional work on behalf of the regulators to ensure that relevant groups are aware of the regulations as, due to their individual situation, they may have difficulty in asserting their rights.²⁴¹

(vii) Principle of Simplicity

The principle of simplicity requires that the regulations are simple and easy to both use and understand: “regulation should be as detailed as necessary and as simple as possible”. This can result in savings for all parties involved while also relieving the public administrative burden.²⁴²

The principles of Better Regulation have been adopted throughout Europe, although not in a uniform fashion. In the UK, the Better Regulation Task Force focused on five principles of better regulation: proportionality, accountability, consistency, transparency and targeting.²⁴³ In Ireland, however, there are six principles of Better Regulation: transparency, accountability, proportionality, consistency, effectiveness and necessity.²⁴⁴ These principles

²³⁷ See Chapter 1.

²³⁸ European Commission, ‘Life Sciences and Biotechnology: A Strategy for Europe’ COM (2002) 27, 23.

²³⁹ Mandelkern (230)10.

²⁴⁰ Grabosky (n 212) 537.

²⁴¹ Mandelkern (n 230) 10.

²⁴² Ibid.

²⁴³ See Annex B “The Five Principles of Good Regulation” in Better Regulation Task Force, ‘Regulation - Less is More Reducing Burdens, Improving Outcomes’ (2005).

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http://www.taoiseach.gov.ie/eng/Publications/Publications_Archive/Publications_2011/Better_Regulation_Web_site_Content.pdf accessed 9 September 2012.

represent a move away from an assumption that there is a need to introduce state regulation towards a system which seeks to determine the best way to deal with an issue. As a result of better regulation, the Commission has claimed that regulation is now simpler, with less red-tape and administrative burden for businesses.²⁴⁵ Although there are deviations at times, Member States have generally followed the principles.²⁴⁶

Recently, there has been a move away from Better Regulation, with the concepts of smart regulation and responsive regulation becoming vogue. At the core of the responsive regulation approach is the premise that the state is not always the most effective regulatory agency, as other actors may be in a position to regulate much more effectively.²⁴⁷ Policy makers will first seek to use less invasive strategies such as education or persuasion, and will gradually begin to use more stringent approaches to ensure compliance.²⁴⁸ The advantage of responsive regulation is that it seeks to determine the most suitable body to regulate a given issue,²⁴⁹ and it is built on three principles:

- First, all formal and informal regulatory strategies must be considered;
- Second, the strategies must be arranged in a hierarchy from the least intrusive to the most intrusive, with preference given to the least intrusive strategy that ensures compliance;
- Third, there must be dialogue about why regulation is necessary which aims to seek out a commitment to voluntary compliance in the future.²⁵⁰

Since 2010, the Commission's focus has shifted from responsive regulation to smart regulation. Under the Commission's definition, smart regulation is about "the whole policy cycle - from the design of a piece of legislation, to implementation, enforcement, evaluation and revision".²⁵¹ It aims to improve EU legislation, ensure that new legislation is the best possible and improve the implementation of EU legislation.²⁵² The focus in smart regulation is not on the regulatory strategy but rather achieving the goal of regulation through a *combination* of necessary regulatory strategies.²⁵³ As Johnson *et al* state "regulation is

²⁴⁵ Commission (n 224).

²⁴⁶ Wiener (n 227) 448.

²⁴⁷ S Hogarth, K Liddell, T Ling, S Sanderson, R Zimmermann & DD Melzer, 'Closing the Gap - Enhancing the Regulation of Genetic Tests Using Responsive Regulation' (2007) 62 *Food and Drug Law Journal* 831, 839.

²⁴⁸ R Baldwin & J Black, 'Really Responsive Regulation' (2008) 71 *Modern Law Review* 59, 62.

²⁴⁹ Hogarth, Liddell, Ling, Sanderson, Zimmermann & Melzer (n 247) 840. For more on the EU's Better Regulation Policy see Commission communication *Smart Regulation in the European Union* COM (2010) 543, Commission (n 224), Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Second strategic review of Better Regulation in the European Union COM (2008) 33 final, COM (2008) 35 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Third strategic review of Better Regulation in the European Union COM/2009/0015 final, Communication from the Commission - Action plan "Simplifying and Improving the Regulatory Environment" COM (2002) 0278 final.

²⁵⁰ Braithwaite (n 207).

²⁵¹ Commission communication *Smart Regulation in the European Union* COM(2010)543 (8 October 2010).

²⁵² *Ibid* at paras 2.1, 2.2, 2.3.

²⁵³ Brownsword (n 205) 14.

smartest when it chooses a mix of regulatory instruments that maximises the achievement of regulatory objectives at minimum cost”.²⁵⁴ By using multiple policy instruments, a regulatory strategy can be tailored to suit a particular problem.²⁵⁵

Smart regulation is now part of the EU 2020 Strategy whereby the Commission will consider the wider use of regulations rather than directives, launch ex-post evaluation of existing legislation, pursue market monitoring, reduce administrative burdens, remove tax obstacles and improve the business environment, particularly for SMEs and support entrepreneurship.²⁵⁶ In other words, a regime which adopts smart regulation, in theory, will adopt the best range of regulatory instruments.²⁵⁷ While smart regulation does look to a mix of regulatory instruments, it is arguably much the same as Better Regulation.²⁵⁸

2.2 Regulatory Impact Assessments

In parallel with the emergence of the principles of Better Regulation and smart regulation, the use of regulatory impact assessments (RIAs) has grown and has been described as being crucial to the reform of regulatory strategy within Europe.²⁵⁹ RIAs involve an examination of the current problem, whether the status quo suffices to deal with the issue, the identification of regulatory options and a consultation with the stakeholders.²⁶⁰ They can also identify the potential impacts of regulation on business costs, the environment and some social groups.²⁶¹ An Impact Assessment Board (IAB) is now in existence and its role is to provide advice and assistance in drafting RIAs within the Commission.²⁶² RIAs should be seen as integral to the regulation of biotechnology. Biotechnology often raises complex ethical issues, with innovations leading to new discoveries that can challenge our regulatory structures.²⁶³ RIAs ensure that policy makers take into consideration these complex issues in areas of rapidly developing science.

In outlining the potential impacts of policy options, the RIA assists in the creation of a regulatory strategy and has been described as “an effective tool for modern, evidence-based policy making”.²⁶⁴ In this way, it is thought that RIAs should result in improved regulatory policies and outcomes²⁶⁵ and they should aid rather than control the political decision making

²⁵⁴ M Johnson & K Petersen, ‘Instruments for ART Regulation: What are the Most Appropriate Mechanisms for Achieving Smart Regulation?’ in S Sclater, F Ebtehaj, E Jackson & M Richards (eds), *Regulating Autonomy: Sex, Reproduction and Family* (Hart Publishing 2009) 172.

²⁵⁵ N Gunningham, ‘Environmental Law, Regulation and Governance: Shifting Architectures’ (2009) 21 *Journal of Environmental Law* 179, 200.

²⁵⁶ EU2020 Strategy, 19.

²⁵⁷ Baldwin (n 2217) 485.

²⁵⁸ A Alemanno, ‘A Meeting of Minds on Impact Assessment: When Ex Ante Evaluation Meets Ex Post Judicial Control’ (2011) 17 *European Journal of Public Law* 485, 485.

²⁵⁹ Ibid 486.

²⁶⁰ F De Francesco, C Radaelli & V Troeger, ‘Implementing Regulatory Innovations in Europe: the Case of Impact Assessment (2012) 19 *Journal of European Public Policy* 491, 492.

²⁶¹ Mandelkern (n 230) 25.

²⁶² Commission (n 224).

²⁶³ G Hermerén, ‘Accountability, Democracy, and Ethics Committees’ (2009) 1 *Law, Innovation and Technology* 154, 163.

²⁶⁴ Mandelkern (n 230) 19.

²⁶⁵ Wiener (n 227) 460.

process.²⁶⁶ The 2009 Regulatory Impact Assessment Guidelines require the following steps to be taken:

- Identification of the problem;
- Defining the objectives;
- Develop main policy options;
- Analyse the impacts of the options;
- Compare the options;
- Outline policy monitoring and evaluation.²⁶⁷

The advantage of an RIA is that an analysis of regulations is done prior to the introduction of any regulations. There is thus opportunity for stakeholders to have influence at the creation of the regulations rather than attempting to alter after the introduction of a regulatory strategy.²⁶⁸ Furthermore any decision will be an informed decision, which has taken into consideration the potential costs of regulation. It has also been cautioned that RIAs open the Commission to scrutiny at the pre-legislative stage, where political bargaining has often been confidential.²⁶⁹ However, despite this concern, encouraging consultation with stakeholders conforms to the principle of democratic deliberation and can ensure that decisions are made as a result of consensus rather than political bargaining.²⁷⁰

RIAs can provide policy makers with a tool with which they can begin to formulate the best regulatory policy. Rather than being seen as another bureaucratic task, RIAs should assist the political process and provide a structured framework for considering policy problems and determining the most suitable response.²⁷¹ The European Commission now requires all major policy proposals to undergo an RIA, which has resulted in a knowledge-based approach whereby decisions are made as a result of evidence.²⁷² Similarly, boards such as the Office of Information and Regulatory Affairs (OIRA) in the USA, the Treasury Board Secretariat in Canada and the Better Regulation Executive and Regulatory Policy Committee in the UK are all tasked with reviewing regulations and whether they are required before they are passed. By conducting a RIA before a policy is put forward, there is the opportunity to explore alternative courses of action.²⁷³

²⁶⁶ Mandelkern (n 230) 25.

²⁶⁷ European Commission *Regulatory Impact Assessment Guidelines* (2009) at 5.

²⁶⁸ De Francesco, Radaelli & Troeger (n 260) 493.

²⁶⁹ Alemanno (n 258) 486.

²⁷⁰ For more on democratic deliberation see Chapter 1.

²⁷¹ Mandelkern (n 230).

²⁷² European Commission, 'Better Regulation-Simply Explained' (2006) 7.

²⁷³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Second strategic review of Better Regulation in the European Union COM (2008) 33 final, COM (2008) 35 final.

2.3 Regulatory Tilt

In drafting a regulatory framework, policy makers may wish to consider the regulatory tilt. This refers to the general permissiveness or restrictiveness of the regulatory framework²⁷⁴ and is thus concerned with the policy aims of the regulation rather than the regulatory tools adopted. The regulatory tilt may be similar to the general permissive or restrictive approach that policy should take, as decided through democratic deliberation, or it may be premised on caution. A restrictive approach may be taken due to social concerns regarding the research or where the eventual impact of the research on human nature or the environment is unclear. For example, the restrictive approach taken by the EU towards genetically modified foods is partly due to concerns regarding their environmental impact.²⁷⁵ In such a case, policy makers may opt to follow the precautionary principle, which means that caution should be taken when the scientific evidence is unknown, but there exists the possibility that a certain technology may be irreversibly damaging to the environment.²⁷⁶ On the other hand, the goal of public policy may be to increase innovation in the biotechnology industry and thus the regulatory tilt may be permissive and generally in favour of the research subject. China is one country that has adopted permissive ESCR regulations, and this has resulted in increased innovation in its biomedicine sector.²⁷⁷

The regulatory tilt can serve as an important interpretive tool for the courts when there is uncertainty as to the application of the regulations. In Germany, the regulations prohibit ESCR except in limited circumstances and thus, in the absence of explicit permission, it will be presumed that the activity is prohibited. On the other hand, the UK generally has a permissive ESCR regulatory framework where, in the absence of guidelines to the contrary, the regulatory tilt will be towards permission.²⁷⁸ Knowing the regulatory tilt is important for the courts, particularly when the law has failed to keep pace with the technology,²⁷⁹ as occurred in *R (Quintavalle) v Secretary of State*.²⁸⁰ Overall, if the regulatory tilt is generally permissive, then courts will likely determine that the default position is in favour of

²⁷⁴ Brownsword discusses this notion of a regulatory tilt stating:

“If the default position is set for prohibition, then the tilt is against permission. Conversely, if the default position is set for permission, then the tilt is against prohibition. Where the regulatory tilt is of the former kind, then ambiguities will be resolved in favour of prohibition and, similarly, where regulation is silent on a point, the presumption is that silence indicated prohibition.” Brownsword (n 190) 21.

See also R Brownsword, ‘Regulating Human Genetics: New Dilemmas for a New Millennium’ (2004) 12 *Medical Law Review* 14, 18.

²⁷⁵ Restrictive environmental regulation is often taken at short notice to protect the environment against chemicals which may be harmful to the environment but the risks of which are currently unknown. “Cloning Trojan Horses: Precautionary Regulation of Reproductive Technologies” in R Brownsword and K Yeung (eds), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Hart Publishing 2008) 222.

²⁷⁶ For more on the precautionary principle see Chapter 3.

²⁷⁷ D McMahon, H Thorsteinsdottir, P Singer & A Daar “Cultivating regenerative medicine innovation in China” (2010) 5(1) *Regenerative Medicine* 35, 39.

²⁷⁸ Brownsword (n 205) 21. Brownsword notes that the decision of the Opposition Division in the LELAND STANFORD/ Modified Animal case means that the regulatory tilt of patent regime under the EPO is in favour of granting patents. Brownsword (n 274) 28.

²⁷⁹ Brownsword (n 205) 21.

²⁸⁰ This case and its impact will be discussed further in Chapter 4.

permitting the research and that silence on a particular type of research should be interpreted as allowing the research.²⁸¹

However, courts should be mindful that there are exceptions to this rule and a general permissiveness towards research may not be due to the regulatory tilt, but rather due to deficiencies in the regulatory framework or poor regulatory oversight. For instance, it has been argued that the permissive policies adopted by the Chinese government concerning ESCR are not in fact as a result of a general permissiveness towards ESCR, but rather as a result of a weak regulatory framework. Such an approach does ignore the differing moral principles underpinning Chinese society,²⁸² which relies on Confucian ethics rather than the principles adopted in the Western world.

Finally there is the possibility that the regulatory tilt is neither permissive nor restrictive, but rather urges caution in the face of scientific uncertainty. Thus, while regulators may be generally in favour of the research, due to the uncertain impacts of the research, or concerns regarding the ethics of the research, the regulatory framework adopts a cautious approach towards it. This is known as the precautionary principle and will be explored further below.²⁸³

2.4 Regulatory Mix

Once the regulatory tilt and the general policy goals of the research are determined, policy makers must next decide the regulatory mix. This refers to the differing regulatory options policy makers may adopt to form part of the regulatory strategy. These may involve direct governmental regulations such as legislation or the appointment of regulatory authorities to oversee the research, or other indirect measures such as market controls or self-regulation.

Prior to determining the regulatory mix, there are a number of issues which are peculiar to biotechnology that policy makers should consider. Biotechnology is a rapidly developing technology which leaves policy makers with the challenge of ensuring that the regulatory strategy does not become outdated and thus have unintended consequences.²⁸⁴ While regulators may want “regulation to bind to the technology and to evolve with it”,²⁸⁵ whether this will be possible will depend upon the regulatory mix.

The traditional command and control system of regulating through legislation tends to be time-consuming due to the need to draft legislation and get it through parliament. On the other hand, soft law (such as codes of conduct) may not require input from parliament and thus is easier to change via the voluntary body from which the soft law norms emerged. The danger with such forms of regulation is that they often do not have the force of law and thus compliance may be harder to obtain. Policy makers will need to balance the need to ensure

²⁸¹ Brownsword (n 274) 18.

²⁸² McMahon, Thorsteinsdottir, Singer & Daar (n 262) 39.

²⁸³ See Chapter 3.

²⁸⁴ Brownsword has noted that due to the fast moving nature of science, there is a sense that the law is only provisional as it too must adapt to new developments. R Brownsword “Stem Cells, Superman, and the Report of the Select Committee” (2002) 65 *Modern Law Review* 568, 587.

²⁸⁵ R Brownsword, ‘So What Does the World Need Now? Reflections on Regulation Technologies’ in Brownsword & Yeung (n 274) 27.

the policy can be easily amended and respond to scientific developments with the need for sustainability in the law.²⁸⁶ In other words, policy makers will need to balance flexibility within the law with the need for predictability while also ensuring that the regulations adhere to the principles of Better Regulation.

3. Regulating Embryonic Stem Cell Research

Policy makers tasked with introducing ESCR regulations must first conduct a RIA. As consultation forms a part of this RIA, this process will build upon the principle of democratic deliberation. The RIA will determine costs associated with regulation and it may also outline the impacts of a failure to regulate. The Commission has stated that “societal scrutiny and dialogue” should be part of the development of the governance of life sciences and biotechnology.²⁸⁷ This is of particular importance for ESCR, which is often the subject of much controversy. Thus it is unsurprising that the Commission considers that science-based regulatory oversight should enhance public confidence.²⁸⁸ A regulatory process that begins by examining the potential impacts of the various policy options will ensure that the public can have confidence in the regulatory system.

Policy makers must next decide on the regulatory mix in regulating ESCR. The focus should be on whether direct legislation is necessary, or whether self-regulation will prove to be sufficient. Internationally, due to the complexity of issues involved in regulating biotechnology, regulators rely on a mix of regulatory options ranging from the traditional command and control methods of regulation, to economic factors and professional guidelines.²⁸⁹ In determining the regulatory mix, policy makers must not lose sight of the principles of Better Regulation and the final regulatory strategy must satisfy these principles. To aid this process, this thesis will later analyse the various models of regulating ESCR used internationally under the principles of Better Regulation. As this thesis aims to propose a regulatory structure suitable for Ireland, it will examine the regulatory strategies under the six principles of better regulation adopted by the Irish government. Briefly these principles are:

1. Necessity: The principle of necessity requires that regulation only occurs when it is required. Furthermore regulatory frameworks and institutions currently in place must be kept under review.
2. Effectiveness: Regulations must be targeted, enforced and complied with to ensure their efficacy.
3. Proportionality: Regulations should be imposed only where necessary and thus regulatory impact assessments must be carried out. Furthermore, the burden for complying, as well as the burden for non-compliance, must be fair.

²⁸⁶ It has been suggested that a general principle of law-making is that the law should be sustainable. Koops, Lips, Prins & Schellekens (n 204) 87.

²⁸⁷ European Commission *Life Sciences and Biotechnology: A Strategy for Europe* COM(2002) 27 at 17.

²⁸⁸ Ibid.

²⁸⁹ Hermerén (n 263) 154.

4. Transparency: Prior to regulation there will be a period of consultation to ensure that stakeholders in the debate can get involved. Regulations must also be clear, accessible and understood by those they seek to affect.
5. Accountability: It must be clear who the regulations seek to control, who is to enforce the regulations and what the appeals process is.
6. Consistency: The regulatory process must be predictable, with the rules enforced equally.²⁹⁰

Analysing the regulatory structures under these six principles will indicate their suitability to become part of the regulatory framework for ESCR.

4. Conclusion

The move towards the principles of Better Regulation and smart regulation has ensured that there is a focus on the entire life cycle of regulatory policy, rather than simply calls for government regulation in response to policy problems. The introduction of RIAs has resulted in not only a consideration of whether regulation is necessary, but also an analysis of the potential impact of various regulatory policies. In the ESCR context this is important as the RIA should illustrate not only the cost associated with regulation for scientists, but also the potential impact of introducing regulations on such a controversial issue such as ESCR. The adoption of the Better Regulation principles has provided policy makers with a framework through which regulations may be assessed. In moving forward with ESCR regulation, policy makers must not only be mindful of these principles, but set out a regulatory regime that conforms to these principles. To aid policy makers in the delivery of such a regime, this thesis will analyse the various regulatory regimes for ESCR under the principles of Better Regulation.

²⁹⁰ For more on these six principles see Department of the Taoiseach, *Regulating Better: A Government White Paper setting out six principles of Better Regulation* (2004).

Chapter 3 The Ethical Precautionary Principle

1. Introduction

Developments in technology have resulted in improved medicine as well as improvements in our daily lives. However, improved technology has often come at a cost and has led to increased risks of environmental damage as well as potentially damaging human health. These risks are not always clear, as scientific evidence may be inconclusive. Yet due to the *potentially* damaging effect of the technology, policy makers may seek to limit or restrain the use of that technology. This act of limiting the use of an activity due to potential, but uncertain, risk is known as the precautionary principle and it is often used as a mechanism by policy makers to protect the environment or human health. Simply put, it is a principle guided by the policy that it is better to be safe than sorry.²⁹¹

Over the past few decades the precautionary principle has become part of international and national legal structure, as a guiding principle in controlling the potentially damaging impact that human activity is having on the natural world.²⁹² The principle has emerged from an increase in environmental awareness amongst society since the 1970s, and is recognition that our technological capabilities exceed our ability to foresee the impact of our increasing capabilities.²⁹³ Despite the principle's long standing relationship with environmental policy, its remit has gone beyond that realm. It has recently been applied to the regulation of genetically modified organisms (GMOs) and it has been argued that the principle could also be applied to human genetics or any science which has a direct impact on humans.²⁹⁴

In the stem cell context the principle may have two applications. First, it could prevent the clinical application of stem cell therapies until it is certain that the therapies are risk-free.²⁹⁵ Second, the principle could be remodelled and applied where there is uncertainty as to whether the technology is ethical. This will be the focus of this chapter and will be termed the *ethical precautionary principle*. It will build upon the concept of deliberative democracy and seek to explain how the differing conservative, intermediate and liberal approaches to the moral status of the embryo and ESCR may manifest in public policy. In this way, it can explain the approaches countries have taken to their ESCR policy. The adoption of the ethical precautionary principle may prevent the use of certain sources of embryos for research and may restrict the use of the research for certain treatments only. Furthermore, as the potential therapeutic benefits of ESCR are currently uncertain, this too feeds into policy makers' decisions and as a result the application of the ethical precautionary principle, for ESCR, involves a combination of ethical uncertainty and scientific uncertainty.

²⁹¹ C Sunstein, 'The Paralyzing Principle: Does the Precautionary Principle point us in any helpful direction?' (2003) *Regulation* 32, 32.

²⁹² See Communication from the Commission on the Precautionary Principle COM (2000) 1, 8.

²⁹³ H van den Belt, 'Debating the Precautionary Principle: "Guilty until Proven Innocent" or "Innocent until Proven Guilty?" (2003) 131 *Plant Physiology* 1122, 1122.

²⁹⁴ R Brownsword, 'Making People Better and Making Better People: Bioethics and the Regulation of Stem Cell Research' (2005) 1 *Journal of Academic Legal Studies* 5, 10.

²⁹⁵ *Ibid.*

Much like the precautionary principle is adopted when the risks associated with a technology are unknown, the ethical precautionary principle will be adopted where the ethics of a new technology are uncertain. In the stem cell context, this precaution can take the form of an outright ban, as has occurred with reproductive cloning, or permitting research but within restrictive confines, such as the current stem cell research policy in Germany. The principle may be adopted in response to public fears that an ethical line will be crossed if certain research is permitted, from which there is no going back. In the stem cell context, the ethical concern is the destruction of the embryo, which many view as human life. For others, the concern is that the patenting of research arising out of ESCR may indirectly lead to the commercialisation of human life.²⁹⁶ As previously illustrated, there may be no agreement on the moral status of the embryo and thus the ethical implications of the research. Yet the fear that embryonic stem cell research could potentially cross an ethical Rubicon is nevertheless present and real for many people. The issue for policy makers to resolve is whether the ethical concerns of some people should trigger the precautionary principle when introducing embryonic stem cell research regulations.

This chapter aims to discuss the idea of ethical precaution as a potentially key regulatory principle for ESCR. A brief overview of the meaning of the precautionary principle and its use internationally will first be offered. The application of this principle in the areas of environmental policy and biotechnology will then be analysed. An attempt to adapt the current principles of precautionary regulation will be made in order to see if it can be adapted to guide regulation where the ethical principles are uncertain. Finally, this chapter will suggest ways in which the ethical precautionary principle can be used to regulate stem cell research.

2. The Precautionary Principle

As previously noted, the precautionary principle occurs when policy makers opt to take preventative measures against a particular damage if it is thought that there will be lasting damage. The damage in question is generally environmental damage. The precautionary principle has also been adopted in other areas and often by people in their everyday lives. For example, many people take out health insurance, car insurance, wear seatbelts or refuse to walk in areas that are known to be dangerous in cities. Arguably the principle has been adopted into criminal procedure whereby the bail requirements guard against a suspect fleeing the jurisdiction.²⁹⁷

There are both weak and strong versions of the principle.

Under the “strong” version of the principle, regulation is required if there is a risk that the technology is harmful to public health or the environment (for example), even if that risk is speculative and the science uncertain.²⁹⁸ In other words, the precautionary principle should be

²⁹⁶ For more on the patenting of ESCR, see Chapter 5.

²⁹⁷ J Remy Nash, ‘Standing and the Precautionary Principle’ (2008) 108 *Columbia Law Review* 494, 517.

²⁹⁸ Sunstein (n 291) 33. An example of a strong version of the principle is the Wingspread Consensus Statement on the Precautionary Principle:

the default response to serious risks when there is scientific uncertainty.²⁹⁹ However, it is argued that the principle in its “strong” version is incoherent as there are risks on all sides of social situations,³⁰⁰ thus the introduction of a strong version of the principle brings risks, risks that the introduction of the principle is seeking to avoid. One such example is the use of Dichlorodiphenyltrichloroethane (DDT), which has been proven to be a cheap and effective method of treating malaria. It has also been linked with the decline of raptors internationally. Had the precautionary principle been applied to DDT, it would have had to be banned to preserve the number of raptors. This however would have led to a rise in malaria. In such a situation, irrespective of the choice of policy makers, there will be some risk involved.³⁰¹ A similar problem has arisen with what is known as the ‘drug lag’. Policy makers usually take a highly precautionary approach to the introduction of new drugs and require that they undergo a series of clinical trials and tests prior to their introduction onto the market. This is to ensure that the public is not adversely affected by any new drug or treatment. The consequence of such an approach is that it causes delay in getting drugs to the market and thus deprives people from receiving potentially life-saving drugs.³⁰²

A “weak” version of the precautionary principle would require strong evidence of the threat of environmental damage before there would be government intervention, thus it does not preclude the possibility of government intervention.³⁰³ The US government has generally adopted the weak approach to the precautionary principle, particularly in relation to environmental policy. However, both the US and Canada are opposed to the precautionary principle becoming a principle of customary international law.³⁰⁴

3. The Precautionary Principle in International and European Law

The precautionary principle has become a mainstay of environmental declarations since the Rio Declaration of 1992.³⁰⁵ The principle came to the fore in 1998 at the Wingspread Conference on the Precautionary Principle. This was followed by the Cartagena Protocol on Biosafety in 2000, which enshrined the principle in the use of GM organisms,³⁰⁶ and the principle has now become part of the EU Treaties:

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”

²⁹⁹ N Sachs, ‘Rescuing the Strong Precautionary Principle from its Critics’ (2011) *University of Illinois Law Review* 1285, 1295.

³⁰⁰ C Sustain, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge University Press 2005) 4.

³⁰¹ I Goklany, *The Precautionary Principle: A Critical Appraisal of Environmental Risk Assessment* (Cato Institute 2001), 1.

³⁰² Sustain (n 291) 25.

³⁰³ Sachs (n 299) 1295.

³⁰⁴ A Trouwborst, *Evolution and the Status of the Precautionary Principle in International Law* (Kluwer Law International 2002) 280.

³⁰⁵ Principle 15 of the Declaration states:

“In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

³⁰⁶ Article 1 states:

“Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.”³⁰⁷

Prior to the formal adoption of the principle by the European Commission, the ECJ considered the principle.³⁰⁸ The Court noted

“Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.”³⁰⁹

The precautionary principle has been criticised as being ambiguous³¹⁰ and being more of an idea rather than a clearly-defined concept.³¹¹ In 2000 the European Commission published a communication on the use of the precautionary principle. Its purpose is to provide guidance for the implantation of the principle to ensure that decisions are made in a proportionate, non-discriminatory, transparent and coherent manner while also providing the chosen level of protection. The Communication stated that a structured decision-making process was required to deal with the scientific and objective information which considers the three elements of risk analysis:

“the assessment of risk, the choice of risk management strategy and the communication of the risk”³¹².

So as to avoid an excessive application of the precautionary principle, the Commission’s communication detailed factors that would trigger the use of the principle. It stated there

“In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.”

³⁰⁷ Article 191(2) of the TFEU states:

In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a procedure of inspection by the Union.”

³⁰⁸ For an overview of the development of the principle in EC law, see A Alemanno, ‘The Shaping of the Precautionary Principle by the European Courts: From Scientific Uncertainty to Legal Certainty’ *Bocconi Legal Studies Research Paper No. 1007404* <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=956952&rec=1&srcabs=1007404&alg=1&pos=1> accessed 27 January 13.

³⁰⁹ *United Kingdom v Commission* Case 180/96 UK v Commission ECR I-3903, para 99.

³¹⁰ G Majone, ‘What Price Safety: The precautionary principle and its policy implications’ (2002) 40(1) *Journal of Common Market Studies* 89, 89.

³¹¹ *Ibid* 93.

³¹² Commission (n 292) 8. In June 2003, the Board of Supervisors of the City and County of San Francisco adopted the precautionary principle as the basis for all of its environmental policy making it the first governmental body within the United States to do so. <<http://www.sehn.org/precaution.html>> accessed 19 October 2012. Majone has argued that the Commission’s definition of the precautionary principle is more permissive than that in the Rio Declaration. Majone (n 310) 94.

should be a scientific evaluation of the potentially negative effects of the technology based on current scientific knowledge.³¹³ However, this risk assessment is likely to be inconclusive as there may be insufficient data, or the current scientific knowledge may be uncertain as to the risk posed.³¹⁴ Furthermore it is argued that uncertainty is inherent in science as “certainty in science is the exception rather than the rule”.³¹⁵ Policy makers must thus assess the potential consequences of inaction based on this incomplete data to determine whether they should act in accordance with the precautionary principle.³¹⁶

Should policy makers opt to act based on the precautionary principle, the following must be adhered to:

1. The response must be proportionate to the level of protection required;³¹⁷
2. It must be applied in a non-discriminatory fashion so that similar situations are treated the same;³¹⁸
3. It must be consistent with measures adopted in similar situations;³¹⁹
4. There should be a cost-benefit analysis of inaction which can include an analysis of the economic and socio-economic impact;³²⁰ and
5. The measures should be re-examined when there is new scientific data.³²¹

While the use of the precautionary principle can be justified on the grounds that without it there may be lasting environmental damage, strong versions of the principle can have an impact on technological innovation, which may impact economic development.³²² Thus a cost-benefit analysis of the application of the precautionary principle may be necessary. This analysis may be useful in guiding policy makers and can ensure that both the benefits and the risks associated with a new technology are examined.

This analysis should begin with a risk assessment of the impact of the new technology, an assessment that the Commission considers should be based on all existing scientific and statistical data.³²³ It must be noted, however, that due to the inherent uncertainty that often triggers the precautionary principle, the risks associated with the new technology may also be unclear or uncertain. This risk assessment should identify the negative effects of the new technology and this should be done by scientific evaluation.³²⁴ Furthermore the evaluation

³¹³ Commission (n 292) para 5.1.1-5.1.2.

³¹⁴ Ibid para 5.1.3.

³¹⁵ Goklany (n 301) 8.

³¹⁶ Commission (n 292) para 6.2.

³¹⁷ Ibid para 6.3.1.

³¹⁸ Ibid para 6.3.2.

³¹⁹ Ibid para 6.3.3.

³²⁰ Ibid para 6.3.4.

³²¹ Ibid para 6.3.5.

³²² New Zealand Treasury, *Environmental Risk Management in New Zealand – Is There Scope to Apply A More Generic Framework?* (July 2006) 3.

³²³ Commission (n 292) para 6.

³²⁴ Ibid para 5.1.1.

should also consider measures necessary to protect the environment or human health.³²⁵ The net result of this evaluation should be an identification of not only the risk associated with the new technology, but also the activities that can prevent or minimise the risk. While the risks discussed may only be potential risks, the lack of scientific certainty as to the impact of the technology must not stand in the way of a comprehensive scientific evaluation.³²⁶ Despite the potential uncertainty of the risks, the European Commission has stated that the precautionary principle may be implemented if some risks associated with a new technology are identified, but scientific uncertainty makes it hard to ascertain the precise nature of the risk.³²⁷

The focus on the scientific evaluation as part of the risk analysis ensures that scientific risks are taken seriously, and the European Commission has stated that scientific information is at the heart of the use of the precautionary principle where safety is an issue.³²⁸ Furthermore the principle does not always assume that developments in technology are always beneficial and thus should be permitted. Rather technological progress cannot come at the expense of the environment or human health.³²⁹

This assessment of risk may now form part of the impact assessment, with the Commission's guidelines on impact assessment requiring the economic, social and environmental impacts of proposed policy to be considered.³³⁰ Furthermore, a risk assessment must be carried out as part of the IA. In particular, where the risks concern the environment or human and animal health, an application of the precautionary principle may be the first step in the assessment of risk.³³¹

4. Assessing Risk

Problems with the precautionary principle can emerge in the assessment of risk. In particular, an inadequate assessment of risk can lead to risk bias and probability neglect. Risk bias occurs when there is a biased opinion that a certain risk will occur, such as a natural disaster.³³² This risk bias can be triggered by reporting certain risks, which, no matter how remote, can heighten the public's fears and result in unnecessary regulation.

A further problem in assessing risk is when the focus is on the "worst case scenario" rather than the probability that an event will occur.³³³ This is known as probability neglect and can lead to situations in which the probable outcome is ignored in favour of the potentially worse outcome. In order to avoid probability neglect, there must be an objective assessment of risk. However, for some, no objective assessment of risk will reduce their fears. One such example is nuclear technology, where opponents focus on its catastrophic potential, as one accident

³²⁵ Ibid para 5.1.2.

³²⁶ Ibid.

³²⁷ Ibid para 5.1.3.

³²⁸ European Commission, *Life Sciences and Biotechnology: A Strategy for Europe* COM(2002) 27, 22.

³²⁹ C Gollier, B Jullien & N Treich, 'Scientific Progress and Irreversibility: An Economic Interpretation of the 'Precautionary Principle' (2000) 75 *Journal of Public Economics* 229, 231.

³³⁰ European Commission *Impact Assessment Guidelines* (January 2009), para 1.1.

³³¹ Ibid para 5.5.

³³² C Sunstein, 'Probability Neglect: Emotions, Worst Cases, and the Law' (2002) 112 *Yale Law Journal* 61, 64.

³³³ Ibid 67.

can result in many deaths.³³⁴ While in democratic societies policy makers respond to the public's fears,³³⁵ they should be careful that they are responding to actual risk rather than the public's perception of risk. This is particularly important when considering the demands of interest groups, as they have been successful in exaggerating risk to further their aims. In 1999, a study revealed that pollen from a GM corn could harm the monarch butterfly.³³⁶ The authors of the study noted that the results had the potential to profoundly impact the conservation of monarch butterflies. However they also cautioned that an assessment of the risks associated with this new technology must be compared with the risks posed by other pesticides.³³⁷ In other words, while the use of GM corn was *potentially* dangerous to the monarch butterfly, the authors considered it necessary to compare the GM corn with other pest control measures before acting. Such an approach would ensure that the least risky pesticide to the monarch butterfly would then be chosen. The Principal Investigator also cautioned against reading too much into the results without more data:

“We need to look at the big picture here. Pollen from *Bt*-corn could represent a serious risk to populations of monarchs and other butterflies, but we can't predict how serious the risk is until we have a lot more data. And we can't forget that *Bt*-corn and other transgenic crops have a huge potential for reducing pesticide use and increasing yields. This study is just the first step, we need to do more research and then objectively weigh the risks versus the benefits of this new technology.”³³⁸

Greenpeace, as part of their opposition to the use of GM crops, focused on the risks highlighted in the study to lobby for the prohibition of the GM crop within the EU. Despite the authors of the study stating that there was a need for further research before action should be taken, Greenpeace was effective and the EU banned the growing of GM maize crops.³³⁹

Similarly, the focus of the media on one risk can lead to government intervention irrespective of the likelihood of the risk. For example, after the attacks on the World Trade Centre on 9 September 2001, there was considerable attention paid by the media to the dangers of anthrax, a threat which did not accurately reflect the probability of death by anthrax. By October 2001, only four people had died from infection and approximately a dozen had fallen ill. Despite the low possibility of infection, the public fear provoked the American government to invest heavily in investigating anthrax infections.³⁴⁰ This government action was likely partly as a result of the potential political gains for responding to the public fears. Rather than educate the public as to the risks involved, there is often more to be gained politically by responding to the public's fears. Sunstein has argued that politicians are prone to exploit the public's fear of a particular risk, irrespective of the probability of the risk, as justification for the introduction of legislation that will result in political gain.³⁴¹ While policy

³³⁴ U Beck, *Risk Society: Towards a New Modernity* (Sage Publications 1992) 29.

³³⁵ Sunstein (n 300) 1.

³³⁶ J Losey, L Rayor & M Carter, 'Transgenic pollen harms monarch larvae' (1999) 399 *Nature* 214.

³³⁷ *Ibid.*

³³⁸ <http://www.news.cornell.edu/releases/May99/Butterflies.bpf.html>.

³³⁹ Van den Belt (n 293) 1122.

³⁴⁰ Sunstein (n 300) 84.

³⁴¹ Sunstein (n 332) 69.

makers are indeed accountable to the people, they must be careful not to introduce unnecessary regulation as otherwise they will fail to conform to the principles of Better Regulation.

5. The Ethical Precautionary Principle

The precautionary principle is used to justify the restriction of a new technology or industry where there is likely to be damage to the environment but the science is inconclusive. The ethical precautionary principle as explained here, on the other hand, may be adopted to restrict the operation of a new technology when the new technology raises ethical concerns, but it is currently unclear whether the technology is actually unethical. It is submitted that it generally arises where there are competing ethical values within society that make it unclear whether the new technology should be prohibited for being contrary to the ethics of society. Arguably, the ethical precautionary principle is part of the Commission's communication on the precautionary principle. The communication states that non-economic factors, such as acceptability by the public, should also be considered, but as Majone points out, it is unclear who determines what is acceptable by the public.³⁴² However, taking into consideration the views of the public may also involve an assessment of the moral values of the public and whether a new technology may impinge upon those values. It has also been noted that in reports considering GMOs, there has been a shift from a risk assessment of the science to reports that consider public perceptions of the science, as considered by experts in ethics.³⁴³

It was previously noted that, depending on the moral argument adopted, policy makers may adopt a permissive, restrictive or intermediate approach to the legal status of the embryo. This may in turn feed into policy makers' approach to regulating ESCR. Depending on the weight that policy makers attach to the moral arguments, they may adopt a restrictive, permissive or intermediate approach to ESCR. Within a generally permissive regime, it is possible for policy makers to restrict the operation of the research due to the ethical concerns raised.

We will now discuss the operation of the ethical precautionary principle and how it is used to restrict potentially beneficial research due to the ethical concerns the operation of the technology raises. In particular, human reproductive cloning, where the potential damaging impact it could have on human dignity has led to its almost worldwide ban, will be discussed before the use of the ethical precautionary principle in regulating ESCR internationally is considered. Finally, a framework for the implementation of the ethical precautionary principle will be outlined.

³⁴² Majone (n 310) 100.

³⁴³ B Wynne, 'Creating public alienation: expert cultures of risk and ethics on GMOs' (2001) 19 *Science as Culture* 445, 446.

5.1 The Ethical Precautionary Principle in Practice

5.1.1 The Strong Version and its Main Manifestation: Prohibition

Cloning hit the headlines in 1997 when a group of Scottish scientists announced that they had cloned the first live animal, commonly known as Dolly the Sheep.³⁴⁴ Following this announcement there were public investigations of cloning world-wide and, in particular, an examination of the ethics of human reproductive cloning. In the US, President Clinton requested an opinion from the National Bioethics Advisory Commission on the ethical implications of cloning,³⁴⁵ while in the UK, the Human Genetics Advisory Commission completed a report on the impact of human reproductive cloning.³⁴⁶ It was reported that the vast majority of people in the UK found reproductive cloning ethically unacceptable and thus were against it.³⁴⁷ Bans on human reproductive cloning were soon introduced as it was considered that human reproductive cloning undermines the dignity of human beings, instrumentalises people³⁴⁸ and interferes with their right to genetic uniqueness.³⁴⁹ An additional protocol was also added to the Council of Europe's Convention on Human Rights and Biomedicine that expressly prohibits human reproductive cloning on the grounds that it misuses biology and medicine, and is an affront to human dignity.³⁵⁰

Similarly, a strong version of the ethical precautionary principle has been adopted in Italy in relation to ESCR. Law 40/2004 prohibits the creation of more than three embryos for IVF, all of which must be implanted, and bans all research on human embryos.³⁵¹ Thus, despite the potential benefits of ESCR, Law 40/2004 prohibits any activity which may damage the dignity of the embryo.³⁵²

The application of the strong version of the ethical precautionary principle recognises that, while scientific progress is generally to be welcomed, such progress should not be to the detriment of society's moral values. As President Clinton stated, "any discovery that touches

³⁴⁴ I Wilmut, A Schnieke, J McWhir, A Kind & K Campbell, 'Viable Offspring Derived from Foetal and Adult Mammalian Cells' (1997) 385 *Nature* 810.

³⁴⁵ National Bioethics Advisory Commission, *Cloning Human Beings* (1997).

³⁴⁶ Human Genetics Advisory Commission, *Cloning Issues in Reproduction, Science and Medicine* (1998).

³⁴⁷ The Human Genetics Advisory Commission discovered this in the course of its public consultation. *Ibid* para 4.3.

³⁴⁸ D Beyleveld & R Brownsword, 'Human Dignity, Human Rights and Human Genetics' (1998) 61 *Modern Law Review* 661, 679. Human Genetics Advisory Commission (n 331) para 4.5.

³⁴⁹ For example the European Group on Ethics (EGE) noted that it is "inherent in the process of sexual reproduction that the progeny differ genetically from one another". European Group on Ethics, *Ethical Aspects of Cloning Techniques* (28 May 1997) para 1.2. The EGE is an independent, interdisciplinary body which is tasked with advising the Commission on the ethics of science and technology in connection with new legislation or policies. For more on the EGE see <http://ec.europa.eu/bepa/european-group-ethics/welcome/index_en.htm> accessed 28 January 2013.

³⁵⁰ Article 1 of Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings.

³⁵¹ For more on Germany's ESCR policy see Chapter 1.

³⁵² For example the freezing of embryos is prohibited under the act.

upon human creation is not simply a matter of scientific inquiry, it is a matter of morality and spirituality as well”.³⁵³

5.1.2 The Intermediate Position: Research under Certain Conditions

While the strong version of the ethical precautionary principle may lead to prohibition, an intermediate version of the principle may permit the new technology under certain conditions. This has been demonstrated internationally in relation to the sources of embryonic stem cell lines that can be used for ESCR. At the more restrictive end of the scale, ESCR is only permitted on imported stem cell lines. Such an approach has been taken by Germany where ESCR is only permitted on imported embryonic stem cell lines which were derived prior to 1 May 2008.³⁵⁴ This limit is due to the importance of human dignity in the German Basic Law. By restricting ESCR to imported embryonic stem cell lines, the embryo is not destroyed in Germany and thus no act that may be considered an affront to human dignity occurs on German soil.³⁵⁵

The most common approach is that supernumerary, or spare, embryos left over after IVF can be used for ESCR. As the embryos are surplus and may be discarded, it is contended that the embryos should be used for research purposes as they may potentially have a benefit. Due to the ready supply of surplus embryos there may be no need for the creation of embryos for research purposes and thus it is considered unnecessary to permit the creation of embryos for research purposes. However this approach is not universal, with some opting to permit the creation of embryos for research purposes.

Despite the ethical concerns that some research does bring, policy decisions are not made in isolation from the potential value of the research. This has been evidenced in the stem cell context. While a strong version of ethical precaution has been associated with human reproductive cloning, the same has not applied to the cloning of embryos for research purposes. In 2001 came the announcement of the first cloned human embryo for therapeutic purposes.³⁵⁶ Due to the negativity towards human reproductive cloning, attempts were made to distinguish between therapeutic cloning and human reproductive cloning.³⁵⁷ While the purpose of human reproductive cloning is to create a genetically identical human being, therapeutic cloning seeks to benefit the person who provides the cells.³⁵⁸ If ESCR realises its potential and is used in regenerative treatments, the best source of stem cells will be a cloned stem cell as it will be an “immune-compatible stem cell”. In other words, the body will not reject the cell treatment as the cells are the person’s own cloned cells. This will eradicate immune rejection in regenerative medicine, something that cannot occur if supernumerary

³⁵³ National Bioethics Advisory Commission (n 345) 7.

³⁵⁴ These lines may be imported from stem cell banks such as the UK Stem Cell Bank. For more on the development of the UK Stem Cell Bank see National Institute for Biological Standards and Control, *UK Stem Cell Bank Progress Report Phase II 2006 – 2010*.

³⁵⁵ This approach raises questions as to whether they should be benefiting from, what they to perceive to be, an immoral act. However such moral conundrums are outside the scope of this thesis.

³⁵⁶ J Cibelli, A Kiessling, K Cunniff, C Richards, R Lanza, M West, ‘Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development’ (2001) 2 *Journal of Regenerative Medicine* 25.

³⁵⁷ EGE (n 349) para 1.14.

³⁵⁸ J Cibelli (n 356) 30.

embryos are only used.³⁵⁹ Thus the purpose of therapeutic cloning is not reproductive, but to derive stem cells that can be used in regenerative medicine to ensure that the treatment is compatible with the patient.³⁶⁰ It is due to the potential regenerative benefits of the science that countries such as the UK permit therapeutic cloning while banning human reproductive cloning. In this way, the act of cloning an embryo may, in general, be considered an affront to human dignity. However, due to the potential therapeutic benefits of cloning an embryo for research, coupled with the fact that the cloning is not for reproductive purposes, therapeutic cloning is treated separately from reproductive cloning, with permissive policies found worldwide.

Finally, as well as considering the potential of the research, policy makers may also consider the purpose of the research. It is not uncommon for restraint to be put on the type of research permitted. In this way, it is perhaps possible that policy makers are acknowledging that there are some risks that the research may raise unethical concerns and, as a result, should only be used for serious medical research. Such a justification is known as the proportionality principle and it was adopted by the Irish Council for Bioethics, which stated that the proportionality approach prevented the use of embryos being destroyed for research on cosmetics but not on therapeutic treatment. The Council also noted that balancing the therapeutic needs of the patient with the moral status of the embryo meant that only treatment which has the potential to have an impact on medical science should be authorised.³⁶¹

5.1.3. The Permissive Approach: No Barriers to ESCR

The permissive approach to ESCR, or the weak version of the ethical precautionary principle, would manifest itself through the absence of barriers to ESCR. In practice, this would mean that scientists could carry out ESCR on any source of embryonic stem cell line and for any reason they desire. There would be no requirement that embryo-destructive research may only be used for research that is deemed to be medically necessary. However, due to the ethical concerns associated with the destruction of the embryo, it is common internationally that ESCR is limited to some degree and that ethical guidelines must be followed. It is for this reason that the restrictive or intermediate position is generally adopted worldwide.

6. Conclusion

While the traditional formulation of the precautionary principle urges caution or government intervention in the face of potential environmental damage, the ethical precautionary principle urges restraint on a new technology where a new technology raises ethical concerns. As the ethical precautionary principle considers the ethics of the research in formulating public policy, it is very much linked to the process of democratic deliberation. Through the process of democratic deliberation, agreement should be reached amongst the stakeholders of the debate as to the legal status of the embryo and the legal status of ESCR. If policy makers opt to permit ESCR, the prior debate should feed into the general policy on ESCR.

³⁵⁹ Ibid 25.

³⁶⁰ Ibid 30.

³⁶¹ Irish Council for Bioethics, *Ethical, Scientific and Legal Issues Concerning Stem Cell Research* (2008) 44.

It may occur that while the stakeholders are generally in favour of permitting ESCR, they do not want this to result in a “free for all” where any source of embryo may be used for any research purposes. It may be that stakeholders agree to permit ESCR due to its potential regenerative promise, but still have concerns that an embryo should only be destroyed if truly necessary. Depending on the ethical concerns expressed in the debate amongst stakeholders, policy makers may apply differing levels of ethical precaution, which will likely manifest itself in the ESCR policy in two ways: first, it may limit the sources of embryos and second it may limit the use of the research to research for the most serious diseases. In this way, stakeholders and policy makers can ensure that while the research is permitted, it is within the confines of their ethical principles.

The ethical precautionary principle can therefore explain the differing approaches countries have taken to their ESCR policy. If some level of ethical concern is enough for policy makers to restrict the research, this may lead to a restrictive policy for ESCR. On the other hand, policy makers may require consensus throughout society that the research is unethical before they will consider restricting ESCR. In such cases, there is likely to be an intermediate position on ESCR. Having thus established the level of ethical precaution, policy makers must next consider the regulatory framework required to implement their policy. As the House of Commons Science and Technology Committee noted:

“Many of the decisions about what to regulate or to legislate about depend on the approach taken with regard to the balance of harm and benefit or potential harm and potential benefit.”³⁶²

The level of ethical precaution will dictate what sources of embryonic stem cell lines may be used and the purposes for which the research may be adopted. The regulatory framework will ensure that these decisions are put into practice. In this way, the ethical precautionary principle provides the basis for ESCR regulatory frameworks.

³⁶² Human Reproductive Technologies and the Law, House of Commons Science and Technology Committee, Fifth Report (2004–5, HC 7-1) 47.

Chapter 4 Regulating Embryonic Stem Cell Research through Command and Control Regulation

1. Introduction

Traditionally, it has been common for policy makers to regulate through the use of “command and control” regulation. This occurs when governments introduce legislation or administrative instruments whereby they can dictate that a certain activity must follow certain rules. Failure to comply with the legislation often results in punishment through fines or criminal sanctions. It is partly due to the power of enforcement that command and control regulation often has high compliance rates and can thus be an effective means of controlling an industry. Internationally, command and control legislation has formed part of the ESCR policy, as governments seek to directly control the development of the research, with breaches of the legislation subject to civil and criminal sanctions.

In recent years, however, there has been a move away from direct state interference, with policy makers opting instead to appoint an independent regulatory authority, or pursue other indirect forms of regulation.³⁶³ Such regulatory authorities have the relevant expertise that may be necessary to ensure adequate regulation of certain activities, particularly when the control of this activity requires a high level of knowledge and skill. With the regulation of ESCR requiring expertise in science, ethics and the law, an independent regulatory authority may be suitable for regulating ESCR. This group could have the necessary expertise to oversee ESCR and be in a position to keep up to date with the advances and changes in the technology.

This chapter will analyse state-based regulation and how it may regulate ESCR. It will involve an examination of the use of legislation as a regulatory tool before turning to a focus on the experiences of the UK. The UK has introduced legislation to regulate ESCR, thus the discussion of the UK legislation as a case study in the use of legislation will be presented. Furthermore this method of regulating ESCR will be examined under the principles of Better Regulation. The focus of the latter half of this chapter will move to independent regulatory authorities and the role they can play in regulating ESCR. Particular focus will be given to the UK’s Human Fertilisation and Embryology Authority (the HFEA) and its role in governing ESCR. This will also involve an examination of independent regulatory authorities under the principles of Better Regulation before concluding with a discussion of the use of state regulation as a legitimate and effective means for regulating ESCR.

2. Command and Control Regulation

Command and control regulations are direct measures enacted by the state to control certain behaviour or impose certain standards, which are usually backed by criminal sanctions in the

³⁶³ Indirect regulation of ESCR will be discussed in Chapter 5.

event of non-compliance.³⁶⁴ Such instruments, which are normally in the form of legislation, are generally relatively clear and accessible to the public, in particular those whom the legislation seeks to control.³⁶⁵ In this way, command and control regulation has been described as being “dependable”. Regulatees are aware of their duties under the legislation, making breaches of the law easily identifiable.³⁶⁶ Command and control regulation ensures that certain activities can be prohibited or limited in accordance with the public interest.³⁶⁷

For embryonic stem cell researchers, this certainty is of importance as they need to know the legal status of ESCR and the legal boundaries of the research, before they commence. For example, it will be necessary to know what sources of embryos may be used and also what aims the research may be used for. Furthermore, as the research is controversial, the introduction of legislation provides an avenue for some public debate. A Bill is generally put forward which is then debated in public in Parliament before it becomes law, thus ensuring that there is some level of public scrutiny.³⁶⁸ If the Bill has the support of the majority in Parliament, it will be passed by democratically elected politicians, thus ensuring that there is some form of democratic accountability.

Problems often begin to emerge with the command and control model of regulation when complex issues are at stake. Gunningham has noted that this model has many limitations when dealing with complex environmental problems.³⁶⁹ At times, what are required is targeted approaches to controlling environmental problems, which provide a range of activities to control or prevent certain environmental damage. Such an approach is preferable to a general law that, while reducing the risk of environmental damage, is not targeted.³⁷⁰ Environmental protection legislation often seeks to impose a “one size fits all” solution that fails to appreciate the difference between the economic, organisational or technical capacities of companies.³⁷¹

Deeper analysis of command-and-control regulation reveals further problems. First, to ensure that the legislation adequately controls the targeted activity, a high level of knowledge of that activity is required. This can lead to an imbalance of power between industry and government, as the industry may seek to take advantage of the expertise that it has over the

³⁶⁴ R Baldwin, ‘Regulation: After Command and Control’ in K Hawkins (ed), *The Human Face of Law* (Clarendon Press 1997) 65. D Sinclair, ‘Self-Regulation Versus Command and Control? Beyond False Dichotomies’ (1997) 19 *Law and Policy* 529, 534.

³⁶⁵ N Gunningham & P Grabosky, *Smart Regulation: Designing Environmental Policy* (OUP 1998) 38.

³⁶⁶ *Ibid* 41.

³⁶⁷ Baldwin (n 364) 66.

³⁶⁸ L Bennett Moses, ‘Understanding Legal Responses to Technological Change: The Example of In Vitro Fertilization’ (2005) 6 *Minnesota Journal of Law, Science and Technology* 505, 576.

³⁶⁹ N Gunningham, ‘Environmental Law, Regulation and Governance: Shifting Architectures’ (2009) 21 *Journal of Environmental Law* 179, 184.

³⁷⁰ *Ibid* 208.

³⁷¹ T Malloy, ‘The Social Construction of Regulation: Lessons from the War Against Command and Control’ (2010) 58 *Buffalo Law Review* 267, 269.

government.³⁷² It can also lead to regulatory capture whereby regulations are introduced for the benefit of certain interest groups rather than the public at large.³⁷³

While policy makers may be in a position to consult widely on the issue to counteract this imbalance, this can be quite time-consuming and costly and thus not always in the public interest. Furthermore, as future changes to the law may be often required, policy makers will have to embark on this consultative process once again, consuming resources that may be best spent elsewhere. The imbalance of knowledge between the industries and the government is often successfully used by lobbyists to ensure that their concerns are met through legislation. Calls for state regulation typically come from interest groups or lobbyists who have a vested interest in regulation. Thus it is not always apparent that the legislation is necessary or in the public interest.³⁷⁴ Likewise, the expertise of interest groups can enable them to influence media reports, which in turn can influence policy. In addition, these interest groups are in a better position than the government to have the expert knowledge necessary to understand the area and also introduce regulations. This can lead to legislators being influenced by inaccurate media reports, and has resulted in claims that regulations are often in the interest of organised groups rather than the public interest.³⁷⁵

Second, developments in technology can reveal gaps in the legislation that may require immediate change. Due to the usual lengthy nature of the legislative process, a substantial period of time can elapse from the drafting of a Bill through to its debate in Parliament and passage into law. In this way, legislation can be perceived as being inflexible and often cannot be quickly amended to respond to technological developments. This is a difficulty for drafters of legislation who may want to ensure that the legislation will not become outdated with developments in technology. There is a danger that in seeking to ensure that the legislation can adapt to change that drafters will make the legislation over-inclusive or under-inclusive.³⁷⁶ Drafters should rather balance this need to ensure that the legislation is not quickly outdated with the requirement that the legislation conforms to Better Regulation principles.

Third, the introduction of legislation can come on foot of electoral promise or political pressure. This can lead to the introduction of unnecessary legislation while other required changes are ignored. Furthermore there is little political incentive to introduce policies where the benefits will only be felt after the next general election.³⁷⁷ Thus policy makers may opt to introduce legislation where the benefits will be felt during the lifetime of that government, rather than long term policy which, while perhaps necessary, provides little political gain.

³⁷² Gunningham & Grabosky (n 365) 44.

³⁷³ Baldwin (n 364) 66.

³⁷⁴ J Blundell & C Robinson, *Regulation Without the State* (The Institute of Economic Affairs 1999) 15. This is not to state that regulations are only introduced in response to pressure from interest groups. Governments also have their own interests that they wish to pursue on behalf of the public or on foot of electoral promise. D Souter, 'A Stakeholder Approach to Regulation' in D Corry, D Souter & M Waterson, *Regulating our Utilities* (Institute for Public Policy Research 1994) 45.

³⁷⁵ Blundell & Robinson (n 374) 21.

³⁷⁶ Bennett Moses (n 368) 532.

³⁷⁷ G Majone, 'Temporal Consistency and Policy Credibility: why democracies need non-majoritarian institutions' Working Paper RSC No. 96/57 (Florence, European University Institute, (1996) 1.

ESCR is a new and highly specialised scientific development. While government scientific advisors are likely to have certain knowledge of the research, it is possible that they may lack the requisite research necessary to regulate the industry. This may give stem cell groups, such as the Irish Stem Cell Foundation, an advantage over policy makers as these groups will seek to use their increased knowledge of the area to lobby for favourable regulations.

A further problem is the fact that ESCR has been a rapidly developing area of science since the first stem cell line was derived in 1998. Thus there is the danger that frequent updating of legislation may be necessary. Failure to do so may result in new developments in the technology remaining outside the confines of the law. This may leave certain forms of the research unregulated and, no legal or ethical guidelines governing the research.

To determine the suitability of legislation for regulating ESCR, the UK Human Fertilisation and Embryology Act 1990 (hereinafter the HFE Act 1990) will be examined. This Act, while introduced prior to the derivation of the first embryonic stem cell line, governs ESCR in the UK and has pertained many of the issues discussed above.

2.1 Case Study: Human Fertilisation and Embryology Act 1990

The HFE Act 1990 was introduced after a long process of debate,³⁷⁸ beginning with the publication of the Warnock Report in 1984 and the 1987 *White Paper Human Fertilisation and Embryology: A Framework for Legislation*.³⁷⁹ The HFE Act's path to the legislative books was by no means smooth, with considerable opposition during its first reading in the House of Lords. In response to the Warnock Report, the Unborn Children (Protection) Bill was introduced in December 1984. This Bill sought to prohibit embryo research and only permit the fertilisation of a human ovum after the permission of the Secretary of State had been obtained. At its second reading the Bill in fact had a majority of 175 and only failed to become law due to the filibustering of supporters of the Warnock Report.³⁸⁰

This opposition to the Warnock Report is hardly surprising, as assisted reproduction was still in its infancy at the time of the passage of the Act and the legislation was only the second of its kind to be introduced internationally.³⁸¹ Despite the apparent disapproval of the Warnock Report and a free vote on issues such as embryo research in which the party whip rules did not apply, the HFE Act 1990 was passed.³⁸² Thus the UK legislation provide, not only

³⁷⁸ This long period of debate may have been influenced by a looming general election. J Gunning & V English, *Human IVF: A Case Study on the Regulation of Medical Innovation* (Dartmouth 1993) 82.

³⁷⁹ The one exception to this prolonged period of consultation was surrogacy. In the aftermath of the Warnock Report and reports in the media of a British woman acting as a surrogate in the US, the government, with all-party support, enacted the Surrogacy Arrangements Act 1985. See Gunning & English (n 378) at 41.

³⁸⁰ Ibid 173.

³⁸¹ The Infertility (Medical Procedures) Act 1984 was introduced in the State of Victoria, Australia. It was the first piece of legislation to regulate IVF and embryo research and came one foot of the recommendations of the Waller Committee. However the provisions of the Act were not only very restrictive but led to much confusion as it was not clearly drafted. Ibid 33-36.

³⁸² HC Deb, 2 April 1990, col 914. In introducing the Bill the Secretary of State for Health, Mr Kenneth Clarke noted that members of parliament were divided on the ethical issues which the Bill confronted. Ibid.

clinical standards for assisted reproduction and embryo research but also ensures public confidence in the processes regulated under the legislation.³⁸³

The Act itself adheres to the traditional command and control structure, as certain activities are prohibited and criminal sanctions are imposed in the event of infringement. The Act also lays out a licence scheme for certain activities and establishes a regulatory authority tasked with licensing clinics, amongst other activities. It provides for three levels of control:

- (i) Legislative control through the absolute prohibitions outlined in the Act itself;
- (ii) Executive control through the powers vested in the Secretary of State to make regulations concerning the storage or use of embryos;
- (iii) The level of control that the HFEA can exercise.³⁸⁴

Under the HFE Act 1990, non-compliance with the Act can lead to a fine, imprisonment, or both. In its 2006 review of the Act, the government was of the opinion that the imposition of criminal sanctions on offenders under the Act should continue. It believed that the model whereby criminal sanctions could apply to those who flout the law had worked well to date.³⁸⁵ Furthermore, the Department of Health has stated that the Act “has engendered public confidence in the ethical development and use of human reproductive technologies”.³⁸⁶ During the debates of the HFE Act 1990, it was noted that the public needed assurance on the issues discussed in the Bill and also assurance that practices such as genetic manipulation and the inappropriate use of spare embryos would be prohibited.³⁸⁷ The Minister of Health was of the opinion that such assurances could only be provided by legislation.³⁸⁸

It is likely that the threat of criminal sanctions under the Act ensures that there is a high level of compliance with the Act, particularly in relation to embryo research. Indeed, the threat of sanctions may have gone some way to alleviating the opposition that the Act faced during the early stages of the Bill.

Although the HFE Act provides clarity to clinics and patients, its passage into law illustrates some of the problems with the command and control model of regulating. While the HFE Act 1990 debates were ongoing, the Voluntary Licensing Authority (VLA)³⁸⁹ was established to issue licences and provide a minimum set of standards that clinics should follow, during the

³⁸³ T Callus, ‘Ensuring Operational Compliance and Ethical Responsibility in the Regulation of ART: The HFEA, Past, Present, and Future’ (2011) 3 *Law, Innovation and Technology* 85, 89.

³⁸⁴ As per Lord Bingham of Cornhill in *R v Secretary for Health ex parte Quintavalle (on behalf of Pro-Life Alliance)* [2003] UKHL 13 at paragraph 4.

³⁸⁵ Department of Health, *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including the establishment of the Regulatory Authority for Tissue and Embryos)* (2006) para 2.4.

³⁸⁶ Department of Health, *Review of the Human Fertilisation and Embryology Act: A public consultation* (2005) para 2.13. During the debates on the Act it was noted that “legislation is necessary not only to regulate research on embryos and to protect the integrity of reproductive medicine, as well as the legal position of the scientist or clinician, but to take account of social and ethical considerations”. HC Deb, 2 April 1990, col 938.

³⁸⁷ HC Deb, 2 April 1990, Col 938.

³⁸⁸ HC Deb, 2 April 1990, col 983.

³⁸⁹ This was later renamed the Interim Licensing Authority until it was named the Human Fertilisation and Embryology Authority under the HFE Act 1990.

interim. The VLA also took it upon itself to educate Members of Parliament about the science behind IVF. This was in response to a concern that the parliamentarians would be influenced by media reports that depicted IVF as growing foetuses in test tubes.³⁹⁰ Despite this, Margaret Brazier is critical of the level of debate during the passage of the 1990 Act, arguing that some basic issues concerning fertility treatment were never addressed. Furthermore, she argues that only the most controversial issues, rather than the most important issues, will be focused on during parliamentary debates.³⁹¹ While this will not always be the case, it serves as an example of the influence that the media can have on parliamentary debates. Attention during debates is often given to what has been discussed in the media. Well-funded interest groups can influence media reports and thus indirectly influence the public debate, leading to a discussion of issues that is often in the interest of a particular group rather than the public. Furthermore, new forms of social media can prove to be particularly useful in accessing a large group of people with minimum cost and effort. Mass media campaigns can thus be easily initiated and quickly get the attention of the media, the electorate, and importantly, parliamentarians.

Further problems with the legislative process were highlighted during the Human Fertilisation and Embryology Act 2008, which sought to reform the provisions relating to the determination of parenthood for children born through assisted reproduction. Despite this being a fundamental change to the HFE Act 1990, it received very little attention from parliamentary committees, Parliament itself, and the media, despite the potentially far-reaching consequences of these reforms.³⁹² The reforms were instead overshadowed by the removal of the “need for a father” from the legislation (it provided for the first time that two women could be recognised as the child’s legal parents from birth), as well the debate on “saviour siblings” and animal-human hybrid embryos.³⁹³

Rather than focusing on certain aspects of the Bill, a debate on the entire Bill should have taken place as parliamentary debates provide one of the few opportunities in which serious debates can take place in public. Members of Parliament are given an opportunity to voice their concerns on behalf of their constituents, thus providing the process with a degree of transparency. Once a Bill becomes law it can only be challenged through the courts, a process which can be both lengthy and expensive.

Furthermore, a number of features of the debate was criticised at the time, in particular the length of time that the Act was available for legislative scrutiny, the power of key individuals to influence the agenda of parliamentary committees, and the limited amount of time available for debate, which meant that certain items simply were not discussed.³⁹⁴ This

³⁹⁰ Gunning & English (n 378) 57.

³⁹¹ Margaret Brazier in evidence to the Human Reproductive Technologies and the Law, House of Commons Science and Technology Committee, Fifth Report (2004–5, HC 7-1) para 313. A similar point has been made in relation to the Human Fertilisation and Embryology Act 2008. See J McCandless & S Sheldon, ‘The Human Fertilisation and Embryology Act (2008) and The Tenacity of the Sexual Family Form’ (2010) 73 *Modern Law Review* 175, 175-176.

³⁹² *Ibid* 176.

³⁹³ *Ibid* 180.

³⁹⁴ *Ibid*.

highlights two problems with the command and control model of regulation. First, if immediate amendments to legislation are required, this can only be done by rushing legislation through in the manner just described. This leads to the second problem of democratic accountability: while the process of enacting legislation is intended to be transparent and open for the public to see, if changes are rushed through, it prevents both parliamentarians and the general public from contributing to the debate in a public forum. Thus if the law is to be flexible, it is to the detriment of a thorough public debate.

Finally, the experience of the HFE Act 1990 illustrates one of the key problems with relying solely on a command-and-control model: its frequent inability to keep pace with technology. While the HFE Act 1990 has often been hailed as setting out an ideal regulatory model,³⁹⁵ it too has at times failed to keep up with science.³⁹⁶ When the HFE Act was passed in 1990, Parliament made two assumptions: first, an embryo would be the result of fertilisation of an egg with a sperm, and second, if there was to be SCNT³⁹⁷ for the purposes of cloning, it would be as a result of the manipulation of the embryo, rather than the replacement of the nucleus of the egg.³⁹⁸ Developments in technology had made it possible to create an embryo through cloning whereby the nucleus of an embryo is replaced by the nucleus of an egg. As the definition of an embryo under the Act referred to fertilisation, a process which an embryo created through SCNT did not undergo, it was unclear whether an embryo created through SCNT came under the definition of an embryo and thus whether a research licence could be granted.

It soon came before the Courts to determine whether embryos created by SCNT came under the definition of an embryo under the Act. In the High Court, Crane J was of the opinion that due to the wording of the 1990 Act, embryos created by SCNT did not come under the definition of an embryo.³⁹⁹ However, in the House of Lords, considerable attention was given to the intention of Parliament and in particular to Lord Wilberforce's dissenting opinion in *Royal College of Nursing of the United Kingdom v Department of Health and Social*

³⁹⁵ Despite its criticisms, the UK government considers that the regulatory model set out in the HFE Act 1990 has generally worked well and continues to do so. Department of Health, *Review of the Human Fertilisation and Embryology Act: A public consultation* (2005) para 2.13.

³⁹⁶ In discussing the HFEA 1990 and the Blood case Morgan and Lee have stated:

“The underlying philosophy of that legislation was that subject to a system of regulated licences, the supervision of reproductive medicine could, by and large, be left in the charge of clinical specialists. The 'case' of Diane Blood only serves to illustrate not only how far we have moved in terms of human reproduction in the past 30 years, but also that the legislative assumptions of 1990 are being cross cut with the articulation of a fresh voice - that of the consumer who comes to the reproductive market with the usual range of assumptions about rights and guarantees.” D Morgan & R Lee, ‘In the Name of the Father? *Ex parte* Blood: Dealing with Novelty and Anomaly’ (1997) 60 *Modern Law Review* 840, 855.

³⁹⁷ For an explanation of SCNT see the Introduction.

³⁹⁸ R Brownsword, *Rights, Regulation and the Technological Revolution* (OUP 2008) at 169. Section 1(1) of the 1990 Act states

“In this Act, except where otherwise stated—

(a) embryo means a live human embryo where fertilisation is complete, and

(b) references to an embryo include an egg in the process of fertilisation,

and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote.”

Section 2(3)(d) states “A licence cannot authorise replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo”.

³⁹⁹ *R v Secretary for Health ex parte Quintavalle (on behalf of Pro-Life Alliance)* [2001] EWHC Admin 918 para 62.

Security.⁴⁰⁰ In determining whether an Act covered something that was not in existence at the time of the passage of the Act, Lord Wilberforce stated that the Court could consider the strictness of the words as laid out in the statute and whether the Act was intended to be restrictive or permissive. What the Courts could not do however is:

“...fill gaps; they cannot by asking the question 'What would Parliament have done in this current case - not being one in contemplation - if the facts had been before it?' attempt themselves to supply the answer, if the answer is not to be found in the terms of the Act itself.”⁴⁰¹

In applying this to the 1990 Act, Lord Bingham was of the opinion that the 1990 Act was concerned about the creation of embryos *in vitro* and Parliament could not have intended to exclude embryos' creation through SCNT as the technology was not in existence at the time of the passage of the Act. Thus the focus of the Act was on the embryos themselves rather than their creation.⁴⁰² Lord Steyn was of the opinion that Parliament created a definition of an embryo as the science was understood at the time,⁴⁰³ but as Lord Millett pointed out, the question is whether Parliament intended to legislate for embryos created through that way only.⁴⁰⁴ According to Lord Millet there is no gap in the legislation as to whether embryos created under SCNT fall under the 1990 Act. Rather, by giving the words their natural meaning, SCNT embryos can be said to fall under the definition as the focus of the Act is on embryos *in vitro* and not the method in which embryos are created. Thus rather than updating the Act, Lord Millett was of the opinion that the Court was simply bringing embryos, created through a process unknown to Parliament at that time, into the regulatory scope of the Act.⁴⁰⁵ Therefore, embryos created through SCNT fall under the definition of embryos under the Act.

As evidenced by this case, developments in technology can bring uncertainty as to the scope of the Act. This can lead to confusion for clinics and researchers as well as patients. In this case, the Court's interpretation of the Act ensured that there was a degree of flexibility in the Act, thus allowing it to include new technological developments. This interpretation has been backed up by a later report which states that all human embryos, regardless of the mode of creation of the embryo, should fall within the regulations set down by the HFE Act 1990.⁴⁰⁶ Furthermore, fears that developments in technology could result in the Act becoming vulnerable to legal challenges have led to a suggestion that future legislation should not

⁴⁰⁰ [1981] AC 800.

⁴⁰¹ [1981] AC 800, 822. Similarly Roger Dworkin has stated

“Nonetheless, a rule is a rule, and if science has created a situation the law does not provide for, it is the legislature's job to create a new statutory category, not the court's job to fit the new situation into the old one.” R Dworkin, *Limits: The Role of the Law in Bioethical Decision Making* (Indiana University Press 1996) 63.

⁴⁰² *R v Secretary for Health ex parte Quintavalle (on behalf of Pro-Life Alliance)* [2003] UKHL 13 para 14.

⁴⁰³ *Ibid* para 20.

⁴⁰⁴ *Ibid* para 39.

⁴⁰⁵ *Ibid* para 49.

⁴⁰⁶ Department of Health, *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including the establishment of the Regulatory Authority for Tissue and Embryos)* (2006) para 2.11.

define an embryo but rather only the circumstances in which it can be implanted.⁴⁰⁷ Such a move would ensure that embryos created by processes currently unknown are covered but the lack of a definition of the term embryo could also lead to difficulties in the future. However, a court in the future might not be so willing to read a new technology into a Parliamentary statute. If the intention of Parliament is unclear, the Courts may have no option but to determine that certain embryos are not covered under the Act thus requiring a change in legislation. Legislation, if rushed through, may bring claims of democratic unaccountability, or if considered appropriately by committees and Parliament, could result in criticisms from researchers that the system cannot adequately adapt to change.

3. Regulating ESCR through Legislation and Compliance with Better Regulation Principles

The HFE Act 1990 is the cornerstone of the regulation of assisted reproduction and embryonic stem cell research in the UK. The Act unambiguously states the permitted boundaries of ESCR and which activities are prohibited. However, further analysis is required to determine its suitability for regulating ESCR, and so the command and control model will now be examined under the Better Regulation Principles.

3.1 Transparency

The principle of transparency requires that there should be a period of consultation prior to the introduction of any regulations. This principle also requires that, once introduced, the regulations are clear, accessible and understandable by those that they seek to regulate.

As the legislative process is quite lengthy, stakeholders to the debate generally have a number of opportunities to put forward their views on the legislation. For instance, this may be done at the committee stage where interested parties may be invited to give evidence, or individual parliamentarians can be lobbied. Furthermore, interest groups may also initiate a media campaign that results in a public reaction to the proposed legislation. Equally as important is that the parliamentary debates are conducted in public with the minutes of the debates accessible to the general public.

In the context of ESCR, problems begin to arise if the law fails to keep pace with technological change, as occurred with the HFE Act 1990. The process of drafting and enacting legislation is time consuming, thus the suitability of this model in regulating activities that require frequent updating of the law must be questioned, particularly when one considers that ESCR is a developing science.⁴⁰⁸ While in the past it would be expected that laws would be sustainable for 20, 30 or 40 years, this is no longer realistic in areas that are rapidly developing, such as with ICT⁴⁰⁹ and biotechnology. Indeed it is argued that due to the

⁴⁰⁷ Human Reproductive Technologies and the Law, House of Commons Science and Technology Committee, Fifth Report (2004–5, HC 7-1) para 53.

⁴⁰⁸ B Koops, M Lips, C Prins & M Schellekens, *Starting Points for ICT Regulation* (Asser Press 2006) 89. The need to constantly update the law can also lead to over-regulation. Baldwin (n 364) 67.

⁴⁰⁹ Koops Lips, Prins & Schellekens (n 408) 89.

lengthy process involved in enacting legislation, once it is passed, it “often relates to a world that no longer exists”.⁴¹⁰

This potential failure of the law to keep pace with the science may be of particular concern to ESCR scientists. Prior to completing a grant application or commencing the research, stem cell scientists will need to know the legal status of ESCR, and in particular, which embryos may be used in the research. Clear and understandable legislation can achieve just that. However if the law cannot adequately respond to changes in science it risks becoming outdated and losing its regulatory effectiveness, which can leave scientists in a legal vacuum. Prior to the *Quintavalle* decision it would not have been clear where embryos created through SCNT were covered under the Act and this could have impacted upon grant applications or international collaborations between scientists. Clarity on such issues is

“required for collaboration, for the performance of laboratory tasks, for the assessment of research results, for peer review, for the development of IP claims and for clinical applications”.⁴¹¹

The introduction of legislation provides stakeholders to the debate with an opportunity to contribute towards the legislation process and also ensures that the debate is held in public, thus ensuring that the legislative process is transparent. Difficulties begin to arise, however, when developments in medical science result in ambiguity in the law, that can negatively impact the progress of the research.

3.2 Accountability

The principle of accountability requires that those who are subject to the regulations are aware of their duties. The strength of the command and control model is that it is supposed to clearly set out who is responsible for what and the consequences for failing to adhere to the guidelines or standards. The legislation can ensure that certain minimum standards are enforced as otherwise criminal or civil sanctions may be imposed.⁴¹²

Legislation can detail what sources of embryos may be used for research purposes, whether ESCR may be used for therapeutic research only, as well as the conditions under which a licence for research may be issued to a clinic. This will make clear which clinics can carry out the research and under what conditions. Furthermore, the legislation will outline the criminal and civil sanctions arising from a failure to follow the legislation. This is important for ESCR as, due to the ethical concerns that the research raises, the public will want to be reassured that ethical standards are adhered to and that violators are punished. As noted above, the sanctions contained in the HFE Act 1990 reassured the public that certain practices would be prohibited. In this way, legislation provides a mechanism through which violators can be punished, a mechanism which also assures the public that certain minimal ethical standards in research will be adhered to.

⁴¹⁰ Ibid 19.

⁴¹¹ H Gottweis, B Salter & C Waldby, *The Global Politics of Human Embryonic Stem Cell Science* (Pallgrave McMillan 2009) 169.

⁴¹² Baldwin (n 364) 66.

3.3 Proportionality

The principle of proportionality requires that the least burdensome, but effective, method be adopted. By following this principle, unnecessary red tape will be avoided. The command-and-control method often requires that certain minimum standards must be followed. The focus is on the activity, rather than the individual clinic or company, and it does not take into consideration the unique situation of each clinic. Clinics may find themselves burdened with what they perceive to be extra bureaucratic processes. The issue, however, is whether this is proportionate. Arguably, where there is the threat of irreversibility, such as the collapse of an ecosystem, there should be strict command and control regulations, with the focus on compliance, and harsh penalties for failure to comply.⁴¹³ Thus while the regulations may require stringent protection methods, due to the threat of permanent environmental damage, these requirements may be perceived to be proportionate.

The HFE Act 1990 is quite liberal in that it permits research on differing types of embryos, but it is also strict as only licence holders can carry out the research. Failure to obtain a licence for research prohibits a clinic from carrying out ESCR. The process of obtaining a licence may prevent many from engaging with ESCR, however this is arguably proportionate to the aims of the legislation. The HFE Act 1990 ensures that ESCR is conducted in an ethically responsible manner, thus the limitations on the issuing of a licence and the research itself are arguably proportionate. The Act ensures that research is permitted while limiting the research to those who follow the ethical and legal standards set out in the Act.

3.4 Consistency

The principle of consistency requires that the rules be predictable and also be applied equally. As legislation is introduced, debated and passed in a public forum (i.e. Parliament), the rules are known in advance. In this way the rules are predictable. Problems, however, can emerge when developments in technology leave the scope of the Act uncertain. Sunstein notes that developments in technology can undermine basis assumptions under which a particular statute was written.⁴¹⁴ Such an issue arose in the *Quintavalle* case discussed above, and can impact upon the predictability of the legislation.

Legislation is consistent when it applies equally to all those in a particular industry, irrespective of the individual circumstances. While it has been noted above that this can lead to problems when smaller companies ought to adhere to the environmental regulations, for example, adhering to the rules ensures that there is consistency in application and thus no allegations of corruption. The HFE Act 1990 is applied consistently. All research institutes that wish to engage in ESCR must obtain a licence and all research institutes must follow identical ethical and legal guidelines. This normally ensures that the research consistently adheres to ethical standards, irrespective of the research institute.

⁴¹³ D Sinclair (n 364) 538.

⁴¹⁴ C Sunstein, 'After the Rights Revolution: Reconceiving the Regulatory State' (Harvard University Press 1990) 94.

3.5 Effectiveness

The principle of effectiveness requires that the regulations be targeted at the activity they seek to control and that they must be complied with. Legislation generally is clear in the activity it seeks to control and thus it should be apparent at whom the legislation is targeted. Due to the threat of criminal or civil sanctions, legislation is normally effective in ensuring compliance. In its 2005 review of the HFE Act, the Department of Health was of the opinion that the regulatory framework set out under the Act enabled medical and scientific progress to flourish within appropriate safeguards, while ensuring that there is sufficient safety and quality of fertility services for patients.⁴¹⁵

However, a unique problem could potentially have arisen if the Court in the *Quintavalle* case had ruled that embryos created by SCNT were not within the definition of an embryo under the HFE Act 1990. Had this occurred, it would have left such embryos outside the scope of the Act. As there was no legislation prohibiting research on embryos created by SCNT, no licence would have been required before research on embryos created through SCNT commenced, and any researcher could have engaged in such research. Thus researchers would have been operating in a regulatory void, which would continue until policy makers consider the issue and enact legislation.⁴¹⁶ As the Court ruled that embryos created through SCNT fell under the Act, no problems arose. This example, however, does illustrate that while legislation can generally be effective, this can be hampered if developments in embryology render the confines of the Act uncertain.

3.6 Necessity

The principle of necessity requires that regulations only be introduced where required and that the regulations be kept under review. This could involve a regulatory impact analysis, which may recommend the introduction of legislation.

Prior to the introduction of the HFE Act 1990, the Warnock Committee considered the legal, ethical and social issues associated with embryo research and assisted reproduction, and recommended the introduction of legislation to govern assisted reproduction and embryo research in its 1984 report. This was followed by a consultation paper in 1986.⁴¹⁷ Due to the comprehensive Warnock Report, this consultation paper was not necessary and was likely an attempt to put off discussing the controversial issues contained in the report, particularly in light of a looming election. The consultation paper was followed in November 1987 by “Human Fertilisation and Embryology: A Framework for Legislation”. By the time the HFE Bill was introduced, it was noted by the Secretary of State for Health during the debates that, while there were areas of disagreement on the Bill, there was agreement on the need for statutory regulation.⁴¹⁸

⁴¹⁵ Department of Health, *Review of the Human Fertilisation and Embryology Act: A public consultation* (2005) para 2.13.

⁴¹⁶ Brownsword (n 398) 162.

⁴¹⁷ Department of Health, *Legislation on Human Infertility Services and Embryo Research* (December 1986)

⁴¹⁸ HC 2 April 1990, col 914.

Furthermore the legislation has been kept under review, which has resulted in a number of amendments to the HFE Act 1990. In 2005 the Department of Health initiated a consultation on the Act and published a review based on this consultation. The purpose was to ensure that the HFE Act 1990 was still fit for purpose and to ensure that the framework established under the HFE Act 1990 is “broadly acceptable to public”.⁴¹⁹ This was followed by a review in 2006 which contained proposals for revised legislation.⁴²⁰ The HFE Act 1990 and the HFEA have also been subject to a House of Commons Science and Technology Review. The Committee recommended submitting any amendments to the Act to pre-legislative scrutiny to ensure that all aspects of a proposed Bill are examined and not just the most controversial elements.⁴²¹

To sum up, regulating ESCR through legislation brings clarity and certainty to researchers and the general public. This is essential for researchers so that they conduct their research in line with the accepted ethical and legal guidelines, and it also reassures the public that ESCR adheres to strict ethical principles. Difficulties begin to emerge where the technology progresses and, as a result, uncertainty as to the application of the legislation arises. As parliamentarians must focus on a wide range of issues, they are unlikely to keep up to date with all the developments in each area of science. While in-house research services and interest groups can raise these issues and push for legislative action, their intentions are not always in the best interest of the public, but rather in the best interests of the group they represent. Thus while legislation is certainly necessary to ensure that the research meets certain legal and ethical standards, its inability to quickly adapt or foresee likely technological developments can only lead one to conclude that legislation for ESCR cannot operate in isolation but should be completed by other, more flexible models, such as the use of regulatory authorities, to which we will now turn to examine.

4. Regulatory bodies or authorities

The use of regulatory authorities is a key feature of the regulatory state.⁴²² This concept is used to describe a government’s willingness to delegate some of their regulatory functions to regulatory bodies or regulatory authorities and in particular, to independent regulatory authorities.⁴²³ A regulatory authority is a public body that has regulatory power, but whose membership is not directly elected by the people, nor directly managed by the government.⁴²⁴ It may be created under an Act of Parliament, which will also outline its powers, and it is generally independent of the government. The authority will often be comprised of members who have the relevant expertise in a given area, which is necessary to ensure the adequate

⁴¹⁹ Department of Health, *Review of the Human Fertilisation and Embryology Act: A public consultation* (2005) para 1.4.

⁴²⁰ Department of Health, *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including the establishment of the Regulatory Authority for Tissue and Embryos)* (2006).

⁴²¹ Human Reproductive Technologies and the Law, House of Commons Science and Technology Committee, Fifth Report (2004–5, HC 7-1) para 313.

⁴²² C Scott, ‘Regulation in the Age of Governance: The Rise of the Post-Regulatory State’ in J Jordana & D Levi Faur (eds), *The Politics of Regulation* (Edward Elgar 2004) 148.

⁴²³ F Gilardi, ‘Policy Credibility and Delegation to Independent Regulatory Agencies: A Comparative Empirical Analysis’ (2002) 9 *Journal of European Public Policy* 873, 873.

⁴²⁴ *Ibid* 67.

regulation of an industry. They are often civil servants whose task it is to implement government policy.⁴²⁵

However the move towards regulatory authorities has brought concerns about their democratic legitimacy, and in particular concerns that such authorities are doing more than simply implementing policy, and are now creating policy.⁴²⁶

This section will examine regulatory authorities and their suitability for regulating ESCR. It will describe regulatory authorities and their general benefits before examining the Human Fertilisation and Embryology Authority (HFEA) as a case study of one authority that regulates ESCR. Regulatory authorities will then be discussed under the Better Regulation principles, before concluding with some general observations.

4.1 Regulatory Authorities

The *Bodies in Ireland with Regulatory Powers* report defines a regulatory authority as a body recognised in statute that has at least two of the following powers: the creation of rules, standards or goals; monitoring, auditing, inspecting, evaluating or gathering information; enforcing, changing behaviour or applying words or sanctions.⁴²⁷ The report also noted that such bodies are generally independent from the state, have some capacity for independent decision making, are generally in place for a period of time, and have some staffing and financial resources.⁴²⁸

Regulatory authorities are often interdisciplinary and the value of regulatory authorities lies in their expert knowledge. These authorities generally have the expertise necessary to regulate, and Thatcher has noted that they tend to have more expertise than government departments, which are mainly composed of civil servants.⁴²⁹ This has proved necessary in economic regulation, as the increased complexity of the markets has led to problems regulating the markets under the traditional regulatory structures.⁴³⁰ While government departments may benefit from their own research units or advisory bodies they may have set up, the appointment of a regulatory authority ensures that decisions are made by a group of people with the requisite expertise.

The political independence of the authorities can ensure that decisions are made, but that decision makers are not subject to the same political pressures as government Ministers.⁴³¹ Although they are a part of the government, they are generally created in such a way that they

⁴²⁵ D Souter (n 374) 80.

⁴²⁶ M Lodge, 'Accountability and Transparency in Regulation: Critiques, Doctrines and Instruments' in J Jordana & D Levi Faur (eds), *The Politics of Regulation* (Cheltenham, Edward Elgar, 2004) at 125.

⁴²⁷ Department of the Taoiseach, *Bodies in Ireland with Regulatory Powers* (2007) para 2.5.

⁴²⁸ *Ibid* 2.6.

⁴²⁹ M Thatcher, 'Regulation after delegation: independent regulatory agencies in Europe' (2002) 9 *Journal of European Public Policy* 954, 967.

⁴³⁰ V Nagarajan, 'From 'Command-and-Control' to 'Open Method Coordination': The Theorising the Practice of Regulatory Agencies' (2008) 8 *Macquarie Law Journal* 5, 7.

⁴³¹ Gilardi (n 423) 67.

“exist essentially as independent agents”.⁴³² This can be important in economic affairs where necessary but unpopular decisions are required to be made. Prosser has noted:

“In the area of policy making where most of the difficulties of this division of labour have arisen, it is important to have an independent authority to amass information, develop expertise and, crucially, to nudge government into taking decisions that it might otherwise be unprepared to do for reasons of potential political unpopularity.”⁴³³

One economic example is that of the Irish Central Bank, which implements interest rate cuts or rises (set by the European Central Bank) that are free from government pressures. These decisions can be made and implemented without resulting in political damage to the government. However, in times of crisis, governments can often use the independent decisions made to shift the blame for failures to regulatory authorities.

Decisions that were once made by ministers are now being made by appointed board members who are unaccountable to the general public. This may be a concern when one considers the argument that regulatory authorities are considered by some to be a “central actor” in policy making in their field.⁴³⁴ Although members of the regulatory authority are generally appointed by government ministers, the decisions of the authority have potentially far-reaching consequences, despite being made by an unelected group.⁴³⁵ As a result there have been questions raised regarding the democratic legitimacy of these authorities, particularly when one considers that a regulatory authority is generally not accountable to any government minister.⁴³⁶ The limitations on its powers are set out in the statutory instrument creating the authority, which must clearly set out the functions and duties of the authority. In carrying out its duties, the authority must be careful that in setting standards it is not creating policy, as that is the function of the executive and legislature.

Furthermore, despite their apparent independence, there have been allegations that regulatory authorities are not always free from political interference. First, the staffing of the authority can influence its workings, as the staff are generally appointed by the government of the day and are likely to be compromised of those in agreement with party policies. Forced resignations, while difficult to distinguish at times from voluntary resignations, can impact upon the independence of the authority.⁴³⁷ Also, the tenure of appointment can affect an authority’s independence, with a longer tenure less susceptible to political influence.⁴³⁸ Membership of such a body is important as the membership can dictate the decisions of the

⁴³² House of Lords, Select Committee on the Constitution, *The Regulatory State: Ensuring its Accountability*, 6th Report of Session (2003-04) para 2.

⁴³³ T Prosser, ‘Models of Economic and Social Regulation’ in D Oliver, T Prosser & R Rawlings, *The Regulatory State – Constitutional Implications* (OUP 2010) 40.

⁴³⁴ M Maggetti, ‘The Role of Independent Regulatory Agencies in Policymaking: A Comparative Analysis’ (2009) 6 *Journal of European Public Policy* 450, 465.

⁴³⁵ D Souter (n 374) 12.

⁴³⁶ House of Lords, Select Committee on the Constitution, *The Regulatory State: Ensuring its Accountability*, 6th Report of Session 2003-04 para 111.

⁴³⁷ Thatcher (n 429) 959.

⁴³⁸ *Ibid.*

authority. Ideally, in relation to issues concerning biotechnology, such bodies should be interdisciplinary so that they are equipped to deal with issues pertaining to science, ethics and the law, as well as other issues that are deemed necessary in the relevant field. While in the UK the HFEA cannot have a majority of scientists or clinicians, in California the Independent Citizen's Oversight Committee (ICOC), set up under the California Stem Cell Research and Cures Initiative,⁴³⁹ is mainly staffed by those from the medical and scientific community, which has led to concerns about possible conflict of interest.⁴⁴⁰ Indeed the three advisory committees set up to advise the ICOC in funding projects are all medical related: the Scientific and Medical Research Funding Working Group, the Scientific and Medical Accountability Standards Working Group and the Scientific and Medical Research Facilities Working Group.⁴⁴¹ Any authority tasked with over-seeing ESCR should take the ethical issues into consideration to ensure that the research is carried out in accordance with the ethical principles. Finally the staffing and resources of an authority can impact upon an authority, as cuts to resources and staffing may be seen as a political decision and affect the authority's capacity to carry out its functions.⁴⁴² Thus while regulatory authorities are designed to be independent, they are not completely free from political pressures.

Despite these issues, in the stem cell context, the establishment of a regulatory authority to regulate ESCR may be suitable. Such an authority should be interdisciplinary, ensuring that the authority has the legal, ethical and scientific expertise necessary to regulate ESCR. The authority can make its decisions free from the same political pressures that government Ministers are subjected to. While it is likely that interest groups will still lobby such an authority, as it is not elected, it should in theory be more likely to withstand the lobbying. While this depoliticisation of decisions may lead to an honest debate that is focused on accurate facts and in an atmosphere that is free from the rhetoric that has marred previous governmental decisions, there is the danger that the regulatory authority will become subject to regulatory capture. Indeed it has been noted that stakeholder interests must be balanced against the interests of the public as often the two can collide.⁴⁴³ As one of the purposes of regulatory authorities is that they provide the expertise in a given area, it is likely that they will be staffed by those drawn from the industry.⁴⁴⁴ Thus it may be difficult to avoid regulatory capture.

⁴³⁹ The California Stem Cell Research and Cures Initiative was passed by the people of California in 2004 under Proposition 71 in which it was agreed that \$295 million per year would be spent on stem cell research for ten years. While the money may be spent on any type of stem cell research, embryonic stem cell research is given priority.

⁴⁴⁰ L Knowles, 'State-Sponsored Human Stem Cell Research: Regulatory Approaches and Standard Setting' in A Levine (ed), *States and Stem Cells: the Policy and Economic Implications of State-Funded Stem Cell Research* (Princeton, 2006) 80.

⁴⁴¹ Ibid 78.

⁴⁴² For example, in 2011, the Irish Human Rights Commission noted that severe cuts to its budget and those of other rights groups had negatively impacted upon human rights in Ireland. Irish Human Rights Commission, *Submission for the Twelfth Session of the Working Group on the Universal Periodic Review: Ireland* March 2011 3.

⁴⁴³ D Souter (n 374) 45.

⁴⁴⁴ A Ogus, *Regulation: Legal Form and Economic Theory* (Hart Publishing 2004) 57.

4.2 Case Study: Human Fertilisation and Embryology Authority

The Human Fertilisation and Embryology Authority (HFEA) was established under the HFE Act 1990. It is tasked with issuing licences, to clinics as specified under the Act, and monitoring clinics as well as updating and enforcing the Authority's Code of Practice.⁴⁴⁵ The Authority is also responsible for providing information to the general public on fertility issues as well as making some ethical decisions. The HFEA's roles can be split into two main purposes: first, it is concerned with the quality control and provision of treatment and second, it evaluates scientific progress.⁴⁴⁶ The establishment of the HFEA was novel as it was the first time that an area of medical practice was made subject to an oversight body in the UK.⁴⁴⁷ However, the Authority ensures that one body is tasked with the regulation of assisted reproduction thus minimising over-lap and providing clarity to both clinicians and patients as to who the regulator is.

The HFEA is also tasked with publishing and maintaining a Code of Practice, which all clinics must adhere to. The Code must be regularly updated and approved by the Secretary of State for Health and laid before Parliament.⁴⁴⁸ Unlike the Secretary of State, members of Parliament do not have the power to reject the Code, nor to make suggestions for change. The Secretary of State has the power to ensure that the HFEA consults with certain groups or individuals when drafting or revising the Code.⁴⁴⁹ If the Secretary of State rejects the Code, they must provide reasons.⁴⁵⁰ The government thus has very little influence in the workings of the HFEA and is limited to the drafting and revising of the Code which can only be achieved through the Secretary of State. This allows the HFEA to make its decisions and implement its Code independently of the government. It has been noted that due to the fast-moving pace of the technology, the HFEA's policy team tends to be reactive. In creating policy to cope with these technological changes, the HFEA is informed by the business sector and the scientific community which, it is argued, has led to buy-in on policy from these groups.⁴⁵¹ There is the danger, however, that this could lead to regulatory capture, with the HFEA more concerned with devising policy that its regulatees will follow, rather than policy that is in the public's interest.

The viability of HFEA is however under question as a result of the UK government's spending review of the NHS. The UK government has committed itself to cutting the NHS administrative costs by 45%, reducing the number of NHS bodies, and reducing the Department of Health's Arms-Length Bodies (of which the HFEA is one).⁴⁵² As part of this

⁴⁴⁵ The HFEA's duties are set out in S.8 of the HFE Act 1990. For a list of what the HFEA perceives to be its duties under the HFE Act 1990, see Human Fertilisation and Embryology Authority *Annual Report and Accounts 2011/12* (July 2012) 9-10.

⁴⁴⁶ Callus (n 383) 89.

⁴⁴⁷ Department of Health, *Review of the Human Fertilisation and Embryology Act: A public consultation* (2005) para 2.10.

⁴⁴⁸ Section 26(5) of the HFE Act 1990.

⁴⁴⁹ Section 26(3) of the HFE Act 1990.

⁴⁵⁰ Section 26(4) of the HFE Act 1990.

⁴⁵¹ Department for Business, Innovation and Skills, Better Regulation Executive, *Internal Review of the HFEA: A Hampton Implementation Review Report* (December 2009).

⁴⁵² Department of Health, *Liberating the NHS: Report of the Arm's Length Bodies Review* (July 2010) 4.

reduction, it has been proposed to merge the Human Tissue Authority and the HFEA into one body⁴⁵³ as well as transferring some of its duties to the Care Quality Commission.⁴⁵⁴ However, for the interim the HFEA and the HTA will be kept separate while the proposal is considered in detail.⁴⁵⁵

Unlike its predecessor, the Voluntary Licensing Committee, the HFEA has a fixed term of reference and it must operate within those terms.⁴⁵⁶ Thus it was envisaged that the HFEA would implement rather than make policy. Although the regulatory structure in place under the HFE Act 1990 is often regarded as the best in the world,⁴⁵⁷ questions have risen over the extent to which the HFEA makes policy and furthermore, whether it should be making certain decisions.

The HFEA's roles in quality control and issuing licences are relatively uncontroversial, but its function in evaluating scientific progress has led to criticisms, particularly as this role can involve an ethical evaluation of new research.⁴⁵⁸ It is contended that while parliament sets the ethical framework within which the Authority may make some ethical choices,⁴⁵⁹ it has been suggested that the HFEA should not be making ethical decisions as they are an interested regulator.⁴⁶⁰ Indeed it is this role in ethical-decision making that has led to suggestions that the Authority has over stepped its role and is in fact creating law.⁴⁶¹

Formally speaking, the HFE Act 1990 has given the Authority wide discretion to create policy but it must be done within the confines of the Act. Indeed, the decision-making powers granted to it by Parliament have been recognised by the courts,⁴⁶² which have cautioned against quickly interfering with that power.⁴⁶³ However, it has been argued that the Authority has become the final arbitrator in ethical decisions on which there is no consensus.⁴⁶⁴ It has been countered that it is due to the controversial nature of the issues with which the Authority is dealing, that its decisions have been contentious, rather than the manner in which it has

⁴⁵³ Department of Health, *Liberating the NHS: Report of the Arm's Length Bodies Review* (July 2010) paragraph 3.3.

⁴⁵⁴ *Ibid* 3.16.

⁴⁵⁵ *Ibid* 3.33.

⁴⁵⁶ See generally the Human Fertilisation and Embryology Act.

⁴⁵⁷ See comments of Geraldine Hartshorne, secretary of the Association of Clinical Embryologists, in J Meikle 'Axe IVF watchdog, says fertility expert' *The Guardian*, 11 December 2004 <<http://www.guardian.co.uk/society/2004/dec/11/health.medicinemandhealth>> (accessed 23 June 2012). Brazier has also stated that the HFE Act has put in place a system whereby patients can be assured of a basic standard of practice. M Brazier, 'Regulating the Reproduction Business' (1999) 7 *Medical Law Review* 166, 173-4.

⁴⁵⁸ *Ibid*.

⁴⁵⁹ T Callus, 'Ensuring Operational Compliance and Ethical Responsibility in the Regulation of ART: The HFEA, Past, Present, and Future' (2011) 3 *Law, Innovation and Technology* 85, 94.

⁴⁶⁰ *Ibid* 87.

⁴⁶¹ Scott has argued that

"The paradox of regulatory agencies is that they frequently possess too much power outside the normal structures of ministerial responsibility to be legitimate, but too little power to secure the outcomes sought." C Scott, 'Regulating Everything' *UCD Geary Discussion Paper* (2008) 6.

⁴⁶² *R v Human Fertilisation and Embryology Authority, ex parte Blood* [1997] 2 All ER 687, 698.

⁴⁶³ *Ibid*, 701.

⁴⁶⁴ D Morgan, 'Ethics, Economics and the Exotic: The Early Career of the HFEA' (2004) 12 *Health Care Analysis* 7, 11.

made its decisions.⁴⁶⁵ Furthermore this discretion in the fulfilling of the Authority's role is necessary due to the technological developments in this area.⁴⁶⁶ The Hampton Review, in its assessment of the HFEA, stated that it has a "central role" in developing policy and regulation in the areas of fertility treatment and embryo research.⁴⁶⁷ Yet it is argued that this role is expanding, with Dame Anne McLaren suggesting that "the HFEA seems to have a wider sphere of responsibility with every year that passes".⁴⁶⁸

While this policy-making function has been described as unusual,⁴⁶⁹ it is a power that Parliament has given the HFEA. Yet the Hampton Review did express some reservations in relation to some of the Authority's decisions and in particular questioned its policy on pre-implantation genetic diagnosis (PGD) and tissue typing. The UK government is embarking on a drive to ensure that bodies such as the HFEA have clear and defined functions and do not assume new roles. What impact this will have on the HFEA remains to be seen but clarification as to the extent of its policy-making role would be welcomed.⁴⁷⁰

The ethical review function of the Authority has included determining whether treatment such as PGD should be permitted and also which diseases PGD can test for. This dual ethical review has given the Authority "a real ethical decision-making power"⁴⁷¹ and arguably it is making decisions that should be made by Parliament. The Chair of HFEA has also acknowledged that the Authority is looking at treatments that Parliament did not envisage when it was established. Thus questions should be asked as to whether the Authority should be making these decisions.

Due to the area of science the Authority regulates, its decisions involve both ethical and scientific decisions.⁴⁷² It is this ethical decision-making role that has caused the most disquiet, and it has been argued that the differing perceptions on whether the HFEA is a good regulator are often due to disagreements over the ethical approach taken by the HFEA, particularly in relation to embryo research.⁴⁷³

In December 2001, the HFEA published its policy on PGD and stated that while it was prepared, in principle, to permit testing to ensure the birth of a "saviour sibling",⁴⁷⁴ it was envisaged that the test for this purpose would only be carried out in "very rare circumstances and under strict controls".⁴⁷⁵ Permission for PGD for tissue typing⁴⁷⁶ had to be granted by

⁴⁶⁵ A Dawson, 'The Human Fertilisation and Embryology Authority: Evidence Based Policy Formation in a Contested Context' (2004) 12 *Health Care Analysis* 1, 2.

⁴⁶⁶ Ibid 3.

⁴⁶⁷ Department for Business, Innovation and Skills, Better Regulation Executive, *Internal Review of the HFEA: A Hampton Implementation Review Report* (December 2009). This role is unusual as it is thought that regulators should not create policy. D Souter (n 374) 80.

⁴⁶⁸ D Morgan (n 464) 12.

⁴⁶⁹ A Dawson (n 465) 3.

⁴⁷⁰ Department of Health, *Liberating the NHS: Report of the Arm's Length Bodies Review* (July 2010) para 2.3.

⁴⁷¹ Callus (459) 94.

⁴⁷² J Meikle, 'Axe IVF watchdog, says fertility expert' *The Guardian* 11 December 2004 <http://www.guardian.co.uk/society/2004/dec/11/health.medicineandhealth> (accessed 23 June 2012).

⁴⁷³ T Prosser, *The Regulatory Enterprise – Government, Regulation and Legitimacy* (OUP 2010) 21.

⁴⁷⁴ A saviour sibling is a child born to treat a sibling who has a fatal disease.

⁴⁷⁵ The circumstances include: That all other possibilities of treatment and sources of tissue for the affected child should have been explored; the condition of the affected child should be severe or life-threatening. The

HFEA on a case-by-case basis and one family, the Hashmi family, were successful in getting permission from HFEA to carry out the test. This permission was granted despite nowhere in the HFE Act 1990 stating that HFEA had the power to grant a licence for tissue typing. However, paragraph 1(1) of the 1990 Act permits the Authority to authorise certain activities provided they are necessary in providing IVF services to the public. Thus if tissue typing is necessary for providing fertility treatment then HFEA has the power under the Act to licence such services.

Ms Quintavalle, on behalf of Comment on Reproductive Ethics (CORE) later sought judicial review of this decision. It was argued that HFEA did have the authority under the 1990 Act to issue a licence for tissue typing to select between embryos.⁴⁷⁷ In the High Court, Kay J found that HFEA had acted outside of its powers under the 1990 Act and could not issue a licence for tissue typing. In the Court of Appeal, the HFEA argued that it had the authority to grant a licence for purpose of “developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation” and that Parliament could not have intended to prohibit an activity arising from such research. By permitting such embryo research, it could be implied that Parliament had approved PGD to ensure that women could avoid implanting embryos with genetic defects.⁴⁷⁸

The Court of Appeal found this argument persuasive. It was of the opinion that if having a child with a genetic defect is an impediment to seeking fertility treatment then PGD and tissue typing are considered treatment services under the Act. The Court of Appeal held that the HFEA has the power to issue a license for such research.⁴⁷⁹ Schiemann LJ noted that Parliament did not give HFEA a “free-for-all” to grant licenses for tissue typing irrespective of the reasoning⁴⁸⁰ but the circumstances under which tissue typing could be authorised did reside with HFEA.⁴⁸¹

The powers of the HFEA were further discussed by the House of Lords on appeal. Lord Hoffman noted that subject to certain prohibitions, the licensing power of the HFEA was

technique should not be available where the intended tissue recipient is a parent; couples undergoing this type of treatment should receive appropriate implications counselling.; embryos should not be genetically modified to provide a tissue match.” HFEA to allow tissue typing in conjunction with preimplantation genetic diagnosis 13 December 2001 <<http://www.hfea.gov.uk/961.html>> accessed 14 September 2012.

⁴⁷⁶ Tissue typing “is a technique which allows for the selection of embryos in order to bring about the birth of a child who can provide a matched tissue donation to an existing sibling”. <http://www.hfea.gov.uk/515.html> accessed 30 January 2013.

⁴⁷⁷ Up to this case PGD had been licensed but tissue typing had not. *R (on the application of Quintavalle) v Human Fertilisation and Embryology Authority* [2003] EWCA Civ 667 para 5. The House of Commons Committee on Science and Technology was critical of the decision allowing PGD in conjunction with tissue typing as HFEA’s publication consultation only considered PGD and not the use of tissue typing with PGD. The Committee was of the opinion that on decisions of ethical importance, such as the use of tissue typing, the public should be consulted. House of Commons Science and Technology Committee, *Developments in Human Genetics and Embryology* (Fourth Report of Session 2001–2) para 17.

⁴⁷⁸ *R (on the application of Quintavalle) v Human Fertilisation and Embryology Authority* [2003] EWCA Civ 667 para 38.

⁴⁷⁹ *Ibid* para 43.

⁴⁸⁰ *Ibid* para 87.

⁴⁸¹ As per Lord Philips. *Ibid* para 50.

defined in broad terms.⁴⁸² Lord Hoffman was of the opinion that such broad powers would raise difficult ethical issues, but the membership of the Authority as outlined in the Warnock Report was designed to ensure that the Authority could deal with these issues.⁴⁸³ Furthermore, Lord Hoffman stated that as the Act was silent on tissue typing, despite considerable debate in Parliament on tissue selection for sex selection, it could only be inferred that Parliament intended the HFEA to decide on such issues.⁴⁸⁴

In the HFEA's defence, allegations that it is creating policy can be defended on two grounds. First, its functions as laid out in legislation are quite broad, subject to a number of restrictions. Furthermore, despite being quite critical of the HFEA, the House of Commons Science and Technology Committee noted that the HFEA was created as an independent body whose policy decisions cannot be interfered with by Parliament, and the relevant Minister's function is limited to one of overseeing the Authority's performance.⁴⁸⁵ Second, in an area of science, such as reproductive technology, that is rapidly developing, a regulatory authority will find that it must make certain decisions which can be perceived to be straying into the policy making arena. Should it be forced to consult Parliament each time there were concerns that its decision had the potential to be perceived as policy making, it would not be able to carry out its regulatory function. Indeed the House of Commons Committee has agreed that there are times when the HFEA could not have carried out its functions without developing a policy-making function. However the Committee did caution that any changes in legislation should define whether this policy-making function should be present.⁴⁸⁶ While arguably the HFEA did go beyond its powers in authorising PGD for tissue typing, it is equally arguable that this was necessary to ensure that the regulations keep pace with the science. It is thought that without this function, policy would stagnate.⁴⁸⁷ Despite the evidence that one of the advantages of the HFEA was its ability to respond quickly to changes in the science, the House of Commons Science and Technology Committee was of the opinion that this flexibility should be reduced and more detailed legislation should be introduced.⁴⁸⁸

Yet the line between implementing decisions and creating policy is not always clear, particularly where it is unclear whether new scientific developments come under current regulations or require the introduction of new regulations. For stem cell researchers, if the functions and powers of a regulatory authority are explicit, it should be clear whether a new technology is to be regulated by the authority. If it is to be covered, this ensures that researchers can proceed provided they are within the guidelines set down by the authority. However, if the research is outside of the powers of the authority, this will require a legislative amendment to the regulations by parliament, which raises in turn the same

⁴⁸² Ibid at para 24.

⁴⁸³ Ibid at para 26.

⁴⁸⁴ Ibid at para 29.

⁴⁸⁵ Human Reproductive Technologies and the Law, House of Commons Science and Technology Committee, Fifth Report (session 2004–5, HC 7-1) para 194.

⁴⁸⁶ Ibid para 218.

⁴⁸⁷ Dawson (n 465) 5.

⁴⁸⁸ Human Reproductive Technologies and the Law, House of Commons Science and Technology Committee, Fifth Report (session 2004–5, HC 7-1) para 315.

problem with the command and control model. On the other hand, if the powers and duties of the authority are less explicit and more flexible, this could reduce the need to revert to parliament, but the distinction between policy making and policy implementation becomes less clear. This particular problem is one that is faced by the HFEA.

6. Regulating ESCR through Regulatory Authorities and the Principles of Better Regulation

The advantage of regulatory authorities is that they can be composed of a group of experts with the necessary expertise to regulate a technology such as ESCR. Furthermore, in theory they are independent and thus free from political pressure. However, while the HFEA has been both criticised and commended, it has been alleged that the Authority falls short of the principles of Better Regulation.⁴⁸⁹ Attempts to rectify this situation have been made with the introduction of Section 8ZA under the 2008 amendment that “the Authority must carry out its functions effectively, efficiently, and economically and have regard to the principles of best regulatory practice”. It would therefore seem appropriate to examine regulatory authorities, and the HFEA in particular, in light of the Better Regulation principles.

6.1 Transparency

One of the values of the HFEA is that debates concerning new techniques or treatment occur in the public domain.⁴⁹⁰ In this respect it has been described as a “conduit for ethical discussion around medical advancements and the use of human embryos”.⁴⁹¹ It has been said that it has a good relationship with its stakeholders, thus ensuring that they take part in consultations and contribute to the debate, which the Hampton Review considered to be good practice.⁴⁹² However concerns were voiced that the relationship between the fertility industry and the HFEA should not become too close, and that the HFEA should guard against even being perceived as being too close as that would be damaging to its reputation.⁴⁹³ There appears to be a concern that the HFEA could be in danger of regulatory capture. While there is currently no evidence of this, the HFEA should be careful to ensure that this does not occur.

6.2 Accountability

It has been noted that regulators decisions are independent from the government and may be contrary to department policy. Furthermore they often do not justify their decisions.⁴⁹⁴ This has led to concerns that a regulatory authority is unaccountable and not subject to the will of the people.

⁴⁸⁹ Ibid para 2.90.

⁴⁹⁰ Brazier (n 457) 174.

⁴⁹¹ Department for Business, Innovation and Skills, Better Regulation Executive, *Internal Review of the HFEA: A Hampton Implementation Review Report* (December 2009).

⁴⁹² Ibid

⁴⁹³ Ibid

⁴⁹⁴ D Souter, ‘A Stakeholder Approach to Regulation’ in D Corry, D Souter and M Waterson, *Regulating our Utilities* (Institute for Public Policy Research, 1994) 79.

From the outset, the purpose of the HFEA was to remove the “sensitive” issues it considers from the political process. Such a move received wide support in the discussions prior to the HFE Act 1990.⁴⁹⁵ However the HFEA is an unelected authority and is not accountable in the same way as politicians, despite having a policy-making role. This is not a problem exclusive to the HFEA and it has been acknowledged that the extent to which the government should have a residual power to review decisions of regulatory authorities is unclear.⁴⁹⁶ However, it is argued that while regulatory authorities should be accountable, this should not be to the detriment of their independence.⁴⁹⁷ In particular, governments should not use control on resources to erode the independence of regulatory authorities.

During the debates on the HFE Bill 1990, there were concerns raised that the Parliament would not have a mechanism whereby the decisions of the HFEA could be reviewed.⁴⁹⁸ Indeed the only accountability the government has over the HFEA is through the Secretary of State for Health, who has the power to reject a revision of the Code of Practice. Neither the Secretary of State nor the government has the power to intervene with the decisions of the HFEA, and its decisions can only be appealed through judicial review as demonstrated by Mrs Quintavalle. The HFEA’s decision on the posthumous use of sperm has also been challenged.⁴⁹⁹ Although the judicial review application ultimately failed, the issues raised in the proceedings led to the Human Fertilisation and Embryology (Deceased Fathers) Act 2003 and the Courts have stated that the HFEA’s decisions can be challenged when it exceeds its powers as set out by Parliament.⁵⁰⁰ Furthermore, indirectly, the government can hold the Authority to account by failing to renew appointments to the Authority.

There have also been concerns raised over the decisions of the HFEA. It has been criticised by scientists for being too restrictive in licencing new techniques, criticised by patients for failing to licence new techniques or treatments and criticised by lobby groups for going beyond what they perceive to be its statutory powers.⁵⁰¹ Its wide discretionary powers in carrying out its functions have been described as both its greatest strength and weakness, but they remain discretionary powers which are exercised by an unelected body.⁵⁰² The source of this multitude of criticism may lie in the dual mandate of the HFEA: not only must it review and approve scientific techniques but it also must consider the circumstances in which a new technique or treatment can be used. This ultimately involves an element of ethical decision-

⁴⁹⁵ Hansard 2 April 1990 col 983.

⁴⁹⁶ A Ogus, *Regulation: Legal Form and Economic Theory* (Hart Publishing 2004) 106.

⁴⁹⁷ Department of the Taoiseach, *Regulating Better: A Government White Paper setting out six principles of Better Regulation* (2004) at 31.

⁴⁹⁸ Hansard 2 April 1990, col 983.

⁴⁹⁹ *R v Human Fertilisation and Embryology Authority, ex parte Blood* [1997] 2 All ER 687.

⁵⁰⁰ *R (on the application of the Assisted Reproduction and Gynaecology Centre and another) v Human Fertilisation and Embryology Authority* [2003] 1 FCR 266, 270.

⁵⁰¹ Callus (n 444) 86-7. See also J Meikle, “Axe IVF watchdog, says fertility expert” *The Guardian* 11 December 2004 <http://www.guardian.co.uk/society/2004/dec/11/health.medicineandhealth> (accessed 23 June 2012).

⁵⁰² *Human Reproductive Technologies and the Law*, House of Commons Science and Technology Committee, Fifth Report (Session 2004–5, HC 7-1) para 3.15.

making.⁵⁰³ It has been argued that it is this aspect of HFEA's functions that has led to confusion in its role and ultimately a neglect of its licensing and quality control functions.⁵⁰⁴

It has been suggested that the HFEA's policy-making role should be separated from its inspectorate role.⁵⁰⁵ This recommendation was recently considered by the Department of Health, which recommended the splitting of the HFEA's mandate, with the Care and Quality Commission identified as potentially assuming HFEA's licensing and quality control role.⁵⁰⁶ It has been further suggested that, irrespective of such a move, if the policy making function of the HFEA were retained, criticisms would continue to be levied against the HFEA. If this splitting of the HFEA's roles does go ahead, this would not resolve the issue of whether a largely unaccountable body should be making some of the decisions it does. While the advantage of the HFEA is that it can interpret the HFE Act 1990 in line with developments in science as occurred with embryos created through SCNT, there is the danger that decisions that should be made by politicians are being made by the HFEA.

6.3 Proportionality

The purpose of the HFEA and the HFE Act 1990 was to ensure that the public has confidence in fertility services and embryo research. Regulatory authorities generally implement legislation and may also publish a set of guidelines or Code of Practice that those it seeks to control should follow. Failure to follow these guidelines will generally result in sanctions. Following these guidelines may result in extra bureaucracy for the regulatees.

The HFEA issues a Code of Practice that clinics must follow and it is arguable that these standards could increase red tape for businesses. It has been alleged that the HFEA is overly bureaucratic and that a more flexible regime is needed. It has also been argued that the legislation sets out what is permitted and there is no need for a regulator to enforce the law.⁵⁰⁷ However this view ignores the HFEA's role in setting standards and inspecting clinics.

The Hampton Review stated:

“The HFEA's legislative framework is about enhancing public confidence in the fertility and embryology research sectors. Its remit is broader than just licensing IVF clinics and research centres which use human embryos – the HFEA also provides information and support to patients of infertility clinics and acts as a conduit for ethical discussion around medical advancements and the use of human embryos.”⁵⁰⁸

Due to the need to ensure a high standard of quality for embryo research and a need to reassure the public that embryos are treated with respect and that embryo research is only operated within the confines of the law, the standards set out in the Code are proportionate.

⁵⁰³ Callus (n 459) 94.

⁵⁰⁴ Dawson (n 465) 2.

⁵⁰⁵ Ibid 5.

⁵⁰⁶ Department of Health, *Liberating the NHS: Report of the Arm's Length Bodies Review* (July 2010) para 3.16.

⁵⁰⁷ J Meikle “Axe IVF watchdog, says fertility expert” *The Guardian* 11 December 2004 <http://www.guardian.co.uk/society/2004/dec/11/health.medicinandhealth> (accessed 23 June 2012).

⁵⁰⁸ Department for Business, Innovation and Skills, Better Regulation Executive, *Internal Review of the HFEA: A Hampton Implementation Review Report* (December 2009).

6.4 Consistency

Regulatory authorities must apply the rules and standards equally across all regulatees. It has been acknowledged that the HFEA applies its rules consistently in the issuing of licences and in ensuring the quality of practice.⁵⁰⁹ This ensures clarity for the clinics and also assures the general public that the clinics are adhering to the legal, ethical and quality standards set out under the HFE Act.

However in relation to its policies there has been some inconsistency. Despite statements in the past encouraging sperm donation and seeking to change practices that would negatively impact upon donation, a House of Commons committee in 2004 stated that “it is not the HFEA’s function to promote or encourage donation or treatment”.⁵¹⁰ Such inconsistency in policy should not occur as clinics must be confident in the consistency of the HFEAs guidance⁵¹¹ and furthermore, an effective compliance system must underpin any regulatory structure.⁵¹²

6.5 Effectiveness

When regulating ESCR, it is crucial to ensure that the policies keep pace with the developing science, otherwise the policies risk losing their effectiveness. To ensure that its guidance keeps up to date with the technology, the HFEA established a Horizon Scanning Panel in 2004, which is tasked with identifying new science and clinical developments that may impact upon assisted reproduction or embryo research. The Panel then considers the legal, ethical and scientific issues associated with the new technology.⁵¹³ In this way the Authority keeps its guidance current, thus ensuring that its guidance is effective and is prepared to regulate developments in science.

However in relation to issuing sanctions to ensure that there is compliance with the law and the HFEA’s policies, it has been noted that there is reluctance within the HFEA to use the full spectrum of its available sanctions. In particular there is wariness amongst staff to recommend the removal of a clinic’s licence for fear that patients would travel abroad for treatment.⁵¹⁴ While such patient safety issues do not arise in the regulation of ESCR, a regulatory authority must have the ability and confidence to use its enforcement procedures to ensure compliance. Otherwise the Authority could risk being perceived as being “soft” on compliance, which could impact upon scientists’ adherence to the regulations.

⁵⁰⁹ Department of Health *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including the establishment of the Regulatory Authority for Tissue and Embryos)* (2006) para 2.44.

⁵¹⁰ Human Reproductive Technologies and the Law, House of Commons Science and Technology Committee, Fifth Report (session 2004–5, HC 7-1) para 2.16.

⁵¹¹ It has also been suggested that by encouraging sperm donation the HFEA was acting outside of its statutory remit. *Ibid* para 2.16.

⁵¹² R Macroy, ‘Reforming Regulatory Sanctions-Designing a Systematic Approach’ in D Oliver, T Prosser & R Rawlings *The Regulatory State – Constitutional Implications* (OUP 2010) 229.

⁵¹³ <<http://www.hfea.gov.uk/Horizon-Scanning-Panel.html>> accessed 14 September 2012.

⁵¹⁴ Department for Business, Innovation and Skills, Better Regulation Executive, *Internal Review of the HFEA: A Hampton Implementation Review Report* (December 2009).

6.6 Necessity

Regulatory authorities should only be introduced where required. Furthermore, the roles and functions, as well as the degree to which the authority carries out these duties, should be kept under review. While the HFE Act 1990 brought clarity and certainty to the permitted boundaries of research, the need for the HFEA was to ensure that the law kept pace with the science. The HFE Act 1990 broadly outlined the permitted areas of the research and the criteria for obtaining a licence while the Code of Practice, as issued by the HFEA, contains more detailed guidelines to be followed. Furthermore, the HFEA is an independent body, staffed with experts in fertility treatment and embryo research who thus have the relevant expertise to ensure that the criteria are satisfied before a licence is issued, HFEA staff are also capable of inspecting the clinics to ensure the highest levels of quality are achieved, and have the relevant expertise to issue guidelines on fertility treatment and embryo research.

However, there are questions as to whether the HFEA is necessary to carry out the inspectorate role. The Care and Quality Commission has been identified as a body that is already carrying out similar functions and it would appear to be logical that inspectorate roles be merged into one authority. Thus, while it is necessary that the inspectorate role is fulfilled, the HFEA is not necessarily the body that should have that role. As discussed above, since its inception, the HFE Act 1990 and the HFEA itself have been reviewed a number of times and there are on-going discussions as to whether the functions of the HFEA should be split.

The value of a regulatory authority for ESCR is two-fold. First it provides the expertise necessary. The legal, ethical and scientific issues must be considered when regulating, and provided the regulatory authority is adequately staffed with experts in the field, it is in a position to respond to changes in the law. In this respect, regulatory authorities provide their second benefit, which is their flexibility. As a statute is not always required to change their guidance regulatory authorities can quickly amend its guidance in accordance with developments in technology, ensuring that researchers are not operating in an uncertain environment.

However, as evidenced by the HFEA, at times it is unclear whether the Authority is acting outside of its remit and making policy when it should not be. This will likely occur in the stem cell context as new developments in technology will lead to a revision of scientific terms thus leading to uncertainty as to whether an authority has the power to regulate the new technology.

7. Conclusion

While the UK model has much to be commended, it is submitted that an adaptation of this model is preferable. A regulatory authority should be established by an Act of Parliament and its duties should be set out under the Act. Unlike in the UK, however, there should be more clarity in the Act as to the scope of the Authority's powers. If the Authority is to have a policy making role to ensure that it can respond quickly to technological changes, this should be specified in the Act. However, if Parliament is concerned that the Authority should have a

limited role in deciding whether new treatments or research should be permitted, the functions of the Authority should be much more explicit than that currently set out under the HFE Act 1990.

With a controversial area such as ESCR, irrespective of whether the regulator is the relevant Minister or a regulatory authority, the decisions will be both praised and criticised. By regulating the research through an Act of Parliament and establishing a regulatory authority, the public is given a chance to contribute to the Act through which the power of the Authority comes. The Authority will then have the sufficient expertise to implement the Act and also ensure that the standards set out in the Act are followed. The key to successful regulation of ESCR is to ensure that the Act clearly sets out the research to be regulated and who is to regulate it, while ensuring that there is sufficient flexibility to respond to changes in science.

Chapter 5 Economic Policies and the Regulation of Embryonic Stem Cell Research

1. Introduction

Biotechnology is an industry that has grown exponentially over the past few decades. In the US, the value of publicly trading biotechnology companies increased from \$8 billion in 1992 to \$58.8 billion in 2006.⁵¹⁵ As of December 2006, there were 1,452 biotechnology companies in the United States, 336 of which were publicly owned.⁵¹⁶ By April 2008 publicly trading biotechnology companies in the United States were valued at \$360 billion⁵¹⁷ and despite the global recession, Ernst and Young has reported that the biotechnology industry has shown resilience to the downturn.⁵¹⁸ The industry returned to profitability in 2009 with increased revenue in both 2010 and 2011⁵¹⁹ and expenditure on research and development growing by 2% in 2010 and 9% in 2011.⁵²⁰

While biotechnology companies are certainly witnessing growth accompanied with expanding profits, the biotech sector can only reap the rewards after heavy investment in research and development for their products. It is thus unsurprising that in 2006 public biotechnology firms in the United States spent \$27.1 billion on research and development alone. Investment into research and development not only comes from the biotechnology industry but governments across the world with the National Institutes of Health (NIH) in the United States the largest funder of science in the world.⁵²¹

While government grants are mainly aimed at promoting research in universities or research institutes,⁵²² investors in biotechnology companies will expect a return on their investment. This is largely achieved through the patent industry, which enables an inventor to exclusive property rights for up to 20 years. The patenting policies of each state can thus have a large impact on ESCR. If there are controls or prohibitions on the patenting of certain products, such as inventions that use embryonic stem cells, this will effectively discourage private investment and could result in a dramatic decrease in ESCR. Similarly a ban on the public funding of ESCR would remove a substantial funding source for researchers and may ultimately lead to a cessation of private funding for ESCR. In this way, the funding policies and the policies on the commercialisation of the research can indirectly help shape the regulation of ESCR.

⁵¹⁵ Biotechnology Industry Organisation *Guide to Biotechnology 2008* 2.

⁵¹⁶ Ibid.

⁵¹⁷ Ibid.

⁵¹⁸ Ernst and Young *Beyond Borders: Global Biotechnology Report 2010* 4.

⁵¹⁹ Ernst and Young *Beyond Borders: Global Biotechnology Report 2012* 25.

⁵²⁰ Ibid 26.

⁵²¹ For more on the process through which public funds are spent and the politics behind the spending of funds in the NIH see H Varmus, *The Art and Politics of Science* (Norton & Co 2010).

⁵²² There have been exceptions to this. In May 2011 the Californian Institute of Regenerative Medicine (CIRM), the body that administers the funding of ESCR in California announced that it awarded Geron \$25million to fund the first FDA approved clinical trial based on ESCs www.cirm.ca.gov/pressrelease_2011-05-04 accessed 19 March 2012.

This chapter will examine the role that economic policies can have in regulating ESCR, via public funding and patenting policies. The ESCR regulatory regime in the United States, which is regulated through public funding rules, will be examined and this will be contrasted with the EU model. The model of regulating ESCR through public funding will be analysed under the principles of Better Regulation. The patenting of ESCR will also be explored. Particular focus will be given to the EU patenting policies where recent developments in this field have the potential to significantly curtail ESCR within the EU. Comparisons will be made with the US model to illustrate how differing patenting policies can impact the promotion of the research. The regulation of ESCR through patenting will also be analysed under the principles of Better Regulation. Finally, this chapter will defend the view that while the use of economic policies to regulate ESCR has its benefits, it should not be pursued to the exclusion of other regulatory strategies. Rather it should form part of a coherent stem cell policy that involves some direct state regulation.

2. Funding ESCR internationally

While ESCR is both privately and publicly funded, public actors are the dominant funder.⁵²³ In the UK, research is mostly funded by research councils and the Wellcome Trust, although some research is also financed by large pharmaceutical firms.⁵²⁴ In China, the government has actively encouraged universities to invest heavily.⁵²⁵ This has not only led to China becoming an emerging player in the stem cell market but it has had the net effect of attracting funding by firms such as the Beijing Stemcell Medengineering Company.⁵²⁶

This dual funding of research is vital to the development of biomedical research. Public funding is essential for research where there may not be a commercial return, or for early stage research where the potential advances are uncertain.⁵²⁷ Privately funded research will continue where there is likely to be a commercial benefit through the selling of a therapy or new treatment. This makes the research less likely to face cuts during an economic downturn.

If ESCR is solely regulated through the use of public funds, researchers in receipt of private funding will remain outside the regulatory regime. In other words, if the public regulations for ESCR only apply to those in receipt of public funds, there is no obligation for privately funded researchers to follow these guidelines. In this way, a significant portion of the research remains outside of the regulatory regime. The US is one example of such a regime, as the ESCR federal guidelines only apply to researchers who are publically funded. Similarly, the EU now funds ESCR but its guidelines are only applicable to those in receipt of EU funds.

⁵²³ House of Lords Select Committee, *Stem Cell Research* (2002) para 6.3.

⁵²⁴ *Ibid.*

⁵²⁵ For more on the history of Chinese public funding of regenerative medicine see D McMahon, H Thorsteinsdottir, P Singer & A Daar, 'Cultivating regenerative medicine innovation in China' (2010) 5 *Regenerative Medicine* 35.

⁵²⁶ House of Lords Select Committee, *Stem Cell Research* (2002) para 6.5.

⁵²⁷ The public funding of research should not be underestimated. For example, the United States federal government is the biggest funder of scientific research in the world. J Schechter, 'Promoting Human Embryonic Stem Cell Research: A Comparison of Policies in the United States and United Kingdom and Factors Encouraging Advancement' (2009-2010) 45 *Texas International Law Journal* 603, 609.

The regulatory impact that funding policies have on the development of a stem cell policy within the US and the EU will be examined below. It is submitted that they raise a number of problems within a regulatory regime, particularly as they impact upon the principles of democratic deliberation and Better Regulation.

2.1 The Federal Funding of ESCR in the United States

The debate on the federal funding of ESCR in the US began in 1993 with the formation of the Human Embryo Research Panel (HERP) by the National Institutes of Health (NIH). HERP recommended to President Clinton that research on spare embryos should be permitted and that federal funds should be spent on the creation of embryos for certain research purposes.⁵²⁸ However, Congress intervened and proposed via the Department of Health and Human Services (DHHS) appropriations process, that any activity that involved the creation of, destruction of, or exposure or risk of injury to human embryos could not be supported by federal funds.⁵²⁹ On foot of this recommendation, Congress passed an amendment to the 1996 Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, known as the Dickey-Wicker amendment. This amendment prohibits the DHHS and the NIH from funding the creation of a human embryo for research. More importantly, research “in which a human embryo or embryos are destroyed or discarded” is prohibited from receiving federal funds.⁵³⁰

The amendment was initially passed prior to the derivation of the first stem cell line and thus it is unclear whether Congress intended the amendment to extend to ESCR.⁵³¹ However as an embryo is destroyed in the derivation of embryonic stem cell lines, it could potentially prohibit the federal funding of ESCR.

Due to this uncertainty, following the derivation of the first stem cell line in 1998 the NIH sought a legal opinion from the DHHS to determine whether embryonic stem cell lines came within the definition of the term “embryo” under the Dickey-Wicker amendment. The DHHS responded that an embryo was defined as an “organism” under the amendment, a definition which could not apply to stem cells as they were neither alive nor did they have the potential to become human beings.⁵³² Thus the amendment did not prohibit the federal funding of ESCR. The focus of the legal opinion was on whether an embryonic stem cell line came under the definition of an embryo, rather than the broader consideration of whether ESCR was research in which “a human embryo or embryos are destroyed or discarded”. This interpretation enabled a distinction to be made between research, that destroys an embryo and research on embryonic stem cell lines, with ESCR falling into the latter category. Relying on

⁵²⁸ *Report of the Human Embryo Research Panel* (September 1994) xi. HERP was established to consider research on embryos *in vitro* and to recommend areas of research that were acceptable for federal funding. See Chapter 6 of the report for the list of recommendations.

⁵²⁹ H Gottwels, ‘The Endless hESC Controversy in the United States: History, Context and Prospects’ (2010) 7 *Cell Stem Cell* 555, 556.

⁵³⁰ Section 509 of Consolidation Appropriations Act 2010.

⁵³¹ The amendment is attached to the Appropriations Act each year and thus has been passed by Congress each year since 1996.

⁵³² For a criticism of the legal opinion see S Wills, ‘Federal Funding of Embryonic Stem Cell Research: Illegal, Unethical and Unnecessary’ (2001-2002) 18 *Journal of Contemporary Health Law & Policy* 95.

this advice, the NIH published guidelines on the federal funding of research on pluripotent cells.⁵³³

A change in President brought a change in policy. On 9 August 2001, President Bush announced that federal funds could only be used to fund ESCR on embryonic stem cell lines that had been derived prior to 9 August 2001.⁵³⁴ This was supplemented in 2007 by Executive Order 13435, which aimed to increase research into alternative sources of pluripotent stem cell research that did not destroy a human embryo.⁵³⁵ While public funding was not prohibited outright, confining the federal funding of ESCR to lines derived prior to 9 August 2001 limited the available lines for federally funded researchers. Furthermore President Bush's order meant that many universities and research institutes that were both privately and federally funded found it necessary to build separate laboratories and purchase separate equipment for ESCR to ensure that federal funds were not spent on ESCR in their laboratories.⁵³⁶ These strict funding requirements, coupled with problems that emerged with the available stem cell lines, could only have served to discourage and limit ESCR.⁵³⁷

In an attempt to clarify the legality of federal funding of ESCR, Congress passed the Stem Cell Research Enhancement Act of 2005, which permitted the federal funding of ESCR irrespective of when the stem cell lines had been derived, provided that only spare embryos were used. This amendment, however, was vetoed by President Bush, and the ban on the federal funding of ESCR on lines derived prior to 9 August 2001 remained.⁵³⁸

This policy was once again reversed with a change in administration. Upon election, President Obama fulfilled a campaign promise to revoke President Bush's order on stem cell research and remove the limitations on ESCR.⁵³⁹ Obama however failed to articulate any particular standards governing the origin of the stem cell lines but gave the NIH only 120 days to produce guidelines.⁵⁴⁰ This deadline was met by the NIH and within three months it published guidelines for embryonic stem cell researchers in receipt of public funds. The guidelines placed two limitations on researchers: first research is only permitted on

⁵³³ National Institute of Health *Guidelines for Research Using Human Pluripotent Stem Cells* (2000) 51976. At this stage ESCR was privately funded with Geron Corporation supporting research in both John Hopkins University and the University of Wisconsin. H Gottwels, 'The Endless hESC Controversy in the United States: History, Context and Prospects' (2010) 7 *Cell Stem Cell* 555, 556.

⁵³⁴ <<http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html>> accessed 19 June 2012.

⁵³⁵ Executive Order 13435: Expanding Approved Stem Cell Lines in Ethically Responsible Ways (revoked).

⁵³⁶ J Fossett, 'Beyond the Low-Hanging Fruit: Stem Cell Research Policy in an Obama Administration' (2009) 9 *Yale J. Health Policy Law & Ethics* 523 at 527. J Robertson "Embryo stem cell research: ten years of controversy" (2010) 38 *Journal of Law, Medicine and Ethics* 191, 195.

⁵³⁷ Soon after President Bush's initial announcement problems arose with the cut off date as fewer stem cell lines were available than thought. Those lines that were available had also been cultured with mouse feeder cells, which raised concerns of infection and contamination. J Robertson (n 521) 195.

⁵³⁸ Another attempt was made in 2007, with the Stem Cell Research Enhancement Act of 2007 which aimed to support ESCR on supernumerary embryos irrespective of when the lines were derived, and also to support alternative sources of pluripotent stem cells. Once again this was vetoed by President Bush.

⁵³⁹ Executive Order 13505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells.

⁵⁴⁰ *Ibid.*

embryonic stem cell lines that are on the NIH registry; and second these lines must be derived from spare embryos only.⁵⁴¹

The last decade of legislative and political activity regarding ESCR has illustrated the problem with relying on Executive Orders as the basis of a stem cell policy: a lack of certainty and continuity. As Executive Orders can be easily repealed by a new president, the ESCR policy within the US has been temporary at best. This problem could have been resolved had the policy been dictated by legislation, thus providing much more certainty for researchers.⁵⁴² Furthermore, legislation would have clarified whether it was intended that the Dickey-Wicker amendment was to prohibit the federal funding of ESCR. In the absence of legislation, the issue was left to the courts to resolve when an injunction for the freezing of grants was taken in 2010 against the National Institute of Health Guidelines in *Sherley v Shelbius*.⁵⁴³

2.2 *Sherley v Shelbius*

The focus of *Sherley v Shelbius* was on whether the federal funding of ESCR was permitted under the Dickey-Wicker amendment, with the applicant arguing that it was not. The respondent argued that the NIH guidelines were not contrary to the amendment as the guidelines only authorised the funding of stem cell research and not the creation of stem cells. In other words, it is not the destruction of the embryo that is funded by the research on the stem cells. The District Court disagreed:

“The Dickey-Wicker Amendment unambiguously prohibits the use of federal funds for all research in which a human embryo is destroyed. It is not limited to prohibit federal funding of only the "piece of research" in which an embryo is destroyed. Thus, if ESC research is research in which an embryo is destroyed, the Guidelines, by funding ESC research, violate the Dickey-Wicker Amendment.”⁵⁴⁴

Following this, Lamberth J granted an injunction freezing grants for ESCR as he was of the opinion that the derivation of the ESCs could not be separated from ESCR. His decision had the effect of prohibiting the funding of all ESCR irrespective of when the stem cell lines were derived, and thus went further than President Bush’s Executive Order.

This decision was appealed and reversed on appeal in April 2011.⁵⁴⁵ The Court ruled that the Dickey-Wicker amendment is ambiguous and thus it is reasonable for the NIH to conclude that while the amendment bars funding for the destruction of an embryo, it does not bar

⁵⁴¹ The guidelines also ban payments of cash or in kind for the embryos and also require informed consent from the donors. See National Institutes of Health *Guidelines for Research Using Human Stem Cells* (2009).

⁵⁴² This is not to state that the issue would have been beyond doubt as if the use of federal funds on ESCR had been permitted, the amount of money available would depend upon budget considerations.

⁵⁴³ *Sherley v Shelbius* 704 F. Supp. 2d 63 2010 US Dist. Kathleen Sebelius is the secretary of the DHSS and Drs James Sherley and Theresa Deisher who took the case are stem cell scientists who only use adult stem cells for their research.

⁵⁴⁴ *Ibid* at 71

⁵⁴⁵ United States Court of Appeals for the District of Columbia Circuit. No. 11-5421. Decided August 24, 2012.

funding for ESCR. The Court also considered it important that Congress passed the amendment each year in full knowledge that NIH was funding ESCR.⁵⁴⁶ Furthermore the Court noted that in considering funding applications, the NIH considers research that is intended to be carried out, not research that has already been done. Thus the NIH did not have to consider whether embryos had been destroyed in the past, but rather whether the funds would be used for the destruction of embryos. In other words, the NIH would look at the funding application from that date and the research that would be carried out after that date. If no embryos would be destroyed in future research on which the application is based, it can be federally funded.⁵⁴⁷

Unlike the DHSS legal opinion, the Court in this decision looked at the entirety of the amendment rather than focusing on whether an embryonic stem cell came under the definition of an embryo. While the majority of the Court is correct that the amendment is ambiguous, particularly in light of the development of ESCR after the passing of the amendment, the decision does ignore the very clear link between the destruction of an embryo and ESCR. The sole purpose for the derivation of an embryonic stem cell line is for ESCR. It thus seems peculiar that federal funds cannot be spent on the creation of embryonic stem cell lines but can be utilised for ESCR. Federally funded ESCR could potentially increase the demand for embryonic stem cell lines which may increase the destruction of embryos. In this way funding ESCR federally could likely fuel the demand for embryonic stem cell lines, indirectly supporting the destruction of embryos.

In January 2013 the US High Court ruled that it would not hear a challenge to the Appeals Court decision, bringing an end to the judicial dispute. However it is unlikely that this will be end of the debate as the Court simply stated that the funding of ESCR is permitted under the amendment and not that ESCR *must* be publicly funded. Thus it is possible that a different president in the future may opt for a restrictive funding approach similar to that of President Bush, which will once again limit ESCR within the US.⁵⁴⁸

2.3 Public funding in the European Union

In contrast to the funding policies of the US, the EU has taken a considered approach to its funding policy. While the development of the EU's policy was not without controversy, there was a period of consultation and debate before the European Commission issued guidance on the matter. In this way the funding policy of the EU has a much greater degree of permanence to it, with the funding likely to be affected by budgetary considerations rather than by the whims of the Executive.

⁵⁴⁶ Ibid.

⁵⁴⁷ The case once again went back to Lamberth J and as he felt bound by the decision of the Court of Appeals, the claim was dismissed. Ibid.

⁵⁴⁸ This would not lead to a cessation of ESCR within the US as many states have opted to fund ESCR themselves, such as California through the California Stem Cell Research and Cures Initiative or Proposition 71 and Connecticut, where \$49.24million had been spent on ESCR projects by 2010 under An Act Permitting Stem Cell Research and Banning the Cloning of Human Beings in 2005.

Scientific research is funded by the EU under programmes known as ‘Framework Programmes’ (FPs). FPs are the main financial tools through which the EU supports research and development activities covering almost all scientific disciplines. FP6 (2003-2006) was adopted in 2002, and although it was agreed that ESCR could be funded, a moratorium on the funding of ESCR was agreed between the European Commission and the Council. This was to give them time to put in place detailed provisions for implementation.⁵⁴⁹ This moratorium did not apply to stem cell lines that were already in existence.⁵⁵⁰ The Commission was in favour of funding ESCR, as the purpose of the FPs was to ensure collaboration across the Union.⁵⁵¹ This collaboration would avoid a duplication of research within the EU and would ultimately reduce the number of embryos destroyed for research purposes. The Commission did however recommend that only spare embryos left over after IVF treatment prior to 27 June 2002 could be used to derive an embryonic stem cell line.⁵⁵² Furthermore, it had to be proven that other research methods, such as adult stem cell research, would not yield the desired results of the research.⁵⁵³

No agreement was reached on this proposal prior to the moratorium deadline. As a result, ESCR funding commenced under the guidance agreed during the debates on FP6. Thus research on human cloning for reproductive purposes, research to modify the genetic heritage of human beings, and research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer, are not to be funded.⁵⁵⁴ All research proposals must undergo an ethical review, which is to be submitted to a Regulatory Committee.⁵⁵⁵ Finally, research that is prohibited in a Member State will not be funded.⁵⁵⁶ Thus if ESCR is prohibited in a certain Member State, it will not be funded despite the research project meeting the other requirements. In December 2006 it was decided to continue funding ESCR under FP7 (2007-2013)⁵⁵⁷ but it was made clear that FP7 would not finance research activities prohibited under FP6.⁵⁵⁸

⁵⁴⁹ Commission of the European Communities (2003) *Proposal for a Council decision amending decision 2002/834/EC on the specific programme for research, technological development and demonstration: “Integrating and strengthening the European research area” (2002–2006)*. Brussels, 9.7.2003, COM (2003) 390 final 3.

⁵⁵⁰ Ibid.

⁵⁵¹ Ibid 4.

⁵⁵² Ibid 8.

⁵⁵³ Ibid.

⁵⁵⁴ Council Decision 2002/834/EC of 30 September 2002 adopting a specific programme for research, technological development and demonstration: “Integrating and strengthening the European Research Area” (2002-2006).

⁵⁵⁵ Ibid para 1.1. The discussion process on FP5, FP6 and FP7 led to is recognition of the importance of ethical review and in particular the role of the European Group on Ethics (EGE). It was during FP5 that the EGE became formerly involved in the policy formation of the FPs. H Gottweis, B Salter & C Waldby, *The Global Politics of Human Embryonic Stem Cell Science* (Palgrave MacMillan 2009) 151.

⁵⁵⁶ Council Decision 2002/834/EC (n 554) para 1.1.

⁵⁵⁷ Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013).

⁵⁵⁸ See also C Staunton “Issues Concerning Embryonic Stem Cell Research in Ireland” (2012) 18(1) *Medico Legal Journal of Ireland* 38.

3. Regulating ESCR through public funds and Better Regulation Principles

Although both the US and the EU regulate ESCR to a degree through their funding policies, the origins and development of these policies have taken very different routes. It is now necessary to assess these policies under the principles of Better Regulation to determine which policy, if any, is a suitable model for regulating ESCR.

3.1 Transparency

If one is to understand transparency as ensuring that all stakeholders to the debate have been consulted and that the policy is clear and understood by all, the policy adopted by the EU trumps that of the US. Within the EU there was a long period of debate whereby all national governments could put forward their views on the funding of ESCR. Indeed, the debate waged for over ten years.⁵⁵⁹ This resulted in a decision whereby, under certain conditions, ESCR could be funded. This period of discussion was extended so that the European Parliament could consider the issue further, which led to the introduction of a moratorium on funding until December 2003. While agreement was not reached on the Commission's proposals, there was already a set of guidelines in existence which were part of the rules of funding under FP6, which all parties were aware would come into effect after December 2004 if no agreement was reached. Thus while it is not ideal that the moratorium passed without agreement, there had previously been a detailed discussion of the issue and thus there was a procedure in place which could then be adopted. This process has provided certainty to scientists, who know from the announcement of each individual FP whether ESCR will be funded for the duration of that FP.

Problems with the policy begin to emerge however when one considers the framework of the individual Member State. Mindful of the debate that is ongoing in many EU countries, the Commission noted that funding would depend upon the legal framework of the Member State involved. The EU has in fact stated that it does not consider itself to have a role in determining the ethics of ESCR due to the diverging policies of Member States, but rather its focus should be on the funding of ESCR.⁵⁶⁰ However not all Member States have legislation that clearly permits or prohibits ESCR. Ireland, for example, has benefited from FP7,⁵⁶¹ but the question remains whether Irish researchers can apply for funding, due to the uncertain legal status of ESCR.⁵⁶² Scientists based in Ireland are thus left in an uncertain position whereby it is unclear whether they can seek funding for ESCR under FP7.

In the US, the debate has involved an ethics committee (HERP), an ambiguous amendment, the NIH, numerous Executive Orders, and the courts. As the HERP made its report prior to

⁵⁵⁹ Gottweis (n 555) 148.

⁵⁶⁰ "Inter-institutional debate on stem cell research reveals extent of ethical split within Europe" 25 April 2003 <http://cordis.europa.eu/search/index.cfm?fuseaction=news.document&N_LANG=EN&N_RCN=20147&pid=34&q=D947BD405B4FECE44933948AB2209F56&type=sim> accessed 16 June 2012.

⁵⁶¹ For example, REMEDI, which is based in NUI Galway, has secured funding under FP7 as part of a collaborative project that focuses on adult stem cells. It is in partnership with other universities. European funding is €2.75million with €0.86 million going to REMEDI.

⁵⁶² For more on this situation *see* Chapter 6.

the derivation of the first embryonic stem cell line, the courts have been the only avenue open to the various stakeholders to contribute to the debate as to whether ESCR should be federally funded. While the NIH did have a consultation period when devising its guidelines, that consultation focused on what the guidelines should contain rather than whether ESCR should be federally funded. Rather than determining the funding of ESCR through Executive Orders, the US should have engaged in an open consultation on the issue, ensured that the various stakeholders could contribute and ensured that there is a reasoned debate following the principles of democratic deliberation. Such a process would have provided clarity to the remit of the Dickey-Wicker amendment and would have ensured that it was not left to the courts to resolve the issue. Furthermore, as the funding policy within the US tends to be changed with a change in administration, this policy fails to provide any certainty for researchers.

3.2 Accountability

Both the processes adopted by the EU and the US satisfy the criteria of accountability. Within the EU, the Commission is responsible for ensuring that all the conditions for funding are met and Commission officials are supported by the national ethics committees. Within the US, the NIH ensures that the conditions of the grants are met. Both the EU and US will revoke the grant in the event of non-compliance.

However, both the EU and the federal US government are only accountable for the implementation of their own guidelines. In the case of the EU, the Commission is not responsible for the implementation of all national guidelines on ESCR, nor is the US federal government responsible for the implementation of any state guidelines. In this way neither the Commission nor the US federal government are accountable for all of the stem cell policy but rather only those researchers to whom the policies applies.

3.3 Proportionality

To put it concisely, EU policy appears to be proportionate to its goals. As noted above, the purpose of funding ESCR is indeed to ensure that there is collaboration between scientists within the EU and also that there is no duplication of research. During the grant application process, weight is given to projects that involve collaborations⁵⁶³ and successful grant applicants are made public, which should ensure that there is no duplication of research. Furthermore EU policy does not state that ESCR will be funded in each Member State, but rather that it can be. Member States are given the option of ensuring that ESCR is not funded in a state if it is contrary to the laws of that state. In this way, the EU can pursue a policy of supporting ESCR while not requiring that it must be permissible in each of its Member States.

As the US funding policy is subject to change, it is much more difficult to assess whether its policy is proportionate. It is for this reason that the Bush policy will be evaluated separately from the Obama policy. President Bush's policy was in essence a political compromise.

⁵⁶³ See National Institutes of Health *Guidelines for Research Using Human Stem Cells* (2009).

While it generally prohibited the funding of ESCR, it did permit some funding of ESCR on limited embryonic stem cell lines. However, focusing on the general ban on the federal funding of ESCR, requiring research institutes to have separate labs to ensure that no federal funds are spent on ESCR cannot be called proportionate. Such a policy could likely dissuade researchers from carrying out ESCR, particularly in smaller institutes where resources are limited. Thus this policy not only prevents researchers from obtaining federal funds for ESCR but it may indirectly prevent researchers from obtaining private sources of funding. President Obama's policy on the other hand is entirely proportionate as it funds the research provided the research meets the requirements set out by the NIH.⁵⁶⁴

3.4 Consistency

EU policies are designed to supplement rather than supplant the ESCR policy of each Member State. Thus the funding application must not only follow the guidelines set out under FP7, but also must follow the laws and guidelines of the Member State in which the research is undertaken. The guidelines, however, only apply to projects funded under FP7. It is thus possible that ESCR projects that are funded through private funds or other sources of public funds may be subject to differing guidelines. The enforcement of these guidelines on projects that are only funded under FP7 is likely due to a recognition that there are differing policies amongst Member States. Thus the EU is not in a position to enforce uniformity, but consistency concerns within Member States do arise. If no national laws exist on ESCR, it is possible that other funding agencies within Member States will have differing guidelines, thus the degree of ethical oversight may depend on the source of funding.

In the US there has been very little discussion of whether ESCR should be permitted as a matter of policy at a federal level. Those discussions have been confined to the Human Research Embryo Panel and the National Bioethics Advisory Committee. The minimal discussion of the issue in public tends to focus on religious and ethical concerns, with very little in-depth discussion of the issue. The focus at federal level has been on whether ESCR should be federally funded. This has led to a situation whereby only those in receipt of private funding are governed by the public guidelines espoused by the NIH as these guidelines only apply to federally funded research. Such an approach has been described as a Pontius Pilate approach as it permits the research in the private sector while preventing public funds from being spent on ethically divisive research.⁵⁶⁵

The danger associated with regulating ESCR through public funding is thus that the debate can often centre on whether ESCR should be publicly funded and ignores the more

⁵⁶⁴ While a ban on federal funding does not directly impact the private funding of ESCR, it has been suggested that a ban would impact ESCR as the NIH's role is in funding research. J Robertson, 'Embryo Culture and the "Culture of Life": Constitutional Issues in the Embryonic Stem Cell Debate' (2006) *University of Chicago Legal Forum* 1, 2. It has also been noted that grants from state funding in the US enables research institutions to attract further grants. L Baker & B Deal 'Some Economic Implications of State Stem Cell Funding Programs' in A Levine (ed), *States and Stem Cells: the Policy and Economic Implications of State-Funded Stem Cell Research* (Princeton 2006) 67.

⁵⁶⁵ R Levine, 'Federal Funding and the Regulation of Embryonic Stem Cell Research: The Pontius Pilate Maneuver' (2009) 9 *Yale Journal of Health Policy, Law & Ethics* 552, 553.

fundamental issue of whether ESCR should be permitted at all. It is a piece-meal approach to regulation which leaves the majority of the decision-making power in the hands of the private funders, with very little input from the general public through a debate. Prior to the authorisation of controversial research, ethical, social and scientific issues⁵⁶⁶ should be considered before the issue of whether the research is publicly funded is addressed.

In his executive order, President Bush addressed some of these issues, questioning whether supernumerary embryos should be used for research, whether an embryo is life, and whether ESCR can deliver on its potential. The NIH guidelines also cover issues such as sources of embryos, remuneration for donors and the consent procedures that must be followed before an embryo is donated.⁵⁶⁷ Such issues should be discussed on a national level to ensure that they are applicable to all researchers and thus ensure that there is a coherent ESCR policy.

Private companies funding ESCR either within universities, research centres or within the companies themselves are motivated by financial gain. Commercial companies do play a key role in developing science from research to therapies for patients⁵⁶⁸ but many see governmental regulation as interference and a “poison gift” that would curtail research that is presently permitted in the private sector.⁵⁶⁹ However, a policy that only requires guidelines to be adhered to based on funding source may lead to companies cutting ethical corners to stay competitive and keep ahead in industry. Viewing regulation as interference in industry ignores that the general public has an interest in ensuring that certain ethical guidelines are followed and that certain forms of the research should not be pursued. If the privately funded research is left outside the domain of regulation, it has no incentive to balance conflicting interests such as the respect for the embryo against the need for medical advancement. Rather its interest is in ensuring that its research is commercially viable. While the National Academies have published guidelines on ESCR, not only are there no obligations to follow these guidelines but there are no sanctions bar the removal of professional membership, if a professional membership exists.⁵⁷⁰

When Geron announced that it had derived the first embryonic stem cell line it published its ethical guidelines but these guidelines had no application to the research in the lead up to its breakthrough. In the aftermath of its announcement on the derivation of the first human embryonic stem cell line,⁵⁷¹ the Geron Ethics Advisory Board (EAB) published guidelines to

⁵⁶⁶ House of Lords Select Committee *Stem Cell Research* (2002) para 6.10.

⁵⁶⁷ National Institutes of Health *Guidelines for Research Using Human Stem Cells*.

⁵⁶⁸ House of Lords Select Committee *Stem Cell Research* (2002) para 6.10. The private industry first isolated stem cell lines. J Schechter, ‘Promoting Human Embryonic Stem Cell Research: A Comparison of Policies in the United States and United Kingdom and Factors Encouraging Advancement’ (2009-2010) 45 *Texas International Law Journal* 603, 608. By 1999 Geron Corporation was supporting research in the University of Wisconsin and John Hopkins. H Gottwels, ‘The Endless hESC Controversy in the United States: History, Context and Prospects’ (2010) 7 *Cell Stem Cell* 555, 556.

⁵⁶⁹ G Outka, ‘The Ethics of Human Stem Cell Research’ (2002) 12(2) *Kennedy Institute of Ethics Journal* 175, 199.

⁵⁷⁰ National Academies Guidelines *Guidelines for Human Embryonic Stem Cell Research* (2005) subsequently amended in 2007, 2008 and 2010.

⁵⁷¹ J Thompson, J Itskovitz-Eldor, S Shapiro, M Waknitz, J Swiergiel, V Marshall & J Jones, ‘Embryonic Stem Cell Lines Derived from Human Blastocysts’ (1998) 282 *Science* 1145.

be followed by Geron when carrying out ESCR.⁵⁷² The guidelines cover concepts such as respect for the human embryo, informed consent for embryo donors and the requirement that all research be reviewed by an independent Ethics Advisory Board and an Institutional Review Board.⁵⁷³ Such guidelines are somewhat similar to those of the NIH and these guidelines should be welcomed. However, closer inspection leads one to question whether, by publishing these guidelines, Geron was seeking to ensure that all research funded by the company follows strict ethical guidelines or whether the guidelines were published to satisfy any public disquiet that was likely to follow the announcement of advancements on embryo destructive research. By publishing the guidelines, Geron may have been attempting to convince the federal government and the American people that it was adhering to ethical standards and thus that there was no need for direct government regulation.

First, the EAB formulated these guidelines after the November 1998 announcement and it does not appear that Thompson's research had to follow these guidelines. The formulation of ethical guidelines should not take place after an event has taken place but rather before it,⁵⁷⁴ particularly when a contentious issue, such as the destruction of the human embryo, is at the centre of that debate. Second, the EAB states that the blastocyst must be treated with respect but fails to state what this respect is or how the blastocyst will be treated with respect during research except to state that the embryo will be treated "with care" and only used for research that "incorporates substantive values such as reduction of human suffering".⁵⁷⁵ Furthermore the failure of the EAB to reconcile the destruction of the embryo with treating the embryo with respect has also been the subject of criticism.⁵⁷⁶ A final point is the requirement that all "research must be done in a context of concern for global justice".⁵⁷⁷

In expanding on this guideline, the EAB is of the opinion that ESCR is pointless unless people have access to this research and that this includes global access and not leaving the research as the preserve of the rich.⁵⁷⁸ While certainly a noble quest, it has been queried whether any for-profit company such as Geron could ever adhere to such a guideline or furthermore how it would be implemented.⁵⁷⁹ Overall the guidelines have been criticised as providing "an ethical rationalization rather than as an ethical guidance for research",⁵⁸⁰ and perhaps a proactive attempt by Geron to minimise the negative criticism that followed the publication of the research.

What the examination of the EAB guidelines serves to illustrate is that companies engaged in privately funded research, driven by a profit motive and with no incentive to ensure that research is conducted ethically, may only make a tokenistic attempt to follow ethical

⁵⁷² Geron Ethics Advisory Board, 'Research with Human Embryonic Stem Cells: Ethical Considerations' (1999) 29 *Hastings Center Report* 31.

⁵⁷³ *Ibid.*

⁵⁷⁴ G Annas, A Caplan & S Elias 'Stem cell politics, ethics and medical progress' (1999) 5 *Nature America* 1339, 1340.

⁵⁷⁵ Geron Ethics Advisory Board (n 572) 32.

⁵⁷⁶ G Annas, A Caplan, S Elias (n 574) 1340.

⁵⁷⁷ Geron Ethics Advisory Board (n 572) 31.

⁵⁷⁸ *Ibid* 34.

⁵⁷⁹ G Annas, A Caplan, S Elias (n 574) 1341.

⁵⁸⁰ *Ibid*

guidelines. Knowing that the majority of the population will not examine the timeline of the creation of the guidelines nor the guidelines themselves, Geron can use the creation of the guidelines to argue to the public that it is an ethical company rather than formulate the guidelines prior to the commencement of the research to ensure that it is a company engaged in ethical research.⁵⁸¹

3.5 Effectiveness

The policy pursued by the European Commission is effective as it balances the promotion of the research with the individual policies of Member States. Thus, provided that the research is permitted in the host Member State, any research can be funded. Furthermore the guidelines espoused by the Commission under FP7 must be complied with, otherwise the funding will be refused or revoked. The guidelines thus ensure that there is some ethical oversight of ESCR within Europe and that this oversight complements the national policies within the EU.

Similarly, the policies of the NIH are effective to the extent that the research will not be funded if they fail to meet the requirements set out. However, while there are national policies within the EU that will regulate research not funded by the Commission, within the US there are no federal guidelines that regulate ESCR funded by means other than federal funds. This potentially leaves some research outside of any public regulatory framework which effectively means that the industry self-regulates the research, leading to the possibility that there are vague ethical guidelines in place, as occurred with Geron described above. The National Academies have produced guidelines on ESCR, but there is currently no requirement that these are followed.⁵⁸²

3.6 Necessity

Within the EU, the policy on ESCR funding may be said to comply with the principle of necessity. Due to the varied policies across Member States, it could not have been possible to fund ESCR without some basic guidelines. The rules under FP7 clearly state what research can be funded but also give a certain amount of power to Member States and national ethics committees to review the project before funding is granted. In this way national governments retain some control over the funding of research within the state, and it also ensures that national ethical structures are used rather than creating another layer of bureaucracy within the EU.

Within the US, clarity was required. Although the DHSS had obtained an opinion that the Dickey-Wicker amendment did not prohibit the federal funding of ESCR, the ambiguous nature of the amendment left it uncertain. This clarity came in the decision of *Sherley v*

⁵⁸¹ Public perception of companies is important. For instance if it comes to light that a company has been acting unethically the financial markets may react negatively. Similarly it has been noted that the environmental policies of companies are now being examined by lenders as markets have reacted negatively to environmental problems arising out of companies. N Gunningham, 'Regulating Biotechnology: Lessons from Environmental Policy' in H Somsen (ed), *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents* (Edward Elgar Press, 2007) 4.

⁵⁸² National Academies Guidelines *Guidelines for Human Embryonic Stem Cell Research*.

Shelbius. President Obama's Executive Order announcing that federal money could be used to fund ESCR did not contain any regulations or ethical guidelines that a research application must satisfy before it is awarded funding. Rather President Obama directed the NIH to draft guidelines to guide researchers seeking federal funding. Thus the introduction of the guidelines were necessary as part of the US regulatory framework.

4. Patenting of Embryonic Stem Cell Research

A patent is granted to the maker of an invention giving them exclusive rights to monopolise their invention for 20 years. In this way it provides an economic incentive for investment into research and development. The patent holder can sell their patent under a licence agreement, opt to exploit the invention or simply do nothing with the patent while still preventing others from using the patented product. Individual countries have their own patent laws but these have been harmonised to an extent by virtue of international agreements such as the Trade Related aspects of Intellectual Property Rights (TRIPS) agreement and the European Patent Conventions (EPC).

The TRIPS agreement is an instrument of the World Trade Organisation (WTO). It came into force on 1 January 1995 and provides for international harmonisation of patents and other intellectual property rights.⁵⁸³ The European Patent Convention came into force in 1973 with the purpose of strengthening patent cooperation between European States⁵⁸⁴ but it is not a product of the European Union and is therefore not a source of EU law. Rather patent issues arising under the Convention must be argued before the European Patent Office (EPO) and not the European Court of Justice (ECJ). Furthermore the European Patent Office does not issue a "European" patent but rather it grants the inventor a bundle of national patents, and infringement proceedings must be taken in the national courts.⁵⁸⁵

At EU level, the European Council concluded negotiations on a unitary patent system whereby one application will soon be made for all 27 Member States. The Unified Patent Court will resolve issues relating to a unified patent infringement thus eliminating the risk of multiple lawsuits in different Member States.⁵⁸⁶ Most importantly for ESCR, Directive 98/44/EC on the Legal Protection of Biotechnology Inventions (hereinafter known as "the Biotechnology Directive") was introduced in 1998 to "promote research and development in the field of genetic engineering in the European Community, the way in which it does so is to remove the legal obstacles within the single market that are brought about by differences in

⁵⁸³ Prior to the agreement there were more than 50 countries that did not grant patents for chemicals and pharmaceuticals. T Sommer, 'The scope of gene patent protection and the TRIPS agreement - an exclusively nondiscriminatory approach?' (2007) *International Review of Intellectual Property and Competition Law* 30, 30.

⁵⁸⁴ Under Article 2(2) of the EPC, the patent shall have effect in each of the contracting states and subject to the conditions by which it was granted.

⁵⁸⁵ It has been noted that while national courts may diverge from the opinion of the EPO, there is "a strong aspiration to achieve unanimity on most issues". RS Crespi, 'The Human Embryo and Patent Law: A Major Challenge Ahead' [2006] 28 *European Intellectual Property Review* 569, 569.

⁵⁸⁶ <http://www.european-council.europa.eu/home-page/highlights/eu-unitary-patent-%E2%80%93-a-historical-breakthrough?lang=en> accessed 19 March 2012.

national legislation and case law and are likely to impede and disrupt research and development activity in that field”.⁵⁸⁷

Prior to the adoption of the Directive, the parliament of Netherlands sought to annul the Directive due to the opposition “to genetic manipulation involving animals and plants and to the issuing of patents for the product of biotechnological procedures liable to promote such manipulation”. The parliament of Netherlands also considered that the discretion under the *ordre public* exception and the belief that the Directive undermined human dignity required the annulment of the Directive. These arguments were ultimately rejected by the ECJ.⁵⁸⁸

The Biotechnology Directive governs the patenting of biotechnology patents within the EU.⁵⁸⁹ The Directive has been adopted by the European Patent Council and now forms part of the European Patent Convention.⁵⁹⁰ Thus all patent applications by EU Member States and those signatories to the EPC must adhere to the provisions of the Directive.

To clarify the criteria for patentability in Europe, the exclusions to patentability will first be discussed before the exclusions under Article 53(a) of the European Patent Convention and Article 6(2) of the Biotechnology Directive, are examined. The exclusions under the European Patent Convention and the Biotechnology Directive will be contrasted with the respective exclusions under the patent regimes in Canada and the United States. Finally the suitability of the patent system as a mechanism to regulate ESCR will be analysed.

5.1 Criteria for patentability

Article 52(1) of the EPC sets out the criteria for patentability: the invention must be new, it must involve an inventive step and it must be capable of industrial application.⁵⁹¹ However, under Article 51(2)(a), “discoveries, scientific theories and mathematical methods as such” are not regarded as inventions. To be defined as “new” the invention must not “form part of the state of the art”,⁵⁹² an invention will be deemed to have involved an inventive step if “having regard to the state of the art, it is not obvious to a person skilled in the art”,⁵⁹³ and

⁵⁸⁷ Case C-377/98 Netherlands v European Parliament [2002] ECR 574 para 27.

⁵⁸⁸ *Ibid* para 4.

⁵⁸⁹ For the history of the introduction of the Directive see Crespi (n 584), D Curley & A Sharples, ‘Patenting Biotechnology in Europe: The Ethical Debate Moves On’ [2002] *European Intellectual Property Review* 565 and G Porter, ‘The Drafting History of the European Biotechnology Directive’ in A Plomer & P Torremans (eds), *Embryonic Stem Cell Patents: European Patent Law and Ethics* (OUP 2010).

⁵⁹⁰ See Implementing Regulations to the Convention on the Grant of European Patents of 5 October 1973, as adopted by decision of the Administrative Council of the European Patent Organisation of 7 December, Chapter V-Biotechnological Inventions, Rules 26-29.

⁵⁹¹ For more on the criteria for patentability see P Torremans, ‘Legal Problems Raised by Patents on Human Stem Cell-Based Inventions’ in K Hug & G Hermeren (eds), *Translational Stem Cell Research* (Humana Press 2011).

⁵⁹² Article 44. Novelty for a natural substance includes a “natural substance which has been isolated for the first time and which had no previously recognised existence”. *Howard Florey/Relaxin* T-74/91 [1995] EPOR 541 at para 4.3.1.

⁵⁹³ Article 46.

finally an invention will be deemed to be capable of industrial application if “it can be made or used in any kind of industry, including agriculture”.⁵⁹⁴

5.2 Permitted Patents under the Biotechnology Directive

Under the Directive, inventions that satisfy the three criteria above can be patentable even if “they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used”.⁵⁹⁵ Furthermore, any biological material that has been “isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature”.⁵⁹⁶ The isolation of the biological material is key to its patentability as an element of the human body in its natural state is not patentable.⁵⁹⁷ There had been concerns that biological materials could not be patented as the novelty requirement requires that the material had not been available in that form prior to the patent application. The isolation principle thus permits biological materials to be patented as isolated materials are considered to be novel so long as the isolation and use of the material has an inventive quality. This formulation permits copies of naturally-occurring genes to be patented but the approach has been met with criticism for stretching the novelty requirement to fit biotechnology.⁵⁹⁸ Thus only an invention that uses a technical process to isolate a natural element for use as an industrial application may be patented.⁵⁹⁹ The ECJ has stated that it is this distinction that permits the patenting of human gene sequencing.⁶⁰⁰ It is through this distinction that only the result of the “inventive, scientific or technical work” may be patented, and not the biological material in its natural state.

5.2.1 Exclusions relating to Embryonic Stem Cell Research

As human biological material that has been isolated from its natural state can be patented, it is possible to patent human gene sequencing.⁶⁰¹ This distinction could equally apply to ESCR as stem cells are isolated, or created, using scientific inventions. However, a patent may be excluded on grounds of morality under either the *ordre public* exclusion under Article 53(a) of the European Patent Convention and Article 6(2)(c) of the Biotechnology Directive. It has been noted that one of the reasons for introducing the Biotechnology Directive was to provide clear guidance on morality and patenting.⁶⁰² However, the moral provisions were not in the

⁵⁹⁴ Article 57. See *BDPI Phosphatase/Mas-Planck* (2005) T 870/04 where the patent was refused for failing to indicate how the invention could be exploited.

⁵⁹⁵ Article 3(1) of the Biotechnology Directive.

⁵⁹⁶ Article 3(2) of the Biotechnology Directive. Examples of isolated biological material include proteins and cells.

⁵⁹⁷ See Recital 20 and 21 of the Biotechnology Directive and Case C-377/98 *Netherlands v European Parliament* [2002] ECR 574 at para 73-74.

⁵⁹⁸ M Llewelyn, ‘Schrodinger’s Cat: An Observation on Modern Patent Law’ in P Drahos (ed) *Death of Patents* (Lawtext Publishing 2005) 23-4, P Drahos, ‘Biotechnology Patents, Markets and Morality’ (1999) *European Intellectual Property Review* 441, 443.

⁵⁹⁹ Case C-377/98 *Netherlands v European Parliament* [2002] FSR 574, para 72.

⁶⁰⁰ *Ibid* para 74.

⁶⁰¹ *Ibid*.

⁶⁰² Llewelyn (n 598) 40.

initial drafts of the Biotechnology Directive when it was proposed in October 1998 but were introduced after lobbying by the Greens.⁶⁰³

5.2.2 Ordre Public exclusion in the European Patent Convention

Article 53(a) of the European Patent Convention states:

“European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.”⁶⁰⁴

Thus, if the exploitation of an invention, and not the invention itself, is contrary to the *ordre public* it cannot be patentable. Furthermore an invention will not be denied a patent simply because it is prohibited in a Contracting State; rather there must be something more that renders its exploitation contrary to *ordre public*.

The Greens and animal rights campaigners have traditionally invoked Article 53(a) to prevent the patenting of specific inventions⁶⁰⁵ and this has led to arguments that the Biotechnology Directive is based more on ethical concerns than on substantive patent law.⁶⁰⁶ One such example is *Harvard/Oncomouse* where the application of Article 53(a) was considered.⁶⁰⁷ It was argued that the patenting of a transgenic mouse bred solely as a tool for cancer research was immoral as it was created simply to suffer. The Examining Division stated that while patent law is not the correct forum for deciding ethical decisions arising out of genetic manipulation of animals, this was a case in which the Board could consider the issue of patentability in light of Article 53(a).⁶⁰⁸ In determining whether an invention is contrary to *ordre public*, the Examining Division stated that a balance needed to be struck between the suffering of animals and possible damage to the environment, and the invention’s usefulness to mankind.⁶⁰⁹ In particular it was stated that for each invention the question of “morality has to be examined and possible detrimental effects and risks have to be weighed and balanced against the merits and advantages aimed at”.⁶¹⁰ Based on this balancing test the Examining Division considered the usefulness of the invention to mankind, i.e. the potential advances in cancer treatment, and also the smaller number of animals to be used for testing purposes. This

⁶⁰³ Crespi (n 599) 571.

⁶⁰⁴ Article 6(1) of the Biotechnology Directive has a similar exclusion and states

“Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or by regulation.”

⁶⁰⁵ Crespi (n 599). D Curley & A Sharples, ‘Patenting Biotechnology in Europe: The Ethical Debate Moves On’ [2002] *European Intellectual Property Review* 565, 565.

⁶⁰⁶ T Sommer, ‘The scope of gene patent protection and the TRIPS agreement - an exclusively nondiscriminatory approach?’ (2007) *International Review of Intellectual Property and Competition Law* 30, 38.

⁶⁰⁷ [1990] EPOR 476.

⁶⁰⁸ *Ibid* para 490.

⁶⁰⁹ *Ibid*.

⁶¹⁰ *Ibid* at para 3.

balancing test has since been reiterated as the test to be applied when considering an Article 53(a) exclusion.⁶¹¹ However it must be shown that there was actual damage or a disadvantage, otherwise this test will not be applicable.⁶¹²

The EPO has stated that it is not intended that Article 53(a) should be regularly invoked but rather only in extreme cases such as an attempt to patent a letter bomb⁶¹³ or if the granting of a patent “would universally be regarded as outrageous”.⁶¹⁴ The difficulties in invoking this exclusion is compounded first, by the generality of the provision and by second, the lack of consensus across contracting states of the European Patent Convention on moral issues.

Regarding the generality issue, the EPO has stated that the concept of *ordre public* encompasses the protection of public security, the physical integrity of individuals and the protection of the environment, while the concept of morality regards certain behaviour as wrong on the basis of “the totality of the accepted norms which are deeply rooted in a particular culture”.⁶¹⁵ However this provides very little practical guidance in assessing a patent application. Article 53(a) of the EPC contains the proviso that “merely because [an invention] is prohibited by law or regulation in some or all of the Contracting States” does not exclude the invention from patentability. The EPO has also stated that the fact that exploitation of an invention is permitted in some or all the Member States does not necessarily mean that the invention complies with Article 53(a).⁶¹⁶ Thus it is possible that a patent could be denied even if the exploitation of the subject matter of the patent application is permitted in some or all of the Member States. Similarly a patent may also be granted despite the illegal nature of the exploitation of that invention in many of the Contracting States.

Turning to the consensus issue, the EPO has acknowledged that while there are many areas through which a definition of morality can be found, no one area can be regarded as the European moral standard.⁶¹⁷ Furthermore, the EPO does not consider itself to be an appropriate institution to decide on ethical issues⁶¹⁸ but rather the interpretation of European morality should be a function of the main EU institutions.⁶¹⁹ However, while discussing the Biotechnology Directive, the ECJ considered that it is common that issues of morality are determined by individual Member States.⁶²⁰ Thus while the EPO considers it a function of the EU to provide guidance on how to interpret “morality”, the ECJ has ruled that it is in fact a

⁶¹¹ *Harvard/Oncomouse* [2005] EPOR 31 para 10.5.

⁶¹² *Plant Genetic Systems* [1995] OJ EPO 545 para 18.8.

⁶¹³ *Howard Florey/Relaxin* T-74/91 [1995] EPOR 541 para 6.2.2. See also EPO Guidelines Part C *Guidelines for Substantive Examination* Chapter 4: Patentability para 4.1.

⁶¹⁴ *Howard Florey/Relaxin* T-74/91 [1995] EPOR 541 para 6.2.2.

⁶¹⁵ *Plant Genetic Systems* [1995] OJ EPO 545 para 6. Mills has questioned whether there is acceptance among Member States on such issues. O Mills, *Biotechnological Inventions: Moral Restraint and Patent Law* (Ashgate Publishing Ltd 2010) 66.

⁶¹⁶ *Plant Genetic Systems* [1995] OJ EPO 545 para 7.

⁶¹⁷ *Harvard/Oncomouse* [2005] EPOR 31 para 10.10.

⁶¹⁸ *Howard Florey/Relaxin* T-74/91 [1995] EPOR 541 para 6.5. In the *Plant Generic Systems* case it was stated that the EPO has always stated that the interpretation of a concept of morality should be left for the European Institutions to decide. *Plant Genetic Systems* [1995] OJ EPO 545 para 5.

⁶¹⁹ *Plant Genetic Systems* [1995] OJ EPO 545 para 4.

⁶²⁰ *Case C-377/98 Netherlands v European Parliament* [2002] FSR 574 para 37.

matter for the Member States, leaving it unclear as to who is primarily responsible for defining moral standards.

5.2.3 Article 6(2)(c) of the Biotechnology Directive

Unlike the general exclusion of Article 53(a) of the EPC, the exceptions under Article 6(2) of the Biotechnology Directive contain specific prohibitions to the general rule of patentability. Importantly for ESCR, Article 6(2)(c) prohibits the patenting of “uses of human embryos for industrial or commercial purposes”. This means that any patent application that uses human embryos cannot be patented under the Biotechnology Directive.

Despite the focus of the exclusion on the embryo, the term itself is not defined in the Directive and thus it was not clear whether inventions that used ESCR could be patented. Much would depend on the approach that the EPO would take to defining the embryo. If it followed the approach of *Sherley v Shelbius*, ESCR inventions are patentable as an embryonic stem cell is not an embryo. On the other hand, if the entirety of the research was examined, the EPO may consider such research to be unpatentable as an embryo was used to create the embryonic stem cell line and is thus part of the research. The European Group on Ethics (EGE) has suggested that stem cells that come from non-viable embryos are patentable as such embryos cannot result in a live birth and it follows that they are not covered by Article 6(2)(c).⁶²¹

Despite the uncertainty, over 500 patent applications involving embryonic stem cell research have been made worldwide with a quarter of these applications being granted.⁶²² Furthermore, both Sweden and the United Kingdom have granted patents for inventions that use ESCR.⁶²³ However in 2008 this issue came before the EPO in the *Wisconsin Alumni Research Foundation (WARF)* case.⁶²⁴

(a) The WARF case

The Wisconsin Alumni Research Foundation (WARF) case concerned a patent application submitted by WARF that involved the use of embryonic stem cell lines. The invention could

⁶²¹ Opinion on the European Group of Ethics on Science and New Technologies to the European Commission *Ethical Aspects of Patenting Inventions Involving Human Stem Cells* 7 May 2002 13.

⁶²² *Ibid* 10.

⁶²³ The various processes that have been considered for patent application include the processes for isolation of stem cells from embryos and the processes to create embryos by transferring a somatic cell nucleus to an enucleated egg to derive stem cells as well as stem cells, stem cell lines, differentiated stem cells and genetically modified stem cells. *Ibid*.

⁶²⁴ Wisconsin Alumni Research Foundation (WARF) G 0002/06. For commentary on this case see S Sterckx, ‘The European Patent Convention and the (Non)Patentability of Human Embryonic Stem Cells—the WARF Case’ [2008] 4 *Intellectual Property Quarterly* 478, M Rowaldson, ‘WARF/Stem cells (G2/06): the ordre public and morality exception and its impact on the patentability of human embryonic stem cells’ (2010) 32 *European Intellectual Property Review* 67, J Shun, ‘Moral Disharmony: Human Embryonic Stem Cell Patent Laws, WARF and Public Policy’ (2010) 33 *Boston College International and Comparative Law Review* 153 and S Sterckx & J Cockbain, ‘Assessing the Morality of the Commercial Exploitation of Inventions Concerning Uses of Human Embryos and the Relevance of Moral Complicity: Comments on the EPO’s WARF Decision’ (2010) 7 *SCRIPTed* 83.

not be created without using embryonic stem cell lines.⁶²⁵ The question that the Enlarged Board of Appeal therefore had to answer was whether embryonic stem cell lines came under the Article 6(2)(c) definition (or Rule 28(c) of the EPC). In particular the Enlarged Board was asked four questions:

- Does Rule 28(c) apply to the patent application as the application was filed before the Rule came into force?
- If the Rule did apply, does it prohibit the patenting of inventions that use embryonic stem cell lines, lines that can only be created by destroying the embryo?
- If the answers to either of the first two questions are no, does Article 53(a) of the EPC prohibit the patenting of embryonic stem cell lines?
- Would the answers to questions two and three be different if it had been possible to obtain embryonic stem cell lines without the destruction of the embryo?

Regarding the first question, the EPO ruled that Rule 28(c) applies to all patent applications irrespective of their filing date.⁶²⁶ In discussing the second question, the EPO noted that despite the differing definitions of the embryo across Member States, it had been opted to leave the term undefined. The EPO was thus of the view that rather than giving the term a restrictive meaning, the term should be interpreted in the context of each individual patent application.⁶²⁷ Looking to the WARF patent application, the EPO ruled that, as an embryo was destroyed in the making of the invention, it was unpatentable under Rule 28(c).⁶²⁸

As the answer to the second question was positive, the EPO did not need to concern itself with the third question. However, in relation to the fourth question the EPO stated that it was not relevant that an embryonic stem cell line could be created without destroying an embryo after the filing date of the patent application, as technical developments since the filing date could not be taken into consideration.⁶²⁹

In filing the patent application, WARF did not mention the term embryo in its application. The EPO did not consider this important, stating that it would look at the invention rather than the claim as otherwise this would enable inventors to circumvent the prohibitions through “clever and skilful drafting of such claim”.⁶³⁰ Furthermore the EPO noted that before “human embryonic stem cell cultures can be used they have to be made” and that they are made from embryos, which results in their destruction, thus the invention falls under the Rule 28(c). This is a departure from EPO policy, which usually takes the inventions as defined in the patent application.⁶³¹

⁶²⁵ Wisconsin Alumni Research Foundation (WARF) G 0002/06 para 15.

⁶²⁶ Ibid para 14.

⁶²⁷ Ibid para 20.

⁶²⁸ Ibid para 29.

⁶²⁹ Ibid para 33.

⁶³⁰ Ibid para 22.

⁶³¹ S Sterckx, ‘The European Patent Convention and the (Non)Patentability of Human Embryonic Stem Cells-the WARF Case’ [2008] 4 *Intellectual Property Quarterly* 478, 484.

Such an expansive meaning of the term embryo is questionable. First, the Biotechnology Directive was passed prior to the announcement of the derivation of the first stem cell line and, similar to the Dickey-Wicker amendment, it is not clear whether the term embryo was intended to cover embryonic stem cell lines. Second, the exceptions to the general principle of patentability are intended to be interpreted narrowly. The expansive meaning given to the term embryo is contrary to this judicial policy. Finally, the potential impact of this decision is considerable as under the EPO's decision it would appear that if an embryo was destroyed at some point in the creation of the invention, it is unpatentable. It is not clear how far back the EPO will examine in assessing the patentability of an invention. If the EPO took into consideration the entire making of the invention, it would appear that if an embryo was destroyed at some point in the making of the invention it is unpatentable. This interpretation has the potential to impact upon a considerable number of patent applications and thus render a large part of biotechnology unpatentable, a move that would appear to be contrary to the general principle of patentability.

While it is clear that the drafters of the Biotechnology Directive wanted to prohibit the commercialisation of embryos, it is unclear whether they intended this prohibition to extend to ESCR. While the laws of the Contracting Parties to the EPC are not intended to be a determining factor in considering the patentability of an invention, due to the diverging laws of the Contracting States on ESCR, the EPO should have considered the varying national legislation when interpreting this Rule. It would have noted the mixed and varied approaches individual Contracting States take to ESCR and the differing moral arguments as to whether the research should be permitted. In taking into consideration this lack of consensus, a better approach would have been for the EPO to recognise the diverging opinions and opt for a restrictive definition of the term "embryo".

In the aftermath of this decision, the UK IPO updated its guidance. It noted that since the WARF patent, which the UK IPO had granted, the storage of embryonic stem cell lines have improved which has reduced the need for the destruction of the embryo. In its guidance the IPO noted that it is possible to carry out ESCR using existing embryonic stem cell lines. Thus if a patent application uses a stem cell line which was already in existence at the filing date and the invention could be made using existing embryonic stem cell lines, the destruction of an embryo would not be required. As a result, the invention may be patentable, provided it satisfies the other requirements of patentability.⁶³²

Thus the UK IPO took a restrictive view of the destruction of the embryo prohibition. This view, however, was to be challenged in the case of *Brustle v Greenpeace*, which was decided by the ECJ.

(b) The case of *Brustle v Greenpeace*

Due to the ambiguous nature of Article 6(2)(c), it was unsurprising that questions about its scope came before the European Court of Justice (ECJ). In the case of *Brustle v*

⁶³² UK IPO, *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the Intellectual Property Office* (April 2011) para 112.

Greenpeace,⁶³³ the ECJ was asked by the Bundesgerichtshof (the Federal Court of Justice of Germany) to clarify the scope of Article 6(2)(c). The Court was asked to consider three specific questions:

- What is the definition of the term “embryo” under the Directive?
- Should commercial exploitation for scientific research come under the definition of “uses of human embryos for industrial or commercial purposes”?
- Should an invention that uses an embryo at any stage be precluded from patentability?⁶³⁴

Concerning the first question, the Court noted that the lack of a definition coupled with a lack of reference to national laws implies that the term must have a uniform concept across the EU.⁶³⁵ For the Court, this conclusion was supported by the aims and objectives of the Directive,⁶³⁶ which sought to harmonise patent protection across the EU.⁶³⁷ While recognising that there were debates across Member States as to the status of the embryo, the Court was of the opinion that it was required to give a legal decision as to the definition of the term “human embryo” in the context of the Directive.⁶³⁸ In other words the Court had to provide a uniform definition for the embryo that binds all Member States when considering patent applications under the Biotechnology Directive.

The Court ruled that due to the importance of the principle of respect for human dignity within the Directive, and the importance in ensuring that no activity that would affect human dignity is patented, the term embryo must be given a broad definition.⁶³⁹ Thus, under the Directive, the ECJ ruled that a human embryo is formed once an egg is fertilised⁶⁴⁰ or when the cell nucleus from a mature human cell has been transplanted into a non-fertilised human ovum. A non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis will also be considered an embryo under the Directive as they are capable of beginning the process of developing in a human being.⁶⁴¹ The Court did not state whether a stem cell derived from an embryo at the blastocyst stage is a human embryo. This is a decision for the Bundesgerichtshof to make in light of scientific developments.⁶⁴²

Regarding the second question, the Court ruled that the use of embryos for scientific purposes comes under the definition of “the use of human embryos for industrial or commercial

⁶³³ Case C-34/10 18 October 2011.

⁶³⁴ Ibid para 23.

⁶³⁵ Ibid para 26.

⁶³⁶ Ibid para 27.

⁶³⁷ Recital 4 of the Biotechnology Directive.

⁶³⁸ Case C-34/10 18 October 2011 para 30.

⁶³⁹ Ibid para 34.

⁶⁴⁰ Ibid para 35.

⁶⁴¹ Ibid para 36.

⁶⁴² Ibid para 38.

purposes”⁶⁴³ and that only uses “for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it being patentable” can be patented.⁶⁴⁴

Finally and most importantly for ESCR, the Court stated that if an embryo is destroyed in the making of the invention, it is unpatentable, irrespective of how far removed the destruction of the embryo was from the patent application.⁶⁴⁵ The Court was of the opinion that to decide otherwise would render Article 6(2)(c) redundant.⁶⁴⁶

As the ECJ’s decision is quite similar to that of the EPO, the *Brustle* decision can be subject to much of the same criticism as the *WARF* decision. For the purposes of this thesis our criticisms will be focused on the issue of destruction of the embryo.⁶⁴⁷ First, it is not clear whether the Biotechnology Directive was intended to prohibit the patenting of ESCR. The Directive explicitly prohibits the patenting of human embryos, organisms that have the capacity to develop into human beings. An embryonic stem cell is a cell that has been isolated from an embryo and does not have the capacity to develop into a human being and thus is not the same as an embryo, as recognised by the Court of Appeals in *Sherley v Shelbius*. However the ECJ did not consider this distinction.

Second, the wide application of the destruction of the embryo criteria effectively ignores any developments in biotechnology. Under this decision the UK IPO cannot grant patents under its own guidance, as an embryo was created at some point in the past. This effectively prohibits the commercialisation of ESCR within Europe and raises some very serious questions regarding the private funding of ESCR. Therefore, while the text of the Directive prohibits the commercialisation of inventions that use human embryos, the wide definition given to the phrase “uses of human embryo” effectively prohibits the commercialisation of an emerging sector of the biotechnology industry. Considering one of the aims of the Directive was to ensure that biotechnology can be commercialised, it is unclear whether the drafters of the Directive would have intended that such an emerging area of biotechnology would fall outside the patent system.

6. Regulating ESCR through the patent system and the Better Regulation principles

While the impact of the *Brustle* decision on patents that have already been granted may not be apparent for some time, it appears that following the decision of the ECJ, any research that at any point results in the destruction of an embryo cannot be patented. This removes the commercial incentive for biotechnology to engage in ESCR. Thus one of two outcomes is possible: first biotechnology firms could stop funding ESCR research in the EU and fund research in jurisdictions where patents can be obtained, and second, if biotechnology firms do continue to invest in European research, they are more likely to keep their research a trade

⁶⁴³ Ibid para 42.

⁶⁴⁴ Ibid para 46.

⁶⁴⁵ Ibid para 52.

⁶⁴⁶ Ibid para 50.

⁶⁴⁷ For a critique of this case see C Staunton, ‘*Brustle v Greenpeace*, Embryonic Stem Cell Research and the European Court of Justice’s New Found Morality’ [2013] Medical Law Review (forthcoming).

secret, which will hamper research and discourage collaboration amongst researchers. As the economic incentive for engaging in ESCR is removed, profit-driven private investors are less likely to fund ESCR in Europe, which may lead to a reduction in ESCR within EU Member States.

In this way, the patent system can indirectly regulate ESCR. Similar to the analysis of the funding policies that regulate ESCR, the patent system as a tool of regulation will now be analysed under the principles of Better Regulation.

6.1 Transparency

The introduction of the Biotechnology Directive was necessary as it was unclear whether certain biological processes were patentable.⁶⁴⁸ The effect of the Directive on ESCR is less transparent, largely due to the uncertainty surrounding the meaning of the term “embryo”. It is not clear whether the drafters intended a literal definition of the term “embryo” and thus meant to prohibit the patenting of processes in which an embryo as defined by the ECJ is used, or whether the entire making of the invention should be examined.

Recital 3 of the Directive states that harmonisation of the patent system as it relates to biotechnology is necessary to ensure the continued investment in biotechnology. The *Brustle* decision certainly brings harmonisation but it is questionable whether EU institutions actually had this intention. Moreover it could reduce investment in biotechnology rather than ensuring it.

The ECJ has previously stated that Member States have wide scope for interpreting public morality so that it can be interpreted in accordance with their own set of values. Notably in *R v Henn and Darby* the ECJ noted:

“Under the terms of Article 30 of the Treaty the provisions relating to the free movement of goods within the Community are not to preclude prohibitions on imports which are justified *inter alia* ‘on grounds of morality’. In principle it is for each Member State to determine in accordance with its own scale of values and in the form selected by it the requirements of public morality in its territory.”⁶⁴⁹

From this one would expect that it is for national governments, and not the EU, to determine whether the patenting of ESCR is contrary to common morality. Furthermore when interpreting the Biotechnology Directive, the Court noted that Member State administrative authorities and courts should interpret the morality provisions in accordance with their own values so as to ensure that Member States could consider the social influences unique to each country.⁶⁵⁰ Indeed in its report on the patenting of biotechnology the EGE noted the diverging moral opinions of Member States on the patenting of ESCR and thus recommended that there should be no further harmonisation on this issue. Rather it should be left to individual

⁶⁴⁸ See Recital 3 and 4 of the Biotechnology Directive.

⁶⁴⁹ *R v Henn and Darby* (1979) ECR 3795 para 15

⁶⁵⁰ *Netherlands v Parliament and Council* Case C-377/98 para 37-38.

Member States to decide the issue themselves.⁶⁵¹ It is due to this divergence of opinion that the EPO and ECJ had been encouraged to adopt a minimalist test and narrowly interpret Article 6(2)(c).⁶⁵² This would have left individual Member States with the power to consider Article 6(2)(c) in accordance with its own set of moral principles and thus would not have forced a common morality on Member States where one does not exist.⁶⁵³

6.2 Accountability

The individual patent offices in the Member States of the EU are responsible for ensuring that *Brustle* is complied with, and the patent offices of the Contracting States of the EPO are responsible for ensuring that the *WARF* decision is complied with. While both the *Brustle* and *WARF* decisions can be criticised, they do bring clarity as to the patentability of ESCR. Prior to these decisions there was uncertainty, as evidenced by the UK and Swedish Patent Office granting patents for ESCR.

6.3 Proportionality

In assessing whether the prohibition on the patenting of ESCR is proportionate it is necessary to consider the goals of the EU's biotechnology policy. The European Parliament has noted that biotechnology is playing an increasingly important role in industries, and the protection of biotechnology inventions will be important for the development of Community industries.⁶⁵⁴ Thus the Biotechnology Directive was passed to ensure the continued harmonisation of the patenting of biotechnological inventions. However the EU's policy on ESCR is less clear.

Since the announcement that ESCR is eligible for funding under FP6 and FP7, it is clear that the EU considers ESCR as important research worthy of investment due to its potential benefits in regenerative medicine, among others. Thus if the goal is the furtherance of medical research and ultimately developments in medical therapies for patients, the patent system is an integral part of that process. On the other hand, if the goal is to encourage research for research's sake, with a view that the research should never be commercialised, then Article 6(2)(c), as interpreted by the ECJ in *Brustle* and the EPO in *WARF*, may be seen as proportionate.

The aim of the patent industry is to encourage innovation by granting inventors a monopoly on the exploitation of their invention. It also encourages the publication of the research, as it is protected by that monopoly. However, the net effect of the patent is that it becomes "a state sanctioned anti-competition device",⁶⁵⁵ which prevents other researchers from using that invention unless they pay a licence fee, a fee set by the licence holder. Arguably the patent

⁶⁵¹ Final Report from the Commission to the European Parliament and the Council, *Developments and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* COM (2005) 312 para 2.2.

⁶⁵² P Torremas, 'Legal Problems Raised by Patents on Human Stem Cell-Based Inventions' in K Hug & G Hermeren (eds) *Translational Stem Cell Research* (Humana Press 2011) 298.

⁶⁵³ For more on the issue of common morality see C Staunton, '*Brustle v Greenpeace*, Embryonic Stem Cell Research and the European Court of Justice's New Found Morality' [2013] *Medical Law Review* (forthcoming)

⁶⁵⁴ European Parliament Resolution on Patents for Biotechnology Inventions (October 2005) OJ 272 E/40.

⁶⁵⁵ Llewelyn (n 598) 20.

system encourages innovation but can impede the exploitation of the invention to its maximum potential.⁶⁵⁶ Thus the patent industry is not always suitable for encouraging innovation for early stage research. While the research is in the public domain, the requirement to pay a licence fee may preclude many researchers from accessing the inventions and ultimately prevent collaboration between researchers.

An example of the anti-competitive element of patents can be seen from the US policy of patenting ESCR. Unlike in Europe, WARF's patent application was successfully granted by the US Patent Office.⁶⁵⁷ The patent granted not only covers Dr James Thompson's method for the derivation of embryonic stem cell lines but it also includes the five undifferentiated stem cell lines that he derived. This thus gave WARF complete control over who may work with the five stem cell lines.⁶⁵⁸

In what was arguably recognition of the importance of ensuring that other researchers have access to the stem cell lines, WARF decided that academic researchers would be granted access to the stem cell lines for a nominal fee, while other scientists (presumably those in profit industries) would be granted access for a negotiable fee. However, in return for funding the research, Geron has the exclusive rights to develop the stem cell lines into three specific differentiated stem cell lines for commercial purposes.⁶⁵⁹

Thus while WARF has adopted a policy of encouraging research it essentially retains control over the exploitation of Dr Thompson's work.⁶⁶⁰ It was not required to adopt such a pro-research policy in relation to its licensing arrangements and it is possible that if Geron had complete control of the patent they would have not adopted such a policy, thus hindering the development of research.

The foregoing example illustrates that the patent industry may not be suitable for encouraging the development of early stage research. Arguably such a broad patent should have not been granted to WARF, however this example does serve to illustrate the potentially far-reaching consequences that the patent system can have on research. Thus, if the EU policy is to encourage research and collaboration, the decision of *Brustle* and *WARF* complements that policy. Indeed, it is possible that the decision will improve the research environment within

⁶⁵⁶ R Noll, 'The Politics and Economics of Implementing State-Sponsored Embryonic Stem Cell Research' in A Levine (ed), 'States and Stem Cells: the Policy and Economic Implications of State-Funded Stem Cell Research' (Princeton, 2006) at 28.

⁶⁵⁷ *The foundation for taxpayer and consumer rights v patent of Wisconsin Alumni Research Foundation* Appeal 2010-001854 Decided 28 April 2010.

⁶⁵⁸ Opinion of the European Group on Ethics in Science and New Technologies to the European Commission *Ethical Aspects of Patenting Inventions Involving Human Stem Cells* (May 2002) 11. The EGE has argued that unmodified stem cell lines should not be patented as they are "so close to the human body" as to be considered the commercialisation of the human body. *Ibid* 15.

⁶⁵⁹ *Ibid* 11. Due to ambiguities in the agreement between WARF and Geron, Geron has successfully asserted that it has the exclusive right to additional cell types. J Miller, 'Call to Legal Arms: Bringing Embryonic Stem Cell Therapies to Market' (2002-2003) 13 *Albany Law Journal of Science and Technology* 555, 562.

⁶⁶⁰ The broad patent granted has been criticised, with Shun arguing that "WARF is able to prohibit any derivation, use, importation, or research into hESC lines in the United States unless interested parties first enter into licensing agreements". J Shun, 'Moral Disharmony: Human Embryonic Stem Cell Patent Laws, WARF and Public Policy' (2010) 33 *Boston College International and Comparative Law Review* 153, 173. Broad patents can potentially stifle follow-on inventions.

Europe provided that individual researchers are willing to share their research. In this way, collaboration amongst researchers has the potential to increase free from the constraints of the patent system.⁶⁶¹

However, if the policy of the EU is not only to encourage the development of research but to ensure that the research realises its potential and results in therapies, the *Brustle* and *WARF* decisions are not in line with this policy. If there is a likely return on their investment, biotechnology companies are much more likely to invest in ESCR. The patent industry provides such an avenue for this return, which is important in biotechnology, where the cost of research and development are quite substantial.⁶⁶² Warren-Jones has argued that if society wants new medical therapies, it must get used to the idea of owning DNA.⁶⁶³ Arguably the same could be said for ESCR and the commercialisation of ESCR. The EGE has previously cautioned against a prohibition on the patenting of ESCR, arguing that it could lead to a slowing of ESCR.⁶⁶⁴

The granting of a broad patent to Geron has left the company in a very powerful position regarding the development of ESCR.⁶⁶⁵ Geron will also have complete commercial control over any medical treatments arising out of the research which raises questions over the accessibility of health care if treatments are set at too high a price.⁶⁶⁶ Ensuring access to treatment is an issue that policy makers should consider. The patent granted to WARF, and by default Geron, was simply too broad and perhaps a modified and restricted patent should have been granted. However, the patent does provide the economic incentive for Geron to continue to fund the research, which is particularly important where there is limited public funding.

The biggest effect that the *Brustle* decision will have on ESCR is thus likely to be in relation to funding. It is unlikely that companies will continue to invest in research in which there is no economic return and they are likely to withdraw funding from research institutions based in Europe. This makes these institutions more reliant on public funding, which can fluctuate according to revenues within each jurisdiction. Consequently this may drive researchers out of Europe towards Asia and the US, which have much more favourable patent policies and

⁶⁶¹ Julian Hitchcock, "*Brüstle v Greenpeace: Sorry to be optimistic....*" Tuesday, 18 October 2011 http://www.cellfate.com/CellFate/News/Entries/2011/10/18_Brustle_v_Greenpeace_Sorry_to_be_optimistic....html.

⁶⁶² G Porter, 'The Drafting History of the European Biotechnology Directive' in A Plomer & P Torremans (eds), *Embryonic Stem Cell Patents: European Patent Law and Ethics* (OUP 2010) 7.

⁶⁶³ A Warren-Jones, 'Patenting DNA: a lot of controversy over a little intangibility' [2004] *Medical Law Review* 97, 98.

⁶⁶⁴ Opinion of the European Group on Ethics in Science and New Technologies to the European Commission *Ethical Aspects of Patenting Inventions Involving Human Stem Cells* (May 2002) 14.

⁶⁶⁵ The EGE has warned against granting such a patent as it would be too wide and that the stem cell lines should not be considered to be patentable as they have too broad a range of potential undescribed uses. *Ibid* 15. The group was particularly concerned that the granting of too broad a patent could interfere with further research. *Ibid* para 2.7. For criticism on the awarding of the patent to WARF in the US, see Miller (n 659).

⁶⁶⁶ The EGE has recognised that while the patent industry encourages innovation it can also lead to inaccessible health care, thus a balance within the industry needs to be struck. Opinion of the European Group on Ethics in Science and New Technologies to the European Commission *Ethical Aspects of Patenting Inventions Involving Human Stem Cells* (May 2002) 14. See also A Naimark, 'Biotechnology, Innovation and Health' (2006) 32 *Canada-United States Law Journal* 220, 225.

potentially much more investment. This may gradually reduce the research capabilities of European research institutions. Furthermore, recent developments have indicated that the EU institutions may be unwilling to continue to fund ESCR due to the *Brustle* decision. In September 2012 the Legal Affairs Committee of the European Parliament voted against funding ESCR in Horizon 2020 (Europe's next FP). The committee stated, that as the aim of Horizon 2020 is to stimulate European competitiveness, ESCR should not be funded as it cannot contribute to Europe's overall competitiveness.⁶⁶⁷ While a final decision on Horizon 2020 will not be made until the end of 2013, the impact of *Brustle* may well extend the private funding of ESCR and all but stop ESCR funding within Europe.

The ESCR policy of the EU is therefore in a state of flux and this is likely due to the divergent policies of its Member States in relation to ESCR. However, the EU should consider revisiting its policy so that its research policy complements its patenting policy to ensure that there is a coherent ESCR policy in place. As the effects of *Brustle* begin to take hold, it is likely that there will be a cessation of private funding within Europe, which is likely to reduce ESCR within Europe. Thus the patent policy adopted by the EU is likely to indirectly reduce European embryonic research.

6.4 Consistency

The development of the EU's patent policies is far from consistent. It initially led to differences in the interpretation of Article 6(2)(c) with both Sweden and the UK granting patents for ESCR. This inconsistency has now been resolved by *Brustle*, which clearly states that embryonic destructive research is not patentable. However, as discussed in the previous section, if the funding policy of the EU is to encourage research and development in ESCR, its patenting policy is not consistent with this objective as it may indirectly reduce embryonic research within Europe. Due to the divergence of the funding policy, which encourages ESCR, with that of the patenting policy, which prohibits the commercialisation of ESCR, the EU is lacking a coherent and consistent ESCR policy. The EU should perhaps give consideration to a reevaluation of its ESCR to ensure that its policy meets its aims. While the public funding of the EU can ensure that research is commenced, the private sector's involvement is essential to ensure that the research is commercialised. Favourable patenting policies are necessary to secure the involvement of the private sector in biotechnology.

6.5 Effectiveness

As all Member States must comply with the decisions of the ECJ, the *Brustle* decision will be complied with and enforced across all Member States. In this way, the Biotechnology Directive can be considered an effective regulatory strategy when considered in isolation. However, as the funding policies of the EU appear to ensure ESCR, there is a lack of consistency between the aims of the EU's funding policies and its patenting policies. Thus, as a joined up policy, it is unclear what the policy of the EU is and whether it is effective.

⁶⁶⁷ 'Clouds Gather Over European Stem Cell Funding' <http://blogs.nature.com/news/2012/09/clouds-gather-over-european-stem-cell-funding.html> accessed 31 January 2013.

6.6 Necessity

Prior to the Biotechnology Directive it was unclear whether some biotechnological inventions were patentable. The Directive clarified much of this uncertainty, except in relation to ESCR. The *Brustle* decision has resolved this issue and it is now clear that Article 6(2)(c) prohibits the patenting of ESCR. As outlined above, this indirectly impacts upon the funding of ESCR and it may lead to a cessation of ESCR within Europe. If that was the purpose of the Biotechnology Directive, it is not effective, and the Directive was not required as a tool for reducing ESCR within the EU. A policy that clearly dictates the permissibility of ESCR, the boundaries of the research, and whether ESCR can be patented would be better than the current system in place.

7. Conclusion

Funding and patenting policies have a clear impact on the development of ESCR. Policies can either encourage or discourage the technology without the need for policy makers to expressly permit or prohibit the research. Following President Bush's announcement on 9 August 2001, part of a \$150 million grant to Stanford University from a private investor to fund an interdisciplinary project called Bio X was withheld in protest.⁶⁶⁸ In this way a failure to publicly fund can indirectly affect the private funding of ESCR and result in a freeze of ESCR in that jurisdiction. Thus while the research may not be directly prohibited, funding policies can indirectly lead to that conclusion and in this way indirectly regulate ESCR.

However, problems of consistency begin to emerge where ESCR is publicly funded but the guidelines only apply to those in receipt of public funds. Such a policy ignores the controversial ethical issues that should be addressed by all stakeholders to the debate. It also leaves those in receipt of public funds outside the regulatory regime leaving them free to ignore the ethical concerns of the public. It is for this reason that a funding policy on ESCR should be considered as part of an overall ESCR policy. In this way the issues that apply to all ESCR, irrespective of how it is funded, can be addressed and ensure that all ESCR adheres to any legal and ethical guidelines.

Similarly while the *Brustle* decision has clarified that ESCR cannot be patented within the EU, this clarity will likely come at a price. It is likely that the private funding of ESCR in Europe will diminish, which will have an effect on the development of the research within Europe. The difficulty with the patent system within Europe is that the patenting of ESCR as a matter of policy was not considered. As the patenting of ESCR was not expressly prohibited, it was thought that it was permissible and thus investors and researchers proceeded on this basis. Had Europe considered the patentability of ESCR at the outset, this uncertainty would have been avoided, thus providing clarity to researchers prior to the commencement of the research.

Due to the potential impact of the patenting policies on ESCR, what is needed is a consistent and coherent policy on ESCR. In developing such policies, policy makers should ensure that

⁶⁶⁸ M Schwartz, 'Miffed by stem cell policy, Clark suspends Bio-X gift' *Stanford Report*, September 2001.

individual patenting and funding policies are coherent and complement each other. In the US the funding policy at times has encouraged the private funding of ESCR and this is complemented by its patent laws which permit the patenting of ESCR.

While the EU has focused its policy on the patenting and funding of ESCR, there has been no discussion as to whether ESCR should be patented as a matter of public policy. A study examining European patent law and ethics has stated:

“Needless to say, the fragmented legal landscape and the resulting legal uncertainty on the scope of application of the moral exclusion clause to hESCs carries the risk of a threat to research and investment in the life sciences and innovation in Europe, both of which have been earmarked as a strategic priority for Europe.”⁶⁶⁹

Yet by including a level of ethical assessment through *ordre public* under Article 6, it has indirectly required an assessment of ESCR by a court (the ECJ), which should ideally be done by an elected institution. If there is to be an ethical assessment of ESCR, this should be approached in a rational manner following the principles of democratic deliberation described, and not indirectly through an assessment of whether the patenting of ESCR is contrary to Article 6(2)(c). As Gerald Dworkin states:

“Few would deny that there are major ethical issues relating to developments in biotechnology and genetic engineering; that there is a need to ensure that such ethical issues are properly addressed; that there should be adequate controls and monitoring of undesirable or questionable developments. The real question, though, is whether such control should be exercised in any significant way through the patent system. A rational answer must be “no”.”⁶⁷⁰

An ethical assessment should therefore precede any policy development on ESCR, and it should be done by the EGE or national ethics bodies.⁶⁷¹ This discussion will then feed into the funding and patenting policies, ensuring that both policies are complementary, and this would in turn lead to a development of a coherent policy on ESCR.

⁶⁶⁹ Stem Cell Patents: European Patent Law and Ethics (2006) 17.

⁶⁷⁰ UK House of Lords Committee on the Biotechnology Directive 1994 (HL Paper 28, HMSO, March 1 1994) as cited in D Curley & A Sharples, ‘Patenting Biotechnology in Europe: The Ethical Debate Moves On’ [2002] *European Intellectual Property Review* 565, 566.

⁶⁷¹ While the role of the EGE has become formalised in recent years, there is no link between the EPO and EGE, thus the EPO, which does not have an ethics office, is not required to consider the opinions of the EGE. Thus with no body to provide ethical guidance to the EPO, it is questionable whether the EPO should be deciding issues of an ethical nature. Furthermore it has been argued that by deciding that any invention which involves the destruction of a human embryo at any stage of the development cannot be patented, the EPO, and by implication the ECJ, has gone beyond its remit and begun “to police moral standards in public life”. P Torremans, “The Construction of the Directive’s Moral Exclusions under the EPC” in A Polmer & P Torremans, *Stem Cell Patents: European Patent Law and Ethics* (Ibid 2010) 166.

Part III The Regulation of Stem Cell Research in Ireland

Part II looked at the regulation of ESCR internationally and the differing regulatory frameworks that have been adopted. It began with an overview of the development of regulation within Europe before looking at the adoption of the principles of Better Regulation which are transparency, consistency, proportionality, effectiveness, necessity and accountability. It outlined why it is important for a regulatory framework to adhere to these principles. These principles were then applied to four types of regulatory models that have been used internationally to regulate ESCR, namely, regulation through legislation, regulation by independent regulatory authorities, regulation through the use of public funding, and regulation by the patent system.

Legislation as a means to regulate has the advantage of being clear and accessible and generally understood by those it seeks to regulate. However, the problem with legislation is that it can become outdated, as the law may not keep pace with developments in science. One solution is to keep general principles to the legislation and create an independent regulatory authority to consider issues such as definitions. Had the HFE Act 1990 left it to the HFEA to define embryos, it could have changed the definition in line with developments in technology and thus there would have been no uncertainty as to whether embryos created through SCNT fell under the Act. In this way, independent regulatory authorities can be useful. However, such authorities should only be created when it is clear what their functions will be. It should be clear if they are to be implementing policy or whether they have some policy-making role. The lack of clarity as to what the role of the HFEA is has led to some criticisms of the HFEA.

Policy is also not the sole domain of the legislature but economic policies can indirectly affect policy. Both the US and the EU currently fund ESCR. While the EU has considered and debated the issue, this has not been the case in the US where the decision has been made by the president of the day and recently, the courts. However any funding policy must be complemented by a patenting policy, an area in that the EU has failed. If it is the policy of the EU to fund and promote ESCR, this should be complemented by a policy which encourages the commercialisation of the research as this is essential to ensure that the research gets to through to clinical application.

When creating policy, policy makers need to ensure that they consider all aspects of the policy, which may include the introduction of legislation, the creation of an independent regulatory authority, and economic policies which complement the overall policy. This will ensure that a coherent ESCR policy is in place.

Part III of this thesis will now focus on Ireland. It will first consider the status of ESCR in Ireland before moving onto recommendations for ESCR policy in Ireland. This will build upon the work of Part II and ensure that there is a coherent ESCR policy in Ireland.

Chapter 6 The Legal Status of Stem Cell Research in Ireland

1. Introduction

The legal status of the human embryo has been the subject of much debate in Ireland, particularly in recent decades. Since the introduction of the protection of the unborn into the Irish Constitution,⁶⁷² there has been much confusion as to what the unborn is and whether it extends to the embryo *in vitro*. Successive governments have failed to provide clarity as to the parameters of the protection of the unborn. Problems have also stemmed from the fact that the Irish debate has centred on the moral, religious and ethical concerns of the human embryo, rather than a debate on the implications of a constitutional protection of the unborn. Furthermore there has been a lack of political will to adequately engage with the issues and provide clarity as to the meaning of the “unborn”. This has left the Irish courts with the unenviable task of deciphering the meaning of the undefined constitutional entity of the “unborn” mentioned in Article 40.3.3 of the Irish Constitution.

The purpose of this chapter is to determine whether the embryo *in vitro* comes under the definition of the “unborn” and is constitutionally protected in Ireland. With no legislation in Ireland explicitly protecting the embryo *in vitro*, it is likely that there is currently no legal barrier to the destruction of the embryo *in vitro* and thus, embryonic stem cell research. An analysis of the scope of Article 40.3.3 must not only include an examination of the text itself, as well as judicial decisions since the introduction of the amendment, but also a discussion on the political landscape that led to the introduction of Article 40.3.3 of the Irish constitution and subsequent amendments. This is necessary as it highlights some of the inherent problems with the political process in Ireland in its approach to engaging with reproductive matters and also indicates why successive Irish governments have failed to define the protection of Article 40.3.3

This chapter will begin with an analysis of the law pertaining to abortion prior to the Eighth Amendment to determine whether there was a need for the amendment. It will describe the moves towards a referendum and the origins of the push for a referendum. The case law relating to Article 40.3.3, including both Irish and European jurisprudence, and in particular cases discussing the definition of the unborn, will subsequently be examined. Throughout this analysis, the need for clarification as to the parameters of Article 40.3.3 will be emphasised, with calls coming from the judiciary as well as government reports. Finally, the implications of the jurisprudence relating to Article 40.3.3 for embryonic stem cell research in Ireland will

⁶⁷² The 8th amendment introduced the “unborn” into the Irish Constitution in 1983. Article 40.3.3 currently states:

“The State acknowledges the right to life of the unborn, and with due regard to the equal rights of the mother, guarantees in its laws to respect, and as far as practicable, by its laws to defend and vindicate that right.

This subsection shall not limit freedom to travel between the State and another state.

This subsection shall not limit freedom to obtain or make available, in the State, subject to such conditions as may be laid down by law, information relating to services lawfully available in another state.”

be discussed and some tentative conclusions as to the legal status of stem cell research in Ireland will be drawn.⁶⁷³

2. Prohibition on Abortion prior to the introduction of Article 40.3.3 into the Irish Constitution

Prior to the introduction of Article 40.3.3 in 1983, sections 58 and 59 of the Offences Against the State Act 1861 prohibited abortion in Ireland.⁶⁷⁴ Section 58 states that:

“Whosoever, with intent to procure the miscarriage of any woman, whether she be or not be with child, shall unlawfully administer to her or cause to be taken by her any poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent, shall be guilty of felony.”

Thus procuring an abortion or attempting to procure an abortion was outlawed in Ireland. This prohibition however was limited in *R v Bourne*,⁶⁷⁵ a case which concerned a 14 year old girl who became pregnant as a result of a violent rape. Upon examination of the young girl the defendant doctor performed an abortion as he believed that the pregnancy would probably cause such serious injury to the girl as to justify the abortion. It was subsequently claimed that the abortion was contrary to s58. In directing the jury, Mcnaghten J stated that if the defendant carried out the abortion for the purpose of saving the girl’s life then the abortion was lawful.⁶⁷⁶ Mcnaghten went on to note that if the pregnancy would render the girl a “physical or mental wreck” a doctor is permitted to carry out an abortion for the purposes of saving the life of the mother.⁶⁷⁷ Thus while abortion was prohibited, it was permissible if it was to save the life of the mother or if it was to ensure the physical and mental wellbeing of the mother. Although this was an English case, it likely that a similar ruling would have occurred in Ireland.

3. Moves towards a Referendum

The drive towards an abortion referendum in Ireland was mainly due to two factors. First, it was a response to concerns in relation to developments in the Supreme Court of the United States where a prohibition on abortion was found to be unconstitutional. Second, it was a reaction to a move to liberalise certain areas of Irish society, including contraception and divorce.

⁶⁷³ See also C Staunton, ‘Issues Concerning Embryonic Stem Cell Research in Ireland’ (2012) 18 *Medico Legal Journal of Ireland* 38.

⁶⁷⁴ The 1922 Free State Constitution contained no provision relating to the unborn and the protection of the unborn. The 1937 Constitution as passed on 1 July 1937 also contained no provision relating to the unborn. Prior to 1937 all Acts passed by the United Kingdom were applicable in Ireland. The acts remained in law in Ireland post 1937 unless an act was declared unconstitutional or repealed by Dáil Éireann. Thus the 1861 Act remains law in Ireland.

⁶⁷⁵ [1938] 1 KB 687.

⁶⁷⁶ Ibid 691.

⁶⁷⁷ Ibid 694.

The foundation of a right to abortion in the United States began when in *Griswold v Connecticut* the Supreme Court declared that the ban on contraceptives was contrary to the United States Constitution on the grounds of marital privacy.⁶⁷⁸ Ten years later the Supreme Court held in *Roe v Wade* that the legislative ban on abortion was also contrary to the constitutional right of privacy.⁶⁷⁹ Similar to the *Griswold v Connecticut* decision, the Irish Supreme Court held that the ban on contraceptives in Ireland violated a couple's constitutional right to marital privacy.⁶⁸⁰ Unsurprisingly there was a fear among anti-abortion supporters that the Supreme Court might also declare that a prohibition on abortion was also contrary to the right to marital privacy in Ireland. However in *McGee v Attorney General*, Walsh J made clear that the right to privacy did not extend to permitting measures to limit family sizes by destroying human life, stating:

“any action on the part of either the husband and wife of the State to limit family sizes by endangering or destroying human life must necessarily not only be an offence against the common good but also against the guaranteed personal rights of the human life in question.”⁶⁸¹

Despite this statement, fears of those opposed to abortion were unlikely to have been quelled as Walsh J did state that “no interpretation of the constitution is intended to be final for all times” and interpretations may change according to new ideas or concepts.⁶⁸² Comments such as this led Binchy and others to believe that there was a need for an amendment to the Constitution as, in light of international developments, there was no guarantee that the legislative prohibition on abortion could withstand a constitutional challenge into the future.⁶⁸³ While the Court in *McGee* stated that the right to marital privacy would not extend to “endangering or destroying human life” it was possible that this interpretation could change in the future.⁶⁸⁴

⁶⁷⁸ See *Griswold v Connecticut* 381 U.S. 470 (1965).

⁶⁷⁹ 410 U.S. 113 (1973). The Court held that while the mother had a right to have an abortion based on the right to privacy, this was not an absolute right. The Court noted that the State cannot regulate for abortions in the first trimester but once the foetus becomes viable the State had a legitimate interest in protecting the life of the foetus. The *Roe* decision has faced considerable criticisms in recent years with the Supreme Court permitting the regulation of abortion in the first trimester. It would be unsurprising if the *Roe* decision was ultimately overturned in the future. See *Webster v Reproductive Health Services* (1983) 462 US 416 and *Planned Parenthood of Southeastern Pennsylvania v Casey* (1992) 505 US 833. For more on abortion in the US see L Tribe, *Abortion: The Clash of Absolutes* (W.W. Norton & Company 1992). The United States was not the only jurisdiction with such developments taking place. In Canada, the Supreme Court held in *Morgentaler, Smoling and Scott v Queen* (1988) 44 DLR (4th) 385 that section 251 of the Canadian Criminal Code, which banned abortion was contrary to section 7 of the Canadian Charter of Rights and Freedoms.

⁶⁸⁰ *McGee v Attorney General* [1974] IR 284.

⁶⁸¹ [1974] IR 284 at 312.

⁶⁸² *Ibid* 318.

⁶⁸³ W Binchy, ‘Article 40.3.3 of the Constitution: Respecting the Dignity and Equal Worth of Human Beings’ in J Schweppe (ed), *The Unborn Child, Article 40.3.3 and Abortion in Ireland* (Liffey Press 2008) 210.

⁶⁸⁴ O’Higgins CJ similarly stated in *The State (Healy) v Donoghue* that the preamble makes it clear that the Constitution is a living document:

“In my view, this preamble makes it clear that rights given by the Constitution must be considered in accordance with concepts of prudence, justice and charity, which may gradually change or develop as society changes and develops and which fall to be interpreted from time to time in accordance with prevailing ideas. The preamble envisages a Constitution which can absorb or be adapted to impose for

Walsh J later discussed the protection of the unborn child in *G v An Bord Uchtála*⁶⁸⁵ when he noted that a child's right to have its welfare and health guarded extended to before birth. Indeed the right to life included the right to be born and a child's existence could not be ended if its parents so decided.⁶⁸⁶ Thus it appears that the Courts may have been attempting to reassure the public that developments in the United States would not be followed in Ireland.⁶⁸⁷ Irrespective of the reasoning behind the obiter statements, they did not have the desired effect and the drive for a referendum was continued by the Pro-Life Amendment Campaign (PLAC).

The 1970s saw much debate on contraception and abortion in Ireland with the formation of groups whose aim were to ensure that there was no liberalisation of the availability of contraception and that a referendum on abortion was held.⁶⁸⁸ In 1981 the Pro Life Amendment Campaign was formally launched at a conference in Dublin.⁶⁸⁹ A proposed draft text, which was drawn up by John Blayney SC (who later went on to become a Supreme Court judge) was presented at the conference and stated:

“The State recognises the absolute right to life of every unborn child from conception and accordingly guarantees to respect and protect such right by law.”⁶⁹⁰

By affording the unborn child the absolute right to life, this proposed draft went further than the teachings of the Catholic Church, which allows for abortion in cases of cervical cancer and ectopic pregnancy. By April 1982, as the PLAC prepared to meet with the government, its position had somewhat softened to allowing for abortion in line with the teachings of the Church.⁶⁹¹

As the PLAC began its campaign in earnest, its call for a referendum was aided by the political instability at time, which was used to its advantage. As power swung between Fianna Fáil and Fine Gael both parties sought to please, or in the case of Garrett Fitzgerald, not to offend, the PLAC.⁶⁹² During the general election of 1982, the PLAC managed to play Fianna Fáil against Fine Gael. Charles Haughey came out in public support of an amendment that would guarantee the right to life of the foetus⁶⁹³ and narrowly won the election. Haughey's government lasted only a number of months, yet two days before it fell in November it published its proposed wording, which read:

all time the ideas prevailing ideas. The preamble envisages a constitution which can absorb or be adapted to impose for all time the ideas prevalent or accepted with regard to these virtues at the time of its enactment.” [1976] IR 325 at 347.

⁶⁸⁵ [1980] IR 32.

⁶⁸⁶ Ibid 69.

⁶⁸⁷ Sherlock has noted that in the Supreme Court judgments in *McGee v Attorney General*, *Norris v Attorney General* [1984] IR 36 and *G v An Bord Uchtála*, the judiciary “were making considerable efforts to dispel fears” that a *Roe v Wade*-like challenge to the 1861 Act would not succeed in Ireland. See A Sherlock, ‘The Right to Life of the Unborn in the Irish Constitution’ (1989) 24 *Irish Jurist* 13, 15.

⁶⁸⁸ Some of these groups included the Irish Family League, the Knights of St Columbanus and the Knights' Council of Social Concern (COSC). E O'Reilly *Masterminds of the Right* (Dublin, Attic Press 1992) 55.

⁶⁸⁹ Ibid 62.

⁶⁹⁰ Ibid.

⁶⁹¹ Ibid 67.

⁶⁹² J Sprend, *Abortion and Divorce Law in Ireland* (McFarland and Company Inc. 2004) 87.

⁶⁹³ O'Reilly (n 688) 75.

‘The State acknowledges the right to life of the unborn and, with due regard to the right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right.’⁶⁹⁴

The publication of this proposed text is notable for a number of reasons. First, in the lead up to the publication of the amendment, the Minister for Health, Dr Michael Woods was in frequent contact with prominent members of the PLAC⁶⁹⁵ and was thus, one would assume, heavily influenced by that campaign. Second, it is not clear who actually wrote the provision cited above. When the new Minister for Justice looked for the file in 1983 there was only an empty folder, and it appeared that the normal discussion documents that would be expected between government departments did not occur.⁶⁹⁶ There is no indication who or what groups were consulted, although the close contact PLAC had with the Minister for Health would suggest they were closely consulted, and there is no evidence that legal advice was sought. Finally, by publishing the proposed amendment in the dying days of the government, it was sure to become an election issue thus playing into the hands of the PLAC. The use of the abortion referendum as political gain was criticised by some.⁶⁹⁷ However such criticisms were in vain and a Fine Gael/Labour coalition came to power in December 1982 with a referendum on the proposed text as part of its Programme for Government.

3.1 Problems with the proposed amendment

In February 1983, a Bill to amend the Constitution was put before Dáil Éireann and problems immediately arose over the proposed amendment. The debate was marked by two issues: first that there were deep flaws with the proposed amendment and second, that there was a lack of real debate as to the implications of the amendment.

On the text itself, the Attorney General, Peter Sutherland, voiced his concerns over the wording, stating that it would cause confusion for the medical profession, lawyers and the judiciary.⁶⁹⁸ The AG noted that the use of the word “unborn” was new and warranted detailed consideration as to what class of persons the text meant to protect. Furthermore the AG stated it was generally accepted that a constitutional ban on abortion should allow for abortion in cases of ectopic pregnancy and cervical cancer but the proposed text, as he interpreted it, deemed the life of the unborn as being equal to that of the mother, thus the right to life of the unborn could not be limited in any way. He was of the opinion that if a doctor was faced with the option of saving the life of one and thus terminating the life of the other, under the proposed text, a doctor could do nothing.⁶⁹⁹ The AG’s concerns were also backed up by

⁶⁹⁴ Ibid 79.

⁶⁹⁵ Ibid.

⁶⁹⁶ Ibid 80.

⁶⁹⁷ See comments of Dr Rev William McDonnell in ‘Abortion Amendment Seen as Divisive’ *The Irish Times* 8 June 1983 4 and the comments of the Irish Congress of Trade Unions in John Cooney ‘Stormy Path Towards an Amendment’ *The Irish Times* 9 February 1983 7.

⁶⁹⁸ “Attorney General Rules Out Wording” *The Irish Times* 16 February 1983 6. Taoiseach Garrett Fitzgerald was reported as criticising the previous government for failing to get adequate legal advice nor engage in proper consultation prior to the publication of the amendment. ‘Abortion Text Not Yet Available’ *The Irish Times* 16 March 1983 5.

⁶⁹⁹ ‘Attorney General Rules Out Wording’ *The Irish Times* 16 February 1983 6.

doctors who were reported as stating that cancer treatment for pregnant women would have to stop if the amendment was passed.⁷⁰⁰

During the Dáil debates there was very little discussion of the legal implications of the proposed text. While there was some notice taken of the AG's concerns,⁷⁰¹ there was little attention given to the definition of the unborn and the impact such a definition could have on accepted contraceptive practices of that time.⁷⁰² Furthermore, there was no consideration of whether it was actually appropriate to regard the unborn as a constitutional person.⁷⁰³ Máire Geoghegan-Quinn TD, stated that it was her belief that an embryo has a right to life from the moment of conception, her opinion being a personal one and one she based on the grounds that it has all the genetic elements to develop into a human person.⁷⁰⁴ Dr Sean McCarthy TD, similarly argued that an embryo has the right to life, stating that science had resolved the issue that a fertilised egg is a person.⁷⁰⁵ Such unsubstantiated statements were not uncommon during the debates⁷⁰⁶ and often reflected personal opinion rather than scientific fact. Furthermore, there was little consideration of the impact that the amendment could have on assisted reproduction. Just four years prior to this debate, Louise Brown was the first child to be born from *in vitro* fertilisation treatment. Thus the debate should have acknowledged the possibility of an embryo existing *in vitro*.⁷⁰⁷

It was not until the proposed text was sent to the Seanad for debate that there was any real discussion of the amendment. Senator Mary Robinson noted that in the absence of a legal or medical definition of the term “unborn” it was of the utmost importance to define the term. She was quite critical that in the absence of a definitive scientific definition, the Dáil had failed to define the concept of the unborn.⁷⁰⁸ Senator Catherine McGuinness was similarly critical of both Houses of the Oireachtas for spending too much time focusing on the moral aspects of the embryo and the beginning of life and neglecting their duty as legislators. In order to provide clarity, she proposed to insert “which shall not include fertilised ovum prior to the time at which such ovum becomes implanted in the wall of the uterus” after the “unborn”.⁷⁰⁹ She noted that if her proposed amendment was rejected then the government

⁷⁰⁰ ‘Abortion Poll Date Queried’ *The Irish Times* 22 January 1983 17.

⁷⁰¹ See Barry Desmond TD, 17 February 1983, Dáil Debates, vol. 340, col. 473-474.

⁷⁰² There were some exceptions. See Nuala Fennell TD, 17 February 1983, Dáil Debates, vol. 340, col. 482-483.

⁷⁰³ N Cox, ‘Foetal Personhood in Comparative Perspective’ in J Schweppe (ed), *The Unborn Child, Article 40.3.3 and Abortion in Ireland* (Liffey Press 2008) 97.

⁷⁰⁴ Máire Geoghegan-Quinn, 17 February 1983, Dáil Debates, vol. 340, col. 500. Máire Geoghegan-Quinn was not alone in her belief that the protection of the unborn began at fertilisation. See Eileen Lemass’ comments; Eileen Lemass TD, 17 February 1982 Dáil Debates, vol. 340, col. 508.

⁷⁰⁵ Dr Sean McCarthy TD, 2 March 1983, Dáil Debates, vol. 340, col. 1621-1622.

⁷⁰⁶ For example, in the Dáil Rory O’Hanlon stated that “[l]ife starts in some form at conception”. Dr Rory O’Hanlon TD, 2 March 1983, Dáil Debates, vol. 340, col. 1622.

⁷⁰⁷ The only mention of embryos *in vitro* was made by Máire Geoghegan-Quinn who stated that a person “involved in the test tube baby experiments said that in crushing unwanted embryos he was conscious of destroying human life”. Máire Geoghegan-Quinn, 17 February 1983, Dáil Debates, vol. 340, col. 501.

⁷⁰⁸ Mary Robinson, 25 May 1983, Seanad Debates, vol. 100, col. 1110.

⁷⁰⁹ Catherine McGuinness, 25 May 1983, Seanad Debates, vol. 100, col. 1092.

was attempting to outlaw certain contraceptives, as some contraceptives prevent implantation but not fertilisation.⁷¹⁰

While it would not have resolved the balance of rights issue between the mother and the unborn child, this would have made clear that the embryo *in vitro* is not constitutionally protected and thus there are no constitutional barriers under Article 40.3.3 to either assisted reproductive practices or embryonic stem cell research. However Senator McGuinness's amendment was defeated and the "unborn" remained undefined in the proposed amendment.

3.2 Implications of the amendment

Despite the concerns of the Attorney General and the criticisms voiced in the Seanad, the text was passed and became Article 40.3.3 of the Irish Constitution. Even at this early stage, there was a recognition that there would be a need for "further legislation, amendments or litigations in the courts, either national or European".⁷¹¹ During the debates Mr Quinn TD described the amendment as "opening a legal Pandora's Box",⁷¹² stating:

"Nobody can determine the nature of what will come out of it and, most important of all, nobody can respond to the open-ended legal consequences of what will emanate from such a box when finally opened by some action by a private citizen against the Minister for Health, subsequently the Supreme Court and possibly on to the European Court of Human Rights."⁷¹³

Despite this recognition that there would be a need for further amendment or litigation, there was no move to remedy the uncertainty. Such was the force of the PLAC that Fitzgerald's government was unwilling to stray from the text agreed by the previous government and propose an amendment that would address the concerns of the AG. While the purpose of the amendment was to ensure that abortion would not be permissible in Ireland, the actual extent of the amendment was unclear. The referendum was known as the abortion referendum, thus one would assume that the intention was to protect the embryo *in vivo*. However, unlike the Offences Against the State Act 1861, the amendment makes no reference to abortion. While one would expect Article 40.3.3 to do nothing more than prohibit abortion, focusing on the right to life of the undefined "unborn" rather than prohibiting abortion made it unclear whether the amendment was to protect the embryo from fertilisation. Furthermore, statements in the Dáil that a human life begins at birth and a rejection of Senator McGuinness' proposal, which would have clarified the issue, would suggest that the remit of Article 40.3.3 was intended to not only prohibit abortion but also protect the embryo from the moment of fertilisation. If this was indeed to be the intention, certain contraceptives would be unconstitutional and embryonic stem cell research and all embryos formed through IVF would be required to be implanted irrespective of any medical concerns for the woman

⁷¹⁰ Catherine McGuinness, 25 May 1983, Seanad Debates, vol. 100, col 1094-1095.

⁷¹¹ Kevin Boyle, 'Pre-empting a Delicate Issue' *The Irish Times* 5 August 1982, 10.

⁷¹² Máire Geoghegan-Quinn TD, 2 March 1983, vol. 340, col. 1622.

⁷¹³ Mr Quinn TD, 2 March 1983, Dáil Debates, vol. 340, col. 1622.

involved. However, as noted by those on both sides of the debate, further amendment and litigation would be required.

4. The embryo post 1983 referendum

Despite the uncertainty surrounding the definition of the unborn, the early jurisprudence relating to Article 40.3.3 focused around a woman's right to information on abortion services abroad and a woman's right to travel for an abortion.⁷¹⁴ In these cases there was, however, some mention of the "unborn". In *Attorney General (SPUC) v Open Door Counselling*⁷¹⁵ Hamilton P stated in the High Court that

"the right to life of the unborn includes the right to have that right preserved and to be guarded against all threats to its existence before and after birth."⁷¹⁶

However it is unclear how far back in the developmental process Hamilton J intended the constitutional protection to apply. In the Supreme Court, Finlay CJ stated that there could be no right to information of abortion services abroad if that would serve to "defeat the constitutional right to life of the unborn child".⁷¹⁷ However, there was no further mention of who or what the "unborn" is under Irish law.

4.1 The X Case

The human impact of Article 40.3.3 came into focus in the X case, which concerned a young girl who had become pregnant as a result of rape. The Supreme Court held that abortion is permissible if there is a real and substantive risk to the life of the mother, which includes threat of suicide.⁷¹⁸ Thus for the first time it was clear that the right to life of the unborn was not absolute. Yet while the unborn was discussed, it was not defined. Hederman J noted that every life, either born or unborn, has a right to life and that this right is not qualified by the condition that an independent existence must be achieved after birth. Thus viability is not a concern in affording the protection of Article 40.3.3 to the unborn. Hederman J was of the opinion that no distinction could be made between "individual phases of the unborn life before birth, or between unborn and born life".⁷¹⁹ Notably the learned judge did state obiter that the Eighth Amendment settled beyond doubt that "[d]irect State interference in the developing unborn is outlawed".⁷²⁰ The use of the phrase "developing unborn" by Hederman J could imply that the constitutional unborn is an embryo growing *in vivo*. However, it is possible for an embryo to develop up to 14 days *in vitro* if the conditions are correct. Thus

⁷¹⁴ This is despite Rory O'Hanlon's statement in Dáil Éireann: "It is true that the pro-life amendment will not stop women from going abroad for an abortion but I hope the debate here and the amendment to the Constitution, when carried, will force the Government and society to take a more enlightened and positive attitude towards those women who find themselves forced by social pressures to have abortions". Rory O'Hanlon, 17 February 1983, Dáil Debates, vol. 340, col., 468.

⁷¹⁵ [1989] IR 593.

⁷¹⁶ Ibid 617.

⁷¹⁷ Ibid

⁷¹⁸ [1992] 1 IR 1 53-54.

⁷¹⁹ Ibid 72.

⁷²⁰ Ibid.

due to developing science, the comments by Hederman J could equally apply to the embryo *in vivo* and *in vitro*. However, the Supreme Court went no further in its discussions on the unborn.

McCarthy J was critical of the lack of guiding legislation since the passing of the Eighth Amendment stating that the people of Ireland would have expected legislation clarifying how the life of the mother can be reconciled with that of the unborn.⁷²¹ McCarthy J was of the opinion that the lack of legislation “is no longer just unfortunate; it is inexcusable”⁷²² and that it was the role of the legislature and not the courts to clarify this area.⁷²³ While this criticism focused on the uncertainty for pregnant women and the medical profession, the lack of clarity of the Irish legislation has had also a chilling effect on those working in assisted reproductive medicine and embryo research. Issues such as whether Article 40.3.3 protects the embryo *in vitro* should be determined by the legislature which is democratically elected by the people. As McCarthy J noted the “courts are not equipped to regulate these procedures”.⁷²⁴

As a result of the *X* case, any woman whose life is at a “real and substantial risk,” as a result of the pregnancy is entitled to an abortion in Ireland. It was not however clear what would constitute a “real and substantial risk” to life and further guiding legislation was required. Yet despite this clear need for legislation, particularly when one considers the criticisms of McCarthy J, none was forthcoming. A referendum held in 1992 in the aftermath of the *X* case focused on three issues: the right to information about abortion services abroad, the right to travel abroad to procure an abortion, and the removal of suicide as a ground for an abortion in Ireland. While the amendments in relation to information and travel were passed, the third amendment was rejected. The text of the amendment stated:

“It shall be unlawful to terminate the life of an unborn unless such termination is necessary to save the life, as distinct from the health, of the mother where there is an illness or disorder of the mother giving rise to a real and substantial risk to her life, not being a risk of self-destruction.”⁷²⁵

This proposed amendment would have had the effect of rowing back on part of the *X* case decision. Although it was rejected, it is notable that the legislature did not take on board the criticisms of McCarthy J and failed to clarify the application of Article 40.3.3; rather it focused its energies on restricting abortion in Ireland. It appears that there was only the political will to ensure that Ireland had a very conservative abortion policy and not to address the concerns of the Supreme Court.

McCarthy J was not alone in calling for clarity and in 1996, the Constitution Review Group examined the Constitution and criticised the lack of definition of the unborn. It noted that the

⁷²¹ Ibid 82.

⁷²² Ibid

⁷²³ Ibid 83.

⁷²⁴ Ibid.

⁷²⁵ The amendment was rejected by those on both sides of the debate. For some it watered down the prohibition on abortion while for others it did not go far enough in providing for exceptions to the prohibition on abortion. F Beytagh, *Constitutionalism in Contemporary Ireland: An American Perspective* (Roundhall Sweet and Maxwell 1997) 133.

“unborn” could mean from fertilisation, implantation or some other point in time,⁷²⁶ comments which echo those made by Peter Sutherland in 1983. The group acknowledged that it is likely that the phrase “unborn child” was not inserted into the Constitution as this would lead to confusion as to when a foetus might be properly described as such. The group was of the opinion that a definition is required as to what the unborn is and the point at which this entity has constitutional protection. In the view of the group, the unborn could mean ‘on the way to being born’, ‘capable of being born’ or it could mean another time in the developmental process of the foetus such as fertilisation, implantation or some other time.⁷²⁷ The group noted that a definition of pregnancy was also required and that this law should also specify when a pregnancy could be terminated and by whom.⁷²⁸ Importantly it was of the opinion that this definition was important as it would clarify whether Article 40.3.3 has an impact on assisted reproductive technologies and by implication, embryonic stem cell research.⁷²⁹

The Review Group went so far as to outline a number of approaches that the legislature could take in clarifying Article 40.3.3. Perhaps the most satisfactory approach (and the approach which the majority of the group favoured) was the recommendation to legislate for the application of Article 40.3.3. This would provide a definition of the unborn that would provide certainty as to the legality of certain forms of contraceptives and also whether Article 40.3.3 has an impact on assisted reproductive technologies and stem cell research. It would also specify when medical intervention, that is necessary to prevent the life of the mother but would result in the death of the unborn, is permissible.⁷³⁰

In 1997 the courts were once again critical of the lack of legislation, with the High Court criticising that recourse to the judicial system was the only way in which a woman could secure a lawful abortion in Ireland.⁷³¹ Furthermore Geoghegan J noted that the High Court should not be viewed as “some kind of licensing authority for abortions” in Ireland.⁷³²

4.2 2002 referendum

Politics, rather than concerns about legal clarity and certainty, played a central role in Ireland’s abortion debate at the turn of the century. A Fianna Fáil/Progressive Democrat minority government was formed in 1997 with the support of four independent TDs. The

⁷²⁶ Constitution Review Group, *Report of the Constitution Review Group* (1996) 275.

⁷²⁷ *Ibid.* The Review Group is not alone in its criticisms of Article 40.3.3. Beytagh is of the opinion that the Article would benefit from being rewritten in order to clarify and simplify the language. F Beytagh, *Constitutionalism in Contemporary Ireland: An American Perspective* (Roundhall Sweet and Maxwell 1997) 133.

⁷²⁸ Constitution Review Group, *Report of the Constitution Review Group* (1996) 275.

⁷²⁹ The first stem cells were not derived until 1998 thus the group could not have contemplated embryonic stem cell research in its analysis.

⁷³⁰ The other possible approaches discussed by the group were introducing a constitutional ban on abortion, redrafting the constitutional provisions to restrict the application of the *X* decision, amending Article 40.3.3 so as to legalise abortion in constitutionally-defined circumstances, and reverting to the pre-1983 position. Constitution Review Group, *Report of the Constitution Review Group* (1996) 276-279.

⁷³¹ *A and B v. Eastern Health Board, Judge Mary Fahy and C, and the Attorney General (Notice Party)* [1998] 1 IR 464.

⁷³² *Ibid.*

support of the independent TDs was obtained with the promise of a referendum on abortion.⁷³³ An Inter-departmental Working Group was formed and published a Green Paper on Abortion which set out a number of constitutional and legislative options for the Government. An All-Party Oireachtas Committee, having considered this report, was unable to reach consensus on any of the options put forward in the Green Paper.⁷³⁴ Despite this lack of consensus the Government pressed ahead with a referendum on abortion on 27 March 2002. The proposed amendment, which would have become Article 40.3.4 of the Constitution had the referendum been successful, stated:

“In particular, the life of the unborn in the womb shall be protected in accordance with the provisions of the Protection of Human Life in Pregnancy Act, 2002.”

Article 1(1) of the Protection of Human Life in Pregnancy Bill 2001 stated that abortion is to mean the “intentional destruction by any means of unborn life after implantation in the womb of a woman”. This would have meant that the embryo, under Article 40.3.4, would only have constitutional protection once had it implanted in a womb. This led to much concern in the Dáil but this was mainly due to many members of the Dáil assuming the 1983 amendment intended to protect the embryo from the moment of conception, and there was concern that a future Supreme Court would take the proposed amendment to mean that the entire article referred only to the embryo post-implantation.⁷³⁵ The proposed amendment was opposed by opposition parties Fine Gael, Labour and other smaller parties on the left.⁷³⁶

While the amendment was ultimately rejected, it should be briefly analysed as it may help clarify whether Article 40.3.3’s protection only applied to the embryo post-implantation. The Government of the day was clear that the proposed amendment did only intend to protect the implanted embryo. It was noted that the Commission on Assisted Reproduction had been appointed and the government was unwilling to bring forth any legislation on the embryo *in vitro* until such time that the Government had time to consider the Commission’s report. Thus this amendment was intended to be restricted to embryos *in vivo* only. Therefore if this amendment was passed, it would have been clear beyond any doubt that the embryo *in vivo* is protected from implantation.⁷³⁷

Madden has rightly argued that the words “in particular” meant that the Bill was only concerned with the embryo post-implantation and the existing constitutional provision was concerned with the right to life of the embryo pre-implantation. However, the use of the words “in particular” could easily have meant that the Bill aimed to deal with issues such as when constitutional protection applies to the foetus, as the previous sub articles dealt with

⁷³³ S Mullally, ‘Rights Discourse, Dissent and Reproductive Autonomy’ in J Schweppe (ed), *The Unborn Child, Article 40.3.3 and Abortion in Ireland* (Liffey Press 2008) 226-227.

⁷³⁴ All Party Oireachtas Committee on the Constitution *Fifth Progress Report: Abortion* (2000).

⁷³⁵ Mr G Mitchell, 25 October 2001 Dáil Debates, vol. 543, col. 36.

⁷³⁶ S McSvoy, ‘From Anti-Amendment Campaign to Demanding Reproductive Justice: The Changing Landscape of Abortion Rights Activism in Ireland’, 1983-2008 in J Schweppe (ed), *The Unborn Child, Article 40.3.3 and Abortion in Ireland* (Liffey Press 2008) 38.

⁷³⁷ Comments made by Minister for State at the Department of Health and Children, Dr Moffatt, in Seanad Éireann. Dr Moffatt, 7 December 2001, Seanad Debate, vol. 168, col. 1291.

abortion information and travel to another state for an abortion.⁷³⁸ In any event the referendum was ultimately rejected and there has been no further attempt to revise the wording of Article 40.3.3.

4.3 A, B and C v Ireland

Ireland's abortion policy came before the European Courts in *A, B and C v Ireland*.⁷³⁹ The case concerned three women resident in Ireland who challenged Ireland's restrictive abortion laws under the European Convention on Human Rights (ECHR). Specifically, the plaintiff known as C argued that the lack of guidance as to when it was permissible to have an abortion in Ireland violated her right to respect for private and family life under Article 8 of the ECHR, as in the absence of guidelines no doctor was willing to carry out an abortion.⁷⁴⁰ The Irish Government argued that the rules governing abortion in Ireland were clear and that if a woman did not agree with the decision of her doctor, an emergency application could be made to the High Court.⁷⁴¹ The European Court on Human Rights (ECtHR) did not agree with the Irish government but espoused the position adopted by the Irish courts, namely that the courts were a suitable forum in which to determine abortion law.⁷⁴² Furthermore it considered it unreasonable that a woman be expected to make an application to the Court for an abortion where there was no doubt that there was a "real and substantial risk" to the life of the mother.⁷⁴³ Due to the lack of clarity as to when an abortion is permissible in Ireland, the ECtHR found that Article 8 rights were infringed.⁷⁴⁴ As a result of this decision the Irish government must clarify when an abortion is permissible in Ireland to ensure that its abortion policy conforms to the ECtHR.

The decision however came amidst an economic crisis and political uncertainty in Ireland. The Minister for Health of the day stated that the Government would consider the judgment but was of the opinion that there would be no need for a referendum on the issue.⁷⁴⁵ Before the Government could consider the issue there was a general election held the following spring. In its Programme for Government, the Fine Gael/Labour coalition stated:

"We acknowledge the recent ruling of the European Court of Human Rights subsequent to the established ruling of the Irish Supreme Court on the X-case. We will establish an expert group to address this issue, drawing on appropriate medical

⁷³⁸ During the Dáil debates the Minister for Health and Children noted that the use of the words "in particular" was to make it clear that the Bill was not intended to be a restatement of the term "unborn" as used in Article 40.3.3. Michael Martin, 25 October 2001 Dáil Debates, vol. 543, col. 26.

⁷³⁹ [2010] EHRH 2032.

⁷⁴⁰ [2010] EHRH 2032 at paragraph 179. For more on A and B's application and further analysis see C Staunton, 'As Easy as A, B and C: Will A, B and C v. Ireland Be Ireland's Wake-up Call for Abortion Rights?' (2011) 18 *European Journal of Health Law* 205.

⁷⁴¹ [2010] EHRH 2032 at paragraph 189.

⁷⁴² *Ibid* para 258.

⁷⁴³ *Ibid* para 259.

⁷⁴⁴ *Ibid* para 267.

⁷⁴⁵ P Cullen and H McGee, 'Proposing Legal Changes Will Take Time, says Harney' *Irish Times*, Friday, 17 December 2010, online at: <<http://www.irishtimes.com/newspaper/ireland/2010/1217/1224285736670.html>, accessed 4 January 2011.

and legal expertise with a view to making recommendations to Government on how this matter should be properly addressed.”⁷⁴⁶

This expert group reported in November 2012, the same week in which the death of Savita Halappanavar was reported. Ms Halappanavar was 17 weeks pregnant when she began to miscarry. She requested an abortion but was refused as the foetal heart was still beating. After three days in ICU, the foetus died. Ms Halappanavar subsequently developed septicaemia and died. Although the Coroner’s Court is not due to sit until late Spring of 2013, her death served as an impetus for the government to introduce legislation as to when an abortion is lawful in Ireland. Three days of hearings were held by the Joint Oireachtas Committee on Health in January 2013⁷⁴⁷ and the draft Heads of a Bill are expected before summer 2013.

4.4 International Perspective

The status of the foetus and the embryo *in vitro* in Ireland may possibly be influenced by international conventions or EU law. Since World War II, a number of international agreements governing experimentation on human life have emerged. In the aftermath of the Nazi regime, the Nuremberg Code was drawn up to ensure that respect for human life is superior to medical or scientific advancement. Although drawn up by a war tribunal and thus not binding on any jurisdiction, its importance lies in the recognition that medical ethics should be central to research involving human life.⁷⁴⁸ The Nuremberg Code was followed in 1964 by the Declaration of Helsinki which is a statement of medical ethics for research involving human subjects and is applicable to doctors.⁷⁴⁹

However the first legally binding obligation on states to protect human rights came when the Council of Europe drew up the European Convention on Human Rights (ECHR) in 1950. Ireland ratified the Convention in 1953⁷⁵⁰ but by virtue of Article 29.6 of the Convention, no international agreement is binding in Ireland unless an Act is passed incorporating the agreement into domestic law.⁷⁵¹ The status of the ECHR in Irish law was confirmed in *Re Ó Laighléis*⁷⁵² in which the Supreme Court held that as the Oireachtas had not incorporated the

⁷⁴⁶ Government for National Recovery 2011-2016 38.

⁷⁴⁷ The Committee heard from medical and legal experts as well as various lobby groups. For example see Opening Statement of Ciara Staunton <http://www.oireachtas.ie/parliament/media/committees/healthandchildren/Opening-Statement_CiaraStaunton_final.pdf> accessed 1 February 2013.

⁷⁴⁸ The Code states: “The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally.” For more on the Nuremberg Code see ‘Embryonic Stem Cell Research: One Small Step for Science or One Giant Leap Back for Mankind?’ (2003) 1 *University of Illinois Law Review* 211.

⁷⁴⁹ This declaration has subsequently been amended in 1975, 1983, 1989, 1996, 2000, 2002 and 2008.

⁷⁵⁰ The Convention came into force in September 1953.

⁷⁵¹ Article 29.6 states “No international agreement shall be part of the domestic law of the State save as may be determined by the Oireachtas”.

⁷⁵² [1960] 1 IR 93.

Convention by an act of the Oireachtas, the Convention cannot be invoked in Irish courts if domestic legislation is contrary to the Convention.⁷⁵³

No attempt was made to incorporate the ECHR until 1998.⁷⁵⁴ In that year the government signed the Good Friday Agreement in which it was agreed that Ireland would take steps to strengthen and bring its protection of human rights in line with that of Northern Ireland.⁷⁵⁵ The practical impact of this agreement was the incorporation of the ECHR.⁷⁵⁶ The ECHR was thus incorporated into Irish law by virtue of the European Convention on Human Rights Act 2003. Under the Act, the Convention has become part of Irish law but it is at a sub constitutional level. Thus a breach of the rights protected in the Convention can be argued before the Irish courts but the rights contained in the Constitution are superior to those in the ECHR. However if the Convention rights conflict with the Constitution, the constitutional rights will be deemed to be superior in Irish courts.⁷⁵⁷

There is the potential for the ECHR to impact on the status of the Irish embryo. Article 2 of the Convention protects the right to life.⁷⁵⁸ However, the Convention is silent on whether the right to life extends to the unborn child or the embryo *in vitro*.⁷⁵⁹ The parameters of Article 2

⁷⁵³ Ibid 125. In *Kavanagh v Governor of Mountjoy Prison*, the Supreme Court held that while there may be an expectation that the ECHR would be incorporated into Irish law, the doctrine of legitimate expectations does not extend to incorporating the ECHR into Irish law. While there may be an expectation that by entering into an international agreement the terms of the agreement will be respected, the court stated that in the absence of incorporating legislation there is no obligation that Irish law must follow its terms. The court stated that the Constitution makes a clear distinction between domestic and international law and that international law is only binding on Irish law after an act of the Oireachtas. [2002] 3 IR 97 127-129.

⁷⁵⁴ In 1996 the Constitutional Review Group recommended incorporating the convention into Irish law. See *Constitutional Review Group Report*, 1996.

⁷⁵⁵ See Northern Ireland Peace Agreement 1998, chapter 6 “Rights, Safeguards and Equality of Opportunity”. The United Kingdom fulfilled its human rights obligations by virtue of the Human Rights Act 1998 on which the European Convention on Human Rights Act 2003 is modelled. For a comparison of the Human Rights Act 1998 and the European Convention on Human Rights Act 2003 see S Besson, ‘The Reception Process in Ireland and the United Kingdom’ in H Keller & S Stone, *A Europe of Rights: The Impact of the New ECHR on National Legal Systems* (OUP 2008).

⁷⁵⁶ Prior to the incorporation of the ECHR into Irish law, if a litigant’s Convention rights were infringed, they could only bring a case in the Irish courts if there was a comparable constitutional right. If there was no comparable right, the litigant would have to bring the action to the ECHR. For more on the incorporation of the ECHR into Irish law and the status of the ECHR in Irish law see F de Londras & C Kelly, *European Convention on Human Rights Act: Operation, Impact and Analysis* (Roundhall 2010) and G Hogan, ‘Incorporation of the ECHR: Some Issues of Methodology and Process’ in U Kilkelly, *ECHR and Irish Law* (Jordan Publishing Limited 2004).

⁷⁵⁷ While the ECHR was not in force in Ireland until January 2004, by virtue of its ratification by Ireland, the Convention had persuasive authority in Ireland and a case could be taken to the European Court of Human Rights against Ireland. Post 2004, if a case that concerns a breach of Convention rights is not successful in the Irish courts due to the superiority of the Irish Constitution, the case can be appealed to the European Court of Human Rights.

⁷⁵⁸ Article 2 states

“Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.”

⁷⁵⁹ Article 2 parameters are not just unclear in bioethical cases which concern the status of the human embryo, but also in other cases also. See M O’Neill, ‘Article 2, the Right to Life and the Investigation of Deaths Following Police Contact’ in U Kilkelly (n 756).

arose for discussion in *Bruggeman and Scheuten v Federal Republic of Germany*⁷⁶⁰ which concerned the abortion laws of Germany. The European Court of Human Rights (ECHtR) noted that due to the link between a pregnant woman and the developing foetus, pregnancy is not completely in the sphere of private life.⁷⁶¹ However, the court did not think it necessary to decide whether the unborn child is considered life under Article 2 of the Convention.⁷⁶²

The issue came before the European Commission on Human Rights in *X v United Kingdom*.⁷⁶³ The applicant sought an injunction in the English High Court to prevent his wife having an abortion. The injunction was denied on the grounds that the foetus does not have any legal rights until the child is born and that the father had no legal right to prevent the abortion provided the requirement of the English Abortion Act 1967 was followed. Within hours of the dismissal of the application, the abortion was carried out. The applicant thus alleged that the 1967 Act violates Article 2 of the ECHR.

In considering the issue, the Commission was mindful of the divergence of opinion on when life begins.⁷⁶⁴ It noted that the life of the foetus is intimately connected with that of the mother. However, it was of the opinion that if there was an absolute right to life of the foetus then abortion would be prohibited, even where the continuance of the pregnancy would involve a serious risk to the life of the pregnant woman. This would mean that the unborn life would be regarded as being of higher value than the life of the pregnant woman.⁷⁶⁵ The Commission was of the opinion that this interpretation would be contrary to the object and purpose of the Convention.⁷⁶⁶ However, once again the Commission was of the opinion that it was not necessary in the present case to decide whether the foetus has a right to life under Article 2.⁷⁶⁷ Thus the Commission left open the question of whether the unborn child was protected under Article 2.⁷⁶⁸

The ECHtR was once again asked to consider the impact of Article 2 on abortion laws in *Open Door and Dublin Well Woman v Ireland*.⁷⁶⁹ The Irish government argued that the majority of the people of Ireland were of the opinion that abortion was morally wrong and

⁷⁶⁰ (1977) 3 EHRR 244. A breach of Article 2 was claimed in *X v Austria*. App. No. 7045/75 Comm. Dec. 10.12.1976. However the European Commission on Human Rights did not discuss Article 2 as the applicant's case was held to be inadmissible.

⁷⁶¹ (1977) 3 EHRR 244 para 59. The court stated "Article 8(1) cannot be interpreted as meaning that pregnancy and its termination are, as a principle, solely a matter of private life of the mother". Ibid para 61.

⁷⁶² Ibid para 60.

⁷⁶³ App. No.8416/79 Comm. Dec. 13.05.1980.

⁷⁶⁴ The Commission noted that "while some believe that it starts already with conception others tend to focus upon the moment of nidation, upon the point that the foetus becomes "viable", or upon live birth". Ibid para 12.

⁷⁶⁵ Ibid para 19.

⁷⁶⁶ Ibid para 20. The Commission was influenced by the fact that when the Convention was signed, all contracting parties with one exception permitted abortion when necessary to save the life of the mother. *Ibid*.

⁷⁶⁷ Ibid para 23.

⁷⁶⁸ The Commission's justification was that it fell within one of the limitations: the abortion was necessary to protect the life of the mother. A similar case arose a decade later in *H v Norway* in which the applicant was refused an injunction to prevent the abortion of his unborn child. Once again the Commission was of the opinion that it did not have to determine whether Article 2 protects unborn life. App. No. 17004/90 Comm. Dec. 19.05.1992.

⁷⁶⁹ (1993) 15 EHRR 244.

that it was not a function of the court to impose a different viewpoint.⁷⁷⁰ While the Court did not consider it necessary to determine the level of protection Article 2 extends to the foetus,⁷⁷¹ the Court did state:

“It acknowledges that the national authorities enjoy a wide margin of appreciation in matters of morals, particularly in an area such as the present which touches on matters of belief concerning the nature of human life.”⁷⁷²

Thus it appears that the Court considers issues relating to abortion, assisted reproduction and, by implication, matters pertaining to embryonic stem cell research to be within Member States’ margin of appreciation.⁷⁷³ However in *Boso v Italy*⁷⁷⁴ the Court appears to recognise the need for some level of protection for the unborn child as the Court noted that the relevant domestic law struck a fair balance between the need to ensure the protection of the foetus and the women’s interests. However it is unclear whether this protection of the foetus is necessary for compliance with Article 2 of the Convention.⁷⁷⁵

The Court was presented with an opportunity to clarify the parameters of Article 2 in *Vo v France*.⁷⁷⁶ The applicant argued that the time at which life began had universal meaning and that it was scientifically proven to begin at fertilisation. Thus, the applicant argued, an unborn child is not a cluster of cells, and the term “everyone” in the Convention meant human beings, rather than individuals who had legal personality.⁷⁷⁷ However the Court noted that it had yet to decide when the right to life began and whether the unborn child had a right to life.⁷⁷⁸ Reviewing the limited case law on the application of Article 2, the court noted that in the context of abortion the unborn is not regarded as having a right to life under Article 2. However in certain circumstances the unborn may be safeguarded but this is determined by

⁷⁷⁰ Ibid para 65.

⁷⁷¹ The court was only required to determine whether a ban on the dissemination of abortion information was contrary to European law, thus the application of Article 2 was not an issue in this case.

⁷⁷² (1993) 15 EHRR 244 at paragraph 68.

⁷⁷³ The margin of appreciation is the degree to which Member States have discretion on certain Convention rights. While Member States have a certain margin of appreciation regarding the applicability of Article 2 to the status of the embryo. The amount of discretion on Article 2 issues is unclear. See M Enright “Justice, Convention and Anecdote: Evans and the Right to Become a Mother” (2006) 9 *Irish Journal of Family Law*. On the margin of appreciation generally see de Londras & Kelly (n 759) para 6.34-6.38 and M Hutchinson, ‘The Margin of Appreciation Doctrine in the European Court of Human Rights’ (1999) 48 *International and Comparative Law Quarterly* 638.

⁷⁷⁴ App No. 50490/99 Dec. 05.09.2002.

⁷⁷⁵ See N Priaulx, ‘Testing the Margin of Appreciation: Therapeutic Abortion, Reproductive ‘Rights’ and the Intriguing Case of *Tysiqc v. Poland*’ (2008) 15 *European Journal of Health Law* 361 which suggests that there are limits on a Member State’s discretion in abortion cases.

⁷⁷⁶ (2005) 40 EHRR 12. This was the first case that concerned Article 2 outside of voluntary abortion. In this case the applicant required an abortion due to medical negligence resulting in injury to the applicant’s amniotic sac. The foetus was between 20 and 24 weeks at the time of the abortion. The doctor was subsequently charged with causing unintentional injury to the foetus but was acquitted on the grounds that the foetus was not a human person at this stage. The applicant brought her case to the ECtHR arguing that the foetus’s right to life under Article 2 had been violated.

⁷⁷⁷ Ibid para 47.

⁷⁷⁸ Ibid para 65.

weighing up the conflicting rights of the mother *vis a vis* the unborn child.⁷⁷⁹ The Court went on to state that:

“[T]he interpretation of the Convention in this connection has been informed by a clear desire to strike a balance, and the Convention institutions’ position in relation to the legal, medical, philosophical, ethical or religious dimensions of defining the human being has taken into account the various approaches to the matter at national level. This has been reflected in the consideration given to the diversity of views on the point at which life begins, of national standards of protection, and the state has been left with considerable discretion in the matter.”⁷⁸⁰

It was for this reason, and for the lack of a consensus on when life begins and the level of protection for the foetus, that the Court held that the issue of whether the foetus has a right to life is within the margin of appreciation afforded to States.⁷⁸¹

However, the Court was not asked to determine when life began. It was asked to determine whether the unborn has a right to life under Article 2. While acknowledging that this is a sensitive area with differing legislation in the contracting states, this decision has only served to muddy the waters regarding the right to life under the ECHR. States that permit abortion also have legislative provisions that require respect for the foetus or the unborn. Thus if the ECtHR had decided that the unborn does not have a right to life under the Convention this would not automatically mean that the unborn has no protection.⁷⁸²

While it is apparent that under Article 2 the mother’s right to life is superior to that of the embryo if her life is in danger, the ECtHR is reluctant to strike down abortion legislation as being contrary to Article 2. While the Court has declined to discuss the application and remit of Article 2 in the past, *Vo v France* presented an opportunity for the Court to discuss Article 2 in detail. It was not necessary to determine of the being of life as this is an ethical issue that, while something the Court should be cognisant of, is not the role of the Court to resolve. The Court’s function is to determine the remit of Article 2 and whether the unborn is protected under the Convention.

⁷⁷⁹ Ibid para 79.

⁷⁸⁰ Ibid para 82.

⁷⁸¹ Ibid. However note the judgement of *Tysiąc v Poland* in which the Court held that Poland’s abortion legislation was contrary to Article 8.

⁷⁸² In a dissenting judgement, Ress J stated:

“I am prepared to accept that there may be differences in the level of protection afforded to an embryo and a child after birth. Nevertheless, this does not justify reaching the conclusion that it is a person for the purposes of Article 2 of the Convention.” (2005) 40 EHRR 12 at paragraph O-III3.

Ress J was critical of the Court’s failure to give a clear answer on the status of the unborn child and was of the opinion that the mother and embryo are separate and thus require separate protection.

Although *Evans v United Kingdom* concerned embryos *in vitro*, there has been no detailed consideration of the status of the embryos under the Convention.⁷⁸³ Rather the Court considered in the *Evans* case

“Where, however, there is no consensus within the Member States of the Council of Europe, either as to the relative importance of the of the interest at stake or as to the best means of protecting it, particularly where the case raises sensitive moral or ethical issues, the margin will be wider.”⁷⁸⁴

Due to the wide margin of appreciation, it is unclear whether the implied protection for the foetus that emanates from the case law would apply to the embryo *in vitro*. However in 1997 the Biomedicine Convention⁷⁸⁵ was written, coming into force in December 1999.⁷⁸⁶ While Ireland has not yet signed it, the Convention is significant as it permits research on embryo *in vitro* where the domestic law permits it.⁷⁸⁷ Thus there is not a right to life for the embryo *in vitro*.⁷⁸⁸ The Convention also does not define the term “everyone”. The explanatory report states that as there is a lack of agreement on this term, Member States can define the terms for the purpose of the application of the Convention.

It thus appears that European case law provides no guidance as to the status of the embryo in Ireland. The ECtHR has implied that there must be respect for the foetus, but it is unclear whether this would apply to the embryo *in vitro*. Due to the lack of legislation surrounding stem cell research in Ireland, it is unlikely that the Irish government would sign or ratify the Biomedicine Convention any time soon. Thus it would appear that the embryo *in vivo* is constitutionally protected but, at present, there is no legislative or constitutional protection for the embryo *in vitro*. Thus this is no legal impediment to the commencement of human embryonic stem cell research in Ireland.

5. Article 40.3.3 and the Embryo *In Vitro*

While there were numerous reports and case law criticising the lack of abortion guidelines within the parameters of Article 40.3.3, developments in embryology resulted in uncertainty regarding the impact of this constitutional provision on the embryo *in vitro*. In 2000 the Commission on Assisted Human Reproduction (CAHR) was established by the Minister for Health and Children to consider the legal, ethical and scientific factors to be considered in regulating assisted human reproduction (AHR). In its report, the Commission referred to the

⁷⁸³ (2006) 43 EHRR 21. In *Evans v United Kingdom* it was argued that embryos *in vitro* had a right to life under Article 2. However the Court did not consider this issue as it held that such an issue must be decided by the domestic courts and not the ECtHR.

⁷⁸⁴ *Ibid* para 77.

⁷⁸⁵ The Convention’s full title is Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine.

⁷⁸⁶ To date 26 countries have both signed and ratified the Biomedicine Convention and 8 countries have signed but not yet ratified it.

⁷⁸⁷ The ECtHR has referred to the Convention in its decision. *See Vo v France* (2005) 40 EHRR 12 at paragraph 84.

⁷⁸⁸ Article 18(1) does require that if the domestic law permits research on embryos *in vitro* there must be adequate protection of the embryo. Article 18(1) is subject to article 18(2) which prohibits the creation of embryos for research purposes.

lack of clarity surrounding the meaning of the “unborn” and the point post-fertilisation that the embryo was protected. The Commission was of the opinion that clarity could only come from an interpretation from the Supreme Court or by way of referendum.⁷⁸⁹ However, the Commission did recommend (with one dissent) that the embryo should not be legally protected until it is “placed in the human body”.⁷⁹⁰ Furthermore, the Commission recommended the establishment of a regulatory authority to regulate AHR, which would also encompass embryo research.⁷⁹¹ On the issue of embryo research, the Commission recommended that research should be permitted on spare embryos that are specifically donated for research up to fourteen days after fertilisation.⁷⁹² The Commission also recommended that the creation of embryos for research purposes should be prohibited⁷⁹³ but the majority recommended that the cloning of embryos for therapeutic purposes should be permitted.⁷⁹⁴

This report was followed in 2008 by similar recommendations issued by the Irish Council for Bioethics. In its report on the *Ethical, Legal and Scientific Issues Concerning Stem Cell Research*, the Council recommended the introduction of regulations so that supernumerary IVF embryos, which would otherwise be destroyed, could be used for embryonic stem cell research which is aimed at alleviating human suffering.⁷⁹⁵

While both the CAHR and Irish Council for Bioethics made similar recommendations, no legal clarity as to the status of the embryo *in vitro* was forthcoming. In the absence of legislation,⁷⁹⁶ AHR services continued in Ireland with supernumerary embryos (spare embryos left over after AHR) frozen indefinitely leaving clinics unclear as to whether they must be implanted, remain frozen indefinitely, or could be destroyed. In its 2004 edition of *A Guide to Ethical Conduct and Behaviour*, the Medical Council of Ireland for the first time considered AHR. It provided limited guidance on donation of gametes, payments, and counselling, but the guidelines also stated

“Any fertilised ovum must be used for normal implantation and must not be deliberately destroyed.”⁷⁹⁷

⁷⁸⁹ Commission on Assisted Human Reproduction *Report of the Commission on Assisted Human Reproduction* (2005) at 37.

⁷⁹⁰ Ibid 34.

⁷⁹¹ Ibid 8.

⁷⁹² Ibid 58.

⁷⁹³ Ibid.

⁷⁹⁴ Ibid 62.

⁷⁹⁵ Irish Council for Bioethics *Ethical, Legal and Scientific Issues Concerning Stem Cell Research* (2008) 45.

⁷⁹⁶ The only legislation which relates somewhat to AHR is under the Human Tissue and Cells Regulations that concerns the use of “reproductive cells”. The regulations however are not concerned with the human application of these cells. Regulation 12 does state:

“In the case of assisted reproduction, any type of gamete or embryo misidentification or mix-up shall be considered to be a serious adverse event. All persons or procurement organisations or organisations responsible for human application performing assisted reproduction shall report such events to the supplying tissue establishments for investigation and notification to the Irish Medicines Boards.”

See Quality and Safety of Human Tissues and Cells Regulations (S.I. No. 158 of 2006).

⁷⁹⁷ Medical Council of Ireland, *Guide to Professional Conduct and Ethics for Registered Medical Practitioners*, 6th ed. (2004) 35.

However, in its updated 2009 edition, this proviso is removed. The new edition instead states that doctors “should not participate in creating new forms of life solely for experimental purposes.”⁷⁹⁸ Yet despite the removal of the requirement that embryos must not be deliberately destroyed, no legislation was forthcoming from the Oireachtas.⁷⁹⁹ This change in guidance may have been due to on-going litigation which raised the issue of the status of the embryo *in vitro*.

5.1 *Roche v Roche*

The constitutional status of embryos *in vitro* came before the Irish courts in *Roche v Roche*.⁸⁰⁰ The case concerned a couple who underwent IVF treatment but subsequently separated. There were a number of frozen embryos left over from their previous relationship which Mrs Roche wanted to implant. However, this was contrary to the wishes of Mr Roche. The Court thus had to determine whether the embryo *in vitro* came under the definition of the “unborn” and if so whether it was constitutionally protected. If embryos *in vitro* are protected under Article 40.3.3, Mrs Roche would be entitled to implant the embryos over the expressed wishes of Mr Roche.

In the High Court,⁸⁰¹ McGovern J noted that while the background to the amendment was to ensure that there would be no constitutional challenge to the 1861 Act and thus ensure that abortion was constitutionally prohibited, the courts have never stated that the amendment was solely concerned with preventing abortion.⁸⁰² Although the case law solely discussed the Eighth Amendment in the context of abortion, McGovern J stated that this was not to imply that Article 40.3.3 was only concerned with abortion as this provision had only come before the courts in the context of abortion. When looking at the meaning of the word “unborn”, McGovern J was of the opinion that there was no evidence that in voting for the Eighth Amendment that the people of Ireland meant to do more than outlaw the termination of a pregnancy. While evidence had been put forward by the plaintiff as to when human life begins, the learned judge stated that the Court was not concerned with the beginning of human life but rather whether the embryo *in vitro* is protected by Article 40.3.3. For McGovern J, there was evidence to suggest that the term “unborn” included the embryo *in vivo* but did not extend to the embryo *in vitro*. McGovern J did state however that while there

⁷⁹⁸ Ibid 21.

⁷⁹⁹ In any case the guidelines only apply to registered doctors and not scientists involved in embryo research who are not practising doctors, thus the guidelines do not cover the use of all embryos *in vitro*.

⁸⁰⁰ [2006] IEHC 221, [2006] IEHC 359, [2010] 2 ILRM 1. There were two High Court cases concerning the frozen embryos. The first discussed the contract law issues; the second examined the constitutional position of the frozen embryos. Both the High Court and the Supreme Court neglected to discuss whether there was a right to have the embryos implanted; in other words, whether there is a right to procreate. For more on the right to procreate see M Enright, ‘Justice, Convention and Anecdote: Evans and the Right to Become a Mother’ (2006) 9 *Irish Journal of Family Law* and M Eljkholt, ‘The Right to found a Family as a Still born Right to Procreate’ [2010] *Medical Law Review* 127. The government cannot generally prevent the creation of a child through forced sterilisation nor can the government ban contraception. However, this should not be seen as a right to procreate.

⁸⁰¹ [2006] IEHC 221, [2006] IEHC 359.

⁸⁰² While the court can look at the historical reasoning for the amendment, the Supreme Court has noted that before this is done, the court must first examine the ordinary meaning of the constitutional Article. See *Campaign to Separate Church and State v Minister for Education* [1998] 3 IR 321, 360-361.

is disagreement as to whether embryos prior to implantation constitute life, there appeared to be agreement that embryos *in vitro* are deserving of respect.

McGovern J did not explain what he meant by “respect” and how embryos may be respected. Rather he stated that in the absence of regulations protecting embryos *in vitro*, they are in a very precarious situation. Furthermore, McGovern J stated that it is not for the Courts to decide whether Article 40.3.3 should include embryos *in vitro*. Rather this is a matter to be decided by the Oireachtas or the Irish people through a referendum. He was critical of the lack of legislation forthcoming since the publication of the CAHR Report and of the resulting situation. In the absence of legislation the courts were being forced to deal with complex issues which should be the subject of a regulatory regime established by the Oireachtas.

This decision was subsequently appealed and in the Supreme Court Murray CJ noted that while the embryo may have moral status and society may wish to protect and respect it, the level of status or protection was not the issue before the Courts. Murray CJ was of the opinion that the issue was whether “the frozen embryo is human life within the meaning of Article 40.3.3”. He did not consider the Court a place to resolve the moral, ethical, philosophical, theological or scientific issues which the status of the human embryo raises. While there is no broad consensus on this issue, Murray CJ stated that it is for the legislature to resolve such policy issues as it has “initial responsibility for the protection and regulation of constitutional rights”. The Chief Justice was of the opinion that the issue of when life began was a matter for the Oireachtas and not the Courts and thus dismissed the appeal.⁸⁰³

However the issue before the Supreme Court was not whether the embryos constituted *human life* under Article 40.3.3 but rather whether the embryos could be considered to fall within the scope of the term “unborn” under Article 40.3.3. Murray CJ was indeed correct that the status and protection that the embryo *in vitro* is to have is a matter for the Oireachtas. This is a matter that the Oireachtas has consistently failed to resolve despite numerous requests to do so. Yet the Court was not asked this. Rather it was asked to consider whether the embryos were protected under the Eighth Amendment, a matter which was entirely justiciable. As Denham J noted the Court was being asked to interpret an article of the Constitution rather than engaging in philosophical debates on human life:

“This case is not about the wonder and mystery of human life. This is a court of law which has been requested to make a legal decision on the construction of an article of the Constitution of Ireland. The question raised is whether the term “unborn” in the Constitution includes the three frozen embryos in issue in this case. It is a matter of construing the word in the Constitution to determine its constitutional meaning.”⁸⁰⁴

In determining that the embryos were not protected under Article 40.3.3, Denham J focused on the historical background to this provision. She noted that this provision was inserted to ensure that there would be no constitutional challenge to the statutory ban on abortion.⁸⁰⁵

⁸⁰³ *Roche v Roche* [2010] 2 ILRM 1, 10.

⁸⁰⁴ *Ibid* 24.

⁸⁰⁵ *Ibid*.

This view, however, ignores the positive wording of the 1983 amendment; rather than explicitly prohibit abortion, Article 40.3.3 affords rights to the undefined “unborn”. Binchy, who was a prominent member of the PLAC at the time of the amendment, has argued that the constitutional amendment was to do more than simply prohibit abortion; it was also to protect the unborn at all stages of development.⁸⁰⁶ The truth is that neither the Court nor Binchy are entirely correct. As there are no documents relating to the drafting of the amendment, and due to the fact that the concerns of the AG at the time were not addressed, it is unclear really what the amendment intended to protect. The only certainty is that Article 40.3.3 constitutionally prohibits abortion.⁸⁰⁷

Denham J also examined the link between the mother and unborn child. In her view, this relationship could only occur once the embryo is implanted. She was of the opinion that the “concept of unborn envisages a state of being born, the potential to be born, the capacity to be born, which occurs only after the embryo has been implanted in the uterus of the mother.”⁸⁰⁸

In dismissing the appeal, Hardiman J drew attention to the issues that rose in this case, which included when life begins, the level of respect for the embryo and also the impact such respect may have on the available methods of contraception. He noted that while such issues were raised in this case, the Oireachtas is not absolved of its duty to consider the degree of respect afforded to embryos *in vitro*. While Hardiman J stopped short of explicitly criticising the legislature, he was concerned that if such issues were not addressed, practices that are controversial could potentially be unregulated in Ireland. Geoghegan J similarly stated that while he believed that the embryo was deserving of respect, the lack of regulations indicating how the embryo should be respected “is undesirable and arguably contrary to the spirit of the Constitution”. The learned judge did not consider it appropriate that the Courts provide any guidance, as that was considered to be a task for the Oireachtas.

5.2 Implications of the *Roche* Judgment

One may draw the following conclusions from the judgments previously analysed. First, the embryo *in vitro* is not protected under Article 40.3.3; second, both the High Court and Supreme Court consider the embryo *in vitro* of deserving of some level of respect; and third, the degree of respect and how the embryo may be respected is a matter for the Oireachtas to resolve and not the Courts.

While the Courts determined that the embryo *in vitro* is not protected under Article 40.3.3, it is possible that protection for the embryo may lie elsewhere in the Constitution. Geoghegan J stated that “if there are constitutional aspects, they do not arise pursuant to the particular

⁸⁰⁶ W Binchy, ‘Article 40.3.3 of the Constitution: Respecting the Dignity and Equal Worth of Human Beings’ in J Schweppe (ed), *The Unborn Child, Article 40.3.3 and Abortion in Ireland* (Liffey Press 2008) 210.

⁸⁰⁷ Although discussing McGovern’s J decision prior to the Supreme Court decision, Madden praised the decision for clearly stating that it is not the role of the courts to make law where none exists. D Madden, ‘Article 40.3.3 and Assisted Human Reproduction in Ireland’ in J Schweppe (ed), *The Unborn Child, Article 40.3.3 and Abortion in Ireland* (Liffey Press, Dublin, 2008) 317.

⁸⁰⁸ *Roche v Roche* [2010] 2 ILRM 1 at p.26. In giving his judgment, Hardiman J also referred to the wording of this article and was of the opinion that the right to life of the unborn was from implantation. *Roche v Roche* [2010] 2 ILRM 1, 36.

provision in the Constitution relied on in this case”. Thus there is the possibility that the embryo *in vitro* may be protected elsewhere in the Constitution. As noted above, prior to the passing of the Eighth Amendment, it was stated obiter by the Courts that the unborn is constitutionally protected. Thus it is possible that the embryo *in vitro* may be protected in as part of an unenumerated right under Article 40.3.⁸⁰⁹

However in the absence of a judicial pronouncement on the issue, it is submitted that the embryo *in vitro* is not constitutionally protected. While the Courts are of the opinion that it is deserving of some form of respect, without any forthcoming legislation, the meaning of this respect is unclear and thus any researcher wishing to experiment with embryos *in vitro* is in uncertain waters, with the possibility of the legality of their research being challenged in the Courts.⁸¹⁰ Indeed Fennelly J stated that if no legislation is forthcoming “it may be open to the courts in a future case to consider whether an embryo enjoys constitutional protection under other provisions of the Constitution”.

Despite this legal vacuum, both University College Cork (UCC) and Trinity College Dublin (TCD) have announced that embryonic stem cell research is permissible on their respective campuses.⁸¹¹ Although there is no guiding legislation, both UCC and TCD drew up guidelines in line with the ethical guidance of the Irish Council. Although UCC’s and TCD’s guidelines are broadly similar, there are some minor differences. If there were national guidelines, discrepancies between research institutes would be minimal, a move which is best suited for collaborative research.⁸¹²

While the legislature has not brought forth any regulations for embryonic stem cell research, it has not been completely silent on the issue. In October 2010 Science Foundation Ireland and the Health Research Board announced that it would not consider grant applications that use embryonic stem cells.⁸¹³ This funding ban was as a result of direction from the government through the Department of Health, as the Department had stated that it is preparing a regulatory framework for assisted reproduction, which would encompass stem cell research. Thus it is likely that the funding ban will remain in place until such regulation is in place. While this policy remains in place, no public funds can be spent on embryonic stem cell research. However this does not prevent private funding of embryonic stem cell

⁸⁰⁹ Article 40.3 states:

“The State guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate the personal rights of the citizen.

The State shall, in particular, by its laws protect as best it may from unjust attack and, in the case of injustice done, vindicate the life, person, good name, and property rights of every citizen.”

See I Clissmann & J Barrett, ‘The Embryo *in vitro* after *Roche v Roche*: What Protection is Now Offered?’ (2012) 18 *Medico Legal Journal of Ireland* 13, 16-18.

⁸¹⁰ In 2008, Senator Ronan Mullen introduced a private members bill entitled the Stem Cell Research (Protection of Human Embryos) Bill 2008 into the Seanad. The Bill prohibited all types of stem cell research that resulted in the destruction of the embryo. However the Bill did not go any further than the Seanad.

⁸¹¹ See Trinity College Dublin, *Policy on Good Research Practice* (2009) and University College Cork, *Code of Practice for research Using Embryonic Stem Cell Lines* (2008), available at: <http://www.ucc.ie/en/mandc/news/newsarchive/2008PressReleases/fullstory-63377-en.html> accessed 13 March 2012.

⁸¹² <http://www.molecularmedicineireland.ie/show/item/1/1387> accessed 13 March 2012.

⁸¹³ <http://www.sfi.ie/funding/grant-policies/research-using-human-embryonic-stem-cells/> accessed 13 March 2012.

research. In reality, however, with the uncertainty remaining over the legal status of embryonic stem cell research, it is unlikely that a private investor will be willing to invest in embryonic stem cell research in Ireland.

6. Conclusion

Despite numerous referenda and abundant case law, the legal status of the embryo *in vitro* remains unclear. While it would appear that, by virtue of it not being protected under Article 40.3.3 of the Irish Constitution, the embryo *in vitro* does not have constitutional protection, clarity is needed on the issue. As indicated from the courts in the *Roche* case, this clarity could come from legislative change and thus the introduction of regulations to outline the protection of the embryo *in vitro* is needed to clarify the status of the embryo and also the legality of embryonic stem cell research.

The danger is that although the regulation of stem cell research is on the Programme for Government, it will meet the same fate as that of the abortion referendum. The first concern is that any regulations, like the abortion referendum, would not be properly thought through. If Ireland decided to prohibit embryonic stem cell research, it would not do to simply outlaw the research, but consideration would also have to be given to whether Ireland could benefit from the research while outlawing it. In other words, could Ireland still import medicines that are a product of embryonic stem cell research? It would be paradoxical to state that Ireland is against the research but is willing to use the products derived from the research. This is of particular note when one considers that embryonic stem cell research is becoming a platform technology where developments are being used in other areas of medical technology unrelated to embryonic stem cell research. Must Ireland refuse to take advantage of this knowledge as it is stating in its laws that it is opposed to embryonic stem cell research? Furthermore, if embryonic stem cell research is prohibited, what impact will this have on contraceptives that allow for fertilisation but prohibit implantation? Is there any difference between permitting the destruction of an embryo for contraceptive purposes and permitting it for research purposes?

A second concern is that the debate on embryonic stem cell research should not become caught up in the debate on abortion. These are two separate issues. With abortion, the embryo has implanted into the womb of a woman and thus begun the process of developing into a foetus. As it may be some time before a woman is aware that she is pregnant the foetus may have begun to resemble that of a human being. Embryonic stem cell research on the other hand is concerned with the embryo up to the 14 day stage. Thus the embryo does not leave the cellular stage. The primitive streak has not begun nor have any organs begun to develop. Furthermore unless the embryo is implanted into the womb of a woman it will not develop into a human being.

Some of these issues have been considered by the Irish Council for Bioethics and the CAHR in the past, thus there is a basis for discussion by government on this issue. However, issues relating to reproductive matters have always been politically sensitive, with liberalising legislation slow to come. What is necessary is a matter for considered debate, which takes

into consideration the views of all sides of the debate. This should be followed with the introduction of legislation clarifying the legal status of the embryo *in vitro* that is reflective of Irish society.

Chapter 7 Recommendations for the Introduction of ESCR Policy in Ireland

1. Introduction

In Part I the process in which policy makers may begin to consider the legal status of the embryo was outlined. Part II focused on the regulatory issues that policy makers must consider when regulating ESCR. It discussed the ethical precautionary principle as a principle to guide the regulation of ESCR. Furthermore this Part analysed direct and indirect approaches to the regulation of ESCR under the principles of Better Regulation. Part III has turned the focus to Ireland and the current legal status of the embryo *in vitro* and ESCR has been outlined. The purpose of this chapter is to now make a series of recommendations for Irish policy makers on the implementation of a regulatory framework for ESCR in Ireland. It must be noted that this chapter will not recommend whether ESCR should be permitted nor the parameters of the research; rather the recommendations will focus on the formulation of a regulatory framework.

2. The Legal Status of the Embryo

As has been illustrated, the legal status of the embryo in Ireland is currently unclear. The judgment in the *Roche* case simply stated that the embryo *in vitro* is not constitutionally protected under Article 40.3.3. Irish policy makers must now clarify the status of the embryo in Ireland and, by extension, the status of ESCR. This need for clarity is further heightened as non-profit organisations such as the Irish Stem Cell Foundation have now actively begun to seek donations for funding for ESCR in Ireland.⁸¹⁴ A failure to introduce regulations will continue to leave scientists in a legal vacuum, with many unsure whether they are permitted to accept funding for the research.

In determining the legal status of the embryo, Irish policy makers should learn from the previous abortion debates, in particular, how the debate on the status of the embryo *in vitro* is conducted. As previously discussed, the introduction of Article 40.3.3 was marked by secret negotiations as both Fine Gael and Fianna Fáil sought to gain the support of the Pro Life Amendment Campaign. Rather than considering the necessity of an amendment and in particular what the wording should be, the focus was on gaining the electoral upper hand. This resulted in decades of legal uncertainty as both doctors and the courts sought to grapple with a definition of the unborn and lawful abortion, issues which still have not been resolved.

In the stem cell context, it is clear that there is the need to clarify the legal status of the embryo. This is recognised by the Fine Gael and Labour coalition, as the regulation of assisted reproduction is listed on the current Programme for Government.

Currently (February 2013), the government is considering proposals on lawful termination of pregnancy in Ireland under Article 40.3.3, and there does not appear to be any movement on

⁸¹⁴ http://www.irishstemcellfoundation.org/go/get_involved/donate accessed 29 November 2012.

ESCR. However, as the issues arising out of Article 40.3.3 are currently debated in Irish society, the time is perhaps now for a public debate on the meaning of the unborn, and in particular, the status of the embryo *in vitro*. This public debate on the status of the embryo should not be characterised by the polarised abortion debate of the past, but rather by the principles of democratic deliberation. As previously noted, this is a collaborative decision making process that focuses on common ground during a debate to ensure that there is mutual respect amongst the stakeholders to the debate. This process seeks to build consensus and reach a decision that all stakeholders to the debate can agree on.⁸¹⁵ This can be done through the building of a partnership to address complex social issues. It is a process which at times is adopted by governments and can be rolled out state wide or focus on one particular area or grouping.⁸¹⁶

Furthermore, it is arguable that there is movement by Irish policy makers towards this type of policy making. Due to the fall-out over the death of Savita Halappanavar, the government announced its intention to bring forth legislation on lawful termination of pregnancy in Ireland. As part of this process, the Joint Oireachtas Committee on Health held three days of public hearings, with oral evidence heard from medical experts, legal experts and lobby groups. All members of the Oireachtas were given an opportunity to question these experts and the oral hearings were broadcast nationally as well as being widely covered in the national press. These hearings provided an opportunity for differing groups to get together to discuss their views with policy makers, a move that a former President of Ireland, who also opposed the 1983 amendment, described as a good step forward in our debate on abortion.⁸¹⁷

2.1 Deliberative Democracy in Action: Social Partnership

This is not the first time that Ireland has taken this approach, as consensus building was a key feature of an Irish policy-making approach in what is known as social partnership. Social partnership is the name given to the process in Ireland that is used to negotiate and achieve consensus on a range of economic and social issues.⁸¹⁸ It focuses on a dialogue between the representatives of civil society and policy makers, and considers social dialogue key to maximising common understanding across society.⁸¹⁹ It began in Ireland with a series of wage agreements between the Government and the main social partners: employers, the trade unions and the farming organisations.⁸²⁰ These became known as the three pillars of social

⁸¹⁵ See A Guttman & D Thompson, *Why Deliberate Democracy?* (Princeton University Press, Princeton, 2004), P Teague, 'Social Partnership and Local Development in Ireland: The Limits to Deliberation' (2006) 44 *British Journal of Industrial Relations* 421, 424.

⁸¹⁶ C Wallace, 'Optimising horizontal and vertical partnership connections: bringing partnerships together to create a network advantage' (2009) 15 *Australian Journal of Primary Health* 196, 196.

⁸¹⁷ Mary Robinson in interview with Fintan O'Toole, National University of Ireland, Galway, 14 January 2013.

⁸¹⁸ <http://communityplatform.ie/social-partnership.html>.

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http://www.taoiseach.gov.ie/eng/Work_of_The_Department/Economic_and_Social_Policy/Social_Dialogue/.

See also Article 11 of the TEU.

⁸²⁰

http://www.taoiseach.gov.ie/eng/Work_of_The_Department/Economic_and_Social_Policy/Social_Dialogue/Background_to_Social_Partnership.html.

partnership.⁸²¹ The first agreement was formed in 1987 with the Programme for National Recovery and the agreements since have included the Programme for Economic and Social Progress, the Programme for Competitiveness and Work, Partnership 2000 for Inclusion, Employment and Competitiveness, the Programme for Prosperity and Fairness, Sustaining Progress and Towards 2016 and the Ten-Year Framework Social Partnership Agreement 2006-2015. It has become the principle mechanism for trade unions and diverse interest groups to lobby and influence government policy.⁸²²

Initially, the focus of social partnership was on wage agreements to aid Ireland's economic development. It was thought that such agreements would ensure industrial stability, thereby encouraging foreign investment.⁸²³ Indeed it has also been credited with bringing about the improved economy of the 1990s and early 2000s.⁸²⁴ It has been "characterised by a trade-off between moderation in wage demands with social benefit improvement and income tax reduction".⁸²⁵ Its remit however has been expanded in the final four agreements to include a role for the voluntary and community groups within society, which became the fourth pillar of social partnership. This was further expanded in 2009 to include environmental groups.⁸²⁶

The inclusion of community, voluntary and environmental groups is to ensure that the concerns of these groups are considered in social partnership decisions⁸²⁷ and to enhance the social aspect of social partnership.⁸²⁸ Membership of the community and voluntary pillar is not universal and is confined to groups involved with the Labour Market (Irish National Organisation of the Unemployed and Congress Centres for the Unemployed), Children and Youth (National Youth Council of Ireland and Carers Association), Older People (Age Action Ireland and Irish Senior Citizen's Parliament), Poverty (St Vincent de Paul and Protestant Aid), Housing (Irish Council for Social Housing and National Association for Building Co-operatives), Gender (National Women's Council of Ireland), Rural (Irish Rural Link), Social Analysis (Social Justice Ireland), Voluntary Networks (The Wheel and

⁸²¹ Wallace (n 816) 197. N Gaynor, 'Associations, Deliberation, and Democracy: The Case of Ireland's Social Partnership' (2011) 39 *Politics and Society* 497, 500.

⁸²² P Stafford, 'The rise and fall of social partnership: its impact on interest group lobbying in Ireland' (2011) 11 *Journal of Public Affairs* 74, 74.

⁸²³ N Gaynor (n 821) 500.

⁸²⁴ K Nicholls, 'Why social partnership matters: Irish policies for work-life balance' (2006) 29 *West European Politics* 513, 513.

⁸²⁵ N Smith, 'Mapping Processes of Policy Change in Contemporary European Political Economies: The Irish Case' (2006) 8 *British Journal of Politics & International Relations* 519, 528.

⁸²⁶

http://www.taoiseach.gov.ie/eng/Work_of_the_Department/Economic_and_Social_Policy/Social_Dialogue/Background_to_Social_Partnership.html.

⁸²⁷

http://www.taoiseach.gov.ie/eng/Work_of_the_Department/Economic_and_Social_Policy/Social_Dialogue/Background_to_Social_Partnership.html.

⁸²⁸ P Stafford (n 823) 75.

Community Platform).⁸²⁹ By extending the remit to include these groups and the issues that they represent, social partnership in Ireland is considered unique.⁸³⁰

These interest groups bring added expertise and experience to policy-making and thus can contribute effectively in ensuring that policy makers consider all the necessary issues. By extending the scope of social partnership to include these social groupings, there is an opportunity to build shared understanding across society, which can increase social solidarity.⁸³¹

2.2 Social Partnership: The Problems

Despite the apparent economic success of social partnership, it is not without its problems, in particular for those within the community and voluntary pillar. First only those groups selected by the government whose activities fall under those categories are involved in social partnership. Thus while some groups have official government recognition and must be consulted with during negotiations, many more remain outside the influence of power. Furthermore, there is the focus on groups, rather than individual members of society. Besides the power of the individual to lobby their local representative, there is no formal process for an individual to engage with social partnership. In this sense social partnership is very much concerned with certain lobby groups only.

Questions have been asked about the motivation for including community groups within the process. In a series of interviews carried out with members of the social partners, it was suggested that at times itself used the process to reduce the potential attacks on the government. In other words, by involving stakeholders in the process, the likelihood of them using the media to attack the government was reduced, as they were involved in the decision-making process.⁸³² It was noted that interest groups signed up to the process believing that their voice would be heard, when in reality they were effectively ignored and forced to sign the agreement. In this way the “government bought their silence”.⁸³³ This problem is a hallmark of such agreements as, while those contributing to the debate may feel that they are impacting upon policy, the lack of any formal arrangements whereby policy makers must follow or adhere to the views of those participating has meant that recommendations of stakeholders are often ignored.⁸³⁴

When the community pillar refused to endorse the Sustaining Progress agreement, it was excluded from the social partnership process until 2006.⁸³⁵ Such a move suggests that the involvement of the community pillar is to rubber-stamp the decisions and, it lacks any real

⁸²⁹ <http://communityplatform.ie/structure-of-community-voluntary-pillar.html> accessed 29 November 2012.

⁸³⁰ P Teague, ‘Social Partnership and Local Development in Ireland: The Limits to Deliberation’ (2006) 44 *British Journal of Industrial Relations* 421, 423.

⁸³¹ Gaynor (n 821) 498.

⁸³² Stafford (n 822) 75.

⁸³³ Ibid.

⁸³⁴ Nicholls (n 824) 514.

⁸³⁵ <http://communityplatform.ie/community-platforms-involvement-in-social-partnership.html> accessed 29 February 2013.

negotiating powers. Furthermore not only was the community and voluntary pillar removed from the negotiating process but it was also removed from other policy fora, such as consultative committees on policy issues and bilateral meetings with officials.⁸³⁶ Thus a policy that seeks to build consensus and social cohesion, effectively removed one pillar from the process as punishment for failing to comply with the “agreement”. This suggests that the process is not built on consensus but is in fact a process whereby interest groups are given an avenue in which to voice their concerns, with some attempts made at consensus but the government will continue to make its own decision and punish those groups which do not acquiesce.

It has also been noted that while the community and voluntary groups were added later, at the core of social partnership were the economic issues, which the employers and unions dominated. Until those issues were resolved, no other issues could be discussed,⁸³⁷ which likely led to a diminution of the impact of the community groups on social partnership. This has led to suggestions that social partnership really was a process in which economic issues were agreed while also silencing outspoken lobby groups.⁸³⁸ Their lack of “economic clout” has meant that these groups only have minimal influence in the Irish political landscape.⁸³⁹ Thus the actual influence of the community and voluntary pillar really must be questioned, particularly when participants in the process have noted that while they are involved in the debate, the decisions are made elsewhere and by someone else.⁸⁴⁰

The concept of social partnership, that is the inclusion of groups in the policy-making process, is to be lauded. For an area such as ESCR, it may be one solution to creating policy as it brings groups who may have divergent opinions together, in an effort to achieve consensus on policy. However, in practice, the promise for the social pillar has not transpired, with social partnership viewed more as a talking shop than a truly policy-making group. If policy-makers are to adopt social partnership as a model, it will need to be a remodeled concept where groups genuinely have an impact on policy issues.

2.3 Deliberative Democracy in Action: Commission on Assisted Human Reproduction

The Commission on Assisted Human Reproduction was established in 2000 by the then Minister for Health Micheál Martin. It had the following terms of reference:

“To prepare a report on the possible approaches to the regulation of all aspects of assisted human reproduction and the social, ethical and legal factors to be taken into account in determining public policy in the area.”⁸⁴¹

⁸³⁶ Gaynor (n 821) 510.

⁸³⁷ Stafford (n 822) 75.

⁸³⁸ Ibid.

⁸³⁹ R Meade, ‘We hate it here, please let us stay! Irish social partnership and the community/voluntary sector’s conflicted experiences of recognition’ (2005) 25 *Critical Social Policy* 349, 349.

⁸⁴⁰ Gaynor (n 821)509.

⁸⁴¹ Commission on Assisted Human Reproduction, *Report of the Commission on Assisted Human Reproduction* (2005) x.

The Commission was also directed to seek submissions from the public, to consult with service providers and consumers, and also to consult with theological and philosophical experts.⁸⁴² To achieve this end, the Commission undertook a number of activities.

First it held two conferences. The first was held in 2001 and considered the social, legal and ethical factors surrounding assisted human reproduction. Although it was only attended by the members of the Commission and a number of invited Irish and international experts,⁸⁴³ it provided an opportunity for public debate and discussion. The second conference was held in 2003 and was attended by 250 members of the public who responded to a public invitation from the Commission.⁸⁴⁴

Second, in 2001 an advertisement was placed in the national press inviting members of the public and interested organisations to send in written submissions. Third, the Commission appointed a market research organisation to conduct a telephone poll to carry out a survey of a quota of people over the age of 15 living in Ireland. Fourth, the National Infertility Support and Information Group (NISIG) made available to the Commission results of a survey regarding the satisfaction of users of fertility treatment. Finally, surveys of service providers were also conducted in consultation with the College of General Practitioners in Ireland and the Institute of Obstetricians and Gynaecologists of the Royal College of Physicians of Ireland.⁸⁴⁵

Thus, the general public was given the opportunity to contribute through written submissions (over 1700 were received),⁸⁴⁶ attendance at a public conference, and the telephone poll (1003 participants),⁸⁴⁷ while interest groups could contribute through the written submissions, both conferences, and the focused surveys. By including the general public in its debate, the process followed by the CAHR trumps that of social partnership. Furthermore the public was given the opportunity to engage with members of the Commission at the public conference providing all groups with an opportunity in which to give reasons for their opinions, a process that is integral to democratic deliberation. However the deliberations of the Commission were held in private and thus while the general public and relevant stakeholders could contribute to the debate, unlike social partnership, there was no stipulation that they would be listened to. The final recommendations were also made by the Commission in a private setting. Furthermore all recommendations did not achieve consensus, with Gerry Whyte notably dissenting from the majority's recommendation on the legal status of the embryo.

2.4 Deliberative Democracy in Action: Irish Council for Bioethics

Similarly, the Irish Council on Bioethics engaged in a public consultation as part of its report on the *Ethical, Scientific and Legal Issues Concerning Stem Cell Research*. Prior to its

⁸⁴² Ibid 1.

⁸⁴³ Ibid 3.

⁸⁴⁴ Ibid.

⁸⁴⁵ Ibid.

⁸⁴⁶ Ibid 38.

⁸⁴⁷ Ibid.

closure, the Council considered public consultation integral to its work.⁸⁴⁸ Following advertisements and publicity in the media, the Council made public a questionnaire covering all the issues the Report was considering.⁸⁴⁹ Due to concerns that, despite careful designing of the questionnaire, issues which are in the public interest were not anticipated, there was an “open” question in which the public could express their opinions at length or raise further issues. The Council also prepared an information leaflet on the technical aspects of stem cell research to ensure that the public understood the scientific issues of the research.⁸⁵⁰

The Council did note that this process was a public consultation and not a survey. One of its aims was to generally educate the public on stem cell research without focusing on one particular source of stem cell, such as embryonic stem cells over adult stem cells. The second aim was to facilitate a debate on stem cell research and, from this, gather public responses and opinions, which would form part of the deliberations of the Council. It also noted that due to the low awareness of the public on stem cell research, the response to the questionnaire was likely to be low and thus this should not replace any public debate on the issue.⁸⁵¹ In total the Council received 2,188 submissions with 1,124 respondents opting to contribute in the “open” question.⁸⁵²

2.5 Recommendation 1: Democratic Deliberation and ESCR

Since the resignation of Bertie Ahern as Taoiseach and the collapse of the Irish economy, the importance of social partnership has waned⁸⁵³ and the website dedicated to the community and voluntary pillar of social partnership has not been updated since 2011. Despite the many flaws inherent in social partnership, the process may in fact prove to be a suitable template in which to determine the legal status of the embryo in Ireland, provided the criticisms identified are addressed.

First the process should recognise that all sectors of Irish society, not merely economic, should be included in the deliberative process. Translating that into the stem cell context, this would mean that all stakeholders to the debate should be included in the policy making process. During the drafting of Article 40.3.3 of the Irish Constitution, consultation was limited to the PLAC, a process that should not be repeated. Policy makers should engage with ethicists, scientists, and legal experts, as well as interested parties. Rather than confining the involvement of stakeholders as occurred under social partnership, all interested parties should be given the opportunity to engage with the process. This is in line with the policy of the European Commission, which requires that external groups are consulted with when formulating its policies.⁸⁵⁴

⁸⁴⁸ Irish Council for Bioethics, *Ethical, Scientific and Legal Issues Concerning Stem Cell Research* (2008) 70.

⁸⁴⁹ Ibid Appendix B.

⁸⁵⁰ Ibid 70.

⁸⁵¹ Ibid 71.

⁸⁵² Ibid. The Council sought some submissions from a number of organisations while others voluntarily sent in submissions.

⁸⁵³ Stafford (n 822) 74.

⁸⁵⁴ <http://ec.europa.eu/governance/better_regulation/consultation_en.htm> accessed 6 February 2013.

Policy makers should also adopt the public consultation process of the CAHR to ensure that the general public has an opportunity to contribute to the debate on the legal status of the embryo. Thus members of the public who are not part of a particular interest group can then voice their opinion on this controversial matter. These considerations of the public must be fed into the negotiation processes followed by social partnership. However, it is important that the process does actively involve the stakeholders in achieving a consensus, rather than the apparent policy under social partnership whereby decisions in reality were made elsewhere outside of the negotiation process. In this way, real efforts must be made toward achieving a consensus on the legal status of the embryo and also embryonic stem cell research. As evidenced by the CAHR, not all stakeholders will agree, but this must not prevent the process from taking place. Through this process common ground may be found and a decision that most stakeholders can accept agreed upon.

Recommendation 1: The process of social partnership should be improved and adopted as a mechanism for determining the legal status of the embryo and the legal status of embryonic stem cell research in Ireland.

3. Permitted Research in Ireland

Once the legal status of the embryo is clarified, it should become clear whether the embryo can be destroyed for research purposes. As previously noted, while ESCR may be permitted, due to the ethical concerns associated with the research, policy makers may opt for a restrictive regulatory framework. In this way, policy makers may adopt a strong version of the ethical precautionary principle.

This restrictive policy may manifest itself in the prohibition of all types of ESCR. Should Ireland adopt that approach, it must be considered whether patients in Ireland can benefit from developments in the treatment. This point was indeed raised in the House of Commons in the United Kingdom during the debates on the HFE Act 1990:

“If research were to be banned in the United Kingdom, surely the benefits from such research undertaken elsewhere should also be banned from use in this country. To do otherwise would be a major hypocrisy.”⁸⁵⁵

If the research is prohibited in Ireland due to moral objections, policy makers must address whether the treatments arising out of ESCR will be permitted in Ireland. While the issue of moral complicity is outside the scope of this thesis,⁸⁵⁶ this is an issue which policy makers must consider. The ethical precautionary principle is most likely to manifest itself through the permitted sources of embryonic stem cell lines. A strong version of the ethical precautionary principle which will reflect a restrictive policy may result in a complete ban of the research or the use of imported stem cell lines only. An intermediate approach, however may be reflected in the use of spare embryos while a permissive approach may permit the creation of embryos

⁸⁵⁵ Hansard 2 April 1990, Sir Column 940.

⁸⁵⁶ For more on this see Irish Council for Bioethics, *Ethical, Scientific and Legal Issues with Stem Cell Research* (2008) 45-46.

for research or the creation of embryos through SCNT. The important issue for policy makers is that they consider which sources of embryos should be permitted and that the sources adopted reflect the appropriate level of the ethical precautionary principle, as determined through democratic deliberation.

3.1 Imported Stem Cells

Ireland may adopt a restrictive ESCR policy while permitting some degree of the research to take place. This restrictiveness may be expressed in the sources of embryos that are permitted to be used for research purposes. The first potential source of embryo is imported stem cell lines. As previously discussed, Germany is one jurisdiction that has adopted this approach. By importing the stem cell lines, the embryo would not be destroyed in Ireland, thus policy makers can prohibit the destruction of the embryo while permitting ESCR. Such a policy would have some parallels with Irish abortion policy in which abortion is prohibited but women are not prohibited from seeking an abortion abroad.

Imported stem cell lines are likely to come from a stem cell bank, which has been described as “a stock of cells frozen in a viable state, which can provide reproducible cells for future use”.⁸⁵⁷ Ireland would have a number of options in which to import stem cells from a stem cell bank. On foot of a House of Lords Select Committee Report, the National Institute of Biological Standards and Control (NIBSC) was selected to host the UK Stem Cell Bank in 2002. The bank has a repository of embryonic, adult and foetal stem cell lines. Its sole function is to host the cell lines. It has no role in deriving the lines, or in approving applications to access the lines, thus avoiding any potential conflict of interest. Access to the stem cells can only be provided by the UK Stem Cell Bank. Stem cells can only be exported provided the research fulfils the stem cell bank’s Code of Practice and also complies with the legislation in the country of origin.⁸⁵⁸

There is now also a centralised registry of stem cell lines within the European Union known as the “European Human Embryonic Stem Cell Registry” (hESCreg).⁸⁵⁹ Funded under EU Framework Programme 6, its purpose is to hold information on all ESC lines derived in Europe. While recognising the differing regulatory frameworks of ESCR within Europe, hESCreg attempts to seek agreement on informed consent, transparency and traceability, and no intention to use an embryo for reproduction with regard to ESCR.⁸⁶⁰ In particular, the objections of hESCreg are:

- To define and implement eligibility criteria for listing of hESC in the registry;

⁸⁵⁷ G Stacey, ‘Stem Cell Banks: Reality, Roles and Challenges’ in K Hug and G Hermeren (eds), *Translational Stem Cell Research* (Humana Press 2011) 227.

⁸⁵⁸ Under the Code of Practice it is noted that once the ESC lines have been established they are not considered to be embryos in the UK and thus do not have the same level of regulation as embryos. *Code of Practice for the Use of Human Stem Cell Lines* (2006) 2. For more on the development of the UK Stem Cell Bank see National Institute for Biological Standards and Control UK Stem Cell Bank Progress Report Phase II 2006 – 2010.

⁸⁵⁹ See www.hescreg.eu.

⁸⁶⁰ *Ibid.*

- To establish a working mechanism for registry performance whereby input from existing registries, banks, networks and research initiatives will be incorporated;
- To establish and disseminate registry criteria as well as registration, access and quality control mechanisms to hESC providers and users;
- To develop the technical backbone of the registry and to design and implement an Internet-based access mode for cell lines listed in the European hESC-registry;
- To develop the registry into a knowledge-service tool of registered hESCs for research and application and provide regular dissemination, communication and updating mechanisms of the registry content.⁸⁶¹

It follows that through hESCreg, researchers in Ireland can access information on the location of stem cell lines within Europe. Furthermore, they can be satisfied that these stem cell lines satisfy certain criteria as espoused by the registry. Equally, they may actually access the stem cell lines from the UK Stem Cell Bank and be satisfied that these stem cell lines satisfy the conditions in the Bank's Code of Practice.⁸⁶² Therefore, should Irish policy makers opt to permit ESCR on imported stem cell lines only, there are sources from which researchers in Ireland can import the stem cell lines.

3.2 Supernumerary Embryos

Another potential source of stem cell lines is from supernumerary embryos. Supernumerary embryos are spare embryos left over after IVF treatment. Due to the intensive hormone treatment that a woman must undergo prior to the treatment, it is common that more embryos are created than are required. It is standard practice that up to three embryos are implanted and the remaining embryos are cryopreserved. These cryopreserved embryos may be thawed out and implanted at a later date, or the couple may no longer want to use the embryos for reproductive purposes. The "couple"⁸⁶³ are then faced with a decision of implanting the embryos, donating the embryos to an infertile couple, donating the embryos for research or thawing out the embryos and allowing them to be "die" naturally.⁸⁶⁴

In its report on ESCR, the Irish Council for Bioethics recommended that supernumerary embryos be permitted for ESCR in Ireland.⁸⁶⁵ Its reasoning was based on the principle of proportionality and it argued that if the supernumerary embryos are going to be destroyed, research should be permitted on them if they have the potential to improve life.⁸⁶⁶ The

⁸⁶¹ Ibid.

⁸⁶² *Code of Practice for the Use of Human Stem Cell Lines* (2006).

⁸⁶³ "Couple" in this section refers to the gamete providers. It is recognised that the gamete providers may not be a couple and may not in fact know each other. However couple will be used instead of gamete providers.

⁸⁶⁴ The vast majority of embryos created through IVF are only used for reproductive purposes. For example, in 2003 in Switzerland, 94% of all embryos created were used for reproductive purposes. U K Puorger, 'Ethics, Social, Legal, Counselling, Surplus Embryos in Switzerland in 2003: Legislation and Availability of Human Embryos for Research' (2006) 13(6) *Reproductive Biomedicine Online* 772, 776.

⁸⁶⁵ Irish Council for Bioethics, *Ethical, Scientific and Legal Issues with Stem Cell Research* (2008) 45.

⁸⁶⁶ Ibid.

Commission on Assisted Human Reproduction also recommended that research on supernumerary embryos be permitted.⁸⁶⁷ As until the judgment in the *Roche* case it was unclear whether embryos in Ireland left over after IVF could be destroyed, there is likely to be a ready supply of supernumerary embryos that could potentially be used for research purposes. Thus, provided adequate consent measures are put in place, researchers in Ireland could derive embryonic stem cells from these embryos, using the most up to date technology.

3.3 Embryos created through SCNT

Finally, embryonic stem cells may also be derived from embryos that are solely created for research purposes or created through SCNT. Embryonic stem cells created through SCNT will be invaluable when ESCR gets to its clinical application stage as these stem cell therapies will not be rejected by the patient as they will be genetically identical to the patient. This will also avoid the patient spending a lifetime on immunosuppressant drugs.⁸⁶⁸

3.4 Recommendation 2: Sources of embryos and the Ethical Precautionary Principle

While it is outside the scope of this thesis to recommend which sources of embryonic stem cell lines should be permitted in Ireland, it is important that it is clear which sources of embryos are permitted to be used in ESCR. During the process of determining the status of the embryo, it may become clear whether the ethical precautionary principle will apply and whether a strong or weak version of the principle should apply. Thus if there is a concern that only very limited ESCR should be permitted, policy makers may opt to restrict ESCR to imported stem cell lines only. On the other hand if there is a move towards a liberal approach to ESCR, policy makers may adopt a weak version of the ethical precautionary principle and permit research on all sources of embryonic stem cell lines. What is important is that the appropriate level of ethical precaution is discussed during the deliberative process. In this way, policy makers can ensure that the sources of embryonic stem cell lines lie within the ethical precautionary principle.

Recommendation 2: Policy makers must take into account the ethical precautionary principle when determining the sources of embryos permitted to be used in ESCR.

4. Regulating Embryonic Stem Cell Research in Ireland

4.1 Regulatory Impact Assessment

Should Ireland opt to permit some form of ESCR, policy makers will also have to determine the structure of its regulatory framework. To aid policy makers, a Regulatory Impact Assessment (RIA) should be conducted as indeed is the policy for all policy proposals in Ireland.⁸⁶⁹ Similarly, the Commission requires an RIA to be carried out on all policy

⁸⁶⁷ Commission on Assisted Human Reproduction, *Report of the Commission on Assisted Reproduction* (2008) para 8.2.

⁸⁶⁸ For a discussion and explanation of SCNT, see the Introduction.

⁸⁶⁹ See Department of the Taoiseach, *Regulating Better: A Government White Paper setting out six principles of Better Regulation* (2004).

proposals.⁸⁷⁰ This study should illustrate the likely effects of proposed rules and reforms, including the potential costs, and an indication as to whether the contemplated regulation would achieve the desired results. In this way, RIAs can improve the substance of regulatory decisions and can enable public authorities to engage stakeholders at this early stage.⁸⁷¹

In the Irish Government's White Paper *Regulating Better*, it was envisaged that there should be a two phased approach to RIAs: the preliminary assessment would simply provide a "light" assessment of the likely costs and impacts while the second stage would involve a much more thorough analysis. While an RIA on ESCR policy would likely address issues such as the ethical concerns of the public in introducing policy, it will also assess the likely economic cost and value. Research institutions that are likely to commence ESCR may have to take on additional economic costs that the regulations may impose. These will be examined during the RIA and it can be assessed whether they are reasonable. However, there is likely to be an economic benefit to these research institutions and the Irish economy in general, as funding may be sourced from the EU under its Framework Programmes or through national and international funding bodies.

4.2 Recommendation 2: RIA and ESCR Policy

As is now standard practice in the formation of Irish policy, a RIA must be carried out before ESCR policy is introduced. This should include an assessment of the impact ethical and economic issues on introducing regulations. While there is likely to be a cost to research institutions which may engage in ESCR, as they will have to adhere to ethical, safety and economic standards to name but a few, this should also include an assessment of the economic benefits to both the research institute and the Irish economy.

Recommendation 3: Prior to the introduction of ESCR policy, in accordance with government policy, a RIA should be carried out to assess the likely impact of any new regulations.

4.3 Proposed Irish Regulatory Model

As discussed in Part II, international regulatory frameworks have adopted legislation, established independent regulatory authorities or adopted funding and patenting policies which impact upon the research. Current Irish policy centres on funding and patenting policies. While there is a ban presently on the use of public monies to fund ESCR, there is no such ban on the private funding of ESCR. As previously noted, despite University College Cork and Trinity College Dublin deciding to permit ESCR, it is currently not clear whether such research has commenced. In the absence of national guidelines or legislation on ESCR, the research will be carried out within the guidelines of that particular institution.⁸⁷² The

⁸⁷⁰ European Commission, *Regulatory Impact Assessment Guidelines* (2009).

⁸⁷¹ For a definition of RIAs see Department of the Taoiseach (n 869) 4.

⁸⁷² See Trinity College Dublin, *Policy on Good Research Practice* (2009) and University College Cork, *Code of Practice for research Using Embryonic Stem Cell Lines* (2008), available at: <http://www.ucc.ie/en/mandc/news/newsarchive/2008PressReleases/fullstory-63377-en.html> accessed 13 March 2012.

problem with such an approach is that although the Irish Council for Bioethics and the Commission on Assisted Human Reproduction have coordinated a dialogue amongst the public and various stakeholders, a national dialogue, which includes policy makers, has not occurred to date. Thus guidelines on this issue are being introduced on an ad hoc basis, without any input from policy makers and the general public.

One exception would be if a research institution, based in Ireland, applied for funding under FP7. While ESCR is not expressly prohibited in Ireland, EU funds may be deemed to come under the ban on public funds. However, if it is decided that EU funds are considered private funds, researchers would have to follow the guidelines under FP7.⁸⁷³ Furthermore, if Irish researchers are prohibited from applying for ESCR funding under FP7, there is a very limited pool from which they could seek funding, as due to the prohibition of patenting inventions arising out of ESCR, it is unlikely that a biotechnology company would be willing to invest in Ireland. Thus, they would have to seek funding from philanthropic organisations or international funders such as the Wellcome Trust.⁸⁷⁴

A regulatory framework that is solely based on funding and patenting policies does not satisfy the Better Regulation principles. As was illustrated by the analysis of the funding model of the US, this policy is subject to change depending on the political orientation of the government, a situation that fails to provide certainty for scientists. Furthermore, researchers in receipt of private funds are essentially unregulated, with no public control over their research. This leads to inconsistency in the legal and ethical requirements that researchers are required to adhere to. As evidenced by the approach that the US company Geron took, private funders may not require strict adherence to ethical principles but may publish or apply their principles after the research has proven successful.

Such ambiguity is not acceptable for researchers and may be detrimental to their research. Indeed, researchers will want to ensure that their work will not be prohibited at a future date due to illegality that they were unaware of at the commencement of the research project. It is crucial that this uncertainty be resolved, as without legal clarification, stem cell researchers will be operating in a legal limbo. A solution to this problem would come with clarity on the status of the embryo *in vitro* and the circumstances in which ESCR is permitted. An announcement on the prohibition of the public funding of the research does not provide sufficient clarity.

Due to the importance of clarity for researchers, it is submitted that legislation be used to regulate ESCR in Ireland. As previously outlined, the legislative process is transparent, as interested parties have the opportunity to lobby their elected representative or give evidence at committee stage. The debates on a Bill are also heard in public place (Parliament) and the legislation is accessible to all, in particular, to the researchers. This legislation will also apply to *all* researchers thus ensuring that no researcher falls outside of the regulatory framework.

⁸⁷³ Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013).

⁸⁷⁴ <http://www.wellcome.ac.uk/> accessed 6 February 2013.

Equally, potential funders will be aware of the legal status of the research and will be certain of the legal status of the research prior to granting any funding.

Despite the clarity that legislation can bring, the possibility of the law failing to keep pace with advances in science has previously been discussed. Therefore while legislation should clearly state the permitted boundaries of research, it should be careful not to be overly prescriptive and include terms and definitions that are likely to become outdated with developments in technology. It is submitted that such issues should be the responsibility of an independent regulatory authority such as the UK Human Fertilisation and Embryology Authority. Although it is against Irish policy to create a new regulatory authority unless there is a proven need for it,⁸⁷⁵ it is submitted that due to the unique scientific, legal and ethical issues involved with regulating ESCR, there is the need to establish such an authority. Such a body should be tasked with overseeing the implementation of the legislation and can make decisions, such as the issuing of research licences, in light of current scientific knowledge. The Commission on Assisted Human Reproduction in its 2005 report recommended the introduction of a regulatory authority to oversee assisted human reproduction and embryo research practices in Ireland.⁸⁷⁶ This was echoed by the Irish Council for Bioethics, which recommended the establishment of an independent regulatory authority to oversee ESCR regulation in Ireland.⁸⁷⁷ This proposed regulatory authority could be staffed with people who have the requisite legal, ethical and scientific expertise necessary to regulate ESCR. In particular it would be in a position to anticipate potential scientific advances that may require a change in the legislation or relevant policy of the authority, ensuring that the law keeps pace with changes in the science.

However, Ireland should learn the lessons of the HFEA and ensure that the powers of the regulatory authority are clearly stated. This would help avoid any criticism that the body is over-stepping its remit. If it is to have a role in policy making, this should be clearly stated. While the need for legal clarity must be balanced against the need to ensure that the regulatory authority can respond to changes in the science, a good RIA should guide how this balance may be struck. Furthermore, policy makers must address issues of accountability. If it is to be truly independent, then the model of the HFEA, whereby the government has no influence in its policy-making role could be adopted. However, if it is preferred that the Minister for Health or the Department of Health and Children should have some oversight, the independence of the authority will be eroded. It is submitted that the independence of such an authority is crucial due to the ethical issues at stake. However, clearly outlining the body's roles and duties in legislation or supplementary regulations will ensure that the role of the body is clearly understood and that the Minister can hold the body accountable to its duties. In this way the balance between independence and accountability can be struck.

⁸⁷⁵ See Department of the Taoiseach (n 869) 14.

⁸⁷⁶ Commission on Assisted Human Reproduction, *Report of the Commission on Assisted Reproduction* (2005) 8.

⁸⁷⁷ Irish Council for Bioethics, *Ethical, Scientific and Legal Issue with Stem Cell Research* (2008) 67.

4.4 Recommendation 4: The Legal Status of the Embryo

Central to the regulation of ESCR in Ireland is clarity as to the legal status of the embryo *in vitro*. Once this is established in law, stem cell policy can begin to emerge. Clarifying the legal status of the embryo will make it clear whether the research is permitted in Ireland and also the circumstances in which the research is permitted. It is submitted that to ensure clarity for scientists, research institutions, and funders, the legal status of the embryo should be enshrined in legislation. This legislation should also clearly state the legal status of ESCR.

Recommendation 4: The legal status of the embryo in vitro should be clearly stated in legislation. This legislation should also clearly state the legal status of ESCR.

4.5 Recommendation 5: The Establishment of an Independent Regulatory Authority

As illustrated by the HFE Act 1990, certain issues such as a definition of an embryo, should not be explained in legislation as these definitions are subject to change. Rather, an independent body, composed of experts in law, ethics and science, should consider such issues. Furthermore, such a body should be tasked with the issuing of licences and the determination of circumstances in which the research is permitted. This body will have the requisite expertise to ensure that only necessary research using an embryonic stem cell is carried out. However, the functions and duties of the body should be clearly outlined to ensure that it is not engaging in policy making if that is not to be its role.

Recommendation 5: An independent regulatory authority should be established to oversee the regulation of ESCR in Ireland. The roles and duties of this authority should be clearly stated in legislation.

4.6 Recommendation 6: A Coherent Regulatory Framework

If Irish policy makers decide to permit the research, there should be a coherent regulatory framework put in place. Legislation that permits the research should also be reflected by the policies of the independent regulatory authority. Equally, the funding policies should reflect this and the ban on the public funding of ESCR should be lifted. This applies to the current patenting policy under the Biotechnology Directive. If ESCR is to get to clinical application, it must be possible to patent the research as patents provide the economic incentive for private companies to engage in the research. The Commission should reconsider its current patent policy. It is peculiar that it encourages the public investment of the research through its FPs, yet removes the economic incentive for private companies to invest in the research. In the interim, Irish policy makers should ensure that there is a coherent policy in place and that funding policies reflect legislative policy.

Recommendation 6: Irish policy makers should revise their current ban on the public funding of ESCR to ensure that it reflects their legislative policy. This will ensure that there is a coherent framework in place.

5. Conclusion

The divisive abortion debate in Ireland has provided us with a valuable lesson in how not to create policy. The introduction of new policy should not come on foot of a lobby campaign, which in the case of abortion, successfully managed to use a time of political uncertainty to its advantage. Rather it should come in response to a need for new policy. The regulation of ESCR in Ireland is currently in a state of uncertainty with lawyers, scientists and the funders of science uncertain as to its legal status. To rectify this situation, Irish policy makers must address the issues that ESCR brings and engage in a campaign of consultation with the various stakeholders in the process of democratic deliberation. Ireland has experience with this policy during social partnership. Despite its flaws, social partnership has a good model in place, which should be improved upon and used to begin the process of determining the status of the embryo and ESCR.

Finally Irish policy makers should ensure that policy is coherent. For too long, it has been guided by a funding policy that bans the public funding of ESCR without expressly prohibiting the research itself. Similarly, in Europe, the Commission funds the research but prevents the commercialisation of the research. This lack of consistency and coherency leads to questions about what the true policy goals of the Commission are. Ireland should ensure that this does not occur but rather that its overall policy goals are reflected in its legislative scheme as well as its funding policies. Such an approach will ensure a coherent policy is in place, which provides clarity to both researchers and the public alike.

Appendix A List of Recommendations

Recommendation 1: The process of social partnership should be improved and adopted as a mechanism for determining the legal status of the embryo and the legal status of embryonic stem cell research in Ireland.

Recommendation 2: Policy makers must take into account the ethical precautionary principle when determining the sources of embryos permitted to be used in ESCR.

Recommendation 3: Prior to the introduction of ESCR policy, in accordance with government policy, a RIA should be carried out to assess the likely impact of any new regulations.

Recommendation 4: The legal status of the embryo *in vitro* should be clearly stated in legislation. This legislation should also clearly state the legal status of ESCR.

Recommendation 5: An independent regulatory authority should be established to oversee the regulation of ESCR in Ireland. The roles and duties of this authority should be clearly stated in legislation.

Recommendation 6: Irish policy makers should revise their current ban on the public funding of ESCR to ensure that it reflects their legislative policy. This will ensure that there is a coherent framework in place.

BIBLIOGRAPHY

Books

- T Beauchamp & L Walters (ed) *Contemporary Issues in Bioethics* (4th ed) (California, Wadsworth Publishing Company, 1994)
- U Beck, *Risk Society: Towards a New Modernity* (Sage Publications 1992)
- F Beytagh, *Constitutionalism in Contemporary Ireland: An American Perspective* (Roundhall Sweet and Maxwell 1997)
- A Bickel, *The Least Dangerous Branch* (Yale University Press 1962)
- J Blundell & C Robinson, *Regulation Without the State* (The Institute of Economic Affairs 1999)
- R Brownsword, *Rights, Regulation and the Technological Revolution* (OUP 2008)
- R Brownsword and K Yeung (eds), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Hart Publishing 2008)
- C Cohen, *Renewing the Stuff of Lie: Stem Cells, Ethics, and Public Policy* (OUP 2007)
- D Corry, D Souter & M Waterson, *Regulating our Utilities* (Institute for Public Policy Research 1994)
- P Devlin, *The Enforcement of Morals* (OUP 1965)
- P Drahos (ed) *Death of Patents* (Lawtext Publishing 2005) 23-4
- R Dworkin, *Life's Dominion: An Argument about Abortion and Euthanasia* (Harper Collins Publishers 1993)
- R Dworkin, *Limits: The Role of the Law in Bioethical Decision Making* (Indiana University Press 1996)
- E Emanuel, C Grady, R Crouch, R Lie, F Miller & D Wendler (ed), *The Oxford Textbook of Clinical Research Ethics* (OUP 2008)
- T Engelhardt, *Global Bioethics: The Collapse of Consensus* (M & M Scrivener Press 2006)
- D Evans (ed), *Conceiving the Embryo: Ethics, Law and Practice in Human Embryology* (Martinus Nijhoff Publishers 1996)
- F De Francesco, C Radaelli & V Troeger, 'Implementing Regulatory Innovations in Europe: the Case of Impact Assessment (2012) 19 *Journal of European Public Policy* 491
- F Francoini *Biotechnologies and International Human Rights* (Hart Publishing 2007)

- I Goklany, *The Precautionary Principle: A Critical Appraisal of Environmental Risk Assessment* (Cato Institute 2001)
- H Gottweis, B Salter & C Waldby, *The Global Politics of Human Embryonic Stem Cell Science* (Pallgrave MacMillan 2009)
- C Grobstein, *From Chance to Purpose* (Addison-Wesley Publishing Company: Massachusetts, 1981)
- J Gunning & V English, *Human IVF: A Case Study on the Regulation of Medical Innovation* (Dartmouth 1993)
- N Gunningham & P Grabosky, *Smart Regulation: Designing Environmental Policy* (OUP 1998)
- D Curley & A Sharples, 'Patenting Biotechnology in Europe: The Ethical Debate Moves On' [2002] *European Intellectual Property Review* 565
- A Guttman & D Thompson, *Why Deliberate Democracy?* (Princeton University Press 2004)
- J Harris, *The Value of Life: An Introduction to Medical Ethics* (Routledge & Kegan, 1985)
- K Hawkins (ed), *The Human Face of Law* (Clarendon Press 1997)
- G Hogan, 'Incorporation of the ECHR: Some Issues of Methodology and Process' in U Kilkelly, *ECHR and Irish Law* (Jordan Publishing Limited 2004)
- K Hug & G Hermeren (eds), *Translational Stem Cell Research* (Humana Press 2011)
- H Keller & S Stone, *A Europe of Rights: The Impact of the New ECHR on National Legal Systems* (OUP 2008)
- U Kilkelly, *ECHR and Irish Law* (Jordan Publishing Limited 2004)
- B Koops, M Lips, C Prins & M Schellekens, *Starting Points for ICT Regulation* (Asser Press, 2006)
- H Kuhse and P Singer *A Companion to Bioethics* (Blackwell Publishing, 1998)
- M Leinhos *The Logic and Legitimacy of American Bioethics* (Cambria Press 2008)
- A Levine (ed), *States and Stem Cells: the Policy and Economic Implications of State-Funded Stem Cell Research* (Princeton, 2006)
- J Locke, *An Essay Concerning Human Understanding* Vol I, Bk II Ch 27
- F de Londras & C Kelly, *European Convention on Human Rights Act: Operation, Impact and Analysis* (Roundhall 2010)
- J Jordana & D Levi Faur (eds), *The Politics of Regulation* (Edward Elgar 2004)

M Lockwood, 'When Does Life Begin' in M Lockwood (ed), *Moral Dilemmas in Modern Medicine* (OUP 1985)

B Morgan & K Yeung, *An Introduction to Law and Regulation: Text and Materials* (Cambridge University Press 2007)

A Ogus, *Regulation: Legal Form and Economic Theory* (Hart Publishing 2004)

D Oliver, T Prosser & R Rawlings, *The Regulatory State – Constitutional Implications* (OUP 2010)

L Ostnor (ed), *Stem Cells, Human Embryos and Ethics: Interdisciplinary Perspectives* (Springer 2008)

A Plomer & P Torremans (eds), *Embryonic Stem Cell Patents: European Patent Law and Ethics* (OUP 2010)

T Prosser, *The Regulatory Enterprise – Government, Regulation and Legitimacy* (OUP 2010)

J Rawls, *Political Liberalism* (Columbia University Press, 1993)

E O'Reilly *Masterminds of the Right* (Dublin, Attic Press 1992)

K Renwick Monroe, R Miller & J Tobis, *Fundamental of the Stem Cell Debate* (University of California Press 2008)

J Schweppe (ed), *The Unborn Child, Article 40.3.3 and Abortion in Ireland* (Liffey Press 2008)

S Sclater, F Ebtehaj, E Jackson & M Richards (eds), *Regulating Autonomy: Sex, Reproduction and Family* (Hart Publishing 2009)

N Snow, *Stem Cell Research: New Frontiers in Ethics and Science* (Notre Dame Press 2003)

H Somsen, *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents* (Edward Elgar Publishing Ltd 2007)

J Sprend, *Abortion and Divorce Law in Ireland* (McFarland and Company Inc. 2004)

D Steinberg (ed), *Biomedical Ethics: A Multidisciplinary Approach to Moral Issues in Biomedicine and Biology* (University Press of New England 2007)

N St John-Steva, *Law and Morals* (Hawthorn 1964)

C Sunstein, 'After the Rights Revolution: Reconceiving the Regulatory State' (Harvard University Press 1990)

L Tribe, *Abortion: The Clash of Absolutes* (W.W. Norton & Company 1992)

A Trouwborst, *Evolution and the Status of the Precautionary Principle in International Law* (Kluwer Law International 2002)

C Sustain, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge University Press 2005)

H Varmus, *The Art and Politics of Science* (Norton & Co, 2010) 197

Articles

A Alemanno, 'A Meeting of Minds on Impact Assessment: When Ex Ante Evaluation Meets Ex Post Judicial Control' (2011) 17 *European Journal of Public Law* 485

A Alemanno, 'The Shaping of the Precautionary Principle by the European Courts: From Scientific Uncertainty to Legal Certainty' *Bocconi Legal Studies Research Paper No. 1007404*

F Ankersmith, 'Representational Democracy An Aesthetic Approach to Conflict and Compromise' (2002) 8 *Common Knowledge* 24

G Annas, A Caplan & S Elias 'Stem cell politics, ethics and medical progress' (1999) 5 *Nature America* 1339

T Callus, 'Ensuring Operational Compliance and Ethical Responsibility in the Regulation of ART: The HFEA, Past, Present, and Future' (2011) 3 *Law, Innovation and Technology* 85

R Baldwin, 'Is Better Regulation Smarter Regulation?' [2005] *Public Law* 485

R Baldwin & J Black, 'Really Responsive Regulation' (2008) 71 *Modern Law Review* 59

H van den Belt, 'Debating the Precautionary Principle: "Guilty until Proven Innocent" or "Innocent until Proven Guilty?" (2003) 131 *Plant Physiology* 1122

L Bennett Moses, 'Understanding Legal Responses to Technological Change: The Example of In Vitro Fertilization' (2005) 6 *Minnesota Journal of Law, Science and Technology* 505

D Beyleveld & R Brownsword, 'Human Dignity, Human Rights and Human Genetics' (1998) 61 *Modern Law Review* 661

V Braithwaite, 'Ten Things You Need to Know about Regulation and Never Wanted to Ask' (2006) RegNet Occasional Paper No. 10

M Brazier, 'Regulating the Reproduction Business' (1999) 7 *Medical Law Review* 166,

C Brown & C Scott, 'Regulation, Public Law and Better Regulation' (2011) 17 *European Public Law* 467

R Brownsword, 'Making People Better and Making Better People: Bioethics and the Regulation of Stem Cell Research' (2005) 1 *Journal of Academic Legal Studies* 5

R Brownsword, "Regulating Human Genetics: New Dilemmas for a New Millennium" [2004] *Medical Law Review* 14

- R Brownsword “Stem Cells, Superman, and the Report of the Select Committee” (2002) 65 *Modern Law Review* 568
- D Callahan, ‘Bioethics and the Culture Wars’ (2005) 14 *Cambridge Quarterly of Healthcare Ethics* 424
- D Callahan ‘Bioethics, Our Crowd and Ideology’ (1996) 26 *The Hastings Center Report* 3
- D Callahan, ‘Promises, Promises. Is embryonic Stem Cell Research Sound Public Policy?’ (2005) *Commonweal* 12
- D Callahan, ‘The Puzzle of Profound Respect’ (1995) 25 *The Hastings Center Report* 39
- T Callus, ‘Ensuring Operational Compliance and Ethical Responsibility in the Regulation of ART: The HFEA, Past, Present, and Future’ (2011) 3 *Law, Innovation and Technology* 85
- R Charo, ‘Bush’s Stem Cell Compromise: A Few Mirrors?’ (2001) 34 *The Hastings Center Report* 6
- R Charo, ‘Passing on the Right: Conservative Bioethics is Closer Than it Appears’ (2004) 32 *Journal of Law, Medicine & Ethics* 307
- J Childress, ‘An Ethical Defence of Federal Funding for Human Embryonic Stem Cell Research’ (2001-2002) 2 *Yale Journal of Health Law and Policy* 157
- I Chowcat, ‘Moral Pluralism, Political Justification and Deliberative Democracy’ (2000) 48 *Political Studies* 745
- J Cibelli, A Kiessling, K Cunniff, C Richards, R Lanza, M West, ‘Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development’ (2001) 2 *Journal of Regenerative Medicine* 25
- I Clissmann & J Barrett, ‘The Embryo *in vitro* after *Roche v Roche*: What Protection is Now Offered?’ (2012) 18 *Medico Legal Journal of Ireland* 13
- RS Crespi, ‘The Human Embryo and Patent Law: A Major Challenge Ahead’ [2006] 28 *European Intellectual Property Review* 569
- A Dawson, ‘The Human Fertilisation and Embryology Authority: Evidence Based Policy Formation in a Contested Context’ (2004) 12 *Health Care Analysis* 1
- O Doyle, ‘Legal Positivism, Natural Law and the Constitution’ (2009) 31 *Dublin University Law Journal* 206
- P Drahos, ‘Biotechnology Patents, Markets and Morality’ (1999) *European Intellectual Property Review* 441
- Editorial, ‘The Promise of Stem Cells’ (2004) 7 *Nature Neuroscience* 1013

- M Eljkholt, 'The Right to found a Family as a Still born Right to Procreate' [2010] *Medical Law Review* 127
- M Enright "Justice, Convention and Anecdote: Evans and the Right to Become a Mother" (2006) 9 *Irish Journal of Family Law*
- The Ethics Committee of the American Society for Reproductive Medicine, 'Human Somatic Cell Nuclear Transfer and Cloning' (2012) 98 *Fertility and Sterility* 804
- J Fossett, 'Beyond the Low-Hanging Fruit: Stem Cell Research Policy in an Obama Administration' (2009) 9 *Yale J. Health Policy Law & Ethics* 523
- H Fowler, Federal Stem Cell Mandates Lack Global Focus and Market Foresight, (2003-2004) 36 *Cornell Journal of International Law* 521
- B Frist, 'The Promise and Peril of Embryonic Stem Cell Research: A Call for Vigilant Oversight' (2001-2002) 2 *Yale Journal of Health Policy, Law and Ethics* 167
- N Gaynor, 'Associations, Deliberation, and Democracy: The Case of Ireland's Social Partnership' (2011) 39 *Politics and Society* 497
- Geron Ethics Advisory Board, 'Research with Human Embryonic Stem Cells: Ethical Considerations' (1999) 29 *Hastings Centre Report* 31
- F Gilardi, 'Policy Credibility and Delegation to Independent Regulatory Agencies: A Comparative Empirical Analysis' (2002) 9 *Journal of European Public Policy* 873
- C Gollier, B Jullien & N Treich, 'Scientific Progress and Irreversibility: An Economic Interpretation of the 'Precautionary Principle'' (2000) 75 *Journal of Public Economics* 229
- P Grabosky, 'Using Non-governmental Resources to Foster Regulatory Compliance' (1995) 8(4) *Governance* 527
- N Gunningham, 'Environmental Law, Regulation and Governance: Shifting Architectures' (2009) 21 *Journal of Environmental Law* 179
- A Gutmann, 'The Ethics of Synthetic Biology' (2011) 41 *The Hastings Centre Report* 17
- C Harlow, 'Law and Public Administration: Convergence and Symbiosis' (2005) 71 *International Review of Administration Sciences* 279
- G Hermerén, 'Accountability, Democracy, and Ethics Committees' (2009) 1 *Law, Innovation and Technology* 154
- Julian Hitchcock "Brüistle v Greenpeace: Sorry to be optimistic...." Tuesday, 18 October 2011
http://www.cellfate.com/CellFate/News/Entries/2011/10/18_Brustle_v_Greenpeace_Sorry_to_be_optimistic....html.

M Hutchinson, 'The Margin of Appreciation Doctrine in the European Court of Human Rights' (1999) 48 *International and Comparative Law Quarterly* 638

J Kahn, 'Organ and Stem Cells: Policy Lessons and Cautionary Tales' (2007) 37 *The Hastings Centre Report* 11

H Gottwels, 'The Endless hESC Controversy in the United States: History, Context and Prospects' (2010) 7 *Cell Stem Cell* 555

S Hogarth, K Liddell, T Ling, S Sanderson, R Zimmern & DD Melzer, 'Closing the Gap-Enhancing the Regulation of Genetic Tests Using Responsive Regulation' (2007) 62 *Food and Drug Law Journal* 831

S Holm 'Going to the Roots of the Stem Cell Controversy' (2002) 16 *Bioethics* 493

H Johnson Kukla, 'Embryonic Stem Cell Research: An Ethical Justification' (2001-2002) 90 *Georgetown Law Journal* 503

J Habermas 'Religion in the Public Sphere' (2006) 14 *European Journal of Philosophy* 1,

R Latham, 'The Once and Future Debate on Human Embryonic Stem Cell Research' (2009) 9 *Yale Journal of Health Law and Policy* 483

R Levine, 'Federal Funding and the Regulation of Embryonic Stem Cell Research: The Pontius Pilate Maneuver' (2009) 9 *Yale Journal of Health Policy, Law & Ethics* 552

J Losey, L Rayer & M Carter, 'Transgenic pollen harms monarch larvae' (1999) 399 *Nature* 214

A Lotierzo, 'The Unborn Child, a Forgotten Interest: Reexamining *Roe* in Light of Increased Recognition of Fetal Rights' (2006) 79 *Temple Law Review* 279

R Lovell-Badge, 'The Future for Stem Cell Research' (2001) 414 *Nature* 88

R Macklin, 'The New Conservatives in Bioethics: Who are they and What do they Seek?' (2006) 36 *The Hastings Centre Report* 34

M Maggetti, 'The Role of Independent Regulatory Agencies in Policymaking: A Comparative Analysis' (2009) 6 *Journal of European Public Policy* 450

G Majone, 'Temporal Consistency and Policy Credibility: why democracies need non-majoritarian institutions' Working Paper RSC No. 96/57 (Florence, European University Institute, (1996) 1

G Majone, 'What Price Safety: The precautionary principle and its policy implications' (2002) 40(1) *Journal of Common Market Studies* 89

T Malloy, 'The Social Construction of Regulation: Lessons from the War Against Command and Control' (2010) 58 *Buffalo Law Review* 267

- J McCandless & S Sheldon, 'The Human Fertilisation and Embryology Act (2008) and The Tenacity of the Sexual Family Form' (2010) 73 *Modern Law Review* 175
- R McGough, 'A Case for Federal Funding of Human Embryonic Stem Cell Research: The Interplay of Moral Absolutism and Scientific Research' (2001-2002) 18 *Journal of Contemporary Health Law and Policy* 147
- D McMahon, H Thorsteinsdottir, P Singer & A Daar "Cultivating regenerative medicine innovation in China" (2010) 5(1) *Regenerative Medicine* 35
- R Meade, 'We hate it here, please let us stay! Irish social partnership and the community/voluntary sector's conflicted experiences of recognition' (2005) 25 *Critical Social Policy* 349
- G Meilaender, 'Less Law? Or Different Law?' (1996) 26 *The Hastings Center Report* 39
- M Meyer & L Nelson, 'Respecting What we Destroy: Reflections on Human Embryo Research' (2001) 31(1) *The Hastings Centre Report* 18
- J Miller, 'Call to Legal Arms: Bringing Embryonic Stem Cell Therapies to Market' (2002-2003) 13 *Albany Law Journal of Science and Technology* 555
- D Morgan, 'Ethics, Economics and the Exotic: The Early Career of the HFEA' (2004) 12 *Health Care Analysis* 7
- D Morgan & R Lee, 'In the Name of the Father? *Ex parte* Blood: Dealing with Novelty and Anomaly' (1997) 60 *Modern Law Review* 840
- A Morgan Capron, 'Morality and the State, Law and Legalism' (1996) 26 *The Hastings Center Report* 35
- V Nagarajan, 'From 'Command-and-Control' to 'Open Method Coordination': The Orising the Practice of Regulatory Agencies' (2008) 8 *Macquarie Law Journal* 5
- A Naimark, 'Biotechnology, Innovation and Health' (2006) 32 *Canada-United States Law Journal* 220
- K Nicholls, 'Why social partnership matters: Irish policies for work-life balance' (2006) 29 *West European Politics* 513
- D Orentlicher, 'The Legislative Process is Not Fit for the Abortion Debate' (2011) 41 *The Hastings Centre Report* 13
- D Perry, 'Patients' Voices: The Powerful Sound in the Stem Cell Debate' (2000) 287 *Science* 1423
- N Poplawski & G Gillett, 'Ethics and Embryos' (1991) 17 *Journal of Medical Ethics* 62

U K Puorger, 'Ethics, Social, Legal, Counselling, Surplus Embryos in Switzerland in 2003: Legislation and Availability of Human Embryos for Research' (2006) 13(6) *Reproductive Biomedicine Online* 772

N Priaulx, 'Testing the Margin of Appreciation: Therapeutic Abortion, Reproductive 'Rights' and the Intriguing Case of *Tysiqc v. Poland*' (2008) 15 *European Journal of Health Law* 361

J Remy Nash, 'Standing and the Precautionary Principle' (2008) 108 *Columbia Law Review* 494

J Robertson, 'Embryo Culture and the "Culture of Life": Constitutional Issues in the Embryonic Stem Cell Debate' (2006) *University of Chicago Legal Forum* 1

J Robertson, 'Ethics and Policy in Embryonic Stem Cell Research' (1999) 9 *Kennedy Institute of Ethics Journal* 116

M Rowaldson, 'WARF/Stem cells (G2/06): the ordre public and morality exception and its impact on the patentability of human embryonic stem cells' (2010) 32 *European Intellectual Property Review* 67

N Sachs, 'Rescuing the Strong Precautionary Principle from its Critics' (2011) *University of Illinois Law Review* 1285

J Schechter, 'Promoting Human Embryonic Stem Cell Research: A Comparison of Policies in the United States and United Kingdom and Factors Encouraging Advancement' (2009-2010) 45 *Texas International Law Journal* 603

M Schwartz, 'Miffed by stem cell policy, Clark suspends Bio-X gift' Stanford Report, September 2001

C Scott, 'Regulating Everything' *UCD Geary Discussion Paper* (2008)

J Scott & D Trubek, 'Mind the Gap: Law and New Approaches to Governance in the European Union' (2002) 8 *European Law Journal* 1

H Semb, 'Human Embryonic Stem Cells: Origins, Properties and Applications' (2005) 113 *APMIS* 743

A Sherlock, 'The Right to Life of the Unborn in the Irish Constitution' (1989) 24 *Irish Jurist* 13

J Shun, 'Moral Disharmony: Human Embryonic Stem Cell Patent Laws, WARF and Public Policy' (2010) 33 *Boston College International and Comparative Law Review* 153

D Sinclair, 'Self-Regulation Versus Command and Control? Beyond False Dichotomies' (1997) 19 *Law and Policy* 529

P Singer & A Daar, 'Cultivating regenerative medicine innovation in China' (2010) 5 *Regenerative Medicine* 35

- P Singer & K Dawson, 'IVF technology and the argument from potential' (1988) 17(2) *Philosophy and Public Affairs* 87
- N Smith, 'Mapping Processes of Policy Change in Contemporary European Political Economies: The Irish Case' (2006) 8 *British Journal of Politics & International Relations* 519
- D Smith, 'Stuck in the Middle' (2006) 36 *The Hastings Centre Report* 32
- T Sommer, 'The scope of gene patent protection and the TRIPS agreement - an exclusively nondiscriminatory approach?' (2007) *International Review of Intellectual Property and Competition Law* 30
- P Stafford, 'The rise and fall of social partnership: its impact on interest group lobbying in Ireland' (2011) 11 *Journal of Public Affairs* 74
- C Staunton, 'As Easy as A, B and C: Will *A, B and C v. Ireland* Be Ireland's Wake-up Call for Abortion Rights?' (2011) 18 *European Journal of Health Law* 205
- C Staunton, '*Brustle v Greenpeace*, Embryonic Stem Cell Research and the European Court of Justice's New Found Morality' [2013] *Medical Law Review* (forthcoming)
- C Staunton "Issues Concerning Embryonic Stem Cell Research in Ireland" (2012) 18(1) *Medico Legal Journal of Ireland* 38
- S Sterckx, 'The European Patent Convention and the (Non)Patentability of Human Embryonic Stem Cells-the WARF Case' [2008] 4 *Intellectual Property Quarterly* 478
- S Sterckx & J Cockbain, 'Assessing the Morality of the Commercial Exploitation of Inventions Concerning Uses of Human Embryos and the Relevance of Moral Complicity: Comments on the EPO's WARF Decision' (2010) 7 *SCRIPTed* 83
- C Sunstein, 'The Paralyzing Principle: Does the Precautionary Principle point us in any helpful direction?' (2003) *Regulation* 32
- C Sunstein, 'Probability Neglect: Emotions, Worst Cases, and the Law' (2002) 112 *Yale Law Journal* 61
- K Takahashi & S Yamanaka, 'Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors' (2006) 126 *Cell* 663
- P Teague, 'Social Partnership and Local Development in Ireland: The Limits to Deliberation' (2006) 44 *British Journal of Industrial Relations* 421
- G Teklenburg, M Salker, C Heijnen, N Macklon & J Brosens, 'The Molecular Basis of Recurrent Pregnancy Loss: Impaired Natural Embryo Selection' (2010) 16 *Molecular Human Reproduction* 886

M Thatcher, 'Regulation after delegation: independent regulatory agencies in Europe' (2002) 9 *Journal of European Public Policy* 954

J Thompson, J Itskovitz-Eldor, S Shapiro, M Waknitz, J Swiergiel, V Marshall & J Jones, 'Embryonic Stem Cell Lines Derived from Human Blastocysts' (1998) 282 *Science* 1145

C Wallace, 'Optimising horizontal and vertical partnership connections: bringing partnerships together to create a network advantage' (2009) 15 *Australian Journal of Primary Health* 196

A Warren-Jones, 'Patenting DNA: a lot of controversy over a little intangibility' [2004] *Medical Law Review* 97

H Watt, 'Potential and the early human (1996) 22 *Journal of Medical Ethics* 222

D Wertz, 'Embryo and Stem Cell Research in the United States: History and Politics' (2002) 9 *Gene Therapy* 674

J Wiener, 'Better Regulation in Europe' (2006) 59 *Current Legal Problems* 447

S Wills, 'Federal Funding of Embryonic Stem Cell Research: Illegal, Unethical and Unnecessary' (2001-2002) 18 *Journal of Contemporary Health Law & Policy*

I Wilmut, A Schnieke, J McWhir, A Kind & K Campbell, 'Viable Offspring Derived from Foetal and Adult Mammalian Cells' (1997) 385 *Nature* 810

B Wynne, 'Creating public alienation: expert cultures of risk and ethics on GMOs' (2001) 19 *Science as Culture* 445

L Zucca, '*Evans v United Kingdom*: Frozen Embryos and Conflicting Rights' (2007) *Edinburgh Law Review* 446

Reports

All Party Oireachtas Committee on the Constitution *Fifth Progress Report: Abortion* (2000)

Better Regulation Taskforce, *Imaginative Thinking for Better Regulation* (2003)

Better Regulation Task Force, 'Regulation - Less is More Reducing Burdens, Improving Outcomes' (2005)

Biotechnology Industry Organisation *Guide to Biotechnology 2008*

Constitutional Review Group, *Report of the Constitutional Review Group* (1996)

Commission on Assisted Human Reproduction *Report of the Commission on Assisted Human Reproduction* (2005)

Communication from the Commission on the Precautionary Principle COM (2000) 1

Commission communication, 'Smart Regulation in the European Union' COM (2010) 543

Commission of the European Communities (2003) *Proposal for a Council decision amending decision 2002/834/EC on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European research area"* (2002–2006)

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Second strategic review of Better Regulation in the European Union COM (2008) 33 final, COM (2008) 35 final

Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, 'A Strategic Review of Better Regulation in the European Union' COM (2006) 690 final, COM (2006) 691 final

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Third strategic review of Better Regulation in the European Union COM/2009/0015 final, Communication from the Commission - Action plan "Simplifying and Improving the Regulatory Environment COM (2002) 0278 final

Congregation for the Doctrine of the Faith, *Instruction Dignitas Personae on Certain Biological Questions* (2008)

Department for Business, Innovation and Skills, Better Regulation Executive, *Internal Review of the HFEA: A Hampton Implementation Review Report* (December 2009).

Department of Health, *Legislation on Human Infertility Services and Embryo Research* (December 1986)

Department of Health, *Liberating the NHS: Report of the Arm's Length Bodies Review* (July 2010)

Department of Health *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including the establishment of the Regulatory Authority for Tissue and Embryos)* (2006)

Department of Health, *Review of the Human Fertilisation and Embryology Act: A public consultation* (2005)

Department of Health and Security, *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (Cm 9314 1984)

Department of the Taoiseach, *Bodies in Ireland with Regulatory Powers* (2007)

Department of the Taoiseach, *Regulating Better: A Government White Paper setting out six principles of Better Regulation* (2004)

Ernst and Young *Beyond Borders: Global Biotechnology Report 2010*

Ernst and Young *Beyond Borders: Global Biotechnology Report 2012*

European Commission, 'Life Sciences and Biotechnology: A Strategy for Europe' COM (2002) 27

European Commission *Regulatory Impact Assessment Guidelines* (2009)

European Group on Ethics, *Ethical Aspects of Cloning Techniques* (28 May 1997)

European Science Foundation, *Human Stem Cell Research and Regenerative Medicine European Perspective on Scientific, Ethical and Legal Issues* (2010)

General Report on the Activities of the European Group on Ethics in Science and New Technologies to the European Commission 2000 – 2005

German National Ethics Council, *The Import of Embryonic Stem Cells* (2001)

House of Commons Science and Technology Committee, *Developments in Human Genetics and Embryology* (Fourth Report of Session 2001–2)

House of Lords Select Committee *Stem Cell Research* (2002)

House of Lords, Select Committee on the Constitution, *The Regulatory State: Ensuring its Accountability*, 6th Report of Session (2003-04)

Human Fertilisation and Embryology Authority *Annual Report and Accounts 2011/12* (July 2012)

Human Genetics Advisory Commission, *Cloning Issues in Reproduction, Science and Medicine* (1998)

Human Reproductive Technologies and the Law, House of Commons Science and Technology Committee, Fifth Report (2004–5, HC 7-1)

International Bioethics Committee, *The Use of Human Embryonic Stem Cells in Therapeutic Research* 40

Irish Council for Bioethics, *Ethical, Scientific and Legal Issues Concerning Stem Cell Research* (2008)

Mandelkern Report on Better Regulation (2001)

National Institute for Biological Standards and Control, *UK Stem Cell Bank Progress Report Phase II* 2006 – 2010

National Bioethics Advisory Commission, *Cloning Human Beings* (1997).

National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*

National Institute of Health *Guidelines for Research Using Human Pluripotent Stem Cells* (2000)

National Institute of Health, *Report of the Human Embryo Research Panel* (September 1994)

New Zealand Treasury, *Environmental Risk Management in New Zealand – Is There Scope to Apply A More Generic Framework?* (July 2006)

The OECD Reference Checklist for Regulatory Decision-Making

Presidential Commission for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies* (2010)

Commission to the European Parliament and the Council, *Developments and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* COM (2005) 312

Select Committee on the Constitution, *The Regulatory State: Ensuring its Accountability*, 6th Report of Session 2003-04

Singapore National Bioethics Advisory Committee, *Human Embryonic Stem Cells: Science and Ethics*

Stem Cell Patents: European Patent Law and Ethics (2006)

Fact Sheets

National Institutes of Health, ‘Stem Cell Information’

UK Stem Cell Foundation, ‘Stem Cell Research: Benefits and Future Hopes’

Guidelines

European Patent Office, *Guidelines for Substantive Examination*

Medical Council of Ireland, *Guide to Professional Conduct and Ethics for Registered Medical Practitioners*, 6th ed. (2004)

National Academies Guidelines, *Guidelines for Human Embryonic Stem Cell Research* (2005) subsequently amended in 2007

Trinity College Dublin, *Policy on Good Research Practice* (2009)

UK IPO *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the Intellectual Property Office* (April 2011)

University College Cork, *Code of Practice for research Using Embryonic Stem Cell Lines* (2008)

Table of Cases

Ireland

A and B v. Eastern Health Board, Judge Mary Fahy and C, and the Attorney General (Notice Party) [1998] 1 IR 464

AG v X [1992] 1 IR 1

Fitzpatrick v FK [2009] 2 IR 7

Kavanagh v Governor of Mountjoy Prison [2002] 3 IR 97

McGee v Attorney General [1974] IR 284

Norris v Attorney General [1984] IR 36

Roche v Roche [2010] 2 ILRM 1

R v Bourne [1938] 1 KB 687

The State (Healy) v Donoghue [1976] IR 325

Europe

ABC v Ireland (2011) 53 EHRR 2032

Boso v Italy App No. 50490/99 Dec. 05.09.2002

Bruggeman and Scheuten v Federal Republic of Germany (1977) 3 EHRR 244

BDPI Phosphatase/Mas-Planck (2005) T 870/04

Campaign to Separate Church and State v Minister for Education [1998] 3 IR 321

Case C-377/98 Netherlands v European Parliament [2002] FSR 574

Case 180/96 United Kingdom v Commission UK v Commission ECR 1-3903

Evans v United Kingdom (2006) 43 EHRR 21

Harvard/Oncomouse [2005] EPOR 31

Howard Florey/Relaxin T-74/91 [1995] EPOR 541

NHS Trust v Bland [1993] 2 WLR

Open Door and Dublin Well Woman v Ireland (1993) 15 EHRR 244

Plant Genetic Systems [1995] OJ EPO 545

R v Henn and Derby (1979) ECR 3795

R v Human Fertilisation and Embryology Authority, ex parte Blood [1997] 2 All ER 687

R v Secretary for Health ex parte Quintavalle (on behalf of Pro-Life Alliance) [2003] UKHL 13

R (on the application of the Assisted Reproduction and Gynaecology Centre and another) v Human Fertilisation and Embryology Authority [2003] 1 FCR 266

Re S (adult: refusal of medical treatment) [1992] 4 All ER 671

Re T [1993] Fam 95

Royal College of Nursing of the United Kingdom v Department of Health and Social Security [1981] AC 800

Vo v France (2005) 40 EHRR 12

Wisconsin Alumni Research Foundation (WARF) G 0002/06

X v United Kingdom App. No.8416/79 Comm. Dec. 13.05.1980

International

Akron v Akron Centre for Reproductive Health (1983) 462 US 416

Morgentaler, Smoling and Scott v Queen (1988) 44 DLR (4th) 385

Planned Parenthood of Southeastern Pennsylvania v Casey (1992) 505 US 833

Roe v Wade (1973) 410 US 113

Sherley v Shebelius 704 F. Supp. 2d 63 2010 US Disct

The foundation for taxpayer and consumer rights v patent of Wisconsin Alumni Research Foundation Appeal 2010-001854 Decided 28 April 2010

Webster v Reproductive Health Services (1989) 492 US 490

Table of Legislation

Ireland

European Convention on Human Rights Act 2003

Offences Against the State Act 1861

International

An Act Permitting Stem Cell Research and Banning the Cloning of Human Beings

Human Fertilisation and Embryology Act 1990

International Conventions

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings

European Convention on Human Rights

European Patent Convention

Trade Related Aspects of Intellectual Property Rights

UN Convention on the Rights of Persons with Disabilities

Newspapers

‘Abortion Amendment Seen as Divisive’ *The Irish Times* 8 June 1983 4

‘Abortion Poll Date Queried’ *The Irish Times* 22 January 1983 17

‘Abortion Text Not Yet Available’ *The Irish Times* 16 March 1983 5

‘Attorney General Rules Out Wording’ *The Irish Times* 16 February 1983 6

“Civil Partnership Bill passes through Dáil” Thursday 1 July 2010

<<http://www.rte.ie/news/2010/0701/gay.html>>

K Boyle, ‘Pre-empting a Delicate Issue’ *The Irish Times* 5 August 1982, 10

J Cooney ‘Stormy Path Towards an Amendment’ *The Irish Times* 9 February 1983 7

P. Cullen and H. McGee, ‘Proposing Legal Changes Will Take Time, says Harney’ *Irish Times*, Friday, 17 December 2010

J Meikle ‘Axe IVF watchdog, says fertility expert’ *The Guardian*, 11 December 2004

C O’Brien, ‘Woman with Cancer Tells of her Abortion Ordeal’ *Irish Times* (Dublin, 21 December 2010).

Websites

www.cirm.ca.gov/pressrelease_2011-05-04

<http://communityplatform.ie/social-partnership.html>

http://cordis.europa.eu/search/index.cfm?fuseaction=news.document&N_LANG=EN&N_RC_N=20147&pid=34&q=D947BD405B4FECE44933948AB2209F56&type=sim>

http://ec.europa.eu/governance/better_regulation/instruments_en.htm

<http://www.european-council.europa.eu/home-page/highlights/eu-unitary-patent-%E2%80%93-a-historical-breakthrough?lang=en>

<<http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html>>

<http://www.hfea.gov.uk/515.html>

http://www.irishstemcellfoundation.org/go/get_involved/donate

<http://www.molecularmedicineireland.ie/show/item/1/1387>

<http://www.news.cornell.edu/releases/May99/Butterflies.bpf.html>.

http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml

<http://www.sfi.ie/funding/grant-policies/research-using-human-embryonic-stem-cells/>

http://www.taoiseach.gov.ie/eng/Publications/Publications_Archive/Publications_2011/Better_Regulation_Website_Content.pdf

http://www.taoiseach.gov.ie/eng/Work_Of_The_Department/Economic_and_Social_Policy/Social_Dialogue/Background_to_Social_Partnership.html

<http://www.wellcome.ac.uk/>