

Irish Ostriches, Embryos and Stem Cells

A thesis submitted to the University of Manchester for the degree of

PhD in Bioethics and Medical Jurisprudence

in the Faculty of Humanities

2012

Fionnuala Gough

School of Law

TABLE OF CONTENTS

	<u>Page</u>
Abstract	5
Declaration & Copyright Statement	6
Acknowledgements	7
The Author	8
Table of Cases	10
Table of Statutes	12
Abbreviations	14

PART I: INTRODUCTION

Chapter

1	<u>THE PROBLEM</u>	16
1.2	Overview of Thesis Structure	18
1.2.1.	<i>Research Questions</i>	19
1.2.2.	<i>Outline of Chapters 2, 3 and 4</i>	19
1.2.3.	<i>Outline of Papers 1, 2 and 3</i>	21
1.2.4.	<i>Conclusions</i>	21
1.3	The Importance of Stem Cell Research	22
1.3.1.	<i>Examples of Stem Cells</i>	22
1.3.2.	<i>Human Embryonic Stem Cells</i>	24
1.3.3.	<i>Stem Cell Research Applications</i>	26
1.3.4.	<i>Conclusion</i>	28
2	<u>ETHICAL APPROACH</u>	30
2.1	Introduction	30
2.1.1.	<i>Europe's Position on hESC Research</i>	32
2.1.2.	<i>Irish Position in Relation to ART and hECS Research</i>	34
2.2	The Moral Status of the Embryo	36
2.2.1.	<i>Human Dignity</i>	38
2.2.2.	<i>Religious Tradition in Ireland</i>	41
2.2.3.	<i>The Potentiality Argument</i>	44
2.2.4.	<i>The Gradualist Argument</i>	48
2.3	Conclusion	49
3	<u>PHILOSOPHICAL APPROACH</u>	53
3.1	The Irish Constitution, Naturally and Deliberatively	53
3.2	What is 'Natural Law'?	54
3.2.1.	<i>The Natural Constitution</i>	60
3.2.2.	<i>Natural law and the X Case</i>	66
3.3	Deliberating Naturally about the Constitution	69
3.3.1.	<i>Deliberative Democracy</i>	70
3.4	Deliberation and Public Policy	73
3.5	Deliberative Politics in Ireland: A Missed Opportunity?	74

4	<u>LEGAL APPROACH</u>	77
4.1	Introduction	77
4.2	The Status of the Embryo in Irish Law	77
4.3	Article 40.3.3	82
	4.3.1. <i>Case Law</i>	85
	4.3.2. <i>The 'X' Case</i>	88
4.4	The Meaning of 'Unborn'	91
4.5	Policy Initiatives	95
	4.5.1. <i>Role of the Irish Medical Council</i>	99
4.6	The 'Frozen Embryos' Case	100
	4.6.1. <i>Practical Implications of Legal Lacuna</i>	106
5	<u>OUTLINE OF SUBMITTED PAPERS</u>	108
5.1	Paper 1	108
5.2	Paper 2	109
5.3	Paper 3	111

PART II: THE SUBMITTED ARTICLES

6	<u>PAPER 1: HUMAN EMBRYONIC STEM CELL RESEARCH IN IRELAND: ETHICAL AND LEGAL ISSUES</u>	112
6.1	Abstract	112
6.2	Introduction	112
6.3	The Moral Status of the Embryo	114
	6.3.1. <i>Potentiality</i>	117
6.4	The Legal Position of hESC Research in Ireland	119
	6.4.1. <i>Article 40.3.3</i>	121
	6.4.2. <i>Recent Legal Developments</i>	124
6.5	hESC Research Policy in Ireland	128
6.6	The Future Enabled?	134
7	<u>PAPER 2: 'SOMETHING MUST BE DONE': A STUDY OF STAKEHOLDER ATTITUDES TOWARDS THE IRISH LEGAL VACUUM IN RELATION TO hESC RESEARCH.</u>	139
7.1	Abstract	139
7.2	Introduction: Stem Cell Research and Ireland	139
7.3	Empirical Methods	143
7.4	Results	144
7.5	The Moral and Legal Status of the Embryo in Ireland	145
7.6	Implications of a Lack of a Legal Framework	150
7.7	Lack of Political Will-Power	156
7.8	Economic and Scientific Impact of a Lack of Legislation	161
7.9	Discussion	165
7.10	Conclusion	170

8	PAPER 3: DELIBERATING OR DITHERING? IRELAND AND HUMAN EMBRYONIC STEM CELL RESEARCH	171
8.1	Abstract	171
8.2	Introduction	171
8.3	hESC Research	173
8.4	Role of Deliberative Democracy	174
8.5	A Three-Tier Framework	178
8.6	Proceduralism in Practice	179
8.7	The German Experience	182
8.8	How Germany Developed its hESC Research Policy	184
8.9	Protection of the Unborn in Germany	186
8.10	Irish Dithering	192
8.11	Conclusion	197

PART III

9	CONCLUSIONS	193
9.1	Stem Cells, Religion and Politics	193
9.2	Stem Cells and Stakeholders	196
9.3	Biotechnology and Deliberative Democracy	198
9.4	Concluding Remarks	202

	Bibliography	204
	Appendix: Published Papers	226

Word Count of main text including footnotes: 80,502

ABSTRACT

The University of Manchester

Doctoral Programme in Bioethics and Medical Jurisprudence

Fionnuala Gough

19th December 2012

Irish Ostriches, Embryos and Stem Cells

Human embryonic stem cell research would seem to offer the prospect of developing a greater understanding of, and potential therapies for, common degenerative diseases such as diabetes mellitus, Alzheimer's and Parkinson's disease. Despite the fact that some Irish institutions engage in such research, Ireland is one of the few countries in Europe which has failed to produce any relevant regulatory framework or legislation. This is largely because embryo research and its regulation remain mired in conflicting socio-political values and interests, despite the fact that the *in vitro* human embryo is not afforded any legal protection under the Irish Constitution. This thesis seeks to examine the current Irish legal lacuna in relation to embryos and embryonic stem cell research.

The first of the three papers making up the core of this thesis reviews the background to the moral, legal and social factors that have contributed to the extant Irish position. A description of the divergent policies enacted in other jurisdictions is also given to outline possible policy options which may be considered by Ireland in the future. The views of relevant stakeholders on the impact of the regulatory lacuna are explored in the second paper through a series of semi-structured interviews. These interviews highlight a surprising level of consensus on the need for the Irish legislature to act and introduce regulations to provide certainty, in one way or the other, in this area of scientific innovation. A procedural mechanism is proposed in the third paper which could allow the development of policy and concomitant regulation in Ireland in this area. It is hoped that the procedural process and resultant framework would be sufficiently inclusive as to be acceptable to the majority of people in Irish society.

In conclusion, it is argued that it is undesirable that a modern pluralist democracy (as Ireland aspires to be) should regard legislative inertia and non-regulation as the preferred method of dealing with morally challenging scientific endeavour. Instead, appropriate procedural mechanism should be utilised to allow for the development of apposite policies.

DECLARATION

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or any other institute of learning.

COPYRIGHT STATEMENT

- i. The author of this thesis (including any appendices and/or schedules to this thesis) owns the copyright in it (the “Copyright”) and has given The University of Manchester the right to use such Copyright for any administrative, promotional, educational and/or teaching purposes.
- ii. Copies of this thesis, either in full or in extracts, may be made only in accordance with the regulations of the John Rylands University Library of Manchester. Details of these regulations may be obtained from the Librarian. This page must form part of any copies made.
- iii. The ownership of any patents, designs, trademarks and any and all other intellectual property rights except for the Copyright (the “Intellectual Property Rights”) and any reproductions of copyright works, for example, graphs and tables (“Reproductions”), which may be described in this thesis, may not be owned by the author and may be owned by third parties. Such Intellectual Property Rights and Reproductions cannot and must not be made available for use without the prior written permission of the owner(s) of the relevant Intellectual Property Rights and/or Reproductions.
- iv. Further information on the conditions under which disclosure, publication and exploitation of this thesis, the Copyright and any Intellectual Property Rights and/or reproductions described in it may take place is available from the Head of School of Law (or the Vice-President) and the Dean of the Faculty of Life Sciences, for the Faculty of Life Sciences’ candidates.

----- 19th December 2012

Fionnuala Gough

ACKNOWLEDGEMENTS

The undertaking of this thesis would have not been possible without the generous support and encouragement of a large number of people. These include family and friends who did the school run when I was in Manchester and made sure the kids didn't starve while I was off pursuing this mad notion, my German translator, Suzanne Kelly, and in particular, the providers of numerous nights' accommodation in Dublin, Caroline Maher, Barry and Rory Lyons (their rates are great!)

I have been fortunate in the calibre of people I have met since starting this programme in Manchester, from the staff in the PGR office, Jackie Boardman and Mary Platt, who have always been very encouraging and helpful, to the members of the academic staff whose work I admire and who were generous enough to suffer through earlier drafts of my work. I am very grateful to Matti Hayry, Margot Brazier, Becki Bennett, John Coggon, Sheelagh McGuinness, Sören Holm, Kirsty Keywood and Charles Erin. I would also like to express my thanks to those I interviewed, without whom the empirical research aspect of my thesis would not have been possible.

I am particularly grateful to my supervisors, those who started out on this journey with me, Tuija Takala and Anne-Maree Farrell, and those who were there to see it finished, David Gurnham and Sarah Devaney, for their help. They all contributed immeasurably to this project but I owe a debt of gratitude particularly to David and Sarah for their encouragement in trying to get me to think and write in a more analytical manner, and seeing me through the 'wall' of the last few months.

The cohort structure of the BMJ PhD in Manchester encourages a great sense of community and mutual support. I am grateful for the helpful comments, friendship and fun I shared with Paul Snelling, Patrick Heavey and particularly Maria de Jesus Arellano. But without the friendship of Barry Lyons I would not have made it over to Manchester - he has held my hand to Africa and back, and over the Irish Sea. He has offered constant encouragement and is always generous with his time, cakes and spare room.

Finally, I want to thank the most important people in my life, my husband Alan Finan, and my children, Seán, Aoife, Ciara and Sorchá, for all their love and tolerance of my many shortcomings as this thesis took much of my emotional and physical energy over the last number of years that should have rightly been given to them. I promise, Sorchá, this is it!

This thesis is dedicated to my parents, Marie and Ciaran Gough, who claim I was born asking 'why' and who taught me to say 'why not', and to the memory of my brother, Dr. Christopher Gough.

THE AUTHOR

Having undertaken general medical study, I trained for a number of years in the speciality of Obstetrics and Gynaecology. Following a Masters in Medical Science (Pharmacology), I combined a research post with teaching. During this time I undertook tissue culture studies using both first and third trimester trophoblast cells. This, along with my earlier interest in assisted reproductive technologies, increased my awareness of the implications of many of the legal issues peculiar to Ireland that I have attempted to address in this thesis. In recent years I completed a LLB through the Open University, and, in undertaking the programme in Bioethics and Medical Jurisprudence in Manchester, I have tried to marry these diverse interests.

Presentations

Some parts of this thesis have been presented at academic meetings:

4th Postgraduate Bioethics and Biolaw Conference, Queen's University, Belfast, June 2009:

Embryonic Stem Cell Research in Ireland: A Case Study

Postgraduate Law Conference, University of Manchester, September 2009:

Human Embryonic Stem Cell Research in Ireland

Trinity Law Colloquium, Trinity College Dublin, February 2010:

Law v. Morality in the Irish Human Embryonic Stem Cell Debate

Centre for Research in Ethics and Bioethics Conference, Uppsala, Sweden, June 2010:

Ethical Issues in Stem Cell Research in Ireland

European Association of Centres of Medical Ethics Conference, Oslo, September 2010:

Human Embryonic Stem Cell Research in Ireland: An Empirical Study

Papers

The core of this thesis is made up of three articles; of these one has been published:

1. Gough, F (2011) Human Embryonic Stem Cell Research in Ireland: Ethical and Legal Issues *Medical Law International* (11) 4, 262-283

The second paper has been accepted for publication by *Science and Public Policy* and is forthcoming.

2. Gough, F (2012) ‘Something must be done’: A Study of Stakeholders Attitudes towards the Irish Legal Vacuum in relation to hESC Research

The third paper, *Deliberating or Dithering: Ireland and Human Embryonic Stem Cell Research*, has been submitted for consideration to the *European Journal of Health Law*

In addition, a published case commentary is also referenced in this thesis and is included in the appendix.

1. Gough, F (2010) Ireland and the Frozen Embryo: A Slight Thawing? *Medical Law Review* (18) 2 239-247

TABLE OF CASES

Irish Case Law

A, B and C v. Ireland 25579/05 [2010] ECHR 2032

Attorney General (Society for the Protection of the Unborn Child (Ireland) Ltd) v. Open Door Counselling Ltd. and Dublin Well Woman Centre Ltd [1988] IR 593

Attorney General v. X [1992] 1 IR 1

Finn v. Attorney General [1983] IR 154

G v. An Bord Uchtála [1980] IR 32

McGee v. Attorney General [1974] IR 284

MR v. TR [2006] IEHC 221, [2006] 3 IR 449

MR v. TR and Others [2006] IEHC 359

Norris v. Attorney General [1984] IR 36

Norris v. Ireland 10581/83 [1988] ECHR 142

Open Door Counselling Ltd and Dublin Well Woman Ltd v. Ireland [1993] 15 EHRR 244

Re: Article 26 and the Regulation of Information (Services outside the State for the Termination of Pregnancies) Bill, 1995 [1995] 1 IR 1 ([1995] 2 ILRM 81)

Roche v. Roche and Ors [2009] IESC 82

Ryan v. Attorney General [1965] IR 294

Society for the Protection of Unborn Children (SPUC) v. Grogan [1989] IR 734, IR 753

The State (Healy) v. Donoghue [1976] IR 325

The State (Ryan) v. Lennon [1935] IR 170, (1935) 69 ILTR 125

Other Jurisdictions

BVerfGE 39, 1 [FRG] 1975

BVerfGE 88, 203 [FRG] 1993

Evans v. The United Kingdom (Application No 6339/05), Fourth Section (7/3/06)
Grand Chamber of the ECHR (10 April 2007)

Grisewold v. Connecticut (1965) 381 U.S. 475

R v. Bourne [1939] 1 KB 687

Regina (on the application of Quintavalle) v. Secretary of State for Health [2003]
UKHL 13, [2003] 2 All ER 113

R (on the application of Smeaton) v. Secretary of State for Health [2002] 2 FLR 146;
also [2002] EWHC 610 (Admin)

Roe v. Wade (1973) 410 U.S. 113

Vo v. France (53924/00) (2004) ECHR 326

TABLE OF STATUTES

Ireland

Criminal Law Amendment Act 1935, s.17

Family Planning Act 1979

Offences Against the Person Act 1861, s.58-60

Quality and Safety of Human Tissue and Cells Regulations (S.I. No. 158 of 2006)

Regulation of Information (Services Outside the State for Termination of Pregnancies) Act 1995

Bunreacht na hÉireann

Preamble

Article 6

Article 13

Article 14

Article 26

Article 40.3.3

Article 41

Article 42

Article 43

Other Jurisdictions

Abortion Act 1967 (UK)

Embryonenschutzgesetz 1990 (Embryo Protection Act, Germany)

European Convention on Human Rights and Biomedicine 1997 (Also known as the Oviedo Convention 1997, CETS 164)

European Convention on Human Rights and Fundamental Freedoms 1950, Articles 2, 3, 8, 13 and 14

Grundgesetz 1949, Articles 1 and 5 (The German Constitution)

Health (Family Planning) Act 1979 (UK)

Human Fertilisation and Embryology Act 1990 (UK),

Human Fertilisation and Embryology Act 1990 (UK), section 13(3)

Human Fertilisation and Embryology Act (Amended) 2008 (UK)

Malicious Shooting or Stabbing Act 1803 (Also known as Lord Ellenborough's Act 1803, UK)

Stammzellgesetz 2002 (Stem Cell Law, Germany)

Treaty Establishing the European Economic Community 1957 (Also known as the Treaty of Rome 1957), Article 60 (now 50).

Treaty on European Union 1992 (Also known as the Maastricht Treaty 1992), Article 177 (now 234).

ABBREVIATIONS

AHR	Assisted Human Reproduction
ART	Assisted Reproductive Technologies
ASC	Adult Stem Cells
BBVA	Banco Bilbao Cayan Argentaris
CAHR	Commission on Assisted Human Reproduction
DNA	Deoxyribonucleic Acid
EC	European Community
ECtHR	European Court of Human Rights
EGE	European Group on Ethics in Science and Technology
END	Endodermal Cell Line
ESC	Embryonic Stem Cells
EU	European Union
hESC	Human Embryonic Stem Cell
hESCR	Human Embryonic Stem Cell Research
HFEA	Human Fertilisation and Embryology Authority
HLA	Human Leucocyte Antigen
HRB	Health Research Board
ICB	Irish Council for Bioethics
ICM	Inner Cell Mass
IMB	Irish Medicines Board
IPS	Induced Pluripotent Cells

IUD	Intra-uterine Device
IVF	<i>in vitro</i> Fertilisation
NUIG	National University of Ireland Galway
OAPA	Offences Against the Person Act
PLAC	Pro-Life Amendment Campaign
R & D	Research and Development
RKI	Robert Koch Institute
SCNT	Somatic Cell Nuclear Transfer
SFI	Science Foundation Ireland
SPUC	Society for the Protection of the Unborn Child
ST	<i>Summa Theologicae</i>
TCD	Trinity College, Dublin
TD	Teachta Dála – Dáil Deputy
UCC	University College, Cork
UK	United Kingdom
UREB	University Research Ethics Board
USA	United States of America
WMA	World Medical Association
ZES	Zentrale Ethik-Kommission für Stammzellenforschung (Central Ethics Commission of Stem Cell Research)

CHAPTER 1

1. THE PROBLEM

*‘Science will not stand still waiting for us to update our laws’*¹

Since its inception as an independent State in 1922,² Ireland has had a largely poor track record in addressing contentious issues pertaining to reproduction and sexuality; such concerns have tended to be ignored for many years until there is a swell of social pressure to initiate change either from within, as with the availability of contraceptives,³ and the eventual acknowledgement of the damage done by institutional child abuse,⁴ or external pressure is applied, for example, by European Institutions, in relation to decriminalising homosexuality.⁵ The issue of abortion, or rather the lack of its availability in Ireland, continues to demonstrate the country’s reluctance to address matters that are socially divisive.⁶ It may be more accurate to say that what happens to embryos *in vivo* has been a matter of great concern in Ireland for many years,⁷ but the development of research using stem cells derived from *in vitro* embryos more recently has revealed a lack of legal oversight. This is, however, only one of the many problems that Ireland has failed to address in the hope that they will just ‘go away’ if ignored for long enough.⁸

¹ Hardiman, J in *Roche v. Roche & Ors* [2009] IESC 82.

² Saorstát Éireann, the Irish Free State, consisting of 26 counties, and Northern Ireland, consisting of 6 counties, were established by the passing of the Government of Ireland Act on 23 December 1920. The War of Independence continued until the signing of Anglo-Irish Treaty on 6th December 1921. This treaty was carried by the Dáil on 7th January 1922, but was shortly thereafter followed by the Civil War, 1922-1923. Saorstát Éireann had formally come into being on 6th December 1922. Ireland was eventually inaugurated formally as a Republic on Easter Monday 1949, although only tenuous links had been retained with the UK since the passing of *Bunreacht na hÉireann*, the Irish Constitution, in 1937. See Keogh, D (1994) *Twentieth-Century Ireland: Nation and State* Dublin, Gill and MacMillan.

³ *McGee v. Attorney General* [1974] IR 284.

⁴ The *Report of the Commission to Inquire into Child Abuse (CICA)* (2009), also known as the ‘Ryan Report’, acknowledged that there was an awareness of extensive child abuse among Church authorities but often no action was taken against the alleged abuser, or they were just moved to a new parish and allowed to continue their activities. Available from www.childabusecommission.com/rpt/pdfs.

⁵ *Norris v. Attorney General* [1984] IR 36; *Norris v. Ireland* 10581/83 [1988] ECHR 142

⁶ *Attorney General v. X* [1992] 1 IR 1; *Society for the Protection of Unborn Children v. Grogan* [1989] IR 753; *A, B and C v. Ireland* 25579/05 [2010] ECHR 2032.

⁷ *McGee*, n above 3.

⁸ Ireland’s current economic problems have largely come about as a result of poor governance structures of the financial and banking industries due to the fact that ‘The response of supervisors to the build-up of risk was not hands-on or pre-emptive.’ This is an example of how Ireland’s failure to address societal issues outside the areas of reproduction and sexuality in a proactive manner, has

The issues raised by advances in reproductive technologies are nudging Irish society towards the prospect of being able to make use of human embryos for ends other than [simply] those of reproduction. It has become a cause of particular concern in Ireland as for many years issues around reproduction have been considered to be ‘at the heart of questions about citizenship, liberty, family and nation.’⁹ Questions are now being asked about the commodification of embryos *in vitro* and, in particular, the status afforded to these entities given that in the extraction of human embryonic stem cells nascent human life, as represented by the *in vitro* embryo, is destroyed.¹⁰

These new challenges have, of course, not just caused disquiet in Ireland; reproductive politics in fact seem to have become ‘the site of competing worldviews for the definition of both nationhood and citizenship’.¹¹ While the ‘politics of biotechnology’ has often served as ‘a theatre for observing democratic politics in motion,’¹² many countries have found it difficult to arrive at the ‘optimal balance among the competing interests and values at play in the use of reproductive and genetic technologies.’¹³ However, there are many good examples of how countries have responded in a measured way to the legal and ethical challenges posed by reproductive technologies.¹⁴ Unlike its nearest European neighbour, the United Kingdom (UK), Ireland has failed to respond at all in legislative terms to these issues. This legislative inertia continues up to the present day despite strong criticism

also led to significant problems. See Regling, K and Watson, M (2010) *A Preliminary Report on the Sources of Ireland’s Banking Crisis*. Dublin: Government Publications, p 6. Accessible at www.bankinginquiry.gov.ie.

⁹ Haraway, D (1997) *Modest_Witness@Second_Millennium.FemaleMan_Meets_OncoMouse: Feminism and Technoscience*. New York: Routledge, p 189.

¹⁰ Corkery, P (2007) Bioethics and Contemporary Irish Moral Discourse. In Fleming, A. (ed.) *Contemporary Irish Moral Discourse: Essays in Honour of Patrick Hannon*. Dublin: Columba Press, pp 26-39.

¹¹ Hanafin, P (2007) Conceiving Life in Law. In: *Conceiving Life: Reproductive Politics and the Law in Contemporary Italy*. Aldershot: Ashgate, p 1.

¹² Jasanoff, S (2005) *Designs on Nature: Science and Democracy in Europe and the United States*. New Jersey: Princeton University Press, p 6.

¹³ Robertson, JA (2004) Reproductive Technology in Germany and the United States: An Essay in Comparative Law and Bioethics. *Columbia Journal of Transnational Law* 43:189-226.

¹⁴ The United Kingdom’s Human Fertilisation and Embryology Act 1990, which established the Human Fertilisation and Embryology Authority, a regulatory body, is often cited as a ‘gold-standard’ response to the advances in reproductive technologies. See Harmon, SH (2008) Motivating Values and Regulatory Models for Emerging Technologies: Stem Cell Research Regulation in Argentina and the United Kingdom. In Freeman, M (ed.) *Law and Bioethics: Current Legal Issues (Volume 11)*. Oxford: Oxford University Press, pp 147-176.

from the Irish Supreme Court,¹⁵ and numerous promises from incumbent governments to address these problems.¹⁶ It may be regarded as yet another indictment of the ineffectiveness of the Irish political system and ‘points to one of our less endearing traits: our enthusiasm for pretence and evasion.’¹⁷ Ireland’s non-decision might ostensibly present the advantage to its politicians of avoiding the alienation of a substantial portion of public opinion.¹⁸ However, as debates about abortion and stem cell research ‘converge and diverge’,¹⁹ human embryonic stem cell research may become the issue which causes political careers to lurch ‘precariously’ and “ ‘passing the buck’ becomes the solution when the personal becomes political”,²⁰ with a non-decision harming the credibility of politicians in the eyes of an electorate that expects an official position on such controversies.²¹ HESC research could ultimately usurp the place of abortion as Ireland’s most ‘avoided’ issue. The practical implications of this avoidance behaviour for those working in the areas of assisted human reproduction (AHR) and human embryonic stem cell (hESC) research are explored in this thesis.

1.2 Overview of Thesis Structure

This thesis seeks to focus on the governance of an important emerging biotechnology, human embryonic stem cell research, in Ireland. As the overall argument to be advanced by this thesis is that embryonic stem cell research should be permitted in Ireland within strict parameters,²² this thesis will focus on the corollary of the overlap of advanced biotechnology, ethics and democratic decision making.²³

¹⁵ Judgment of Geoghegan J in *Roche v. Roche & Ors* [2009] IESC 82. ‘Since most of these problems are of an ultra-modern nature, I rather doubt that there is a constitutional solution to them, but that does not mean that there cannot and indeed should not be regulation by the Oireachtas.’

¹⁶ Minihan, M and Coulter, C (2009) Harney to propose Law on Assisted Human Reproduction *The Irish Times* Wednesday, December 16th, p 1.

¹⁷ Editorial (2009) *The Irish Examiner* Wednesday, December 16th.

¹⁸ Engel, I (2009) The Challenges of Abortion and Assisted Reproductive Technologies Policies in Europe. *Comparative European Politics* 7: 56-74, at p 57.

¹⁹ Outka, GH (2002) *The Ethics of Stem Cell Research. Presentation to The President’s Council on Bioethics*. Available from www.bioethics.georgetown.edu/pcbe/background/outka.html.

²⁰ Fox, M and Murphy, T (1992) Irish Abortions: Seeking Refuge in a Jurisprudence of Doubt and Delegation. *Journal of Law and Society* 19: 454-455.

²¹ Engel, n above 18.

²² This thesis agrees with the proposals of the Irish Council for Bioethics that embryonic research may be carried out on supernumerary embryos up to 14-days post-fertilisation, or until the appearance of the primitive streak. See Chapters 2 and 4 for more detail.

²³ Goggins, ML et al (2004) The Comparative Policy Design Perspective. In Bleiklie, I Goggin, M and Rothmayr, C (eds.) *Comparative Biomedical Policy: Governing Assisted Reproductive Technologies*. London: Routledge, p 4.

Accordingly, within this overview of the thesis structure, the first section (Chapter 1) identifies the research questions which will be raised and subsequently addressed in the thesis. Through a short review of the actual science involved in the area of stem cell research, this thesis seeks to explain why it is important that Ireland legislates to allow human embryonic stem cell research to take place. The potential benefits from this research to patients with particular disease conditions through the development of specific therapies, and possible advances in the scientific understanding of cell biology will be briefly discussed.

1.2.1 Research Questions

There are a number of themes or research questions pertinent to an exploration of the legal lacuna in Ireland in relation to hESC research which will be addressed in the body of this thesis:

- (1) The value of ‘unborn’ life in Ireland and the implications of this for hESC research;
- (2) Ireland’s lack of and need for regulation in the area of reproductive technologies;
- (3) The views of stakeholders on the significance of this lack of regulation in Ireland;
- (4) A consideration of achieving a regulatory framework through a deliberative democratic process.

These questions will initially be considered in some depth in three chapters which separately appraise aspects of the ethical (**Chapter 2**), philosophical (**Chapter 3**) and legal milieu (**Chapter 4**) which, in the Irish context, have shaped this area under examination.

1.2.2 Outline of Chapters 2, 3 and 4

Chapter 2, the ethical approach, considers the first of these research questions, the value of ‘unborn life’ in Ireland and the implication for hESC research, through an appraisal of the moral status of the human embryo, and through a description of a number of positions both for and against embryonic research. These are reviewed in order to discern how the value attached to the human embryo by a particular society

might influence policy positions in relation to hESC research in that society. Ireland's history as a traditionally Catholic country has played a major role in its approach to the human embryo and to what may or may not be done with embryos. The gradualist theory of moral status is advanced as the approach which, this thesis contends, would allow the *in vitro* embryo to continue to be valued by Irish society while still permitting its utilisation in research.

The second question addressed by this thesis is how Ireland's lack of regulation has evolved, and the consequences of this failure to keep up with scientific advances in the field of reproductive technologies. The pre-eminent role of the Constitution in Ireland means that 'bioethical issues are often considered within the constitutional law paradigm'.²⁴ Therefore, the evolution of Irish Constitutional law from natural law theory and how this has influenced constitutional law interpretation is assessed in **Chapter 3**, the philosophical approach. Moreover, how the reasoning associated with natural law has evolved into an approach to resolving difficulties in modern democracies is also discussed in this chapter. It is argued that the theory of deliberative democracy offers a mechanism for helping to develop policies in areas of bioethical controversy.

The 8th Amendment to the Irish Constitution, Article 40.3.3, is central to many of the issues discussed in this thesis. Therefore, developments in Constitutional law leading up to the insertion of Article 40.3.3 into the Irish Constitution to protect 'unborn life' are appraised in **Chapter 4**. Subsequent germane legal cases and their implications are evaluated, with particular emphasis placed on the significance of the Irish Supreme Court's judgment in the 'Frozen Embryos Case'²⁵ for the development of hESC research in Ireland.²⁶ An understanding of the background importance of both Article 40.3.3 and the 'Frozen Embryos Case' are essential for those hoping to advance arguments in favour of human embryonic research in Ireland.

²⁴ McGuinness, S and Úi Chonnachtaigh, S (2011) Implications of Recent Developments in Ireland for the Status of the Embryo. *Cambridge Quarterly of Healthcare Ethics, Special Section: Bioethics beyond Borders* 20: 396-408.

²⁵ *Roche v. Roche & Ors* [2009] IESC 82. Also referred to as *MR v. TR* or simply as *Roche*.

²⁶ This case is reviewed at some length in the case commentary Gough, F (2010) Ireland and the Frozen Embryo: A Slight Thawing? *Medical Law Review* 18: 239-247. See Appendix 1.

1.2.3 Outline of Papers 1, 2 and 3

Potential answers to the issues raised in these first three chapters will be discussed in the papers making up the nucleus of this thesis, with **Paper 1 (Chapter 6)** firstly reviewing the ethical and legal background to the *status quo* in Ireland and then considering relevant policy options. Policy options have been proposed in Ireland by the Commission on Assisted Human Reproduction (CAHR) and the Irish Council for Bioethics (ICB) favouring the use of supernumerary embryos in hESC research. This paper explains why this thesis supports these proposals. **Paper 2 (Chapter 7)** elucidates the views of relevant Irish stakeholders on the implications of the current legal lacuna in the areas of AHR and hESC research to Irish society. This exposition culminates in **Paper 3 (Chapter 8)** in which mechanisms used successfully in other European Union member states to address this issue legislatively are evaluated to determine if such stratagems might also offer a potential solution to this quandary in Ireland.

1.2.4 Conclusions

The final chapter (**Chapter 9**) reviews the arguments expounded in this thesis for allowing stem cell research in Ireland within certain well defined parameters. It appraises the contribution of ethical, legal and social factors to the extant position in Ireland regarding the permissibility or not of embryonic stem cell research.

A theme common to all three papers at the centre of this thesis has been discerned - that the present legal lacuna in Ireland with regard to stem cell research should not be allowed to continue. What Ireland needs is ‘concise regulation with clear limitations and strict sanctions for conduct that is identified as illegal or unethical’, with Irish citizens determining what that conduct may be.²⁷ The realisation of this goal is imperative as the current legal lacuna not only undermines the value of the human embryo but damages Ireland’s reputation as a country which is anxious to provide regulatory certainty, for both its present and future citizens, and for the development of its economy.

²⁷ Harmon, n above 14, at p 176.

1.3 The Importance of Stem Cell Research

Stem cell science, despite being a relatively young science, is regarded as one of the most promising emerging health technologies and a platform for regenerative medicine.²⁸ Some of the commonly asked questions about this area of research are:

- (1) What are Stem Cells?
- (2) Why are they regarded as so important?
- (3) Why is there so much controversy around embryonic stem cell research?

Stem cells are pluripotent cells; in cell biology terms they are ‘derived from totipotent cells of the early mammalian embryo’ and are capable of unlimited, undifferentiated proliferation *in vitro*.²⁹ These cells have the ability to create all three embryonic germ cell layers, the tissues that make up the human body, the endoderm, mesoderm and the ectoderm. Pluripotent cells thus are highly prized because they can ‘both renew themselves continuously in culture and, once released from this self-renewal cycle, can go on to form most mature cell types in the body.’³⁰ There are three main types of stem cells occurring naturally, adult, embryonic and umbilical stem cells. More recently, stem cells can now be produced by inducing an adult somatic cell to behave like a pluripotent cell. These are known as induced pluripotent cells or IPS.³¹

1.3.1 Examples of Stem Cells

There are a number of naturally occurring stem cells which are not usually associated with ethical controversy. These are umbilical stem cells, which are obtained from the umbilical vessels of a new-born infant, and adult stem cells (ASCs) which exist in many places in the body. Umbilical stem cells (USCs) are haemopoietic and mesenchymal precursor cells. They may be extracted from the placenta and from umbilical cord Wharton’s Jelly at birth.³² They can be stored until such times as they

²⁸ Hanafin, n above 11, at p 92.

²⁹ Thompson, JA et al (1998) Embryonic Stem Cell Lines Derived from Human Blastocysts. *Science* 282: 1145-1147, at p 1145.

³⁰ Weissman, IL (2006) Pluripotent Stem Cells. *Nature* 439 (12 January): 145-148, at p 145.

³¹ Takashi, K et al (2007) Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors. *Cell* 131: 861-872.

³² Weiss, ML et al (2006) Human Umbilical Cord Matrix Stem Cells: Preliminary Characterisation and Effect Transplantation in a Rodent model of Parkinson’s Disease. *Stem Cells* 24: 781-792.

might be needed if the donor developed a haemopoietic malignancy or used to treat a haemocompatible sibling who is already suffering from a malignancy or other immunocompromised disease.³³ They are gaining in interest as a source of stem cells as there are more primitive haemopoietic stem cells per volume in the umbilical cord than in bone marrow. Of note, there is a lower incidence of rejection after transplantation with USCs than with bone marrow transplants and perfect antigen matching between donor and recipient is not required, unlike with bone marrow transplants.³⁴

Adult stem cells are developmentally older, specialised cells whose function is to replace damaged cells and diseased tissue in the organs in which they reside.³⁵ ASCs are more restricted in which type of cells they can become than embryonic stem (ES) cells because, as they mature, they lose the ability to change, and ultimately ‘commit’ to becoming, for example, a fully mature skin cell or neuron.³⁶ It is now possible to ‘coax’ adult stem cells into becoming differentiated cells which are not usually associated with these cells, such as the development of haemopoietic stem cells from the bone marrow into neural, myogenic or hepatic cell types, and the differentiation of neural or skeletal cells into blood cells.³⁷ Although it is thought that ASCs do not have the same developmental capacity as ES cells, if used in cell replacement therapies they would have the advantage of not causing tumours to develop, which can occur with ES cells.³⁸

Another problem that may be associated with therapies derived from embryonic stem cells is the potential mismatching of the human leucocyte antigen (HLA) haplotypes between the embryonic stem cell that is the source of the therapy and the recipient patient, thus provoking immune-system rejection.³⁹ This problem could be avoided

³³ Broxmeyer, H et al (1989) Human Umbilical Cord Blood as a Potential Source of Transplantable Hematopoietic Stem/Progenitor Cells. *Proceedings of the National Academy of Sciences* 86: 3828-3832.

³⁴ Weiss, n above 32, at p 781.

³⁵ Scott, CT (2006) *Stem Cell Now: A Brief Introduction to the Coming Medical Revolution*. New York: Penguin, p 10.

³⁶ Wobus, AM and Boheler, KR (2005) Embryonic Stem Cells. *Physiological Reviews* 85: 635-678.

³⁷ *Ibid*, p 666.

³⁸ *Ibid*.

³⁹ The genetic system primarily responsible for distinguishing self from non-self in mammals is the major histocompatibility complex (MHC). The HLA complex is the MHC in humans. It is localised to a specific region on chromosome 6p. It contains genes for histocompatibility antigens, for complement and immune response genes. From Thompson, JS and Thompson, MW (1986) *Genetics in Medicine* (4th ed.) Philadelphia: W.B Saunders Company.

by using a patient's own cells. Induced pluripotent cells are derived from somatic cells such as fibroblasts. The nucleus of the somatic cell can be re-set or reprogrammed to behave like a pluripotent cell by electrical fusion or by the introduction of re-programming factors delivered by a retro virus.⁴⁰ This has the potential to allow the creation of patient- and disease-specific stem cells as these cell lines may be derived relatively easily from patients with genetic diseases.⁴¹ The development of IPS cells does not, however, mean that all ethical problems associated with stem cell research will be resolved. Research has suggested that IPS cells may be converted into cells that are similar to ES cells and have the same potential as ES cells to develop into an embryo.⁴² Therefore, the arguments used to object to hESC research might equally be applied to research using IPS cells. In addition, in the context of stem cell research, none of the strands of research currently developing using USCs, ASCs or IPS cells happens in isolation.⁴³ In reality, research involving these cells and hES cells actually only progresses 'in parallel and mutually supports one another'.⁴⁴ Researchers model IPS cells on hES cells; in order to do so with accuracy, researchers need to know a lot about hES cells. According to Devolder this means that initially at least rather than reducing the need for hESC research, it will in all likelihood encourage such research.⁴⁵

1.3.2 Human Embryonic Stem Cells

Most of the controversy associated with stem cell research is focused on research which uses embryonic stem cells. Embryonic stem cells were first isolated in 1998 by James Thomson working in the University of Wisconsin.⁴⁶ He published a three

⁴⁰ Takashi, n above 31. iPS cells are generated from adult dermal fibroblasts by the introduction of 4 transcription factors, Oct3/4, Sox2, c-Myc and Klf4. See also Takahashik, K and Yamanaka, S (2006) Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors. *Cell* 126: 663-676.

⁴¹ Narsinh, KH, Plews, J and Wu, JC (2011) Comparison of Human Induced Pluripotent and Embryonic Stem Cells: Fraternal or Identical Twins? *Molecular Therapy* 19(4): 635-638; and Takashi, n above 31, at p 861.

⁴² Skene, L (2012) Legal Regulation of Human Stem Cells. In Quigley, M, Chan, S and Harris, J (eds.) *Stem Cells: New Frontiers in Science and Ethics*. Singapore: World Scientific Publishing, pp 85-105. Also Devolder, K (2009) To Be or Not to Be? *EMBO Reports* 10(12): 1285-1287.

⁴³ Quigley, M (2012) Stem Cell Therapies and Benefitting from the Fruits of Banned Research. In Quigley, M, Chan, S and Harris, J (eds.) *Stem Cells: New Frontiers in Science and Ethics*. Singapore: World Scientific Publishing, pp 163-185.

⁴⁴ Devolder, K (2010) Complicity in Stem Cell Research: The Case of Induced Pluripotent Stem Cells. *Human Reproduction*, 25(9): 2175-2180, at p 2178.

⁴⁵ Ibid, at pp 2177-78.

⁴⁶ Thompson, n above 29.

page paper in the journal *Science* which explained how he had succeeded in isolating human embryonic stem cells from donated ‘spare’ embryos, that is, embryos superfluous to reproductive needs, which had been produced during *in vitro* fertilisation cycles. Both fresh and frozen material may be used to produce these stem cells. Thomson briefly, almost casually, suggested some uses to which these cells might be put:

‘Human ES cells will be particularly valuable for the study of the development and function of tissues that differ between mice and humans. Screens based on the *in vitro* differentiation of human ES cells to specific lineages could identify gene targets for new drugs, genes that could be used for tissue regeneration therapies and teratogenic or toxic compounds.’⁴⁷

The potential implications of this research were, however, quickly identified by others. According to Christopher Scott, the director of Stanford University’s ‘Stem Cells and Society’ programme at Stanford’s centre for biomedical ethics:

‘The scientific and medical implications contained in this short paper are profound and unambiguous. Embryonic stem cells could be used to generate new tissue and organs for transplantation. Defective and dying tissues caused by diseases such as Parkinson’s or diabetes could be replaced with an unlimited supply of specially grown stem cells. Cultures of human stem cells could be used as laboratory tools to help identify new drugs and therapies. For pure scientists like Thomson, observing stem cells in the laboratory could provide insights into how all animals embark on the magnificent developmental process that begins with a single cell’.⁴⁸

Most of the controversy around human embryonic stem cells comes from the way in which they are derived. When an oocyte is fertilised it becomes a zygote and undergoes cleavage or successive division to become a 2-celled, 4-celled, 8-celled etc. cluster of cells known as a morula (from the Greek for mulberry). When the morula contains 50-60 cells a cavity forms in the centre; it is now known as a

⁴⁷ Ibid, at p 1146.

⁴⁸ Scott, n above 35, at pp 3-4.

blastocyst. At this stage the embryo consists of two types of cells: an outer superficial layer (the trophoblast) that surrounds a small inner group of cells called the inner cell mass (ICM). It is the cells of the inner cell mass which give rise to the embryo proper as well as a number of extra-embryonic structures, whereas the cells of the trophoblast form only extra-embryonic structures, including the outer layers of the placenta.⁴⁹

To produce embryonic stem cells embryos are cultured to the blastocyst stage in an appropriate medium. The ICM is isolated by disrupting the zona pellicuda digestively using pronase. Subsequent treatment with mouse antibodies directed against human trophoectoderm lyses the cells by an antibody/complement action and leaves the inner cell mass mostly intact.⁵⁰ This is now dissected out manually and placed in an appropriate culture medium.⁵¹ After this procedure has taken place the blastocyst is no longer viable.

The quality of the blastocyst is an important factor for the successful derivation of hES cell lines, with higher quality embryos more often establishing thriving cell lines than those graded as low quality.⁵² If the culture has been well conducted there are similar rates for the successful derivation of cell lines from cryopreserved embryos as from fresh embryos.

1.3.3 Stem Cell Research Applications

The recognised ability of hES cells to differentiate into almost any specialised cell type which is present in an adult human is one of the main reasons for the great interest in these cells. It is possible to 'guide' these cells to develop into particular cells of interest clinically such as cardiomyocytes.⁵³ This is accomplished by culturing the cells under conditions that lack the appropriate components for them to maintain pluripotency. In order to induce hES cells to differentiate into

⁴⁹ Carlson, BM (1999) *Human Embryology and Developmental Biology*. St. Louis: Mosby, pp 38-74.

⁵⁰ Englund, MC, Sartipy, P and Hyllner, J (2011) Human Embryonic Stem Cell. In Steinhoff, G (ed.) *Regenerative Medicine: From Protocol to Patient*. Dordrecht: Springer, pp 169-186, at p 171.

⁵¹ hESC colonies are cultured in foetal calf serum with supporting feeder cells, which are usually mitotically inactive mouse embryonic fibroblasts; these provide support in terms of conditioning of the culture medium, surface matrix components and other direct cell-to-cell interactions. See Englund, n above 50, at p 174.

⁵² Englund, n above 50, at p 171.

⁵³ Ibid, at p 179. Cardiomyocytes are heart muscle cells which can be damaged due to ischaemia following interruption of blood supply and hence of oxygen, resulting in oxygen deprivation.

cardiomyocytes a variety of growth factors are used, or the hES cells may be co-cultured with a visceral endoderm mouse cell line (END-2) where they are directly exposed to growth factors from the END-2 cells. Markers which characterise cardiomyocytes, such as structural proteins, ion-channels and junction proteins have subsequently been identified on the hES cells.⁵⁴ If this direct differentiation of hES cells towards cardiomyocytes could be made sufficiently efficient, it may prove to be an excellent model for developing the understanding of the processes involved in the commitment of mesoderm or endoderm cells to becoming cardiomyocytes, and in so doing, may help to identify some of the genes associated with abnormal development of the human heart.⁵⁵ In addition, pre-clinical studies have begun which are investigating hES cell-based heart regeneration.⁵⁶

Another of the great hopes of hESC research is that a number of specific clinical problems such as Parkinson's disease or type-1 diabetes might be targeted. Parkinson's disease is associated with degeneration of the dopamine-containing neurons of the nigro-striatum, producing symptoms of bradykinesia (poverty of movement), tremor and postural instability. These symptoms are currently relieved by the oral administration of dopamine receptor agonists and L-dopa.⁵⁷ Relief is often short-lived and associated with side effects. The transplantation of dopaminergic neurons developed from ESCs could provide long term relief from symptoms and could counteract the progression of the disease.⁵⁸ In the case of diabetes, the diabetic patient could receive functional beta-pancreatic islet cells derived from embryonic stem cells which would integrate with the cells of the pancreatic islets and help normalise blood glucose levels.⁵⁹

HESCs are also being promoted as having the potential to contribute to the development of tissue models for testing new drugs. They will allow the testing *in*

⁵⁴ Beqqali, A et al (2006) Genome-wide transcriptional profiling of human embryonic stem cells differentiating to cardiomyocytes. *Stem Cells* 24: 1956-1967.

⁵⁵ Ibid, at p 1957.

⁵⁶ Caspi, O et al (2007) Transplantation of Human Embryonic stem cell-derived cardiomyocytes improves myocardial performance in infarcted rat hearts. *J Am Coll Cardiol* 50 (19):1884-1893. Also Condorelli, G and Catalucci, D (2007) Human Stem Cells for Heart Failure Treatment. *J Am Coll Cardiol* 50: 1894-1895.

⁵⁷ L-Dopa is L 3,4-dihydroxyphenylalanine which is a precursor to the neurotransmitters dopamine, noradrenaline and adrenaline. It acts in the brain to relieve the symptoms of Parkinson's disease.

⁵⁸ Lindvall, O and Kokaia, Z (2006) Stem Cells for the Treatment of Neurological Disorders. *Nature* 441: 1094-1096.

⁵⁹ Englund, n above 50, at p 178.

vitro of novel drugs for safety or potential toxicity in humans, thereby improving the prediction of organ toxicity and reducing animal testing in pharmacotoxicology.⁶⁰ It will be important in the development of safe and accurate drug assays and toxicity tests that there is sufficient diversity in the hES cell lines used as some compounds are metabolised at different rates by different ethnic groups or even by individuals from similar ethnic backgrounds.⁶¹

One of the major challenges facing scientists in this rapidly growing field will be the development of appropriate *in vitro* culture conditions which help elucidate and optimise the regenerative potential of these cultured stem cells. Continued studies of both embryonic and adult stem cell biology will contribute to this understanding.⁶² This in turn will allow the transformation of stem cell research from the current development phase to a stage ‘where therapeutic and industrial applications begin to be tangible’.⁶³ At the moment there needs to be an acknowledgement that although regenerative medicine using stem cells is ‘an exciting prospect’ the field needs ‘time to mature’.⁶⁴ To achieve this it will be essential that an appropriate regulatory environment exists to oversee the use of stem cells in both clinical situations and in drug safety assessment to allow the safe development of innovative treatments. Such an environment may be cultivated by the development of appropriate policies to provide certainty to those working in the field and to future patients.

1.3.4 Conclusion

It seems that it is ‘now possible to develop a road map defining the necessary scientific and clinical advances required for stem cells to reach the clinic.’⁶⁵ However, it must be acknowledged that the clinical usefulness of stem cells will be determined by their ability to provide patients with safe, long lasting and substantial improvements in their quality of life.⁶⁶ In light of the potential stem cell research offers to treat many of today’s chronic, debilitating diseases it would seem logical that research using different types of stem cells should continue ‘in parallel’ and

⁶⁰ Wobus, n above 36, at p 658.

⁶¹ Englund, n above 50, at p 182.

⁶² Wobus, n above 36, at p 668.

⁶³ Englund, n above 50, at p 181.

⁶⁴ Bared, Y (2009) Caution Urged in Trial of Stem Cells to Treat Spinal Cord Injury. *Nature* 458: 29.

⁶⁵ Lindvall, n above 58, at p 1096.

⁶⁶ *Ibid.*

being ‘mutually supportive’ in order to achieve its full potential. It is, therefore, a scientific imperative that all the different types of stem cell lines are available for scientist to work on as it is likely that different cell lines will ultimately be best suited for different applications.⁶⁷

⁶⁷ Wobus, n above 36, at p 637.

CHAPTER 2

2. THE ETHICAL APPROACH

2.1. Introduction

Since publication of the report by Thomson of the first successful *in vitro* cultivation of human embryonic stem cell lines in 1998 and the recognition of the potential for a range of new cell based therapies, there has been intense debate in many countries on the legal and ethical implications of such research.¹ Although adult-derived stem cells may have important potential applications in the treatment of neurological diseases such as Huntington's Chorea,² currently the most promising source of stem cells is the early blastocyst-stage embryo, or embryonic germ cells which are derived from the gonadal ridge and mesenteries of aborted fetuses.³

The burgeoning impact of biomedical research on the treatment of degenerative diseases in particular has become apparent in the last ten years, and if this potential is even only partially fulfilled, it will be of great benefit to mankind. In his foreword to the Indian Council of Medical Research's '*Ethical Guidelines for Biomedical Research on Human Subjects*' Justice M.N. Venkatachaliah expressed concern as to how this potential would be managed:

'Biomedical research is perched on the threshold of a bold and brave new world. Crucial to its management is the ability of scientists and the society to handle these forces of change. Correspondingly, as in all frontier researches, our ignorance of the areas of the yet unknown might, paradoxically, expand with the expansion of our knowledge. Biomedical research has acquired dimensions which are at once exciting and awesome. It raises some delicate and difficult questions which need to be [addressed] with

¹ Thomson, JA et al (1998) Embryonic Stem Cell Lines Derived from Human Blastocysts. *Science* 282: 1145-1147.

² Huntington's Chorea is an inherited neurodegenerative disorder of autosomal dominant penetration associated with progressive cell loss and atrophy predominantly in the striatum and neocortex. It results in both physically and psychologically debilitating symptoms. See Dunnett, SB and Rosser, AE (2004) Cell Therapy in Huntington's Disease. *Journal of the American Society for Experimental Neurotherapeutics* 1: 394-405.

³ Schenker, JG (2003) Ethical Aspects of Advanced Reproductive Technologies. *Annals of New York Academy of Sciences* 997: 11-21, at p 13.

sensitivity to human values and with great circumspection. While research which promises to mankind the great blessings of science should not be stifled by too restrictive an approach, however, great care should be taken to ensure that something does not go out of hand. Therefore any system of ethical guidelines on research needs to be cognisant of, and informed by, a sensitive balance of the risks and benefits.’⁴

These important issues around biomedical research need to be acknowledged and addressed by all societies.

In their document ‘Ethical Principles for Medical Research involving Human Subjects’ the World Medical Association (WMA) produced the first universal statement about ethics and research. It was adopted as the basis of ‘*The Helsinki Declaration*’ in 1964. It stated that:

‘In medical research involving human subjects, the well-being of the individual research subject must take precedent over all other interests.’⁵

The Helsinki declaration noted that this principle must apply to all human beings, and that ‘some research populations’, including those who cannot give consent for themselves ‘need special protection’. Although, currently the number of clinical applications of stem cell research is limited,⁶ this is likely to change in the next decade. It is important, therefore, to ensure that the position endorsed by the Helsinki Declaration is applied as rigorously to stem cell research as to any other form of

⁴ Indian Council of Medical Research New Delhi (2000) *Ethical Guidelines for Biomedical Research on Human Subjects*. Foreword by Justice MN Venkatachaliah, p 1. Available at www.scribd.com/doc/7218924/ICMR-Ethical-Guidelines-India. (Accessed on 14/05/12).

⁵ World Medical Association *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. A. Introduction. No.6. In the 2000 version of this statement the WMA said that ‘In medical research on human subjects, considerations related to the well-being of the human subject should take precedent over the interests of science and society’. Available at www.wma.net/en/20activities/10ethics/10helsinki. (Accessed on 14/05/12).

⁶ There are a small number of trials currently on-going involving stem cells, for example in the treatment of retinal disease, see Vogel, G (2011) UK Approves Europe’s First Embryonic Stem Cell Clinical Trial. *Science Insider* September 22nd. Available at <http://news.sciencemag.org/scienceinsider/2011/09/uk-approves-europes-first-embryo>. This is a clinical trial for the treatment of Stargardt’s Macular Dystrophy using retinal pigment epithelium derived from human embryonic stem cells, a leading cause of retinal juvenile blindness, and spinal cord injuries. See Illes, J, Raimor, JC and Kwon, BK (2011) Stem Cell Clinical Trials for Spinal Cord Injury: Readiness, Reluctance, Redefinition. *Stem Cell Review and Reports* 7: 997-1005.

clinical research. The World Medical Association reiterated this principle at the 59th General Assembly in Seoul in 2008.

2.1.1 Europe's Position on hESC Research

Within Europe, a report issued by the European Commission in 2003 contained the *Opinion of the European Group on Ethics* (EGE), first published in 1998, in which the EGE tried to identify a 'set of fundamental ethical principles' applicable to human embryonic stem cell research (hESC research).

These proposals included the:

‘...principle of respect for human dignity, the principle of individual autonomy, justice and beneficence, freedom of research and proportionality’.

However, overall in the report the Commission commented that:

‘...opinions on the legitimacy of experiments using human embryos are divided according to the different ethical, philosophical and religious traditions in which they are rooted.’

The EGE continued that:

‘...the diversity in policies and regulations concerning embryo research in the Member States of the EU reflects fundamentally differing views.....and it is difficult to see how, at these extremes, the differences can be reconciled’.

Consequently, the range of legislative responses in Europe varies from the liberal positions of the UK, Belgium and Sweden,⁷ where the creation of embryos is allowed for research purposes, to the intermediate position of France and Denmark, where stem cell research is allowed on supernumerary embryos under certain conditions, to the restrictive positions of Germany, Austria, Poland and Lithuania where the

⁷ For overview of different regulatory positions in Europe see Isasi, RM and Knoppers, BM (2006) *Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries. European Journal of Health Law* 13 (1): 9-25; and Halliday, S (2004) *A Comparative Approach to the Regulation of Human Embryonic Stem Cell Research in Europe. Medical Law Review* 12: 40-69.

procurement of embryonic stem cells is prohibited even from supernumerary embryos, although Germany allows the importation of stem cell lines developed in other countries.⁸

An attempt to formulate an ethical framework for stem cell research in the European Union, EUROSTEM, proposed that to prevent the task of drafting ethical principles from foundering on the radically different attitudes taken to the question of the moral status of the embryo, the scope of principles should be concentrated on.⁹ By so doing the ‘hope and intention’ of Eurostem was to produce an ethical framework that would be:

‘...as applicable to jurisdictions which, for example, might permit research only on adult stem cells, or permit only non-destructive research on embryonic cells, as it is to those which permit such research only on cell lines created before a specified date, or, as in the UK, on cells from embryos before 14 days development’.

They acknowledged that:

‘...the moral status or degrees of protection to be accorded to the embryo is constituted linguistically, culturally, scientifically, politically and through religious and secular beliefs’.

They also acknowledged that disagreements over the moral status of the human embryo are often framed in terms of human rights and human dignity’, as such ideas ‘command almost universal respect’, but the scope of such principles – the class of individuals covered and the nature of the protections afforded to them – provokes disagreement.¹⁰ More recently the European Court of Justice has attempted to move

⁸ Takala, T and Hayry, M (2007) Benefiting from Past Wrongdoing, Human Embryonic Stem Cell Lines and the Fragility of the German Legal Position. *Bioethics* 21: 150-159, at p150; and Harris, J Bortolotti, L and Irving, L (2005) An Ethical Framework for Stem Cell Research in the European Union. *Health Care Analysis* 13 (3): 157-162, at p 158.

⁹ European Consortium for Stem Cell Research (EuroStemCell) (2006) *Regulations in EU Member States Regarding hES Cell Research*. Available at: www.eurostemcell.org/Documents/Outreach/stemcell_hesc_regulations_2006feb.pdf

¹⁰ Harris, n above 7, at p 158.

away from the moral status argument by adopting the approach of defining embryos in accordance with their capacity to one day become ‘beings’.¹¹

2.1.2 Irish Position in Relation to ART and hECS Research

Despite *in vitro* fertilisation (IVF) having been practised in Ireland since 1987 there is currently no Irish legislative framework regulating assisted human reproduction or research involving either human embryos and either human adult or embryonic stem cells, with Assisted Reproductive Technologies (ART) clinics generally operating under the guidelines of the Irish Medical Council as set out in its *Guide to Professional Conduct and Ethics for Registered Medical Practitioners*.¹² These guidelines, however, are relatively scant when compared to the regulations available in other European countries, such as those contained within the United Kingdom’s Human Fertilisation and Embryology Act,¹³ and do not provide adequate direction for the regulation of ART clinics or in relation to hESC research.¹⁴ They simply advise doctors of their duty not to participate in ‘creating new life forms solely for experimental purposes’ and that they should not ‘engage in human reproductive cloning.’¹⁵

In March 2000 the Commission on Assisted Human Reproduction (CAHR) was set up by the then Minister for Health and Children, Micheál Martin, to prepare a report on:

¹¹ In the case of *Brüstle v. Greenpeace* (C-34/10) (2010/C 100/29) the German Bundesgerichtshof had sought clarification from the ECJ as to the meaning of the word ‘embryo’ for the purposes of EU directive 98/44/EC which relates to patenting. See McGuinness, S (2012) The Construction of the Embryo and Implications for Law. In Quigley, M Chan, S and Harris, J (eds.) *Stem Cells: New Frontiers in Science and Ethics*. Singapore: World Scientific Publishing, pp 51-83, at p 71. The European Court of Justice ruled that ‘all processes that necessitate the destruction of embryos or their use as base material’ are excluded from patent protection. See Holmes, D (2011) Sound and Fury after Stem Cell Ruling. *Lancet* 378 (9803): 1617.

¹² Medical Council of Ireland (2009) *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (7th ed.). Available at <http://www.medicalcouncil.ie>. (Accessed 14/05/12).

¹³ Human Fertilisation and Embryology Act 1990 (as amended 2008) Available at www.hfea.gov.uk/134.html.

¹⁴ Medical Council of Ireland, n above 12, at 20.2: ‘Assisted reproduction services should only be provided by suitably qualified professionals, in appropriate facilities and according to international best practice. Regular clinic audit and follow-up of outcomes should be the norm’.

¹⁵ *Ibid*, at pp 20-21.

‘...the possible approaches to the regulation of all aspects of assisted reproduction and the social, ethical and legal factors to be taken into account in determining public policy in the area.’¹⁶

The CAHR published a report after 5 years of deliberation in 2005 in which the dilemma of the generation of human embryos which are not used for their intended purpose was identified, and it acknowledged that this forces society:

‘...to face the question whether, for the first time in the history of mankind, human embryos may be used for purposes other than human reproduction.’¹⁷

As the remit of the CAHR report was primarily to guide policy in the area of ART, it did not extensively explore why in evaluating hESC research the ‘moral judgments about it widely collide’,¹⁸ but gave a synopsis of the general arguments for and against before ultimately recommending that hESC research be permitted in Ireland on supernumerary or surplus embryos.¹⁹

The opinion of the Irish Council on Bioethics (ICB) provided a more comprehensive overview of the background to the current debate about the generation and use of embryos and stem cells in research, and of the ethical issues central to these debates.²⁰ It acknowledged that:

‘societal attitudes in relation to these questions vary greatly, with some people fundamentally opposed to research involving nascent human life, while others take the view that research on human embryos offer a legitimate opportunity to garner new scientific and medical knowledge’.²¹

¹⁶ CAHR (2005) *Report of the Commission on Assisted Human Reproduction*. Dublin: Government Publications, p x.

¹⁷ Ibid, p v.

¹⁸ Outka, G (2002) *The Ethics of Stem Cell Research: A Paper presented to The President's Council on Bioethics*. Available at <http://bioethics.georgetown.edu/pcbe/background/outka.html>.

¹⁹ CAHR, n above 16, at p 58. Recommendation 34 states that:

‘The Commission recommends that embryo research, including embryonic stem cell research for specific purposes only and under stringently controlled conditions should be permitted on surplus embryos that are donated specifically for research. This should be permitted for up to 14 days following fertilisation’. (For more detail on this report see Chapter 4 (Legal Approach) of this thesis).

²⁰ Irish Council for Bioethics (2008) *Ethical, Scientific and Legal Issues Concerning Stem Cell Research*. Dublin: ICB. Available at www.ICB.ie. (See also Chapter 4 of this thesis).

²¹ Ibid, p ii.

Having reflected on the arguments for and against hESC research being allowed to proceed in Ireland, the ICB stated that:

‘On consideration of the various arguments relating to the moral status of the embryo, the Council adopts a gradualist position, granting significant moral value rather than full moral status to human embryos. The moral value they are seen to possess is based on the recognition of their potential to develop into persons, as well as the value they derive from representing human life at its earliest stages.’²²

The ethical background leading to this conclusion drawn by the Council, and consequently their recommendations for embryonic stem cell research in Ireland will be examined in this chapter as, this thesis contends, an acceptance of the conclusion of the ICB by Irish society would allow the *in vitro* embryo to continue to be valued in Ireland while still permitting its utilisation in research.

2.2. The Moral Status of the Embryo

In the many debates on the moral legitimacy of research using pluripotent stem cells the focus has usually been on two moral concerns: the moral status of human embryos, and the potential harms to the women from whom the ova are obtained to create these embryos.²³ As the issue of donor ‘harm’ is not one which this thesis will attempt to address, the first issue to be addressed in examining the ethical perspectives in embryo and stem cell research is the moral value or status of the *in vitro* human embryo. Stem cell research raises this question because, in the process of generating stem cells, the embryo providing them is destroyed.

The extremes of opinions relating to this problem are not particular to Ireland but in a country where it has been demonstrated that ‘the degree of [moral] value attached to embryos is strong’, if Ireland is ultimately to permit hESC research, its rationale for

²² Ibid, p 41.

²³ Master, Z and Crozier, GKD (2012) The Ethics of Moral Compromise for Stem Cell Research Policy. *Health Care Analysis* 20: 50-65, at p 51.

allowing such research, in which a highly valued entity is destroyed, must be morally defensible.²⁴

The status of the human embryo has continually changed throughout history in response to transformations of cultural values and the acquisition of scientific knowledge.²⁵ The major monotheistic religions, Judaism, Islam, and Christianity, hold differing positions regarding the moral status of the human embryo.

Despite an acknowledged diversity of opinion within Judaism, the majority opinion holds that the Halakah's position on the moral status of the embryo is that no significant moral status is assigned to the embryo until 40 days after fertilisation. Until this time it is considered as 'mere water'.²⁶ A foetus' moral position then develops gradually throughout a pregnancy until birth.²⁷ Within Islam, although human life is considered valuable and deserving of protection, the attainment of personhood is not considered to occur until the body and soul subsist together.²⁸ This ensoulment is thought to occur after the first trimester.²⁹ Few rights and little protection are afforded to the pre-implantation embryo within the Islamic tradition.

Within Christianity, Protestantism and Catholicism demonstrate a different emphasis on the moral status of the embryo. The Church of Ireland (Anglican) acknowledges the embryo as a potential human being with some rights assigned from the moment of fertilisation. The Anglican position distinguishes morally between the adult human being and the embryo, that is, between actually 'being' in existence and the 'potential' to exist.³⁰

²⁴ Holm, S (2002) Going to the Roots of the Stem Cell Controversy. *Bioethics* 16: 493-507, at p 49.

²⁵ Lenoir, N (2000) Europe Confronts the Embryonic Stem Cells Research Challenge. *Science* 287 (5457) at p 1425.

²⁶ Kerridge, IH et al (2009) Religious Perspectives on Embryo Donation and Research. *Clinical Ethics* 5: 35-45.

²⁷ Simonstein, F (2008) Embryonic Stem Cells: the Disagreement Debate and Embryonic Stem Cell Research in Israel. *Journal of Medical Ethics* 34: 732-734.

²⁸ Askoy, S (2005) Making Regulations and Drawing up Legislation in Islamic Countries under conditions of Uncertainty, with Special Reference to Embryonic Cell Research. *Journal of Medical Ethics* 31: 399-403.

²⁹ Ibid.

³⁰ Church of Ireland General Synod Church in Society Committee, Medical Ethics, Science and Technology Sub-Committee. *Submission to the Irish Council for Bioethics – November 2006. Stem Cell Research*. Available at: <http://www.Ireland.anglican.org/index.php?do=information&id=20>.

2.2.1 Human Dignity

In the view of the Catholic Church, human life must be respected as having intrinsic dignity before birth in order to have it after birth.³¹ The notion of human dignity, as first defined by Kant as equal respect for all persons based on their capacity for rational autonomy, is a difficult concept which may be employed by both sides in the embryo and stem cell research debate. According to Plomer, Kant, in expressing the principle that persons should never be treated as a means to an end only, but as an end in themselves, reasoned that since:

‘...persons have the capacity to reason and therefore make autonomous choices and determine their own ends, to treat persons as a means to an end only is to negate a person’s very essence and dignity’.³²

It may be rationalised since it is the capacity to reason and make autonomous choices that is the source of human dignity and not membership of the human species, a human embryo, which lacks this capacity is not endowed with human dignity.³³

Neo-Kantists claim that human dignity as the basis of rights is constituted by the property of being an ‘agent’ but they do not provide any reason to ascribe human dignity to embryos as they do not regard the human embryo as an agent. Therefore it follows that the destruction of an embryo does not violate its dignity.³⁴

A more radical view of this position is advocated by Robertson who claims that:

‘The attribution of moral status depends upon at least the presence of a nervous system, if not also sentience, and not just its precursor cells.... No moral duties are owed to embryos by virtue of their present status and ... they are not harmed by

³¹ Congregation for the Doctrine of the Faith (2008) *Dignitas Personae: On Certain Bioethical Questions*, para 1. Available at http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html.

³² Plomer, A (2005) *The Law of Ethics Of Medical Research: International Bioethics and Human Rights*. London: Cavendish, at p 70.

³³ Boyle, J (1991) The Roman Catholic Tradition and Bioethics. In Brody BA (ed.) *Bioethics Yearbook Vol. 1: Theological Developments in Bioethics, 1988-1990*. Dordrecht: Kluwer Academic Publishers, pp 5-21.

³⁴ Ibid.

research or destruction when no transfer to the uterus is planned'.³⁵

While the objections of opponents of embryo research are intended to reflect their understanding of 'human dignity' and the 'right to life', it is apparent that within this group there actually exist quite fundamental philosophical differences about the ethical nature and scope of the principles of respect for human dignity and right to life as they apply to the use of human embryos.³⁶ Brownsword describes this group as the 'dignitarian alliance', claiming them as 'dignitarian' because their

'...fundamental commitment is to the principle that human dignity should not be compromised; and I say that it is an alliance because there are more than one pathway to this ethic – Kantian and communitarian as well as religious'.³⁷

Expressing the dignitarian perspective in communitarian terms, Brownsword argues that human dignity could be said to be:

'...a good which must not be compromised and that any action or practice that compromises the good is unethical irrespective of the welfare-maximising consequences (contrary to utilitarianism) and regardless of the autonomy rights or informed consent of the participants (contrary to human rights thinking).'³⁸

Assigning moral value to embryos does not, however, outrule their use, as according to Holm it:

'...can be argued that the likely benefits in terms of reduction of human suffering and death in many cases outweigh the sacrifice of a (small) number of human embryos'.³⁹

McGee and Caplan in arguing that:

³⁵ Robertson, J (1999) Ethics and policy in ESCR. *Kennedy Institute of Ethics Journal* 9:109-136.

³⁶ Boyle, n above 33, at p 7.

³⁷ Brownsword, R (2004) Regulating Human Genetics: New Dilemmas for a New Millennium. *Medical Law Review* 12: 14-39, at p 20.

³⁸ Ibid.

³⁹ Holm, n above 24, at p 498.

‘...the destruction of embryonic life, whatever its moral status, would take place only under the most scrupulous conditions and for the best communal reasons’,⁴⁰

assert that:

‘...both the Western ethic of rescue and the practical structure of contemporary health care and other social institutions make it clear that among the deepest moral habits of human life is that of compassion for the sick and vulnerable’.

Therefore, they claim that as stem cell research is compelled by a ‘moral imperative,’ it effectively is ‘...a pursuit of known and important moral goods’.⁴¹ This is similar to Robertson’s argument. He asserts that it is not necessary to attribute basic human worth to pre-implantation embryos as they are:

‘...too rudimentary in structure or development to have moral status or interests in their own right.’⁴²

He does, however, propose that:

‘...the intrinsic value of embryos can be denied whilst still according ‘symbolic value’ to them and ‘special respect’ because of their potential, when placed in a uterus to become a foetus and eventually to be born.’⁴³

This symbolic value may, however, be trumped when necessary to pursue a legitimate scientific or medical end that cannot be pursued by other means.⁴⁴

This question of the value of an embryo is one which the Irish legislature is not addressing, by failing to offer a definition in Irish law of the pre-implantation embryos and in so doing affords little respect to them. This failure may in part

⁴⁰ McGee, G and Caplan, A (1999) The Ethics and Politics of Small Sacrifices in Stem Cell Research. *Kennedy Institute of Ethics Journal* 9: 151-158, at p 152.

⁴¹ Ibid. See also Holm, n above 24, at p 497.

⁴² Robertson, n above 34.

⁴³ Ibid, p 115.

⁴⁴ Outka, n above 18.

be due to Ireland's historical Catholic legacy. The implications of this to those working in the area of hESC research are discussed in Paper 2.

2.2.2 Religious Tradition in Ireland

The Catholic Church has historically defended the sanctity and dignity of human life,⁴⁵ arguing that it should be revered and protected from the beginning of its existence life as,

‘...human corporeality begins at the very moment of conception’.⁴⁶

Ireland is a country which has a strong Catholic tradition. Indeed, *Bunreacht na hÉireann*, the Constitution of Ireland, drawn up in 1937, initially acknowledged the special position of the Catholic Church in the life of the country. Any future legislative framework for embryo and stem cell research in Ireland would have to take the impact of this tradition on the national mores into consideration.

In debates about the protection of the embryo, documents of the Catholic Church such as ‘Instruction on Respect for Human Life in its origins and on the Dignity of Procreation’ or *Donum Vitae* emphasise that from the beginning humans are the image of God and thus carriers of dignity before God, that is, of personhood. The Congregation for the Doctrine of the Faith argues that:

‘...to use human embryos or foetuses as the object or instrument of experimentation constitutes a crime against their dignity as human beings having a right to the same respect that is due to the child already born and to every human person’.⁴⁷

In addition they advocate that:

⁴⁵ Corkery, P (2010) *Bioethics and the Catholic Moral Tradition*. Dublin: Veritas Publications, pp 41-58.

⁴⁶ Lucas, R (1997) The Anthropological Status of the Human Embryo. In De Dios Vial Correa, J and Sgreccia, E (eds.) *Identity and Statute of the Human Embryo. Proceedings of the Third Assembly of the Pontifical Academy for Life*. Vatican: Liberia Editrice Vaticana, pp 178-205.

⁴⁷ Congregation for the Doctrine of the Faith (1987) *Donum Vitae: Respect for Human Life*, Chapter 1. Available at <http://www.vatican.va/roman/curia/congregations/cfaith/documents; Dignitas Persona>, n above 31, First Part: Anthropological, Theological and Ethical Aspects of Human Life and Procreation.

‘...every human being is to be respected for himself and cannot be reduced in worth to a pure and simple instrument for the advantage of others’.⁴⁸

In both *Donum vitae* and *Dignitas personae*, despite the acknowledgment that personhood is a difficult and complex question,⁴⁹ the Church confirmed its position by arguing that an embryo has the same intrinsic value as a fully developed human being and that it:

‘...is to be respected and treated as a person from the moment of conception; and therefore from that same moment its rights as a person must be recognized, among which in the first place is the inviolable right of every innocent human being to life’.⁵⁰

Proponents of this view claim that the Church’s position is not based:

‘...solely on Church doctrine but also on specific interpretation of the empirical observation of human development’,⁵¹

but it is the Church’s interpretation of the biology of early human development that is foundational in its current stand against embryo research. Richard Doerflinger, of the President’s Commission for the Study of Bioethical Issues, defending the Catholic Church’s position, maintains that each human being has a basic and equal human worth and, taking this evaluation to its logical conclusions means that no one should be treated as a means or an instrument:

‘the human individual, called into existence by God and made in the divine image and likeness ... must always be treated as an end in himself or herself, not merely as a means to other ends’.⁵²

⁴⁸ Boyle, n above 33, at pp 6-7.

⁴⁹ *Dignitas Persona*, n above 31.

⁵⁰ Ibid, Second Part: New Problems concerning Procreation, at para 15.

⁵¹ Lee, P and George, R (2001) Reason, Science and Stem cells: Why Killing Human Beings is Wrong. *National Review Online* 20th July. Available at <http://old.nationalreview.com/comment/comment-george072001.shtml>.

⁵² Doerflinger, RM (1999) The Ethics of Funding Stem Cell Research: A Catholic Viewpoint. *Kennedy Institute of Ethics Journal* 9: 137-150, at p138.

Doerflinger forcefully argues that to do so infers inviolability, and that the destruction of embryos as merely a means to another end goes against inviolability. Other writers argue that even the very early human embryo should be respected as a person as the 'indefeasible presumption' exists that 'personal existence begins at conception'.⁵³ According to Boyle this is a presumption because it is:

'...not possible to establish when the human soul is present',

and it is indefeasible:

'...because no further scientific or philosophical evidence could establish that the human individual which begins at conception is not personal'.⁵⁴

Therefore, in the view of the Roman Catholic Church, embryos should be afforded the same moral status as any adult, that is, full moral status from the moment fertilisation is complete. Embryos, by extension of this argument, have the same intrinsic value as a fully developed human being and thus an absolute right to life which cannot be violated at any cost.

Western philosophy generally has established that there can be no human personality without individuality with Dunstan stating that an individual must be there to become eventually the bearer of rights, the embodiment of human attributes and moral agency, and:

'Without individuality there can be no moral agency, no accountability, no identity'.⁵⁵

He claims that it is appropriate to protect the embryo once it has attained the point where individuality is established but not necessarily before that point.

The Catholic Church's presumption that there is a new human individual from conception has been questioned by some Catholic philosophers such as Ford, Farley and Mahoney, who, while accepting the Church's position of condemning abortion,

⁵³ Boyle, n above 33, at p 7.

⁵⁴ Ibid.

⁵⁵ Dunstan GR (1984) The Moral Status of the Human Embryo: A Tradition Recalled. *Journal of Medical Ethics*. 10: 38-44.

argue that it is only at the stage of the development of the primitive streak at day 14 of development that ‘an ontologically human individual’ comes into being.⁵⁶ This position asserts that ‘conception’ differs from ‘individualisation’. They argue that otherwise one cannot account for the possibility of twinning or fusion which can occur after conception and so the:

‘...moral status of the embryo is, prior to the development of the primitive streak, therefore, not that of a person, and its uses for certain kinds of research can be justified’.⁵⁷

Farley recommends that certain safeguards should be put in place such as the maintenance of an absolute barrier between therapeutic and reproductive cloning.

This argument, however, has been rejected by Doerflinger who asserts that more recent studies have established that the overwhelming majority of very early embryos lack the capacity for twinning. Other writers express concern that an acceptance of the argument about twinning would lead to non-therapeutic experimentation and thus to regarding early life:

‘...not as a child but more as manipulable stuff, in the service of (perhaps most praiseworthy) human ends.’⁵⁸

2.2.3 The Potentiality Argument

The potentiality argument is another argument which is often cited when the moral status of the embryo is being examined. Outka claims that potentiality registers both what embryos *are not yet*, that is, incapable of independent existence, and what they *are*, that is, more than mere possibility, an entity in actual motion.⁵⁹

Mahoney has asserted that he finds it:

⁵⁶ Boyle, n above 33, at pp 6-7.

⁵⁷ Farley, MA (1999) Roman Catholic Views on Research Involving Human Embryonic Stem Cells. In Holland, S, Lebacqz, K and Zoloth, L *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy*. Cambridge, MA: MIT Press, pp 113-118.

⁵⁸ Boyle, n above 33. See also Werpehowski, W (1997) Persons, Practices and the Conception Argument. *Journal of Medicine and Philosophy* 22: 479-494, at p 490.

⁵⁹ Ibid.

‘...difficult to consider the early embryo prior to the emergence of the primitive streak as sufficiently developed and individualised to be anything more than a human entity possessed of astonishing promise or potential.’⁶⁰

The potentiality argument expresses the view that embryos are deserving of considerable moral status, and by extension protection, because they have the potential to become fully developed human beings. Outka has examined the potentiality argument and claims that it is ‘double-sided’ as:

‘...conservatives think it nullifies a serious commitment to fetuses and embryos; liberals deride it as ‘mere’ potentiality, a reference too indeterminate ever to be permitted to trump decisions to abort or to conduct research on embryos.’⁶¹

A more moderate version of the potentiality argument proposes that the embryo, even if it does not qualify for consideration as a full person, deserves some protection because of its potential to become a fully-fledged person. If a being is accepted as having moral status then, according to Warren:

‘We may not just treat it in any way we please; we are morally obliged to give weight in our deliberations to its needs, interests or well-being’.⁶²

This argument, however, is rejected by writers such as Brock, as they claim that there is a serious logical flaw in according rights to individuals according to their potential:

‘Moral rights in general have this character – they are grounded in the actual, not just potential, properties of being. So the embryo’s potential to become a person is relevant to the moral status it will have, if and when, it does become a person, but it does not confer the moral

⁶⁰ Mahoney, J (1990) Religion and Assisted Conception. In Bromham, DR, Dalton, ME and Jackson, JC *Philosophical Ethics in Reproductive Medicine. Proceedings of the 1st International Conference*. Manchester: Manchester University Press, p 95.

⁶¹ Outka, GH (2002) The Ethics of Human Stem Cell Research. *Kennedy Institute of Ethics Journal* 12: 175-213, at p 182. See also Outka, n above 17.

⁶² Warren, MA (1997) *Moral Status: Obligations to Persons and Other Living Things*. Oxford: Clarendon Press, p 3.

status on it when still an embryo that it will have later
when it has become a person.’⁶³

Parker, however, abjures Brock’s argument asserting that moral rights are:

‘...bestowed on something or someone; this is not entirely
a scientific enterprise, it is also an emotional or social
one’,⁶⁴

and concludes that Brock’s proposition does not offer any guidance on how to treat
something as:

‘...on this basis, one could positively care for the human
embryo or kill mature persons who have the potential to
save the world’.⁶⁵

Outka proposes a ‘nothing is lost’ principle in relation to embryo research adapted
from Paul Ramsey, who originally applied this principle to parity-conflicts, where
one physical life collides directly and immediately with another physical life, and
one cannot save both.⁶⁶ Outka argues that embryos in reproductive clinics which are
bound either to be discarded or frozen in perpetuity as innocent lives, will die in any
case, and those third parties with maladies such as Alzheimer’s and Parkinson’s are
other innocent lives, ‘who may be saved by virtue of research on such embryos’. The
use of the embryo in research determines how the embryo will die and not whether or
not death will occur. Nothing more is lost according to Outka if they are used in
research as ‘they are destined to die in any case’.⁶⁷ The conduction of research is
thereby justified to alleviate suffering and to advance scientific knowledge.

If, as Brock claims:

‘...one believes that human embryos are neither human persons
nor beings deserving of respect that is incompatible with their

⁶³ Brock, DW (2006) Is a Consensus possible on Stem Cell Research? Moral and Political Obstacles.
Journal of Medical Ethics 32: 36-42, at p 38.

⁶⁴ Parker, C (2007) Ethics for Embryos. *Journal of Medical Ethics* 33: 614-616.

⁶⁵ Plomer, n above 32, p 68.

⁶⁶ Ramsey, P (1961) *War and the Christian Conscience: How Shall Modern War be Conducted Justly*.
Durham, NC: Duke University Press, pp 171-191.

⁶⁷ Outka, n above 61, at p 186.

destruction, then this reasoning provides strong support for the use of surplus embryos for hESC research'.⁶⁸

He, however, believes that this 'nothing is lost' reasoning fails to justify the use of surplus embryos in research as:

'the surplus embryos from IVF will not inevitably die or be destroyed, however, no matter what anyone does; they will only be destroyed if someone makes the decision to destroy them, otherwise they will remain frozen indefinitely retaining the biological potential to develop into human beings if implanted'.⁶⁹

In Brock's view if one wishes to destroy human embryos because of their lack of interests or rights then one should apply that to all embryos and not just surplus ones. This position is also held by Robertson who does not hold any distinction between the creation of embryos for reproductive purposes and their subsequent destruction, and the creation and destruction of embryos for research purposes only.⁷⁰ This is not a position, however, accepted by the ICB, who do not believe that the creation of embryos specifically for research is currently justified based on the 'value of the embryo as a symbol of how we treat each other as members of the human race'.⁷¹ This position is one which this thesis agrees is reasonable in the current situation, particularly as there are numerous surplus embryos available from IVF procedures.

This short review of these diverse ethical arguments demonstrates the width of opinions as to the status of the embryo, and the difficulty any pluralist society may have in adopting a consensus position. How, Brazier has asked, 'should the law respond to such a divergence of moral opinion?'.⁷² She claims consensus is impossible but it is important that a compromise is reached to allow policy development in the areas of ART and hESC research. A gradualist approach to the moral status of the embryo may offer a way of developing this consensus in Ireland.

⁶⁸ Brock, n above 63, at p 37.

⁶⁹ Ibid.

⁷⁰ Robertson, n above 35, at pp 109-136.

⁷¹ ICB, n above 20, at p 54.

⁷² Brazier, M and Cave, E (2007) *Medicine, Patients and the Law* (4th ed.) London: Penguin, p 357.

2.2.4 The Gradualist Argument

As discussed earlier in its report the ICB advocated a gradualist approach to the moral status question in relation to human embryos. A ‘gradualist’ view of moral status proposes that the acquisition of moral status is as continuous a process as biological development, and that embryos gradually gain their moral value. For many centuries the Catholic Church held a gradualist view of embryonic development with the 13th century writing of Thomas Aquinas on the question of embryonic development being influential. Drawing on Aristotle, Aquinas considered that the human embryo did not possess a rational soul and was not therefore a human being until day 40 of development.⁷³ Ensoulment was regarded therefore as one of the critical events determining moral status.

One of the conditions discussed earlier in the development of the normal embryo relevant to embryo protection is the individualisation of the embryo. This occurs with the development of the primitive streak at 14 days post fertilisation and is the point, according to most jurisdictions allowing research on embryos, at which the embryo acquires greater moral status. The nature of these arguments suggests that there is:

‘...more than a single coherent notion of what it is to be a human individual’,⁷⁴

and would appear to concur with the aims of the regulations contained in the UK’s Human Fertilisation and Embryology Act 1990, (which were updated in the Human Fertilisation and Embryology Act 2008) in allowing experimentation on human embryos up to the appearance of the primitive streak. In their 2005 report, the Commission on Assisted Reproduction in Ireland had also recommended that research would be allowed in the Irish Republic on supernumerary IVF embryos up to this point.⁷⁵

Proponents of the gradualist position also consider the protection of an early embryo against the good of existing humans to be justifiable since they consider that the embryo does not deserve full protection at an early stage of development.

⁷³ ICB, n above 20, at p 35.

⁷⁴ Boyle, n above 33, at p 7.

⁷⁵ CAHR, n above 16, at p 58. Recommendation 34.

The deliberated destruction of embryos for research purposes, regarded by proponents of a restrictive approach as unjustified and as violating the notion of human dignity, is considered acceptable to gradualists. They aver to prefer research freedom over the protection of early human life, since they do not regard the destruction of such early life as a violation of the notion of human dignity.

However, some opponents of embryonic stem cell research argue that such research, even that involving so-called ‘spare embryos’,⁷⁶ that is those embryos which have become excess to reproductive requirements, ‘affronts human dignity’, and is a ‘violation of the human embryo’s right to life’.⁷⁷ Doerflinger has asserted that those involved in obtaining embryonic stem cells from such embryos are complicit in the destruction of the embryo, and the use of ‘spare embryos’ does not differ morally from the use of those generated solely for research purposes.⁷⁸ This thesis, however, supports the gradualist notion of moral value, contending that it allows the *in vitro* embryo to be valued, without limiting its potential to be utilised to alleviate human suffering. In this way, through their use in research, spare embryos could be said to offer dignity to the existence to others.

2.3 Conclusion

In granting significant moral value rather than full moral status to human embryos, the Irish Council for Bioethics has supported a gradualist approach to the moral status of the embryo. The ICB has stated that it considers embryonic research justifiable, affirming that it believes that:

‘...the moral value of embryos that will otherwise remain frozen or be destroyed needs to be balanced against the moral value of human welfare, which is likely to increase with advances in medical science that ameliorate quality of life. While accepting the value of human life demands that we hold significant respect for embryos it also demands that we consider our obligations to

⁷⁶ Scott, R et al (2012) Donation of ‘Spare’ Fresh or Frozen Embryos to Research: Who decides that an Embryo is ‘Spare’ and How Can We Enhance the Quality and Protect the Validity of Consent? *Medical Law Review* 20: 255-303.

⁷⁷ Plomer, n above 32, p 68.

⁷⁸ Doerflinger, n above 52.

care for humankind more generally. The Council would therefore consider embryonic stem cell research to be acceptable in certain contexts. That is, the Council supports the carefully regulated use of supernumerary IVF embryos – that are otherwise destined to be destroyed- for the purposes of embryonic stem cell research aimed at alleviating human suffering’.⁷⁹

In so doing they are endorsing the ‘nothing is lost’ principle. This idea in reality espouses the belief that ‘nothing more is lost’ by them becoming research subjects as they will die if they remain unimplanted, and possibly something or someone might be saved if such research is undertaken.⁸⁰ There is, however, no guarantee of actual benefit accruing from the research but it is a ‘fervently held hope’, and

‘...we cannot gainsay the possibility that it may be attained without taking any lethal steps.’⁸¹

The Council did not advocate the creation of embryos specifically for research as discussed above. In addition it did not consider there was currently any need to do so given the number of supernumerary embryos in existence, the need to avoid excessive instrumentalisation of embryos, and women as the source of ova, and the current technical limitation of the process by which such embryos are produced, somatic cell nuclear transfer (SCNT).⁸²

However, since the publishing of this report in 2008 there has been no sign of any political initiative to legislate in this area in Ireland, and the Irish Council for Bioethics has become a victim of Ireland’s economic problems by being absorbed into the Department of Health and Children and is no longer able to function as an independent body.⁸³ The political system in Ireland at present does not seem prepared to undertake the challenge of devising collectively binding decisions about what kind of research shall be allowed within its jurisdiction and which shall be banned. Embryo research and its regulation seems to be at risk of becoming yet

⁷⁹ ICB, n above 20, pp 41-45.

⁸⁰ Ibid.

⁸¹ Ibid.

⁸² Ibid, at p 54.

⁸³ Lyons, B (2012) The Irish Council for Bioethics – An Unaffordable Luxury? *Cambridge Quarterly of Healthcare Ethics* 21: 375-383.

another ‘policy field where the fact that politics is a matter of conflicting interests and values becomes most obvious’.⁸⁴

Dr. Dolores Dooley, previously the chairperson of the Irish Council for Bioethics, in response to the legal uncertainty that exists in Ireland in relation to the appropriate use of non-implanted embryos or the importation of stem cell lines by scientists, had called on behalf of the Council for the Oireachtas to establish an independent regulatory authority, which could be tasked with clarifying ambiguities in the meaning of the term ‘unborn’(as per chapter on legal issues), and legislating for the registration, licensing and inspection of persons and premises working with human embryos, in a manner that would be in line with international best practice. She asserted:

‘Whether or not Irish Society accepts the Council’s conclusion that the embryo has significant moral value rather than full moral status, it is imperative that an end be brought to the legal vacuum.’⁸⁵

The Irish Council for Bioethics, in weighing the moral value of human embryos against the moral value of human welfare, attempted to balance an acceptance of the value of human life against the obligation to care for existing human kind generally. It therefore proposed that embryonic research is acceptable in certain contexts and under certain strictly controlled conditions. This thesis contends that these proposals provide a potential platform for the development of apposite policies in the area of hESC research and should be pursued. However, defining what ‘certain contexts’ will mean in reality or what the ‘strictly controlled conditions’ might be and how to subsequently secure agreement for them from both the conservative and scientific communities in Ireland is likely to prove extremely difficult. Ultimately, Ireland’s difficulties with unravelling and addressing the ethics of reproductive technologies may be due to our:

‘...impoverished ability to recognise and appreciate what is normal about being human’.⁸⁶

⁸⁴ Fink, S (2005) Live and let...? *Measuring and Explaining the Strictness of Embryo Research Laws in 21 Countries*, at p 3. Paper prepared for the ECPR General Conference Budapest, 8-10 September. Available at <http://regulation.upf.edu/ecpr-05-papers/sfink.pdf>.

⁸⁵ Dooley, D (2008) Should the State Legislate for Embryonic Stem Cell Research ? Head to Head. *The Irish Times*, May 12.

The implications of these difficulties will be expanded on in Chapter 6, in which the findings of an empirical study with Irish stakeholders in the area of hESC research are described and the practical implications of the legal lacuna are highlighted.

⁸⁶Jonsen AR (1998) *The Birth of Bioethics*. Oxford: Oxford University Press, p 313.

CHAPTER 3

3. THE PHILISOPHICAL APPROACH

3.1 The Irish Constitution, Naturally and Deliberatively

*The Constitution may for a time seem lost. The character of the country cannot be lost.*¹

The Irish Constitution, *Bunreacht na hÉireann*, is 75 years old this year. Since it was first drafted and enacted Irish society has been so transformed by economic changes, migration, and technological advances that the framers would not recognise it as the country they set out to re-imagine in 1937.² It has been described as a ‘multi-layered representation of Ireland. It is both determinate and indeterminate, both rigid and flat.’³ It fulfils the objective of regulating a polity and performing the symbolic role of representing the nation as, according to Hanafin, a constitutional text is more than a mere source of rules but is to a very real degree an expression of national ethos.⁴ However, the Constitution, a ‘consummate modernist text’ containing within it ‘contradictory ideological constructs’,⁵ was nonetheless an attempt to establish an independent ‘wholeness’ of identity or a nation anew.⁶ One of the anchoring points of this identity was the Constitution’s appeal to natural law.⁷ It is not surprising that natural law was adopted as the legal philosophical basis of the Irish Constitution, *Bunreacht na hÉireann*, as natural law theory, particularly that of Thomas Aquinas, was popular at the time in the social philosophy of the historically dominant Catholic Church.⁸ This popularity derived from the characteristic of the Catholic theological tradition of arguing normative or substantive moral and ethical teaching, personal and social, on ‘reason informed by faith’. In fact, in relation to the Catholic Church ‘most, if not all, its moral teaching is argued on the basis of natural law’.⁹

¹ Grattan, H (1800) Last speech to the Irish House of Commons. Available at <http://elaine.ie/2011/01/21/henry-grattans-last-words-to-the-irish-house-of-commons-1800/>.

² O’Mahony, C (2010) Societal Change and Constitutional Interpretation. *Irish Journal of Legal Studies* 1: 71-110.

³ Hanafin, P (2001) *Constituting Identity: Political Identity Formation and the Constitution in Post-Independence Ireland*. Aldershot: Ashgate, p 10.

⁴ Ibid, p 4.

⁵ Ibid, p 10.

⁶ Ibid, p 4.

⁷ Ibid, p 23.

⁸ Ibid, p 5.

⁹ Ibid, p11.

Constitutional interpretation by the Irish Supreme Court tended for many years to be made in light of natural law. Although the Constitution has been described as ‘a living document to be interpreted in light of changing standards and conditions in society’,¹⁰ difficulties have arisen due to construing it when a constitutional provision has to be applied in a new factual scenario not previously considered, that is at the time of its enactment, or when a provision has been drafted and enacted in a way which no longer reflects the views of today’s society.¹¹ As this is particularly relevant to the interpretation of Article 40.3.3 in relation to Assisted human reproductive technologies (ART) and human embryonic stem cell research (hESC research), the definition of natural law and how it has been applied in Irish constitutional interpretation will now be considered.

3.2 What is ‘Natural Law’?

The definition of natural law varies depending on the source of that definition, with the emphasis appearing to be determined by the outlook of those considering it. Natural Law may be regarded as:

‘...the permanent underlying basis of all laws. The philosophers of Ancient Greece, where the idea of natural law originated, considered that there was a kind of perfect justice given to man by nature and that man’s laws should conform to this as closely as possible’.¹²

Alternatively, it may be described as:

‘A system of rules of conduct based on a set of concepts about human nature; said to be the innate ways people behave towards one another under favourable circumstances. This includes co-operative mutual support, care, and protection of the vulnerable’.¹³

It may also be defined as:

¹⁰ Hannon, P (1998) Rights: Theological Resources. *Milltown Studies* 42, p 97.

¹¹ O’Mahony, n above 2, at p 72.

¹² Martin, EA and Law, J (eds.) (2006) *Oxford Dictionary of Law*. Oxford: Oxford University Press.

¹³ Last, JM (ed.) (2007) *A Dictionary of Public Health*. Oxford: Oxford University Press.

‘Law implanted in nature by the Creator, which rational creatures can discern by the light of reason’.¹⁴

In this definition, natural law is based on value judgements which emanate from some absolute source such as the revealed word of God. Byrne and McCutcheon describe natural law theories as manifesting a concern with the ethical dimension and seeking ‘to identify, or impose, normative limits to human positive law’. They focus on the content and purpose of the law and not just the formal criteria of identification of legal rules that are central to positive theories.¹⁵ Natural law theories are generally concerned with evaluating ‘human laws in the light of higher sources’.¹⁶ This evaluation is as old as Sophocles’ play ‘Antigone’. In this play, Antigone buries her brother Polynices in defiance of an order made by the King of Thebes, Creon. She defends herself by appealing to a higher law:

‘That order did not come from God. Justice that dwells with the gods below, knows no such law. I did not think your edicts strong enough to overrule the unwritten unalterable laws of God and heaven, you being only a man. They are not of yesterday or today but everlasting, though where they came from, none of us can tell’.¹⁷

The classical tradition of natural law is believed to have originated with the pre-Socratic philosopher Heraclitus, who argued that there is a fundamental order in nature to which human reason conforms in making laws and that such laws derive

¹⁴ Livingstone, EA (ed.) (2006) *The Concise Oxford Dictionary of the Christian Church*. Oxford: Oxford University Press.

¹⁵ Byrne, R and McCutcheon, JP (2001) *The Irish Legal System* (4th ed.). Dublin: Butterworth. pp 13-15.

¹⁶ Ibid, p 17.

¹⁷ Hannon, P (1992) *Church, State, Morality and Law*. Dublin: Gill and MacMillan, p 27.

An alternative translation of this passage from Seamus Heaney (2004) in his play *The Burial at Thebes: Sophocles’ Antigone* reads:

‘I disobeyed because the law was not
The law of Zeus nor the law ordained
By Justice, Justice dwelling deep
Among the gods of the dead. What they decree
Is immemorial and binding for us all.
The proclamation had your force behind it
But it was mortal force, and I, also a mortal,
I chose to disregard it. I abide
By statutes utter and immutable-
Unwritten, original, god-given laws.’

their authority from the unchanging and eternal law of nature.¹⁸ It was developed by Aristotle and later through Thomas Aquinas's interpretation of Aristotle.

According to Aristotle virtues are habits cultivated in order to define a moral agent's 'character'. In virtue theory, a person's goal should 'not necessarily be to do virtuous actions but rather to become a virtuous person'.¹⁹ However, a person may only become virtuous through the accomplishing of virtuous acts, with a virtuous act being one which allows the fulfilment of human nature - that is, an act which promotes human 'flourishing'. According to Aquinas, natural law includes a set of principles which, when acted in accordance with, directs the actions of a human being in a virtuous manner, thereby allowing them to become a virtuous person.²⁰ Natural law is one of two ways in which, according to Aquinas, eternal law is promulgated to rational creatures, the second way being through direct revelation or 'divine law'. In *Summa Theologiae* (Ia-IIae.91.2c), Aquinas defines natural law as '*participatio legis aeternae in rationali creatura*', the human way of participating in the eternal law whereby God governs creation.²¹

His first principle of natural law or 'practical reason,' is 'Good is to be done and pursued and evil is to be avoided' (ST, Ia-IIae 94.2). He argues that all other principles of natural law are founded on this first principle because 'everything which practical reason naturally apprehends to be good [or evil] for human beings belongs to the natural law principles to be done or avoided'. (ST, Ia-IIae.94.2)

Aquinas's account of natural law functions as:

'...a way of talking about the sense in which man's natural inclinations reveal a horizon to moral and political life and the

¹⁸ Eberl, J (2006) *Thomistic Principles and Bioethics*. London: Routledge, p 13.

¹⁹ Aristotle and Thomson JA (tr.) (1953) *The Nicomachean Ethics*. London: Penguin Books. See also Eberl, n above 18, at p 9.

²⁰ St. Thomas Aquinas and Gilby, T (tr.) (1966). *Summa Theologiae*. Cambridge: Cambridge University Press, Vol. 23 *Virtues*. See also Eberl, n above 18 at p 10.

²¹ Aquinas, *ibid*, Vol. 28. Law and Political Theory. See also McInerney, R (1980) The Principles of Natural Law. *American Journal of Jurisprudence* 25: 1-15, at p 2; and Hannon, n above 17 at p 24.

place of that horizon within the still-larger context of God's providential government of the universe'.²²

He holds that moral life is potentially present in each human being but it needs to be brought to completion.

According to McInerney, the reason for Aquinas giving such expression to his first principle is 'to draw particular attention to the role of human reason in fashioning precepts directing action to man's ends'.²³ As can be seen from this, natural law principles are quite general, and thus may be 'universally applicable to all human being, no matter what their cultural background'.²⁴

Harris agrees with this conclusion when he describes classical natural law as having the characteristics of being:

- (i) universal and immutable;
- (ii) a 'higher' law; and
- (iii) discoverable by reason.²⁵

Many jurists subscribe to the view that natural law theory – including Thomist natural law theory - involves some definitive idea of justice, and that it invariably comprises 'an independent unassailable moral order capable of expression in the form of axioms or principles'.²⁶ Thus natural law has as its aim the 'common good' and in order to pursue the common good there must be a set of minimum necessary requirements.

This understanding of natural law 'considers that it has an authoritative and certain source in some fashion beyond the vicissitudes and fallibility of human enquiry'.²⁷

²² Lewis, VB (2001) *Liberal Democracy, Natural Law, and Jurisprudence: Thomistic Notes on an Irish Debate*. In Fuller, T and Hittinger, JP *Reassessing the Liberal State: Reading Maintains Man and State*. Washington: Catholic University of America Press, pp 140-158, at p 143.

²³ McInerney, n above 18, at p 3.

²⁴ Eberl, n above 18, at p 11.

²⁵ Harris, JW (1997) *Legal Philosophies* (2nd ed.). London: Butterworth, p 7.

²⁶ Murphy, T (2004) *St Thomas Aquinas and the Natural Law Tradition*. In Murphy, T (ed.) *Western Jurisprudence*. (Dublin: Thomson Round Hall) p 95.

²⁷ Barden, G (1995) *Two Versions of Natural Justice*. In Quinn, G and Ingram, A (eds.) *Justice and Legal Theory in Ireland*. Dublin: Oak Tree Press p 39.

Modern natural law theory, generally thought to have been inaugurated by Grotius in his '*De Jure belli ac Pacis Libri Tres*' is characterised by its secular approach.²⁸ In Grotius' view, the law of nature is essentially an appeal to 'preserve peace by way of showing respect for the rights of others; and so 'rights' [came] to usurp the whole of natural law theory, for the law of nature is simply, respect one another's rights'. He concluded that 'the law of nature would enjoin exactly the same even were we to say there is no God' ('*etiam sidaremus non esse Deum*').²⁹ The idea of a 'divine' aspect to law was also rejected by John Locke, basing his concept of natural law on the fundamental human desire for self-preservation and fulfilment. Locke's natural law implies 'natural rights' associated with duties, and that the natural law standard for judging a government was the ability of that government to secure natural rights for individuals. The people are entitled to these rights by virtue of their humanity.³⁰

The principal modern exponent of natural law theory, John Finnis, whilst describing Aquinas as a 'paradigm natural law theorist', reconstructs his theory in a secular manner and, critically, proposes a theory of individual rights.³¹ He explains in *Natural Law and Natural Rights* that there are:

- (i) 'a set of basic practical principles which indicate the basic forms of human flourishing as goods to be pursued and realised, and which are in one way or another used by everyone who considers what to do, however unsound his conclusions; and
- (ii) a set of basic methodological requirements of practical reasonableness (itself one of the basic forms of human flourishing) which distinguishes sound from unsound practical thinking and,
- (iii) a set of general moral standards'.³²

These 'basic forms of human flourishing' are 'discernible by means of' a simple act of non-inferential understanding' [that allows one to grasp] 'that the object of the inclination which one experiences is an instance of a general form of good, for

²⁸ Finnis, J (2011) *Natural Law and Natural Rights*. Oxford, Oxford University Press, at p 43.

²⁹ Murphy, n above 26, at p 119.

³⁰ Patrick, JJ, Pious, RM and Richie, DA (2001) *The Oxford Guide to the United States Government*. Oxford: Oxford university Press, p 596.

³¹ Finnis, n above 28, at p 28.

³² Ibid, p 23.

oneself (and others like one)'.³³ Finnis explains that Aquinas' first principle of practical reason 'is the concomitant awareness- concomitant to some more specific practical knowledge- that what is to be pursued, willed, chosen, acted on, is what is fulfilling or perfective'.³⁴ Thus, through such awareness is insight brought to one's natural inclinations.

Some authors have pointed out that the term 'natural law' lacks a precise definition. Clarke states 'there is very little agreement, even among experts or proponents of natural law theory about its application to specific, complex moral or legal issues'.³⁵ The theory of Utilitarianism, associated with John Stuart Mills and John Bentham developed partly in response to the perceived 'vagueness of natural law theory and its insistence that a 'higher law' determined whether a positive law was valid'.³⁶ Utilitarianism, while rejecting both the concept that law can include a 'higher law' and the notion of individual or natural rights, may be regarded as a moral theory 'in that it subjects positive laws to a test of whether they are morally good or bad'.³⁷

Finnis argues that, contrary to the utilitarian principle of no absolute human rights, there are absolute human rights and that their maintenance is a 'fundamental component of the common good'.³⁸ He insists that he favours a range of:

'...exceptionless or absolute human claim-rights, most obviously, the right not to have one's life taken directly as a means to any further end; but also the right not to be positively lied to in any situation (e.g. teaching, preaching, research publication, news broadcasting) in which factual communication (as distinct from fiction, jest or poetry) is reasonably expected; and the related right not to be condemned on knowingly false charges; and the right not to be deprived, or required not to deprive oneself, of one's procreative capacity; and the right to be taken into respectful

³³ Ibid, p 34.

³⁴ Lee, P (2005) Comment on John Finnis' Foundations of Practical Reason Revisited. *American Journal of Jurisprudence* 50: 133-138, at p 133.

³⁵ Clarke, DM (1993) The Constitution and Natural Law: A reply to Mr Justice O'Hanlon. *Irish Law Times* 11: 177-178, at p 177.

³⁶ Byrne, n above 15, at p 583.

³⁷ Ibid, p 584.

³⁸ Finnis, n above 28, at p 225.

consideration in any assessment of what the common good requires'.³⁹

Finnis' emphasis on the idea of the unassailability of rights is consistent 'with an idealistic view of natural law as an objective supervening standard'.⁴⁰ It is noteworthy that not being used as a means to an end is a tenet of natural law in light of it being asserted as one of the objections to hESC research.

3.2.1 The Natural Constitution

An idealist version of natural law has formed a significant aspect of debate in relation to constitutional jurisprudence, not only in Ireland but also in the USA, and particularly in Germany following World War II, when a return to natural law was stimulated by the experience of Nazism, in which abuse of law and legal form was widespread.⁴¹

The original 1922 Constitution of the Irish Free State, despite effectively being a legislative instrument of the British Parliament, was unique among Western countries in acknowledging in a declaration in 'the forefront of the Constitution Act that all lawful authority came from God to the people'.⁴² Despite this declaration, the majority of the Supreme Court in *The State (Ryan) v. Lennon*,⁴³ endorsed the view that natural law theory had no role under the 1922 Constitution.⁴⁴ This case centred around an amendment to the 1922 Constitution, Article 2A, whose provisions contained profound changes to fundamental principles of criminal law and procedure. It had been argued unsuccessfully that certain rights were 'so fundamental as to be beyond the power of the Oireachtas to abridge by way of amendment of the written Constitution'⁴⁵ and that Article 2A 'breached the immutable rules of natural law'.⁴⁶ This view was accepted by Kennedy CJ and in his dissenting judgment

³⁹ Ibid, p 225.

⁴⁰ Murphy, n above 26, at p 98.

⁴¹ Byrne, n above 15, at p 15.

⁴² Murphy, n above 26, at p 98; See also Hogan, GW and Whyte, GF (eds.) (2003) *JM Kelly: The Irish Constitution* (4th ed). Dublin: Tottel Publishing, p 50. (Hereafter Kelly).

⁴³ *The State (Ryan) v. Lennon* [1935] IR 170, (1935) 69 ILTR 125.

⁴⁴ Kelly, n above 42, at p 1247.

⁴⁵ Ibid, p 1247.

⁴⁶ Ibid, p 1249.

expressed, for the first time modern Irish legal history, his opinion that a natural law of divine origin is above human law:

‘It follows that every act, whether legislative, executive or judicial, in order to be lawful under the Constitution, must be capable of being justified under the authority thereby derived from God. From this it seems clear that, if any legislation.... were to offend against that acknowledged ultimate Source from which the legislative authority has come through the people to the Oireachtas, as, for example, if it were repugnant to the Natural Law, such legislation would be necessarily unconstitutional and invalid, and would be, therefore, absolutely null and void and inoperative’.⁴⁷

He continued:

‘...judicial power has been acknowledged and declared to have come from God through the people to its appointed depositary, the judiciary and the courts of the State. While they fulfil that trust, dare anyone say that the Natural Law permits it, or any part of it to be transferred to the Executive or their military or other servants.’⁴⁸

The 1937 Constitution may be presented as ‘a stabilising and reforming continuation of that of 1922’ with some significant additions including the ‘very extended recitals of fundamental rights’.⁴⁹ Its author, Eamon de Valera, had attempted during its drafting to secure the approval of the Holy See, while at the same time refusing to declare Ireland a Catholic State. Pius XI responded to the draft constitution with ‘*Ni approvoni non approvo; taceremo*’ (I do not approve, neither do I not disapprove; we shall maintain silence’).⁵⁰ Pius XII, however, was later to praise *Bunreacht na hÉireann* for its foundation in natural law.⁵¹

The Preamble to the 1937 Constitution announces its transcendental origins with the Constitution being given to the people themselves by themselves:

⁴⁷ Murphy, n above 26, at p 98; Also Kelly, n above 42 at 1249.

⁴⁸ *The State (Ryan) v. Lennon* [1935] IR 170 at 204.

⁴⁹ Kelly, n above 42, Preface to 1st Edition.

⁵⁰ Ferriter, D (2007) *Judging Dev: A Reassessment of the Life and Legacy of Eamon de Valera*. Dublin: Royal Irish Academy, p 199.

⁵¹ Ibid, p 200.

‘In the name of the Most Holy Trinity from whom is all authority and to whom, as our final end, all actions of both men and States must be referred. We, the people of Eire, humbly acknowledging all our obligations to our Divine Lord Jesus Christ, who sustained our fathers through centuries of trial.... Seeking to promote the common good, with due observance of Prudence, Justice and Charity, so that the dignity and freedom of the individual may be assured.... Do hereby adopt, enact and give ourselves this Constitution’.⁵²

The philosophical ancestry of the concepts of prudence, justice and charity within the Preamble were referred to by Walsh J in *McGee v. Attorney General*:

‘Both Aristotle and the Christian philosophers have regarded justice as the highest human virtue. The virtue of prudence was also esteemed by Aristotle as by the philosophers of the Christian world. But the great additional virtue introduced by Christianity was that of charity; not the charity which consists of giving to the deserving, for that is justice, but the charity which is also called mercy. According to the Preamble, the people gave themselves the Constitution to promote the common good with due observance of prudence, justice and charity so that the dignity and freedom of the individual may be assured’.⁵³

In 1962 Henchy J wrote that the Preamble to the Constitution:

‘...makes it clear that the Constitution and the laws which owe their force to the Constitution derive, under God, from the people and are directed to the promotion of the common good. If a judicial decision rejects the divine law or has not as its object the common good, it has not the character of law’.⁵⁴

⁵² Kelly, n above 42, Preamble to *Bunreacht na hÉireann*, p 49.

⁵³ *McGee v. Attorney General* [1974] IR 284 at 319.

⁵⁴ Henchy, S (1962) Precedent in the Irish Supreme Court. *Modern Law Review* 25: 544-558, at p 557.

Article 6.1 is another example of the idea of a higher power in the Constitution. It states that: ‘All powers of government, legislative, executive and judicial derive under God, from the people’. Articles 40-44 contain a large body of provisions collectively entitled ‘Fundamental Rights’, with the particular assertion by Article 41 that ‘individuals have rights which are anterior and superior to positive law’.⁵⁵

The Irish Constitution been amended over 20 times since it was first accepted by the citizens of Ireland in 1937. Given that the Irish Constitution invokes natural law principles, and establishes natural law as a ‘higher law’ by which the Constitution itself is bound,⁵⁶ does this mean that amendments to the Constitution must be drafted in such a way that they do not conflict with natural law?

Some academics have argued that ‘interpreting the Irish Constitution in light of natural law is very different from other interpretative strategies because natural law is not a methodological stance’.⁵⁷ In ‘*The Quest for Legitimacy in Constitutional Interpretation*’, Kavanagh has written that:

‘...natural law is a body of principles which can determine the substantive outcome of a case... Natural law is a normative account of what rights are ... A consequence of this is that ...the standard of constitutionality is supplanted by the standards of natural law rather than the Constitution being interpreted in light of it’.⁵⁸

Where the issue of natural law within the Irish Constitution has arisen and caused most problems in the evolution of Irish jurisprudence, is in cases which are concerned natural or human rights.

Ryan v. Attorney General was the first case in which the idea of ‘un-enumerated rights’ within the Constitution was mooted by the judiciary in their interpretation of the Constitution.⁵⁹ Both the High Court and the Supreme Court accepted that some personal rights were derived from the Christian and democratic nature of the State.⁶⁰ In this case, Kenny J accepted the plaintiff’s assertion that there was a ‘right of

⁵⁵ Kelly, n above 42, at p 1245; and Byrne, n above 15, at p 584.

⁵⁶ Byrne, n above 15, at p 584.

⁵⁷ Murphy, n above 26, at p 99.

⁵⁸ Kavanagh, A (1997) *The Quest for Legitimacy in Constitutional Interpretation*. *Irish Jurist* 32: 195.

⁵⁹ *Ryan v. Attorney General* [1965] IR 294.

⁶⁰ Whyte, G (1996) *Natural Law and the Constitution*. *Irish Law Times* 8, at p 9.

bodily integrity’, even though it was not specifically mentioned in the Constitution but could be concluded to exist from contemplation of Article 40.3.1. He concluded that such rights resulted from ‘the Christian and democratic nature of the State’. He supported his conclusion that there was a right to bodily integrity⁶¹ in part by citing *Pacem in Terris*, a papal encyclical of John XXIII: ‘Beginning our discussions of the rights of man, we see that every man has the right to life, to bodily integrity and to the means which are necessary and suitable for the proper development of life’.⁶²

McGee v. Attorney General was the next major case involving Article 40.3.1.⁶³ The court was asked by the plaintiff, a married woman, to invalidate a law, s.17 of the Criminal Law Amendment Act 1935, which prevented her from importing and hence using on the advice of her doctor, contraceptive spermicidal jelly. This, she claimed, was in conflict with her right to privacy within her marriage. The Supreme Court found for the plaintiff in a 4-1 majority decision, allowing her access to contraception contrary to Catholic teaching, with Walsh J ‘alluding to the principle of natural law’ when stating in his judgment that:

‘Articles 41, 42 and 43 emphatically reject the theory that there are no rights without laws, no rights contrary to the law and no rights anterior to the law. They indicate that justice is placed above the law and acknowledge that natural rights, or human rights, are not created by law but that the constitution confirms their existence and gives them protection’.⁶⁴

While noting the association of natural human rights and natural law in both the preamble to the Constitution and Article 6, Walsh J said that:

‘The Constitution acknowledges God as the ultimate source of all authority. The natural or human rights to which I referred earlier in this judgment are part of what is generally called the natural law. ... The natural law as a theological concept is the law of God promulgated by reason and is the ultimate governor of all the laws

⁶¹ Kelly, n above 42, at p 1251.

⁶² Lewis, n above 22, at p 149.

⁶³ *McGee v. Attorney General* [1974] IR 284. See Legal Approach chapter (4) for further discussion of this case.

⁶⁴ *McGee*, *ibid*. See Kelly, n above 42, at p 1252; Also see Byrne, n above 15, at p 586.

of men. In view of the acknowledgment of Christianity in the Preamble and in view of the reference to God in Article 6, it must be accepted that the Constitution intended the natural human rights I have mentioned as being in the category of natural law derived from God'.⁶⁵

However, he also accepted that there are difficulties in the use of natural law in constitutional interpretation, and that the 'use of Thomistic natural law may not adequately respect the diversity of beliefs in Irish society which includes small but significant non-Christian minorities'. He continued:

'What exactly natural law is and what precisely it imports is a question which has exercised the minds of theologians for many centuries and on which they are not yet fully agreed. While the Constitution speaks of certain rights as being imprescriptible or being antecedent and superior to all positive law, it does not specify them'.⁶⁶

Walsh appears to say that the natural law is the basis of the constitution's protection of fundamental rights but there is no actual specific group of rights or criteria that a judge might employ to determine how to come to a decision in a particular case in a balanced manner.

In *Finn v. Attorney General*, it was observed by Barrington J that:

'It is arguable that [the fundamental rights referred to in Article 40 to 44] derive not from a man's citizenship but from his nature as a human being. The State does not create these rights; it recognises them and promises to protect them... Articles 41, 42 and 43 recognise that man has certain rights which are antecedent and superior to positive law'.⁶⁷

⁶⁵ *McGee v. Attorney General* [1974] IR 284 at 317-318.

⁶⁶ *Ibid*, at 318.

⁶⁷ *Finn v. Attorney General* [1983] IR 154.

3.2.2 Natural law and the X Case

The question posed earlier in this chapter ‘must amendments to the Constitution be drafted in such a way that they do not conflict with natural law?’ became particularly pertinent during the debate following the 1992 amendment to Article 40.3.3 of the Constitution which followed from the difficult and controversial case, *The Attorney General v. X*, where the Supreme Court,⁶⁸ on a ‘textual analysis of Article 40.3.3 that Article 40.3.3 allowed abortions where the right to life of the mother was in immediate danger’, gave permission for a 14 year old girl who was pregnant as the result of rape, to travel to England to procure an abortion.⁶⁹ The Irish government held a referendum where three changes to the Constitution were proposed. The first of these, or the proposed 12th amendment to the Constitution, would have allowed for abortion in cases where a threat existed to the life of the mother; this was rejected by the people. However, the 13th amendment, which allowed freedom to travel to another jurisdiction to obtain an abortion, and the 14th amendment, which allowed information on the availability of abortion services in other states, were passed.

Writing extra judicially O’Hanlon J states that the power to amend the Constitution conferred by Article 46 was limited to making amendments which were compatible with natural law theory.⁷⁰ He had no doubts that the Constitution acknowledges the authority of a higher law as the source of ‘inalienable and imprescriptible’ rights, which are ‘antecedent and superior to all positive law’.⁷¹ This argument was subsequently relied on by counsel challenging proposed legislation regulating the provision of information about abortion services outside the State in *Re: Article 26 and the Regulation of Information (Services outside the State for the termination of Pregnancy) Bill 1995* following its referral to the Supreme Court by President Mary Robinson under Article 26 of the Constitution.⁷² Counsel for the ‘Unborn’ argued that the introduction of a provision in the Constitution or legislation permitting the communication of information which:

⁶⁸ *The Attorney General v. X* [1992] IR 1.

⁶⁹ Byrne, n above 15, at p 605.

⁷⁰ O’Hanlon, J (1993) Natural Rights and the Irish Constitution *Irish Law Times* 8.

⁷¹ *Ibid.*

⁷² *Re: Article 26 and the Regulation of Information (Services outside the State for the termination of Pregnancy) Bill 1995* [1995] 1 IR 1([1995] 2 ILRM 81). Bills may be referred by the Irish President to the Supreme Court if they deem them incompatible or potentially incompatible with the Irish Constitution.

‘...constituted assistance in the destruction of the life of the unborn was contrary to the natural law right to life; that the natural law ranked superior to the Constitution and that therefore no constitutional provision or legislation which is contrary to natural law can be enforced’.⁷³

This implies that any provision to allow hESC research in Ireland would also be contrary to natural law. The Supreme Court, however, concluded that the legislation could not be declared invalid despite appearing to conflict with the natural law because, as stated by Hamilton CJ:

‘The courts, as they were and are bound to recognise the Constitution as the fundamental organ of the State, to which all organs of the state were subject, and at no stage recognised the provisions of natural law as superior to the Constitution. The people were entitled to amend the Constitution in accordance with the provisions of Article 46 of the Constitution and the Constitution as so amended by the fourteenth amendment is the fundamental and supreme law of the state representing as it does the will of the people’.⁷⁴

Implicit in this is the conclusion that it could require a constitutional amendment to be passed to allow hESC research to proceed in Ireland without violating constitutional provisions as the Constitution currently stands.

While the outcome of the Supreme Court’s adjudication was awaited public debate was vociferous on all sides. One strand took the approach that as natural law was identified with the Catholic Church and with its traditionally strong hold over Irish life, the Supreme Court should reject it to break this association. Shortly before the ruling was delivered an opinion column in the Irish Times, generally considered to be the most liberal Irish daily broadsheet newspaper, called natural law ‘an instrument of ecclesiastical control at variance with liberal democracy’.⁷⁵ After the

⁷³ Whyte, n above 60.

⁷⁴ *Re: Article 26 and the Regulation of Information (Services outside the State for the Termination of Pregnancies) Bill 1995* [1995] IESC 9; [1995] 1 IR 1 (12 May 1995); [1995] 2 ILRM 81 at 107.

⁷⁵ Browne, V (1995) Will the Country be Run Under Natural Law? *The Irish Times*, April 26th.

decision was handed down allowing the *Regulation of Information (Services Outside the State for Termination of Pregnancies) Act 1995* to become law, Denis Coughlan the chief political correspondent of The Irish Times wrote that the ruling:

‘...cut away the umbilical cord of catholic control inherent in the concept of natural law,’

and concluded that:

‘...the closure of the ‘natural law’ door, with its inherent threat of Catholic control and of a paternalistic/theocratic society, represents the most important step forward.’⁷⁶

The reasoning behind the decision of the Supreme Court to confirm the legislation as valid is felt by some writers to be unsatisfactory, although in concluding that the people are sovereign and the power which rests with the people may only be limited by the provisions of the constitution, which the people may amend through a referendum, the Court was confirming the ‘value of democratic decision-making’ and rejecting the notion that judges may ‘set aside legal norms which have been directly adopted by the people’.⁷⁷ In their adjudication it was felt that ‘previous judicial decisions and constitutional precedents that appear to endorse natural law theory are not properly engaged’. In addition, although the decision confirms that natural law is not recognised as being superior to the Constitution and so:

‘...cannot be relied upon to invalidate any explicit provision of the Constitution, there does not appear to be any credible constitutional basis for the Court’s rejection of natural law and it does not address what residual role natural law plays in the constitutional order’.⁷⁸

Whyte argues that natural law could be read as being complementary, rather than superior to, the Constitution:

‘Is it not at least arguable that the People, in deciding to revoke the constitutional ban on the dissemination of abortion information,

⁷⁶ Coughlan, D (1995) *The Irish Times*, May 13th.

⁷⁷ Kelly, n above 42, at p 1256.

⁷⁸ Ibid, p 1258.

were not violating natural law and that the Supreme Court could have decided this case by ruling that the strong presumption of compatibility of the 14th Amendment with natural law had not been rebutted?’⁷⁹

Although there would seem to be a general acceptance in Ireland of the idea that *Bunreacht na hÉireann* is grounded in a natural law perspective on public morality, and that Thomistic ideas are at the root of the Constitutional’s philosophical outlook,⁸⁰ the Irish Supreme Court seems, in its more recent adjudications, to have taken an approach of ignoring its own previous judgements which acclaimed the position of natural law within the Constitution. It seems to have adopted a more originalist approach to constitutional interpretation, as was evidenced by their judgement in *Roche*.⁸¹ Thus any future legislative initiative in the area of ART and hESC research may not have to contend with Irish Constitutional recognition of natural law as a barrier to its implementation.

3.3 Deliberating Naturally about the Constitution

Natural Law, however, may still have a role to play in Ireland’s democratic process. As discussed earlier Finnis suggests that natural law has a role in helping societies make difficult decisions, while Lewis claims that ‘the most important precepts of the natural law are the very conditions of political association.’ However, the:

‘substantive end towards which natural law is directed, the common good, is greatly attenuated in contemporary liberal democratic nation states both because of their size and their procedural claims’.⁸²

How then is a modern democracy such as the Irish Republic to make decisions on policy matters that are socially divisive?

⁷⁹ Whyte, n above 60.

⁸⁰ von Prondzynski FF (1977) Natural Law and the Constitution *Dublin University Law Journal* 1: 32-37, p 32.

⁸¹ *Roche v. Roche* [2009] IESC 82. See chapter 4 for further discussion of this case.

⁸² Lewis, n above 22, at p 158.

Despite natural law emphasising the importance of ‘reasoning’, it may be said, in relation to the Irish Constitution, that natural law principles have been in the past regarded as more important than the procedural rules and processes in defining and protecting constitutional rights. Decisions taken by the Supreme Court may be seen as upholding the ‘extraordinary law of the Constitution against the ill-considered or short-term considerations introduced by the people’s mere agents in the course of enacting ordinary laws,’⁸³ as politics is often not ‘deliberative’ enough with political choice too often being the result of ‘naked preference.’ How can political deliberation be improved?

3.3.1 Deliberative Democracy

One of the founding principles of any republic is that its citizens should engage in reasoned argument rather than rely on the authority of a Supreme Court to resolve disagreements.⁸⁴ When the Supreme Court simply rules the process of democratic deliberation is effectively subjugated to judicial supremacy. Sometimes this is necessary if the legislature is unwilling to act. However, an attribute of any democracy should be that it is within the rights of its citizens that they are heard on matters relating to prospective laws by the law makers. If a state is to be regarded as a pluralist society then its constitution must incorporate principles of deliberative democracy in its law-making. The potential role of deliberative democracy in improving the process of political decision making, particularly in relation to helping to resolve morally challenging issues, will now be discussed.

Deliberative Democracy is defined as:

‘a form of Government in which free and equal citizens (and their representatives) justify decisions in a process in which they give one another reasons that are mutually acceptable and generally accessible, with the aim of reaching conclusions that are binding in the present on all citizens but open to challenge in the future.’⁸⁵

⁸³ Sunstein, CR (1994) *The Partial Constitution*. Cambridge, MA: Harvard University Press, p 23.

⁸⁴ Ibid.

⁸⁵ Guttmann, A and Thompson, D (2004) *Why Deliberative Democracy?* Princeton: Princeton University Press, p 7.

Like natural law, deliberative democracy can trace its roots back to Aristotle. He defended the value of a process in which citizens publicly discuss and justify their laws to one another, arguing that together, by debating and deciding the ordinary citizens of a state could reach a better decision than ‘experts’ alone.⁸⁶ Modern theories of Deliberative Democracy have been proposed by several notable theorists, such as Michelman (1988)⁸⁷ Rawls (1999)⁸⁸ and Habermas (1996).⁸⁹ There exists among these theorists a basic consensus on the regulative ideals of deliberative democracy⁹⁰ – they all agree on the role of open discussion, the importance of citizen participation and the existence of a well-functioning public sphere.⁹¹

Deliberative Democracy has been described by Chambers as:

‘a normative theory that suggests ways in which we can enhance democracy and criticise institutions that do not live up to the normative standard. In particular it claims to be a more just and indeed democratic way of dealing with pluralism than aggregative or realist models of democracy.’⁹²

It focuses on communicative processes of opinion and will-formation that precedes voting, with accountability replacing consent as the conceptual core of legitimacy. A legitimate political order is one that can be justified to all those living under its laws.⁹³ One of the most important benefits that theorists ascribe to deliberative democracy is that the decisions it produces are more legitimate because they respect the moral agency of the participants. This benefit is inherent in the process, not a consequence of it.⁹⁴

⁸⁶ Ibid, at p 8. See also Aristotle (1984) *Politics*. In Barnes, J (ed.) *Complete Works, Vol. II*. Princeton: Princeton University Press, Bk. III.

⁸⁷ Michelmann, F (1988) *Law’s Republic*. *Yale Law Journal* 97: 1493-1537.

⁸⁸ Rawls, J (1999) *The Laws of Peoples*. Cambridge, MA: Harvard University Press.

⁸⁹ Habermas, J and Rehg, W (tr.) (1996) *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy*. Cambridge MA: MIT Press.

⁹⁰ Gimmler, A (2001) *Deliberative Democracy and the Internet*. *Philosophy and Social Criticism* 27:21-39, p 23.

⁹¹ The public sphere is the space within which citizens can raise and discuss issues they consider relevant and resolve them in a free and equal manner.

⁹² Chambers, S (2003) *Deliberative Democratic Theory*. *Annual Review of Political Science* 6: 307-326, p 308.

⁹³ Ibid.

⁹⁴ Thompson, DF (2008) *Deliberative Democratic Theory and Empirical Political Science*. *Annual Review of Political Science* 11: 497-520, p 498.

The theory of deliberative democracy as developed by Gutmann and Thompson tries to accommodate the problems of representative accountability and, more importantly moral disagreement.⁹⁵ Its aim, according to Gutmann and Thompson, is to provide the most justifiable conception for dealing with moral disagreements in politics.⁹⁶ Deliberative willingness is a potent driver of the quality of political discourse. In order to approach the generative type of consensus systems much will depend on the willingness and the possibilities of parties and politicians to deliberate. The criterion that most clearly distinguishes deliberative from non-deliberative forms of democratic decision making is that in the regulative ideal, coercive power should be absent from the deliberation.⁹⁷ Deliberation really is debate and discussion which is aimed at producing reasonable, well-informed opinions. It is based on reason, aims at consensus, and promotes the common good, with participants willing to revise their preferences in light of discussion or new information or claims coming from fellow participants.⁹⁸ It explicitly excludes bargained compromise and self-interest.⁹⁹ Therefore in an ideal deliberative process, as Habermas says ‘no force except that of the better argument is exercised.’¹⁰⁰

Deliberative theory investigates what ought to be in a constitution if a deliberative order is to be promoted, how a constitution ought to be interpreted to maintain and enhance deliberation and how a constitution ought to be made/drawn up in order to establish a deliberative legitimacy.¹⁰¹ Constitutions, as discussed earlier, are important because constitutions bind citizens into a common narrative or national enterprise. Thus, deliberative democracy can be seen as to promote a form of constitutional patriotism that requires commonality mediated through constitutional principles.¹⁰²

⁹⁵ Knight, J (1999) Constitutionalism and Deliberative Democracy. In Macedo, S (ed.) *Deliberative Politics: Essays on Democracy and Disagreement*. Oxford: Oxford University Press, pp 159-169.

⁹⁶ Gutmann, n above 85.

⁹⁷ Mansbridge, J (2008) *What Does the Ideal of Deliberative Democracy Demand?* p 3. Available at <http://iis-db.stanford.edu/evnts/5216/MansbridgeDelibDem2-08.pdf>.

⁹⁸ Chambers, n above 92, at p 309.

⁹⁹ Mansbridge, n above 97, at p 4.

¹⁰⁰ Habermas, J and Carthy, T (tr.) (1975) *Legitimation Crisis*. London: Heinemann.

¹⁰¹ Chambers, n above 92, at p 312.

¹⁰² Habermas, J and Pensky, M (tr.) (2001) *The Postnational Constellation: Political Essay*. Translated by Cambridge, Ma: MIT Press.

3.4 Deliberation and Public Policy

Although it has been found that deliberation is less successful when opinion is extremely polarised, as on the question of abortion or hESC research, it is still necessary that a decision is made. In a state of disagreement how can citizens reach a collective decision that may be considered to be legitimate?

The first two aspects of the problem, disagreement and decision characterise the circumstances of deliberative democracy. The third, legitimacy, prescribes the process by which, under these circumstances, collective decisions can be morally justified to those who are bound by them.¹⁰³ The field of public policy has become an area where deliberative democracy has been embraced. Habermas recognises that when democracies are faced with instances in which ‘no generalised interest or clear priority of some one value’ is ‘able to vindicate itself’, such as a situation of conflicting interest or deeply held opinion’, there must be in addition to deliberation, fair bargains which are ‘disciplined’ by institutions that attempt to distribute power equally among the parties.¹⁰⁴ In order to achieve this there must be procedures in place to provide all ‘interested parties with an equal opportunity for pressure, that is an equal opportunity to influence one another during the actual bargaining, so that all the affected interests have equal chances of prevailing.’¹⁰⁵ Deliberative models are used to either generate substantive public policy outcomes or a procedural approach may be taken to the design of venues for choosing and developing policy.¹⁰⁶ It is generally considered that it is in policy initiatives and analysis that deliberative democracy is at its most concrete.¹⁰⁷ Della Porta asserts that:

‘We have deliberative democracy when, under conditions of equality, inclusiveness and transparency, a communicative process based on reason....is able to transform individual preferences and reach decisions orientated to the public good.’¹⁰⁸

¹⁰³ Thompson, n above 94, at p 502.

¹⁰⁴ Habermas, n above 89, at p 95.

¹⁰⁵ Ibid.

¹⁰⁶ Chambers, n above 92, at p 315.

¹⁰⁷ Ibid, p 316.

¹⁰⁸ Della Porta, D (2005) *Deliberation in Movement: Why and How to Study Deliberative Democracy and Social Movements*. *Acta Politica* 40: 336-50, at p 340.

Habermas' approach to deliberative democracy is based on a foundation which enables the legitimacy of the constitutional state and civil society to be justified, with the justification emanating from discursive practices providing the framework for solving political conflicts.¹⁰⁹ Procedural rules are the means by which the secure discursive context for solving conflicts is provided but a procedural approach to public policy is one in which the procedures are designed to enhance and facilitate deliberation rather than produce a decision *per se*. Decisions need to be taken in relation to the development of public policies but in a deliberative approach the focus is on the qualitative aspects of the conversation that actually precedes the decision making.¹¹⁰ And although the actual policy recommendations that result from a deliberative process are predominantly procedural ones, procedure blurs into substance at a certain point.¹¹¹ This procedural approach to the process is required when the debate is taking place in a modern pluralism society where the moral and legal spheres are distinct from one another and there is a diversity of values.¹¹² It is through procedural rules that a framework which will accommodate the diversity and pluralism of modern societies can be built.¹¹³

3.5 Deliberative Politics in Ireland: A Missed Opportunity?

In the party manifestos published in advance of the election in 2011, several Irish political parties had proposals for encouraging deliberative politics at national and local levels. All the parties referred to diverse citizens' forums or a Citizens' Assembly.¹¹⁴ One of the provisions set out in the Programme for Government of the current coalition administration in Ireland is for a Constitutional Convention which would undertake a review of the Irish Constitution to 'consider constitutional reform'. In addition, there are a number of proposals for enhanced deliberation within the Oireachtas in terms of the powers of scrutiny of Dáil committees, sittings given over exclusively to committee reports and the provision for allowing

¹⁰⁹ Gimmler, n above 90, at p 23.

¹¹⁰ Chambers, n above 92, at p 316.

¹¹¹ Ibid, p 317.

¹¹² Gimmler, n above 90, at p 24.

¹¹³ Ibid, p 24.

¹¹⁴ Carney, G and Harris, C (2011) Deliberative Democracy and Political Reform. Available from www.politicalreform.ie/2011/03/30/deliberative-democracy-and-political-reform.

backbench TDs to introduce their own bills.¹¹⁵ The idea was first mooted by Fine Gael in 2009. One of the reasons cited for advancing the idea of a Constitutional Convention was that the ‘disconnect’ in Ireland between public opinion and public policy poses a threat to the legitimacy of Irish democracy.¹¹⁶ Such deliberative processes have been used to great effect in other countries, such as Iceland,¹¹⁷ and Canada,¹¹⁸ to improve the nature and form of political participation and thereby improving the level of trust, confidence and legitimacy in the democratic institutions.¹¹⁹ The proposed convention will consist of 99 delegates, and one chair, of which 2/3rds will be ‘citizen members’ drawn from outside politics. The remainder will be members of the Oireachtas, and a few politicians from Northern Ireland.¹²⁰

Among the conditions which have been found in other jurisdictions to be favourable to deliberation are coalition cabinets, multiparty systems, proportional representation, veto provisions and second-chamber debates.¹²¹ All these criteria exist at present within the Irish political system with a two-party coalition government *in situ*. In consensus systems, the problem of who gets the blame and who gets the credit for policy initiatives is strongly tied to the concrete setup of coalition governments. In coalition governments with more than two parties, however, policy clarity tends to be reduced, thereby potentially opening up a greater space for deliberation.¹²²

Although the proposed legislative reforms have the potential to improve the deliberative processes, the process of public consultation by policy and regulatory bodies in Ireland has been poor. Very often the executive or the policy body concerned has set out a very precisely defined (i.e. limited) scope for the consultation stating its preferred position. Even if there has been a seemingly valid deliberative procedure undertaken, the executive will simply acknowledge the submission or

¹¹⁵ Byrne, E (2010) Let the People Have Their Say on Type of Country They Want. Available from <http://elaine.ie/2010/02/02/let-people-have-their-say-on-type-of-country-they-want/>

¹¹⁶ Constitutional Assembly - TCD student submission posted by Byrne, E. (2012) Available at www.politicalreform.ie/2012/03/06/constitutional-assembly-tcd-student-submission.

¹¹⁷ A Constitutional Council was formed in 2011 in Iceland.

¹¹⁸ Citizens’ Assemblies were formed in 2004 in British Columbia and in 2006 in Ontario.

¹¹⁹ Carney, n above 114.

¹²⁰ Clifford, M (2012) Comment: Constitutional Talk Shop proves State is in no Tearing Hurry to Create Reform. *The Sunday Times* June 10th, p 16.

¹²¹ Thompson, n above 94, at p 511.

¹²² Bachtiger, A, Steenbergen, MR and Tschentscher, A (2010) *Developing a Deliberative Democracy: A Research Report and a Research Agenda*. Bern, BIDS: University of Bern.

report and then ignore its recommendations, as has happened with both the report of the Commission on Assisted Human Reproduction and the Opinion of the Irish Council for Bioethics in relation to stem cell research.¹²³

The Irish political system needs to be reformed so that it may become more deliberative in its outlook. Chapter 8, paper 3, discusses how deliberative processes have been used to great effect in other countries and suggests how Ireland might learn from their experiences thereby helping to improve the effectiveness of any future deliberation in general. The capacity, however, for institutions to self-reform is rare, and the possibility of trying to reform and revive the Constitution through the Constitutional Convention may be overly ambitious given the limitation of its remit.¹²⁴ If politicians continue to avoid dealing with difficult, morally contentious issues that Ireland faces, such as legislating to allow human embryonic stem cell research to take place, it may be that ‘it’s time for the politicians to step aside and the people to have their say on how our country should be run.’¹²⁵

¹²³ See chapter 4 for further discussion on reports of the Commission on Assisted Human Reproduction and the Irish Council for Bioethics.

¹²⁴ Byrne, n above 115.

¹²⁵ Kennedy, Baroness H (2010) ‘People Power’ Must Set New Parliamentary Agenda. Available from news.bbc.co.uk/democracylive/hi/comment/newsid.

CHAPTER 4

4. THE LEGAL APPROACH

4.1 Introduction

The 8th Amendment to the Irish Constitution, Article 40.3.3, is central to many of the issues discussed in this thesis. This chapter therefore examines developments in Irish Constitutional law leading up to the insertion of this amendment in 1983 to protect ‘unborn life’. The extent to which legal developments, or lack of them, have influenced assisted human reproductive services in Ireland is examined, with particular emphasis placed on the significance of the Irish Supreme Court’s judgment in the ‘Frozen Embryos’ case for the possibility of hESC research developing in Ireland.¹

The current absence of legislation in Ireland in these two areas, ART and hESC research, is disquieting as it would seem to be at odds with Ireland’s reputation as a country which greatly values unborn life. In addition, the absence of legislation in this area is seen as extremely unsatisfactory by those involved in scientific research in Ireland as it means they are not in a position to look for collaborative partners in other countries due to uncertainty as to the legality of their research.² This in turn affects funding and hence the viability of the research.³ As Ireland attempts to find its way out of its present economic difficulties, it is likely that this will become a more pertinent reason to legislate.

4.2 The Status of the Embryo in Irish Law

In attempting to propose a legal framework in which embryonic and stem cell research may, in the future, take place in Ireland, it is necessary to examine the current status of the human embryo in Irish law, and how this came about, in order to try to define what rights the embryo has and what protections are owed to it.

As discussed previously in Chapter 3, Ireland has a written Constitution, *Bunreacht na hÉireann*, enacted in 1937. The dominant political and social discourse of 1930’s

¹ *Roche v. Roche and Ors* [2009] IESC 82.

² Sullivan, S (2008) *Irish Medical Times* April 25th. See also Paper 2: ‘Something Must be Done’ for the views of stakeholders on the need to legislate in this area.

³ Barry, F (2008) *The Irish Times* October 28th.

Ireland was Roman Catholic, socially conservative and irredentist.⁴ All these elements were reflected in the Constitution, with its legal philosophical basis being Thomist in outlook.⁵

However, the Constitution also acknowledges notions of liberal constitutionalism and, in its fundamental rights articles, *Bunreacht na hÉireann* guarantees the individual citizen freedom, equality and justice. According to Binchy, *Bunreacht na hÉireann* is:

‘...premised on rejection of legal positivism, respect for universalism and an understanding of human beings as entities of equal dignity and value, each with a unique worth’.⁶

Lewis, in fact, suggests that:

‘...the adoption of the Irish Constitution represented an important moment in the history of Catholicism’s relationship with liberalism’,

with the chief author of the Constitution, Eamon de Valera, incorporating some of the elements of liberal democracy endorsed by Leo XIII in *Immortale Dei* (1885).⁷ Article 44 of the Constitution recognised of a range of religions within the state, gave a guarantee of freedom of conscience to all citizens, and although not establishing it, recognised the ‘special position’ of the Catholic Church in the nation-state. This latter part of the article, however, was removed following a referendum in 1972 with the support of the Church itself.

A number of constitutional provisions potentially affect the provision of assisted reproductive technology services (ART), and embryonic and stem cell research in Ireland. These include the rights to privacy and bodily integrity, custody of a child,

⁴ Hanafin, P (1999) Issues of Territoriality and Identity. In Hanafin, P and Williams, MS (eds.) *Identity, Rights and Constitutional Transformation*. Aldershot: Ashgate, p 74.

⁵ Hanafin, P (2001) *Constituting Identity: Political Identity Formation and the Constitution in Post-Independence Ireland*. Aldershot: Ashgate, pp 10-25.

⁶ Binchy, W (2008) Article 40.3.3 of the Constitution: Respecting the Dignity and Equal Worth of Human Beings. In Schweppe, J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, pp 189-212, at p 189.

⁷ Lewis, VB (2001) Liberal Democracy, Natural Law, and Jurisprudence: Thomistic Notes on an Irish Debate. In Fuller, T and Hittinger, JP *Reassessing the Liberal State: Reading Maintains Man and State*. Washington: Catholic University of America Press, pp 140-158, at p 147.

equality before the law, but in relation to embryonic and stem cell research, the most important article is Article 40.3.3, which guarantees the right to life of the ‘unborn’.

Before *Bunreacht na hÉireann* was enacted, the law in Ireland which protected foetuses by prohibiting abortion had evolved primarily from English Common Law. Under Lord Ellenborough’s Act of 1803 the abortion of the ‘quickened’ foetus became a felony, where previously it had been regarded as a misdemeanour at common law. Current statute law prohibiting abortion, whether self-induced or performed by another, derives from s.58 and s.59 of the Offences against the Person Act (1861).⁸

Section 58 O.A.P.A. (1861) provides:

‘Every woman being with child, who, with intent to procure her own abortion shall unlawfully administer to herself any poison or other noxious thing, or shall unlawfully use any instrument or other means with like intent, and whosoever, with intent to procure the miscarriage of any woman, whether or not she 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 with the like intent shall be guilty of felony...’

This 19th century statute has remained valid law in Ireland, despite the fact that the law in England has changed substantially through the introduction of the 1967 Abortion Act, with its legitimacy being re-emphasised by section 10 of the Health (Family Planning) Act (1979). The prohibition, however, was in theory not absolute since the word ‘unlawfully’ recurs throughout the section.⁹ The use of the word ‘unlawfully’ is noteworthy, leading to the implication that there might actually be a form of ‘lawful’ abortion in Ireland.

The legal position in pre-1983 Ireland in relation to abortion is regarded by some authors to be represented by the decision in *R v. Bourne*,¹⁰ where McNaughten J

⁸ Casey, J (2000) *Constitutional Law in Ireland* (3rd ed.). Dublin: Round Hall, Sweet and Maxwell. p 433.

⁹ Schweppe, J (ed.) (2008) *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, p 2.

¹⁰ *R v. Bourne* [1939] 1 K.B. 687.

directed the jury to consider the meaning of the word ‘unlawfully’ and that, in relation to a criminal prosecution taken under s.58 of the OAPA (1861), the prosecution had to prove beyond a reasonable doubt that the abortion had not been carried out in good faith in order to preserve the life of the mother. By so doing, McNaughten had accepted that presence of ‘unlawful’ in the OAPA (1861) allowed for a category of ‘lawful’ abortion.

If this reasoning applied equally to the OAPA (1861) as it operated in Ireland, the possibility now existed of making a distinction within the statute between danger to the ‘life’ and danger to the ‘health’ of the mother.¹¹ In other words, if, as happened in the UK, Irish medical opinion held that an abortion was lawful in certain situations to protect the mother’s mental or physical health as well as her life, then the abortion may not be unlawful.

Despite there being no explicit constitutional rights protecting the ‘unborn child’ following the enactment of *Bunreacht na hÉireann*, a number of judicial statements had indicated a willingness on the part of the judiciary to interpret the Constitution as affording such rights to the unborn. In *McGee v. Attorney General*¹² a case concerning the availability of barrier contraceptives, the Supreme Court through Walsh J recognised a constitutional right to marital privacy but stated that:

‘...any action on the part of either the husband and wife or of the state to limit family size 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.’

Walsh failed, however, to offer any view on how to distinguish barrier contraception from other methods of family planning that have an abortifacient effect. There was concern among anti-abortion campaigners following *McGee* that this right to marital privacy might be used in a manner similar to that used by pro-choice campaigners in the USA to successfully invoke a comparable right to privacy, thereby invalidating

¹¹ Whyte, G (1992) Abortion and the Law. In: *Abortion Law and Conscience: A Special Issue of Doctrine and Life* (May/June), p 259. See also Lee, S (1992) Abortion Law: The Tragic Choices. In: *Abortion Law and Conscience. A Special Issue of Doctrine and Life* (May/June), p 290.

¹² *McGee v. Attorney General* [1974] I.R.284. See also Chapter 3 of this thesis (Philosophical Approach), for discussion of this case.

statutes criminalising abortion; *Roe v. Wade*.¹³ The US Supreme Court had effectively, by re-iterating that privacy is a fundamental personal right, granted American women the right to choose to have an abortion. This decision provided a significant example of the possibilities of judicial action in the area of reproductive rights with the Irish judiciary already having a tendency to be influenced by the Constitutional arguments and decisions of the US Supreme Court given the similar nature of the institutions.¹⁴ This was expressly noted by Binchy in a letter to *The Irish Times* July 22, 1982, where he suggested that:

‘The dangers to the unborn are not limited to the fact that the constitution affords them neither explicit nor implicit protection, but that the constitution could be interpreted as conferring a broad right to abortion on demand based on a woman’s right of privacy in respect of procreation. Such a right, if recognised by the courts, would be a constitutionally protected personal right...’

To prevent this possibility, however unlikely, occurring in Ireland a pressure group, the Pro-Life Amendment Campaign (PLAC) came into being and an amendment to the Constitution was proposed to protect unborn life.¹⁵ Some authors feel that PLAC was formed:

‘not in response to any campaign or specific legislative proposal to legalise access to abortion, but rather in response to a range of cultural and legal shifts that had occurred since the late 1960s’,

¹³ *Roe v. Wade* (1973) 410 U.S.113.

¹⁴ The decision in *McGee* was felt to have been influenced by the decision in *Griswold v. Connecticut* [1965] 381 U.S. 479 involving a similar un-enumerated right to marital privacy. See Cox, N (2008) Foetal Personhood in Comparative Perspective. In Schweppe, J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland: 25 Years of Protection?* The Liffey Press, Dublin, pp 89-112.

¹⁵ Smyth, L (2005) *Abortion and Nation: The Politics of Reproduction in Contemporary Ireland*. Aldershot: Ashgate. PLAC was primarily formed in 1980 by the Catholic Doctors Guild, representatives of the Council of Social Concern and by members of the Irish branch of a British organisation, the Responsible Society. Before the formal launch of PLAC in 1981 the Society for the Protection of Unborn Children (SPUC) also became involved. Following the referendum SPUC was the organisation primarily involved in legal challenges to the 8th Amendment. See McAvoy, S (2008) From Anti-Amendment Campaign to Demanding Reproductive Justice: The Changing Landscape of Abortion Rights Activism in Ireland, 1983-2008. In Schweppe, J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland: 25 Years of Protection?* The Liffey Press, Dublin, pp 15-45.

particularly to the growth in the women's movement.¹⁶ For some lay Catholic fundamentalist groups:

‘abortion had become a symbol which subsumed many of the core values of Irish identity – Catholicism, family, patriarchal domination, fear of sex and opposition to ‘alien’ ideas’.¹⁷

In these circumstances PLAC emerged, with the specific intention of preventing the courts from introducing legal abortion in Ireland, believing their campaign to be the last line of defence against the ‘onslaught of a promiscuous society’ and the ‘encroaching moral decadence of Europe’, and an unjustified fear that the EC harmonisation would foist an abortion policy on Ireland.¹⁸

However, it may be that this ‘futile pre-emptive strike against abortion’ is best seen as a defence of a ‘threatened Irish identity and an aggressive reassertion of ultimate distinctiveness’. Thus, in Ireland, according to Healey, the abortion debate was:

‘...not merely about balancing the rights of the pregnant woman with that of her foetus, but is a site of continued contestation over a particular definition of Irish identity’.¹⁹

4.3 Article 40.3.3

The 8th Amendment to the Constitution of Ireland 1983 inserted a new article, Article 40.3.3 into the Constitution which stated that:

‘The State acknowledges the right to life of the unborn and, with due respect to the equal right of life of the mother, guarantees in its laws to respect, and as far as is practicable, by its laws to defend and vindicate that right’.²⁰

¹⁶ Smyth, *ibid.*

¹⁷ *Ibid.*

¹⁸ McAvoy, n above 15 at p21; also see Whyte, n above 11, at p 262.

¹⁹ Healey, M (2008) ‘I Don’t Want to Get Into This, It’s Too Controversial’: How Irish Women Politicians Conceptualise the Abortion Debate. In Schweppe, J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland: 25 Years of Protection?* The Liffey Press, Dublin, pp 65-88, at p 68.

²⁰ *Bunreacht na hÉireann* (Constitution of Ireland). Dublin: Government Publications Office.

In terms of constitutional interpretation, however, the Irish text is the authoritative one:

‘Admhaíonn an Stát ceart na mbeo gan breith chun a mbeatha agus, ag féachaint go cuí do chomhcheart na máthar chun a beatha, ráthaíonn sé gan cur isteach lena dhlíthe ar an gceart sin agus ráthaíonn fós an ceart sin a chosaint is a shuíomh lena dhlíthe sa mhéid gur féidir é’.

Interpreted literally there is a subtle change in emphasis:

‘The State acknowledges the right of the unborn to their life and, having due regard to the equal right of the mother to her life, it guarantees not to interfere through its laws with that right and it guarantees further to protect and assert that right with its laws as far as it is possible’.

The use of the word ‘*unborn*’ or the Irish language version ‘*beo gan breith*’ introduces an element of uncertainty into the law with *beo* translated principally as ‘living being’, with the secondary sense of ‘life’, while *gan breith* can mean ‘without birth’.²¹ This uncertainty in emphasis has caused difficulty since the insertion of the amendment into the constitution, despite the suggestion by some commentators that 40.3.3 is actually ‘best understood as a strengthening of the prohibition on abortion.’²²

As has been noted, Article 40.3.3 introduced the concept of the ‘*unborn*’ while failing to define its meaning. This failure was flagged by the then Attorney General, Peter Sutherland prior to the passing of the amendment, warning that:

‘The term ‘unborn’ might be broadly interpreted to mean either that abortion was prohibited from conception or that it was permitted up to the point of viability’.²³

²¹ Ó Cearúil, M (1999) *Bunreacht na hÉireann: A Study of the Irish Text*. The All-Party Oircheachtas Committee on the Constitution. Dublin: Government of Ireland Publications, pp 548-549.

²² McGuinness, S and Uí Chonnachtaigh, S (2011) Implications of Recent Developments in Ireland for the Status of the Embryo *Cambridge Quarterly of Healthcare Ethics* 20: pp 396-408.

²³ McAvoy, n above 18, at p 24.

Even as the bill was going through the Houses of the Oireachtas, Senator Mary Robinson, a future President of Ireland and UN commissioner for Human Rights, counselled that this flawed amendment was so uncertain in its scope and so potentially contradictory in its meaning that it could do extensive damage ‘to existing practices in the area of family planning and medical treatment’.²⁴

What is interesting is that Article 40.3.3 despite being generally regarded as ‘the anti-abortion amendment’, does not actually mention the term abortion at all; it is in fact ‘entirely philosophical in character’.²⁵ What it does is to guarantee the ‘right to life of an unborn child’, subject to the equal right to life of its mother and thus effectively bans abortion in Ireland except when the life of the mother is in danger. However, what exactly is implied by the ‘equal right to life of the mother’ has never been clarified, and has been the basis of further litigation, particularly in the European context, such as *A, B, and C v. Ireland*.²⁶ In addition, the legal determination of the stage at which the guarantee ‘to defend and vindicate the right to life’ applies would be particularly important, given its implications for ART and in particular for the potential use of spare embryos from *in vitro* fertilisation (IVF) in research.²⁷

Cox has argued in ‘*Foetal Personhood in Comparative Perspective*’ that:

‘What is significant about the Irish debate....is the absence of any sophisticated analysis of whether it was actually appropriate to regard the foetus as a constitutional person or a rights possessor and what the new requirement to defend and vindicate that right to life of this new constitutional entity would mean in practice.’²⁸

He concludes that despite this, Article 40.3.3:

²⁴ Foley, JA and Lalor, S (eds.) (1995) *Annotated Constitution of Ireland*. Dublin: Gill and McMillan, p 235.

²⁵ Binchy, n above 6, at p 195.

²⁶ *A, B and C v. Ireland* 25579/05 [2010] ECHR 2032. This lack of clarification resulted in criticism by the European Court of Human Rights of Irish governmental procrastination. For full commentary on this case see McGuinness, S (2011) A, B and C leads to D (for Delegation). *Medical Law Review* 19: 476-491.

²⁷ CAHR (2005) *Report of the Commission on Assisted Human Reproduction*. Dublin: Government of Ireland Publications, p 94.

²⁸ Cox, N (2008) *Foetal Personhood in Perspective*. In Schweppe, J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, p 105.

‘...protects an individual foetus as a rights bearer.’²⁹

This is of significance in relation to any future embryonic or stem cell research as the Irish Constitution, according to many academic commentators, has un-enumerated rights within it.³⁰

4.3.1 Case Law

The Eighth Amendment to the Constitution has given rise to considerable litigation, both within Ireland and in the European Courts. In the first case following the 8th Amendment, *Attorney General (Society for the Protection of the Unborn Child (Ireland) Ltd) v. Open Door Counselling*, the plaintiffs sought an injunction:

‘...restraining the defendants from counselling or assisting pregnant women within the jurisdiction to obtain an abortion or to obtain advice thereon’,³¹

with Hamilton J taking the view that:

‘Ss.58 and 59 of the Offences Against the Person Act 1861 protected and protect the foetus in the womb and having regard to the omission of the words ‘Quick with child’ which were contained in the 1803 Statute, that protection dates from conception. Consequently, the right to life of the foetus, the unborn, is afforded statutory protection from the date of conception’.³²

What is not clear, however, from the context, is whether conception means the act of fertilisation or of implantation, a potentially crucial distinction in relation to embryo and stem cell research. Hamilton J also stated that prior to the enactment of the Eighth Amendment to the Constitution the right to life of the unborn had been referred to and acknowledged by Walsh J in his judgment in *G v. An Bord Uchtala* [1980] I.R.32 where he stated at p 69 that a child has:

²⁹ Ibid.

³⁰ Symposium on Un-enumerated Rights in the Irish Constitution. Available at www.nuigalway.ie/law/GSLR/. (Accessed 30/10/2008). See also Casey, n above 8, at p 394.

³¹ *Attorney General (Society for the Protection of the Unborn Child (Ireland) Ltd) v. Open Door Counselling* [1988] I.R. 593. (See discussion on origins of SPUC on p 77).

³² Ibid.

‘... the right to life itself and the right to be guarded against all threats directed to its existence whether before or after birth ...’³³

The High Court initially granted the order but the defendants appealed to the Supreme Court which held that Article 40.3.3 was self-executing and imposed an obligation not only on the Oireachtas but also on the courts. Finlay CJ stated that if:

‘the jurisdiction of the courts is invoked by a party who has a *bona fide* concern and interest for the protection of the constitutionally guaranteed right to life of the unborn, the courts, as the judicial organ of the government of the State, would be failing in their duty as far as is practicable to vindicate and defend that right if they were to refuse relief upon the grounds that no particular pregnant woman who might be affected by the making of an order was represented before the court’.³⁴

The subsequent case of *S.P.U.C. (Ireland) Ltd. v. Grogan (No. 1)*³⁵ confirmed the Supreme Court’s ruling that the provision of information regarding abortion services in other jurisdictions, regardless of the mode of communication, to pregnant women by Open Door Counselling and other providers was determined to be unlawful.³⁶

The defendants argued that the court could not make an order to impede the constitutional right to receive and impart information. However this, and the defendants’ argument that the case involved questions of EC law, necessitating a reference to the European Court of Justice under Article 177 (now 234), EC Treaty, was rejected by the Supreme Court, affirming the High Court’s decision. The defendants, however, took their case to the European Court of Justice claiming that abortion could constitute a service within the meaning of Article 60 (now 50) of the Treaty of Rome. They were unsuccessful, with the Court finding, in 1991, against the defendants, a student body, as the information was not distributed on behalf of an

³³ Walsh, J in *G v. An Bord Uchtala* [1980] I.R.32 at 69; see also Madden, D (2002) *Medicine, Ethics and the Law*. Dublin: Tottel Publishing, p 276.

³⁴ *Attorney General (Society for the Protection of the Unborn Child (Ireland) Ltd) v. Open Door Counselling* [1988] I.R.593 at 623; see also Casey, n above 8, at p 434.

³⁵ *S.P.U.C. (Ireland) Ltd. v. Grogan (No. 1)* [1989] I.R.753.

³⁶ Casey, n above 8, at p 438.

economic operator established in another Member State, and so did not breach Article 60 (now 50) of the Treaty of Rome.³⁷

Open Door Counselling claimed the restraints under Irish law on their freedom to impart and receive information concerning abortion facilities outside the jurisdiction of Ireland had breached their right to freedom of expression as guaranteed by Article 10 of the European Convention on Human Rights, and along with the Dublin Well Woman Centre, took their case to the European Court of Human Rights.³⁸

By a majority of 15-8 the European Court of Human Rights ruled in their favour, finding that despite the fact that the restraints in question pursued an aim allowed by the convention, namely the protection of morals, of which, in Ireland, the protection of the right to life of the unborn is one aspect, the Supreme Court's grant of an injunction in 1988 did breach Article 10. However, as the European Convention on Human Rights was not then part of Irish domestic law, the decision of the Supreme Court was not overridden.³⁹

In May 1992 the Foreign Ministers of the Member States of the European Union adopted a Solemn Declaration relating to Protocol No. 17 of the Treaty of the European Union. Protocol No. 17 states:

‘Nothing in the Treaty on European Union, or in the Treaties establishing the European Communities, or in the Treaties or Acts modifying or supplementing those Treaties, shall affect the application in Ireland of Article 40.3.3 of the Constitution of Ireland’.⁴⁰

Protocol No. 17 to the Treaty of the European Union was adopted to avoid the possibility of Community law overriding Article 40.3.3 of the Irish Constitution should a conflict arise between this constitutional provision and Community law.

³⁷ Ibid, at p 439.

³⁸ Ibid.

³⁹ *Open Door and the Dublin Well Woman v. Ireland* (1992) 15 EHRR 244; see also Cox, n above 28, at p 438.

⁴⁰ Robinson, W (1992) European Dimension of the Abortion Debate. *Abortion Law and Conscience. A Special Issue of Doctrine and Life* (May/June), p 274.

4.3.2 The 'X' Case

In *Attorney General v. X*,⁴¹ the Supreme Court had to consider for the first time the conflict between the right to life of a foetus and that of a mother. This case concerned a 14 year-old rape victim who was believed to be at risk of suicide. She and her parents wished to travel to the UK to obtain an abortion but had been prevented from doing so. The court ruled that Article 40.3.3 did allow an abortion to take place, within or without the jurisdiction, where there was a 'real and substantial risk to the life of the mother', which could only be avoided by terminating her pregnancy.⁴² In relation to how Article 40.3.3 might be interpreted, the court decided that the function of this Article was to:

'enshrine in the Constitution the protection of the right to life of the unborn thus precluding the legislature from an unqualified repeal of s.58 of the Act of 1861 or otherwise, in general, legalising [sic] abortion.'⁴³

This judgment, despite being generally regarded as the leading authority on the interpretation of Article 40.3.3,⁴⁴ appears, however, to be quite narrow, essentially suggesting that the only purpose of 40.3.3 is to prevent the legalisation of abortion in Ireland. It is not of much assistance for the purposes of considering the meaning of Article 40.3.3 in relation to the definition of '*unborn*' and the situation pertaining to the pre-implantation embryo as the court was considering an established pregnancy. Its importance actually lies in the dissenting judgment of Hederman J which is the closest that the Supreme Court has come to discussing what is meant by the term '*unborn*' as used in the Constitution. Hederman J states that:

'The most significant aspect of the provisions of Article 40, s.3 and of the Eight Amendment is the objective of protecting human life which is the essential value of every legal order and central to the enjoyment of all other rights guaranteed by the Constitution. The

⁴¹ *Attorney General v. X* [1992] 1 IR 1.

⁴² Madden, n above 33, at p 274; see also Byrne, R and McCutcheon, JP (2001) *The Irish Legal System* (4th ed.). Dublin: Tottel Publishing Ltd, p 605.

⁴³ *Attorney General v. X* [1992] 1 IR 1, per McCarthy J at 81.

⁴⁴ McGuinness, n above 22, at p 399.

constitutional provisions amount to a dedication to the fundamental value of human life.

‘The Eight Amendment establishes beyond any dispute that the constitutional guarantee of the vindication and protection of life is not qualified by the condition that the life must be one which has achieved an independent existence after birth. The right to life is guaranteed to every life, born or unborn. One cannot make distinctions between individual phases of the unborn life before birth, or between unborn and born life’.⁴⁵

Hederman J is effectively saying that distinctions cannot be made, for the purposes of constitutional protection, between the foetus at 6 days, 6 weeks or at 36 weeks. He adds that:

‘The State’s duty to protect life also extends to the mother. The natural connection between the unborn child and the mother’s life constitutes a special relationship. But one cannot consider the unborn life only as part of the maternal organism.’

Hederman J would appear to be claiming that the protection of unborn life goes beyond the special relationship between the unborn and mother, that is, beyond the implanted foetus. However, other commentators have interpreted the judgment in the *X* case as confirming that it is only through implantation that the ‘unborn’ qualifies for State protection.⁴⁶

Following the *X* case the Irish Government sought to amend Protocol No.17 to ensure that Community law rights to travel and information were not limited by the Protocol. However, other Member States were reluctant to agree to the amendment of the Protocol as they were concerned that this might set a precedent for the renegotiation of other aspects of the Treaty on European Union, agreeing instead to give a legal interpretation of the Protocol which states that:

⁴⁵*Attorney General v. X* [1992] 1 IR 1; See also Madden, n above 33, at p 278.

⁴⁶McGuinness, n above 22, at p 399.

‘In the event of a future constitutional amendment in Ireland which concerns Article 40.3.3 of the Constitution of Ireland and which does not conflict with the intentions of the High Contracting Parties hereinbefore expressed, they will, following entry into force of the Treaty of European Union, be favourably disposed to amending said Protocol so as to extend its application to such constitutional requests’.

Ireland sought to bring its laws into line with Conventions requirements, and as the Supreme Court’s decisions in *Attorney General (S.P.U.C. (Ireland) Ltd) v. Open Door Counselling* and *S.P.U.C. (Ireland) Ltd. v. Grogan*⁴⁷ were based on the terms of Article 40.3.3, in order to do so a referendum was held late in 1992. The proposed Twelfth amendment was defeated. This would have removed the threat of suicide as a grounds for lawful abortion as per the judgment in the *X* case. The Thirteenth Amendment to the Constitution prevents the right to life of the unborn from being invoked to prevent a woman from travelling to another State for the purpose of an abortion (where such an abortion is legal in that other State), while the Fourteenth Amendment to the Constitution precludes the use of Article 40.3.3 to restrict the availability of information on abortion.⁴⁸ These latter two amendments were passed. Despite the insertion of the 13th Amendment into the Constitution some commentators felt that although since *X* there has been a category of ‘lawful’ abortions there has actually been:

‘...no further clarification as to what this means in practice’.⁴⁹

The most recent challenge to Article 40.3.3 was the case of *A, B and C v. Ireland*.⁵⁰ In this case, three women took the Irish Government to the European Court of Human Rights because they felt that being forced to travel to the UK to procure an abortion breached their human rights under articles 2, 3, 8, and 14 of the European Convention on Human Rights (ECHR).⁵¹ Ultimately the ECtHR decided that the

⁴⁷ *S.P.U.C. (Ireland) Ltd. v. Grogan* (No. 1) [1989] I.R.753.

⁴⁸ Casey, n above 8, at p 442.

⁴⁹ McGuinness, n above 26, at p 480.

⁵⁰ *A, B and C v. Ireland* 25579/05 [2010] ECHR 2032.

⁵¹ McGuinness, n above 26, at p 476.

human rights of C only had been breached as she was recovering from cervical cancer when she became pregnant. The Court held that Ireland's failure to actually:

‘...implement the constitutional right to an abortion in Ireland in the case of a risk to the life of the woman,’⁵²

was a violation of her Article 8 rights. In coming to this decision the Court acknowledged that the issue of abortion still provokes controversy in Ireland and that there was no consensus across Europe on the question of when life begins, as it had previously noted in *Vo v. France*.⁵³

4.4 The Meaning of ‘Unborn’

The question of when life begins has caused problems of clarification for some time.⁵⁴ As far back as 1996 in Ireland the Constitutional Review Group, in relation to Article 40.3.3, had identified the absence of a definition of the word ‘*unborn*’ as a difficulty in the state of the law:

‘There is no definition which, used as a noun, is at least odd. One would expect ‘unborn human or unborn human being’. Presumably, the term ‘unborn child’ was not chosen because of uncertainty as to when a foetus might properly be so described. Definition is needed as to when ‘unborn’ acquires the protection of the law. Philosophers and scientists may continue to debate when human life begins but the law must define what it intends to protect. ‘Unborn’ seems to imply ‘on the way to being born’ or ‘capable of being born’. Whether this condition obtains as from fertilisation of the ovum, implantation of the fertilised ovum in the womb, or some other point, has not been defined’.⁵⁵

⁵² *A, B and C v. Ireland* 25579/05 [2010] ECHR 2032 at 3.

⁵³ *Vo v. France* 53924/00 [2004] ECHR 326 (July 8 2004).

⁵⁴ Warnock, M (1987) Do Human Cells Have Rights? *Bioethics* 1: 1-14.

⁵⁵ Constitutional Review Group (1996) *Report of the Constitution Review Group*. Dublin: The Stationery Office, at 275-276; see also Madden, D (2008) Article 40.3.3 and Assisted Human Reproduction in Ireland. In Schweppe, J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, pp 303-318.

The Review Group recommended the introduction of legislation dealing with the definition of ‘unborn’, while recognising that such legislation would have to comply with Article 40.3.3 generally.

The Green Paper on Abortion, 1999, from an interdepartmental working group working under the supervision of a cabinet committee,⁵⁶ also attempted to address this issue by suggesting that in trying to define the term ‘unborn’ in the context of possible further change in the law on abortion:

‘The issue of whether the term ‘unborn’ should be or can be defined may again arise in any option involving the retention of Article 40.3.3 or in any amendment of the article which uses the term. If it is decided therefore that the ‘unborn’ should be defined, at least four types of definition are possible, as follows:

- (i) the time of fertilisation,
- (ii) implantation,
- (iii) some other specified time after fertilisation, or
- (iv) viability.’⁵⁷

In 1983 supporters of the amendment appeared to be satisfied that the term ‘unborn’ provided constitutional protection from the time of conception/ fertilisation, although the actual timing of this cannot be precisely defined.⁵⁸ Although this issue has never directly arisen for consideration by the courts there is some judicial support for this interpretation *Attorney General (SPUC) v. Open Door Counselling*.⁵⁹ Were such an

⁵⁶ The interdepartmental group included officials from the Dept. of Health, Foreign Affairs, Equality and Law Reform and the Office of the Attorney General. The Cabinet committee overseeing its work included the Ministers of Health, Foreign Affairs, Equality and Law Reform, Justice, Public Enterprise and the Attorney General. The working group canvassed for and received submissions from public, professional and voluntary organisations to help inform the process of preparation of the Green Paper on Abortion. This is an example of the kind of deliberative democratic process described in the previous chapter. See www.dohc.ie/publications, and www.irishtimes.com/newspaper/special/1999/abortion/index.htm

⁵⁷ Government of Ireland (1999) *Green Paper on Abortion*. Dublin: Government of Ireland Publications, at paras 7.07-7.13.

⁵⁸ Cox, n above 28.

⁵⁹ Hamilton, J refers to the ‘foetus in the womb as that which has protection and states that the protection begins at conception. *Attorney General (SPUC) v. Open Door Counselling* [1988] IR 593 at 598.

interpretation to be formally confirmed, it would appear to cast some doubt over the legality of the use of post-coital contraception (the ‘morning after pill’ and post-coital IUD) but neither have been subjected to legal challenge since the passing of the 1983 constitutional amendment and do not appear currently to cause any difficulties for the medical profession.⁶⁰ These potential problems were actually recognised when Article 40.3.3 was being drafted in 1982, and the proposal that the definition of the unborn should actually exclude:

‘...the fertilised ovum prior to the time at which such fertilised ovum becomes implanted in the wall of the uterus,’⁶¹

was an attempt to prevent constitutional protection applying immediately post conception. However, the inclusion of this definition in the final draft of Article 40.3.3 was defeated in the Seanad.

There was an also awareness of the problems that could result from the application of constitutional protection immediately post-conception in the Green Paper on Abortion:

‘If it were specified within a definition that the protection of Article 40.3.3 extended to *in vitro* fertilisation, legal problems could arise in relation to some practices in this area. If, as an alternative it was decided to specifically exclude *in vitro* fertilisation from the protection of Article 40.3.3 the result could appear anomalous’.⁶²

Commenting on the uncertainty of the law in this area, Shercock has stated that:

‘It is likely that the courts would hold the *in vitro* embryo to come within the protection of [Article 40.3.3] and if this is the case, it would appear to rule out embryo research in Ireland, certainly in cases involving the destruction of the embryo. It would also appear to have implications for fertility treatments involving *in vitro* fertilisation as it would undoubtedly require that all embryos

⁶⁰ n above 56, at paras 7.07-7.13.

⁶¹ *An Bille um an Ochtú Leasúar an mBunreacht*, 1982 An Tuarascail (Atógáil) www.oireachtas-debates.gov.ie/S/0100/S.0100.19830525006.html.

⁶² n above 56, at paras 7.07-7.13.

produced would have to be placed in the woman's uterus. Presumably, this would have to include the placing in the uterus of embryos even if they were known to be defective'.⁶³

A number of successive governments failed to introduce legislation that would clarify the law on abortion in Ireland following the judgment in the *X* case. Following the All-Party Oireachtas Committee on the Constitution's examination of this issue in its 2000 report on Abortion,⁶⁴ the Government of the day proposed to hold another referendum in 2002 proposing the insertion of yet another amendment, which would make protection of the life of the unborn in the womb dependent on the 'Protection of Human Life in Pregnancy Act 2002'.⁶⁵ This Act would only come into effect if the amendment were passed. This was another attempt to modify the *X* case position in a similar way to the rejected 1992 amendment, making any abortion unlawful in the case of the threat of suicide, but permissible if there were a demonstrable 'real and substantial' threat to the life of the mother. As this amendment was narrowly defeated, the Protection of Human Life in Pregnancy Act, 2002, did not come into effect.

This overview of germane case law demonstrates the difficulties that have been addressed by the courts. Despite criticisms of the legislature from domestic and international courts there has not been any attempt to remove the uncertainty around the definition of the 'unborn' and define the protection it is afforded under the Irish constitution. It has been noted critically by international scientific journals that Ireland is not in a position to develop its stem cell industry until the legal position of the pre-implantation embryo is clarified.⁶⁶ The implications of this uncertainty are highlighted by Paper 2 for stakeholders in the area of hESC research.

⁶³ Shercock, A (1989) The Right to Life of the Unborn and the Irish Constitution. *Irish Jurist* XXIV: 24; and Madden, D (2006) Assisted Reproduction in the Republic of Ireland – A Legal Quagmire. In Gunning, J and Holm, S *Ethics, Law and Society, Vol. II*, pp 27-34, at p 30.

⁶⁴ All-Party Oireachtas Committee on the Constitution (2000) *5th Progress Report: Abortion*. Dublin: Government Publications.

⁶⁵ The key provisions of this act were that (i) no abortions would be permitted in the State, (ii) Abortion would be defined as 'the intentional destruction by any means of unborn human life after implantation in the womb of a woman', and (iii) abortion would not include the carrying out of a justifiable medical procedure to prevent a real and substantial risk of loss of woman's life other than by self-destruction. Mills, S (2007) *Clinical Practice and the Law*. Dublin: Tottel Publishing, pp 290-291.

⁶⁶ Abbott, A (2011) Irish Election Raises Questions for Stem Cell Research. *The Great Beyond* February 28th. Available at www.go.nature.com/ftx2hu. (Accessed 18/4/12). Also see Mitchell, S (2011) Warning Over Stem Cell Research in Ireland. *The Sunday Business Post*, March 6th.

4.5 Policy Initiatives

In an attempt to initiate a legislative response to the uncertainty in the law, Senator Mary Henry introduced the 'Regulation of Assisted Human Reproduction Bill' in the Seanad in July 1999.⁶⁷ This Bill proposed a model of regulation similar to that which already existed in the UK under the HFE Act 1990. It proposed regulating the providers of assisted reproduction and the establishment of an ethics committee for assisted human reproduction. This Bill was defeated on a vote of 22 - 15. However, it did appear to provide some impetus to the Government which then established the Commission on Assisted Human Reproduction (CAHR) in 2000 to make recommendations in the area of *in vitro* practices. The Commission published its report in 2005 which contained 40 recommendations. The first of these was that:

'A regulatory body should be established by an Act of the Oireachtas to regulate AHR services in Ireland.'⁶⁸

A majority of the Commission recommended that:

'The embryo formed by IVF should not attract the legal protection until it is placed in the human body, at which stage it should attract the same level of protection as the embryo formed *in vivo*.'⁶⁹

A majority of CAHR members also recommended that:

'Embryo research, including embryonic stem cell research for specific purposes only and under stringently controlled conditions, should be permitted on surplus embryos that are donated specifically for research. This should be permitted up to 14 days following fertilisation. The regulatory body should stipulate under what conditions and for what purposes embryo research is permitted'.⁷⁰

⁶⁷ *An Bille um Atáirgeadh Daonna Cuidithe A Rialáil*, 1999.

⁶⁸ CAHR (2005) *Report of the Commission on Assisted Human Reproduction*. Dublin: Government of Ireland Publications, p 8.

⁶⁹ *Ibid*, p 34.

⁷⁰ *Ibid*, p 58.

The CAHR advised that the creation of IVF embryos for research should be prohibited but the CAHR members, with one exception, recommended that the creation of Somatic Cell Nuclear Transfer (SCNT) embryos for research should be allowed. The CAHR further recommended that both reproductive cloning and the generation and use of interspecies or hybrid embryos should be prohibited.⁷¹ As of August 2012 none of the recommendations of the CAHR have been enacted in legislation.

Prior to the publishing of the Report of the CAHR in both 2001 and 2003, green papers were drafted and proposed by Daíl Deputy Mary Upton, entitled *An Bille Um Atáirgeadh Daonna*, or Human Reproduction Bill.⁷² In the explanatory memorandum the purpose of the (identical) Bills is described as:

‘An Act to prohibit the bringing into being of a human embryo other than by a process of fertilisation, intended to lead to childbirth’.

They claim to have no general implications for assisted human reproduction or IVF, and aim to create two specific criminal offences, and provide limits within which research or a licensing regime should operate.

Section 1(1) of the Bill provides that:

‘A person who brings into being a human embryo otherwise than by a process of fertilisation shall be guilty of an offence’.

This provision prohibits cloning, whereby an embryo is created by removal of the nucleus from the egg and replaced by the nucleus of a cell taken from an adult human. The embryo thereby created is genetically identical to one parent. According to the explanatory memorandum:

‘such cloned embryos could conceivably be created either for research purposes, connected with possible future

⁷¹ Ibid, p 60.

⁷² *Human Reproduction Bill*, 2001; *Human Reproduction Bill*, 2003. Dublin: Government of Ireland Publications.

forms of therapeutic treatment, or as a substitute for reproduction by fertilisation, assisted or otherwise’.

To be found guilty of committing such an offence is punishable by ‘imprisonment for a term not exceeding ten years or a fine or both’. Scientists, such as those who participated in Paper 2, were well aware of the implications of this proposed bill and apprehensive of it being implemented.

Section 1 (2) of the Human Reproduction Bill provides that:

‘A person who brings into being a human embryo otherwise than-

- (a) by sexual intercourse, or
- (b) in the course and for the purpose of a medical treatment that is intended to lead to a child being delivered alive from the womb of a woman, shall be guilty of an offence’.

This subsection confirms that it is unlawful to create embryos for purely research purposes, whose future birth is not envisaged. It does not, however:

‘...require that every one of the embryos created in a process of assisted fertilisation must survive, or be intended to survive, to viability. But embryos can only be brought into being in a process where childbirth is the ultimate aim of the treatment’.

Neither the *Human Reproduction Bill, 2001* nor the *Human Reproduction Bill, 2003* have advanced beyond the green paper stage in the Oireachtas.

It would appear reasonable from this review of legislation (or lack thereof) and case law to assume that the Irish Constitution currently prohibits embryo and stem cell research and embryo destruction, but according to Madden, such an interpretation may not be strictly accurate. Madden claims for the purposes of IVF if:

‘the ‘unborn’ means the fertilised egg then freezing may not be permissible, at least until there was a guarantee that the embryo would subsequently be transferred to a receptive uterus.

If however the word ‘unborn’ is interpreted as meaning ‘not yet born’ or ‘with the potential to be born’ then, ‘in light of the biological development of the early embryo and the absence of potential in the pre-implantation embryo it is likely that the Constitutional protection extends only to the embryo after implantation in the uterus’.⁷³

Madden argues that the pre-implantation embryo is not sentient, and it:

‘has no ‘potential’ to become anything while it remains in a Petri dish in the laboratory. Therefore it may be argued that the Constitutional provision has no application to the pre-implantation embryo’.⁷⁴

Academic commentators in general have concluded that:

‘It cannot be said with certainty whether the protection afforded by Article 40.3.3 to the ‘unborn’ applies from the moment of fertilisation, the moment of implantation, or from some later date’.⁷⁵

This lack of consensus, even among respected Irish constitutional law experts, leaves those such as research scientists looking for clarification and certainty, frustrated, as they cannot progress their research without knowing what is permissible and what is not. This is important both for themselves and in terms of attracting funding from Ireland’s indigenous scientific funders, such as the Health Research Board and Science Foundation Ireland, and from international collaborators. This thesis would contend that it is essential that Ireland defines exactly what the word ‘unborn’ means, so as to provide clarification with regard to the legal position of pre-implantation embryos, and hence their availability, or not, for use in hESC research.

⁷³ Madden, n above 33, at p 278.

⁷⁴ Ibid.

⁷⁵ Kingston, J, Whelan, J and Bacik, I (1997) *Abortion and the Law: An Irish Perspective*. Dublin: Round Hall.

4.5.1 Role of the Irish Medical Council

The Report of the Irish Council for Bioethics on the ‘*Ethical, Scientific and Legal Issues concerning Stem Cell Research*’, published on April 9th 2008, notes that there is currently no legal impediment to the importation or use of stem cell lines into Ireland by scientists as they, unlike doctors working in the same field are not bound by the only recommendations pertaining to this area of research which come from the Irish Medical Council in their ‘*Guide to Ethical Conduct and Behaviour*’.⁷⁶

During the period of the late 1990’s to mid 2000’s, as a consequence of the numerous referenda to amend the Constitution, the Irish Medical Council set about ‘changing the expression of its stance on abortion contained in its *Guide to Ethical Conduct and Behaviour* (2004).’⁷⁷ This guide had stated in relation to IVF that ‘any fertilised ovum must be used for normal implantation and must not be deliberately destroyed’. The guide also stated that:

‘...the creation of new life forms for experimental purposes or the deliberate and intentional destruction of in vitro human life already formed is professional misconduct’.

A practicing medical doctor must adhere to these guidelines or risk censure or even removal from the register of medical practitioners. In the latest edition of their guidelines the Medical Council changed their position with the revised guidelines simply stating that a doctor should not:

‘...participate in creating new life forms solely for experimental purposes.’⁷⁸

It would appear from this that although it is not possible to create an embryo for research purposes only, surplus embryos could be donated, or more likely, left to perish.⁷⁹ Prof Kieran Murphy, the President of the Medical Council, stated the Council was ‘exercised’ by the lack of legislation in this area but was unable to take

⁷⁶ Medical Council of Ireland (2004) *A Guide to Ethical Conduct and Behaviour* (6th ed.). Dublin: MCI, Section F – Genetic Testing and Reproductive Medicine, at 24.1.

⁷⁷ Mills, n above 65, at p 291.

⁷⁸ Medical Council of Ireland (2004) *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (7th ed.). Available at <http://www.medicalcouncil.ie>.

⁷⁹ Clissmann, I and Barrett, J (2012) The Embryo in vitro after *Roche v. Roche*: What Protection is now Offered? *Medico-Legal Journal of Ireland* 18: 13.

up a more definite position when he was questioned about this new approach.⁸⁰ Prof. Murphy expressed hope that as the process of developing an ethical guide is ‘really a rolling agenda,’ that over the remainder of the term of the present Medical Council further comprehensive guidelines would be developed on AHR and stem cell research.⁸¹ However, the current absence of legislation in the area of stem cell research effectively means that there are no legal restrictions for researchers who are not registered medical practitioners to carrying out embryonic and stem cell research. Madden has confirmed this means that:

‘...hESCR and other related therapeutic and research applications may be carried out in Ireland in the absence of regulatory oversight’.⁸²

As may be seen from this review, Ireland has no legislation or national policy which actually prohibits the use of embryos for research. Nor is there any legal impediment to the importation of stem cell lines by scientists. The only current legislation which relates to ART or hESC research in Ireland, though it does so only obliquely is the Human Tissue and Cells Regulations (2006). This legislation is mainly concerned with the actual cells used in the IVF process.⁸³

4.6 The ‘Frozen Embryos’ Case

In the absence of any clarifying legislation on the protection owed to the pre-implantation embryo an interesting case came before the High Court. This concerned a separated couple who were disputing what was to happen to three frozen embryos from an IVF cycle.⁸⁴ This case was similar in a number of respects to *Evans v. UK*, in that in the UK case the woman had attempted to claim her right to procreate took precedent over the man’s right not to, and over his right to withdraw his consent to the process.⁸⁵ This was ultimately rejected by both the UK courts and the European

⁸⁰ Gantly, D (2009) Cracking the Code of Ethics. *Irish Medical Times*, November 27th.

⁸¹ Ibid.

⁸² Madden, n above 55, at p 314.

⁸³ *Quality and Safety of Human Tissues and Cells Regulations* (S.I. No.158 of 2006). Introduced in compliance with 2004/23; also see Clissmann, n above 79.

⁸⁴ *MR v. TR & Ors* [2006] IEHC 359.

⁸⁵ *Evans v. Amicus Healthcare Ltd* [2004] EWCA Civ 727.

Court of Human Rights.⁸⁶ The applicant in the Irish case, Mary Roche, wished to have the frozen embryos implanted despite the fact the couple had separated since successfully having a child as a result of the IVF cycle which had resulted in three spare embryos. She claimed that by virtue of Article 40.3.3 of the Irish Constitution the withdrawal of her husband's consent was irrelevant as the Constitution conferred the right to life on the frozen embryos. If the Court upheld this claim, there would be serious implications for the many ART practices which have become commonplace in Ireland despite the lack of formal regulation, and legality of post-coital contraception would be unclear.⁸⁷

The judge, McGovern J, stated despite the various definitions offered by the many witnesses called, that in his opinion it was not possible for 'this Court to state when human life begins'.

He examined the legislative history of the Constitution and the amendment in question, claiming as O'Higgins CJ had in *The State (Healy) v. Donoghue*⁸⁸ that in his view the preamble to the Constitution:

'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 such changes in other words the Constitution did not seek to impose for all time the ideas prevalent or accepted with regard to these virtues at the time of its enactment'.

McGovern J quoted Walsh J from *McGee v. Attorney General*⁸⁹ where Walsh J had stated:

⁸⁶ *Evans v. The United Kingdom* (Application No 6339/05), Fourth Section (7/3/06) Grand Chamber of the ECHR (10 April 2007).

⁸⁷ McGuinness, n above 22, at pp 396-408.

⁸⁸ *The State (Healy) v. Donoghue* [1976] I.R.325 at 347.

⁸⁹ *McGee v. Attorney General* [1994] I.R.284 at 319.

‘According to the preamble, the people gave themselves the Constitution to promote the common good with due observance of prudence, justice and charity so that dignity and freedom of the individual might be assured’.

‘No interpretation of the Constitution is intended to be final for all time. It is given in the light of prevailing ideas and concepts.’

McGovern J claimed that these views acknowledged that changing values in society meant that rights not previously acknowledged under the Constitution could now be firmly established but that they were not authority for the proposition that the word ‘unborn’ should be given a different meaning than that intended in 1983 when the amendment was introduced.

He concluded that:

‘The Courts have never, thus far, considered whether the word ‘unborn’ in Article 40.3.3 includes embryos *in vitro*. In the *Smeaton* case⁹⁰ Munby J referred to a number of commentaries on the issue of law and medical ethics and medical legal aspects of reproduction. He cited a publication called *Post-Coital Anti Pregnancy Techniques and the Law* by K. Norrie who, he said puts the argument very clearly:

... The question of when human life begins as a matter of morality, or indeed biology, is not the same as the question of when pregnancy begins for the purposes of the law. Human life may – or may not- begin in a test-tube, but the mere existence of a fertilised egg in a test-tube does not make the woman who produced it pregnant....’⁹¹

McGovern J continued:

‘There has been no evidence adduced to establish that it was ever in the mind of the people voting on the Eight Amendment to the

⁹⁰ *The Queen on the Application of Smeaton v. Secretary of State for Health* [2002] 2 FLR 146.

⁹¹ Binchy, n above 6, at p 208.

Constitution that ‘unborn’ meant anything other than a foetus or child within the womb. To infer that it was in the mind of the people that ‘unborn’ included embryos outside the womb or embryos *in vitro* would be to completely ignore the circumstances in which the amendment giving rise to Article 40.3.3 arose. While I accept that Article 40.3.3 is not to be taken in isolation from its historical background and should be considered as but one provision of the whole Constitution, this does not mean that the word ‘unborn’ can be given a meaning which was not contemplated by the people at the time of the passing of the Eighth Amendment and which takes place outside the scope and purpose of the amendment’.

He found that while embryos *in vitro* are deserving of special respect, the frozen embryos in the case in question were not ‘unborn’ as defined by the Constitution, as:

‘...no evidence has been adduced by the plaintiff which would enable the Court to hold that the word ‘unborn’ in article 40.3.3 includes embryos outside the womb or *in vitro*. I have therefore come to the conclusion that the word ‘unborn’ within Article 40.3.3 does not include embryos *in vitro* and therefore does not include the three frozen embryos which are at the heart of the dispute’.

He further suggested that it should not be a matter for the Courts to decide whether the word ‘unborn’ should or should not include embryos *in vitro*, but that it should be a matter for the Oireachtas or the people through the process of a Constitutional Amendment’ to so decide as the function of the Courts:

‘...is to apply the law, which are the rules and regulations that govern society...laws should, and generally do, reflect society’s values and will be influenced by them. But at the end of the day it is the duty of the Courts to implement and apply the law, not morality’.

In the absence of any regulatory legislation or precedent McGovern J stated that:

‘...embryos outside the womb have a very precarious existence,’

and that:

‘...until the law or the Constitution is changed this issue remains within the sphere of ethics and morality.’

This High Court judgment was appealed on 14 grounds to the Supreme Court in 2009.⁹² In the Supreme Court the rejection of the applicant’s appeal was based on three main issues:

- (1) the validity of the withdrawal of the consent by the defendant father to the implantation of the embryos;
- (2) the question of whether or not the embryos may be defined as unborn for the purposes of the constitution, and
- (3) a claim under Article 41, the article which expresses ‘Respect for Private and Family Life’ in the Constitution, which was contingent on the embryos being considered unborn under the Constitution.

The Supreme Court commentated on the consent procedures in the ART clinic, criticising them as being generally poor but ruled that the withdrawal of the Father’s consent was valid.

In upholding McGovern J’s judgement the Supreme Court ruled that the ‘unborn’ under Article 40.3.3 was equated with an implanted embryo, that is, an embryo *in utero*, and therefore the *in vitro* embryo did not come under 40.3.3 for the purposes of acquiring the protection of the Constitution. Denham J stated that this case was:

‘...not about the wonder and mystery of human life’,

but simply a matter of construing the word ‘unborn’ in the Constitution to determine its constitutional meaning.

⁹² *Roche v. Roche & Ors* [2009] IESC 82. See Appendix for commentary on this case: Gough, F (2010) Ireland and the Frozen Embryos: A Slight Thawing? *Medical Law Review* 18: 239-247.

She emphasised that it was the Court's responsibility to interpret the Constitution and stressed that it should not be up to the Court to make a distinction between the moral status and the legal status of an embryo but only to clarify when the legal protection of this entity begins under Irish law. Denham J also explained that the original aim of the constitutional amendment was to strengthen the protection afforded to the embryo by s.58 of the Offences Against the Persons Act (OAPA) (1861), thereby concurring with McCarthy J in *Attorney General v. X*.⁹³ However, Denham J did not acknowledge that in practical terms these issues are not necessarily quite as distinct as she asserted. In reality any future policy reform in this area would necessitate considerable compromise.

In their judgments Hardiman J and Geoghegan J agreed with Denham J that the purpose of Article 40.3.3 was to prevent the decriminalisation of abortion, and that the appellants had failed to establish that frozen embryos were 'unborn' within the meaning of the Article. This position was supported by Fennelly J who declared his concern:

‘...at the total absence of any form of statutory regulation of *in vitro* fertilisation in Ireland’.

Murray CJ and Hardiman J also noted in dismissing the appeal that there has been a marked reluctance on the part of the legislature to actually legislate on these issues. They emphasised that it is:

‘...for legislatures in the exercise of their dispositive powers to resolve such issues on the basis of policy choices.’⁹⁴

Hardiman J warned that:

‘if the legislature does not address such issues, Ireland may become by default an unregulated environment for practices which may prove controversial or, at least, to give rise to a need for regulation.’⁹⁵

⁹³ *Attorney General v. X* [1992] 1 IR 1.

⁹⁴ *Roche* as per Murray CJ.

⁹⁵ *Roche* as per Hardiman J.

4.6.1 Practical Implications of Legal Lacuna

In the current regulatory lacuna, some institutions involved in research have attempted to forge their own pathway. The Governing body of University College Cork (UCC) in late 2008 backed by one vote (16 to 15) the recommendation of the university's Academic Council allowing embryonic stem cell research at UCC 'under strict guidelines drawn up by the University Research Ethics Board (UREB)'.⁹⁶ A statement from UCC confirmed that it had 'taken cognisance' of the two expert independent reports published in this context in recent years – the *Report of Commission on Assisted Human Reproduction*, (2005) and the *Opinion* of the Irish Bioethics Council, (2008) when drawing up their guidelines, and reiterated that:

'...in the absence of either national legislation or policy, the university has sought to take steps that would ensure that the strictest internal control over research in this area.'⁹⁷

The proposal of UCC's Governing Body did not recommend destructive research on living human embryos.⁹⁸

UCC were able to draw up and approve these proposals because of the total absence of national legislative measures that prohibit such action; in addition it remains unclear as to whether or not embryo freezing and stem cell research actually violate any existing constitutional provisions. Unless the regulatory body suggested by the Commission on Assisted Human Reproduction is established to control assisted human reproduction in Ireland, including clarifying under what conditions and for what purposes embryo research might be permitted, the legality of embryo research

⁹⁶ Culliton, G (2008) UCC's Code of Practice for Stem Cells. *Irish Medical Times*, November 26th. See also Dolan, A (2008) UCC Lauded for Move on Stem Cell Research. *The Irish Times*, November 25th.

⁹⁷ The guidelines include: (1) Every research project involving the use of hESC must be submitted to UREB for ethical review before the start of the project. (2) To facilitate review and monitoring UREB will establish a subcommittee with appropriate expertise to advise UREB in relation to: (a) the scientific merit of the research aims of the project; (b) repository from which it is proposed that the hESC lines will be imported.; (c) source of the cell used in production of the cell lines and in particular the procedures used in the procurement of the cells to ensure voluntary informed consent of donors; (d) adherence to bio-safety and quality assured measures; (e) relevant expertise of investigator to undertake the research; (f) scientific justification of the use of hESC lines, including the feasibility of using alternative research methods that do not require hESCs. (3) Approval of all research projects shall be by majority of UREB members after consideration of the scientific and ethical issues. (4) UREB will decide the frequency of ongoing monitoring of approved projects to ensure that they are complying with the conditions of ethical approval throughout the project. (5) An appeal from UREB's decisions may be made to the Academic Council Research Committee.

⁹⁸ Ibid.

will remain unclear and more third level institutions will be forced to draw up such guidelines. There are no guarantees that they would be as strict as those drafted by UCC, leaving the way open for research projects and treatments to be attempted at perhaps a high cost for those involved.

It is clear that Ireland will in the near future have to face up to the difficult challenge of defining at which point the constitutional protection of the ‘unborn,’ in which ever form that definition encompasses, will begin. The political response to this problem, however, has been uninspiring with the current Fine Gael/Labour coalition responding to the judgment in *A, B and C v. Ireland* (2011) by promising to establish yet another:

‘expert group to address this issue, drawing on appropriate medical and legal expertise with a view to making recommendations to make recommendation to the Government on how this matter should be properly addressed.’

Irish politicians, however, have a long history of ignoring this issue, behaving like proverbial Ostriches in the face of danger, in this case, to their Dáil seats.⁹⁹ If they do success in defining when constitutional protection to the unborn begins under Irish law this would bring a much needed degree of certainty to not only the women who wish to avail of abortion, but also to the doctors engaged in AHR and to the scientists who undertake hESC research in Ireland.

⁹⁹ “The country is effectively sticking its head in the sand and damaging the image of a developed, grown-up state we may now be trying to sell to the rest of the world”. Sullivan, K (2007) Letter to the Editor. *Irish Independent*, May 8th.

CHAPTER 5

5. OUTLINE OF PAPERS

5.1 PAPER 1

‘HUMAN EMBRYONIC STEM CELL RESEARCH IN IRELAND: ETHICAL AND LEGAL ISSUES.’

The introductory section to this thesis sought to portray the reasoning behind the standing of human embryonic stem cell research in Ireland. **Paper 1** examines the ethical and legal background to the current debate in Ireland on the use of hESCs for research, drawing on all the introductory chapters to explain the extant legal lacuna in this area. It identifies some of problems and specific legal difficulties encountered, when trying to advancing scientific research in Ireland, due to this lack of regulation. It discusses proposals made by the Commission on Assisted Human Reproduction (CAHR) and the Irish Council for Bioethics (ICB) in this area to help resolve these issues, while at the same time acknowledging that responsible regulation in this area faces many challenges, particularly in a country where opposing sides in the debate on a matter of public policy are separated by a wide divergence of strongly held ethical opinions.

This paper ultimately argues that although hESC research presents a difficult public policy and regulatory challenge, therapies derived from this research have the potential to deeply affect lives for the good. Therefore, an appropriate regulatory framework should be adopted to bring certainty to this field in Ireland and this paper supports the recommendation from both the CAHR and the ICB that hESC research be permitted on donated supernumerary embryos up to day-14 post fertilisation.

5.2 PAPER 2

“SOMETHING MUST BE DONE”: A STUDY OF STAKEHOLDER ATTITUDES TOWARDS THE IRISH LEGAL VACUUM IN RELATION TO HESC RESEARCH.

Empirical Research Methodology

Ireland’s failure to legislate for hESC research has led to a lack of regulatory certainty. The consequences of this uncertainty for particular groups of stakeholders, those involved in clinical and scientific research in this field and commentators on this area, in effect, Question 3, are addressed in **Paper 2** through an empirical study. This study was carried out in order to identify the multifarious issues which have developed due to the lack of hESC research governance in Ireland as perceived by those on whom the legal lacuna impacts in a practical sense. This was done by inviting a number of stakeholders, whose work, as researchers, in scientific and clinical settings, politicians and ethicists, means that they are in influential positions when it comes to shaping the debate around hESC research in Ireland, to participate in semi-structured interviews.¹

The most significant finding from this study was the call by these stakeholders for a clear legal definition of an embryo, and for all clinical research involving human-derived material to take place within an appropriate ethical and legal framework. Synergies are currently being constructed between the governance of science and society as States compete for advantages both in terms of the funding they commit to stem cell research and the moral values and regulatory framework they consider should guide its development. A cohesive policy should, therefore, be developed to regulate this science, not only in terms of risk and safety, but also taking cognisance of the sensibilities of Irish cultural values. There was, however, an acknowledgement by the stakeholders of the difficulties that will inevitably arise in attempting to institute regulation in this field.

¹ Following university ethical approval, 18 stakeholders were contacted by electronic mail. Twelve replied positively, and were interviewed. Two were willing to talk but did not wish to be formally interviewed, while four failed to respond, despite repeated mailing. Each participant was sent a questionnaire electronically prior to interview. At time of interview the conversation was recorded digitally once permission was obtained from the participant. The digital data obtained has been secured and kept confidential as per university guidelines. The content of the interview was subsequently transcribed and analysed to identify emergent themes.

Within this paper it is argued that as stem cell research offers novel opportunities and challenges, the continuation of the legal lacuna in this area undermines the perception of Ireland, not only as a country where unborn life is valued, but also as one open to investment, since the lack of certainty around what is permitted and what is not, deters potential international investment in Irish biotechnology. This paper concludes that the Irish Government should be the body making the policy choices, designing the laws and creating the institutions to allow stem cell research to flourish. Without such policies future consumer demand for any therapies developed from stem cell research may be fatally undermined.²

² Bared, Y (2009) Caution Urged in Trial of Stem Cells to Treat Spinal Cord Injury. *Nature* 458: 29.

5.3 PAPER 3

DELIBERATING OR DITHERING? IRELAND AND HUMAN EMBRYONIC STEM CELL RESEARCH

A consideration of achieving a regulatory framework through a deliberative democratic process is the final research question addressed by this thesis. The role of deliberative democratic theories in helping to resolve morally challenging bioethical issues, thereby helping to improve political decision making, was introduced in the philosophical chapter. How a public policy framework might be developed in Ireland to balance the potential health benefits of hESC research against the moral values of 21st century Irish society is discussed in **Paper 3**.

Central to these discussions is a consideration of deliberative democracy, in the form of proceduralism, as a mechanism to realise this framework and bring an end to the legal vacuum. Proceduralism allows an evaluation of what choices are available, permits reasonable debate to take place, emphasises reasons and rationales for and against an issue, and ultimately influences how the law in this area is structured and institutions designed through reasonable consensus. Two examples of how proceduralism has been used in different European countries, the United Kingdom and Germany, thereby facilitating the development of quite different but culturally tolerated policies in these States in the area of hESC research, are examined. If there is any possibility of Irish society eventually reaching an accord on this issue, a significant improvement in the Irish public's understanding of this area is needed.³ This could be achieved through just such a deliberative process. Therefore, the lessons the Irish legislature might learn from the experiences of Germany, in particular, which could facilitate the development of an appropriate hESC research policy are discussed. This paper concludes that an Irish-nuanced hESC research policy is possible and should not only be aspired to by the Irish legislature but it should be implemented without delay to provide the certainty that Irish stakeholders, such as those interviewed for paper 2, need.

³ Kennedy, D (2006) Foreword. In Scott, CT *Stem Cell Now: A Brief Introduction to the Coming Medical Revolution*. St Paul: Pi Press, p ix.

CHAPTER 6

6. PAPER 1: HUMAN EMBRYONIC STEM CELL RESEARCH IN IRELAND: ETHICAL AND LEGAL ISSUES

6.1 ABSTRACT

The paper examines the ethical and legal background to the current debate in the Republic of Ireland on the use of human embryos and embryonic stem cells (hESC) for research. How should public policy be formed to balance the potential health benefits of such research against the moral values of 21st century Irish society? The legislature has failed to address the constitutional ambiguities that have contributed to the current uncertainty as to the legal position of hESC research in Ireland. In view of the challenges posed by hESC research, it is argued that an appropriate regulatory framework should be adopted in Ireland, which will bring a degree of certainty as to what is and is not permitted. In adopting such a framework, it is suggested that hESC research should be permitted on donated supernumerary embryos up to day-14 post fertilisation.

6.2 Introduction

Research involving human embryonic stem cells (hESCs) seems to have the potential to produce significant therapeutic benefits in many degenerative diseases, such as Diabetes Mellitus, Alzheimer's disease and Parkinson's disease, through the replacement of damaged cells with appropriately cultured stem cells. Although induced pluripotent stem cells (iPSCs)¹ may have important potential applications by allowing the reproduction of human diseases in culture and the exploration of their progression in different issues,² currently the most therapeutically promising stem cells are those derived from embryos, such as the hESC-derived oligodendrocyte progenitor cells,³ which have recently begun phase 1 trials on spinal injury patients in the United States (US).⁴

¹ Takahashi, K and Yamanaka, S (2006) Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors. *Cell* 126 : 663-676.

² Deng, W (2010) EMBO Reports 11: 161-165.

³ Oligodendrocytes are the cells responsible for the myelination of neuronal axons. From Fitzgerald, MJ (1978) *Human Embryology*. New York: Harper and Row, p 146.

⁴ Strauss, S (2010) Geron trial resumes but standards for stem cells remain elusive. *Nature Biotechnology*. Vol. 28, No. 10, p.989-990.

It has been evidenced for some time that in Ireland ‘unborn life is something which represents a most important social value’.⁵ Despite this, there has been no political response to the question of whether or not human embryonic and embryonic stem cell research should be permitted to take place within Ireland. Currently there is no Irish legislative framework regulating either research involving human embryos and human embryonic stem cells,⁶ or assisted human reproduction (AHR), the source of these cells, although assisted reproductive technologies have been available since 1987.⁷ The absence of legislation in this area is seen as extremely unsatisfactory by scientists involved in stem cell research in Ireland⁸ in terms of their competitiveness internationally,⁹ as well as by clinicians involved in the provision of assisted reproductive services,¹⁰ as they are uncertain as to the legal standing of the services they provide.¹¹

In this paper, I argue that stem cell research presents unprecedented public policy and regulatory challenges, and that as therapies derived from hESC research have the potential to deeply affect lives, I believe that the goal of policy makers should be to pursue a policy that promotes human health, while aiming to protect the interests of the *in vitro* embryo, patients and society as a whole.¹² It is essential, therefore, for the purposes of transparency as well as clarity, that a regulatory regime be adopted that would permit hESC research to take place in Ireland within very strict parameters. The parameters countenanced would limit permissible research to donated supernumerary embryos from *in vitro fertilisation* (IVF) up to 14 days post fertilisation, and prohibit cloning or the production of human-animal chimeras.¹³ These are the parameters which have been advocated by both the

⁵ Cox, N (2008) Foetal Personhood in Perspective. In Schweppe, J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, pp 89-112.

⁶ Available at <http://www.irishstemcellfoundation.org/ethics>. (Accessed on 12/04/2011).

⁷ Mills, S (2007) *Clinical Practice and the Law*. Dublin: Tottel Publishing Ltd, pp 287-310.

⁸ Sullivan, S and Gough, F (2009) Crux of the Unborn. *The Irish Examiner*, December 15th.

⁹ Culliton, G (2008) Doctor Urges Stem Cell Clarity. *Irish Medical Times*, April 24th, p 8.

¹⁰ Donnellan, E and Allstrom, D (2008) UCC Debate to Fuel Calls for National Stem Cell Policy. *The Irish Times*, October 28th; Gartland, F (2008) UCC Ethics Board Calls for Debate on Stem Cell Research. *The Irish Times*, November 13th.

¹¹ Battles, J (2009) Going It Alone: Is IVF in Safe Hands? *The Sunday Times (Irish Edition)* September 27th, p 10.

¹² Holland, S, Lebacqz, K and Zoloth, L (2001) *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*. Cambridge, MA: MIT Press, p 199.

¹³ A human-animal chimera is an organism composed of two genetically distinct populations of cells, e.g. a single cell is taken from an early cleavage-stage human embryo and injected into the blastocyst of a genetically different host such as a mouse. From Carlson, B. M (1999) *Human Embryology and Developmental Biology*. St. Louis: Mosby, pp 38-74.

Commission on Assisted Human Reproduction (CAHR) in their report of 2005,¹⁴ and the Opinion published by the Irish Council for Bioethics (ICB) in 2008.¹⁵

In order to support this position, the particular issues which have contributed to the current Irish policy vacuum will be identified, and local recommendations related to the governance of human embryo research will be examined.

6.3 The Moral Status of the Embryo

The primary ethical issue associated with hESC research arises due to the way in which the embryonic stem cells are obtained. The inner cell mass of a blastocyst is the source of embryonic stem cells.¹⁶ The removal and placement in a suitable culture medium of the stem cells, however, disrupts the biological integrity of the blastocyst, rendering the embryo non-viable, as those elements necessary for successful implantation, the trophoblast cells and the extra-embryonic mesoderm, necessary for implantation and nourishment of the embryo, are no longer present.¹⁷ It is this destruction that has forced an examination of the moral status, or value of the *in vitro* human embryo and the uses to which it may be put.¹⁸

The status of the human embryo has continually changed throughout history in response to transformations of cultural values and the acquisition of scientific knowledge.¹⁹ The major monotheistic religions, Judaism, Islam, and Christianity, hold differing positions regarding the moral status of the human embryo.²⁰

¹⁴ CAHR (2005) *Report of the Commission on Assisted Human Reproduction*. Dublin, Government Publications Office.

¹⁵ Irish Council for Bioethics (Comhairle Bitheitice na hÉireann) (2008) *Ethical, Scientific and Legal Issues Concerning Stem Cell Research*. Dublin: ICB.

¹⁶ When an oocyte is fertilised it becomes a zygote and undergoes cleavage or successive division to become a 2-celled, 4-celled, 8-celled etc cluster of cells known as a morula (from the Greek for mulberry). When the morula contains 50-60 cells a cavity forms in the centre, it is then known as a blastocyst. At the blastocyst stage the embryo consists of two types of cells: an outer superficial layer (the trophoblast) that surrounds a small inner group of cells called the inner cell mass. Cells of the inner cell mass give rise to the embryo proper as well as a number of extra-embryonic structures, whereas the cells of the trophoblast form only extra-embryonic structures, including the outer layers of the placenta. (From Carlson, n above 13).

¹⁷ De Wert, G and Mummery, C (2003) Human Embryonic Stem Cells: Research, Ethics and Policy. *Human Reproduction* 18: 672-682.

¹⁸ <http://www.irishstemcellfoundation.org/ethicdebate>. (Accessed on 15/11/2010).

¹⁹ Lenoir, N (2000) Europe Confronts the Embryonic Stem Cell Research Challenge. *Science* 287 (5457), p 1425.

²⁰ Ibid.

Despite an acknowledged diversity of opinion within Judaism, the majority opinion holds that the Halakah's position on the moral status of the embryo is that no significant moral status is assigned to the embryo until 40 days after fertilisation. It is considered until this as 'mere water'.²¹ A foetus' moral position then develops gradually throughout a pregnancy until birth.²² Within Islam, although human life is considered valuable and deserving of protection,²³ the attainment of personhood does not occur until the body and soul subsist together. This ensoulment is thought to occur after the first trimester.²⁴ Little protection or rights are afforded to the pre-implantation embryo.

Within Christianity, Protestantism and Catholicism demonstrate a different emphasis on the moral status of the embryo. The Church of Ireland (Anglican) acknowledges the embryo as a potential human being but with some rights assigned from the moment of fertilisation. They distinguish morally between the adult human being and the embryo, that is, between actually 'being' in existence and 'potential'.²⁵ The Catholic Church has, however, consistently articulated the sanctity and dignity of human life, arguing that it should be revered and protected from the beginning of its existence,²⁶ as 'human corporeality begins at the very moment of conception'.²⁷ In both *Donum vitae* and *Dignitas personae*, despite the acknowledgment that personhood is a difficult and complex question,²⁸ the Church confirmed its position by arguing that embryos have the same intrinsic value as a fully developed human being and that it 'is to be respected and treated as a person from the moment of conception; and therefore from that same moment its rights as a person must be

²¹ Kerridge, IH et al (2009) Religious Perspectives on Embryo Donation and Research. *Clinical Ethics* 5: 35-45.

²² Simonstein, F (2008) Embryonic Stem Cells: The Disagreement Debate and Embryonic Stem Cell Research in Israel. *Journal of Medical Ethics* 43: 732-734.

²³ Askoy, S (2005) Making Regulations and Drawing up Legislation in Islamic Countries Under Conditions of Uncertainty, with Special Reference to Embryonic Cell Research. *Journal of Medical Ethics* 31: 399-403.

²⁴ Kerridge, n above 21.

²⁵ Church of Ireland General Synod Church in Society Committee, Medical Ethics, Science and Technology Sub-Committee. (2006) *Submission to the Irish Council for Bioethics: Stem Cell Research*. Available at <http://www.Ireland.anglican.org>. (Accessed on 15/11/2010).

²⁶ Corkery, P (2010) *Bioethics and the Catholic Moral Tradition*. Dublin: Veritas Publications, p 41-58.

²⁷ Lucas, RL (1997) The Anthropological Status of the Human Embryo. In De Dios Vial Correa, J and Sgreccia, E (eds.) *Identity and Statute of Human Embryo. Proceedings of Third Assembly of the Pontifical Academy for Life*. Vatican City: Liberia Editrice Vaticana, pp178-205.

²⁸ Congregation for the Doctrine of the Faith (1987) *Donum Vitae: Respect for Human Life*, chapter 1, question 1. Available at <http://www.vatican.va/roman/curia/congregations/cfaith/documents>.

recognized, among which in the first place is the inviolable right of every innocent human being to life'.²⁹ In addition, the Catholic Church advocates that every human being should be respected for themselves, and they should not be commodified as the human embryo has 'from the very beginning the dignity proper to a person'.³⁰ To treat it as 'the object or instrument of experimentation' violates its human dignity.³¹ Proponents of this view claim that the Catholic Church's stand against embryo research is not only based on the doctrine that life begins at conception but also on its particular interpretation of the biology of early human development.³² These views have strong support in Ireland despite a considerable waning of the influence of the Church in the last decade.³³

The Catholic Church's presumption that there is a new human individual from conception is a relatively recent one. For many centuries the Church held a gradualist view of embryonic development with the 13th century writing of Thomas Aquinas on the question of embryonic development being influential. Drawing on Aristotle, Aquinas considered that the human embryo did not possess a rational soul and was not therefore a human being until day 40 of development.³⁴ Ensoulment was regarded, therefore, as one of the critical events in determining the attribution of moral status. This position, however, is not accepted by all Catholic philosophers. Farley has stated that as fertilisation has been shown by embryological studies to be a process rather than a one-off event, the embryo at the blastocyst stage 'is not sufficiently individualised to bear the moral weight of personhood'.³⁵ Similarly, Mahoney and Ford, although accepting the Church's position on abortion, contend

²⁹ Congregation for the Doctrine of the Faith (2008) *Dignitas Personae: On Certain Bioethical Questions*, First Part: Anthropological, Theological and Ethical Aspects of Human Life and Procreation. Available at http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html. (Accessed on 12/4/2011).

³⁰ *Donum Vitae*, n above 24, chapter 1, question 4.

³¹ *Dignitas Personae*, n above 29, para 15.

³² Boyle, J (1991) The Roman Catholic Tradition and Bioethics. In Brody, BA (ed.) *Bioethics Yearbook, Vol 1: Theological Developments in Bioethics, 1988-1990*. Dordrecht: Kluwer Academic Publishers, pp 5-21.

³³ This is due in part to the fallout from clerical abuse scandals (See *The Ryan Report*, 20 May 2009, available at <http://www.childabusecommission.ie>) and increasing multiculturalism of Irish society; see Banks, M (2008) Modern Ireland: Multinationals and Multiculturalism. *Information, Society and Justice* 2: 63-93.

³⁴ Dunstan, GR (1984) The Moral Status of the Human Embryo: A Tradition Recalled. *Journal of Medical Ethics* 10: 38-44.

³⁵ Farley, MA (2001) Roman Catholic Views on Research Involving Human Embryonic Stem Cells. In Holland, S. Lebacqz, K. and Zoloth, L (eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*. Cambridge, MA: MIT Press. pp 113-118.

that it is only at day 14 post-fertilisation, when the primitive streak appears,³⁶ that an embryo becomes ‘an ontologically human individual’.³⁷ Prior to this Mahoney maintains that the early embryo should not be regarded as ‘anything more than a human entity possessed of astonishing promise or potential’.³⁸ This more liberal position also asserts that ‘conception’ differs from ‘individualisation’, with Ford arguing that otherwise the possibility of twinning or fusion which can occur after conception cannot be accounted for, and therefore prior to the development of the primitive streak the moral status of the embryo is not that of a person,³⁹ thereby justifying its use in certain kinds of research.⁴⁰

6.3.1 Potentiality

When the moral status of the embryo is being examined, the potentiality argument is often cited as it expresses the view that because embryos have the potential to become fully developed human beings, the embryos are deserving of moral status, and by extension protection.⁴¹ The main difficulty with this argument, as identified by Devolder, is that the only point of agreement within the argument is the meaning of ‘potentiality’—that is, it applies to something ‘that is potential, not actual but can

³⁶ The primitive streak forms the notochord, a cellular rod which lies ventral to the central nervous system.

³⁷ Part of the development of a normal embryo is the individualisation of the embryo through the development of the primitive streak at 14 days post fertilisation; twinning can no longer take place and a new individual now exists. Most twins arise from the subdivision of the inner cell mass of a blastocyst, not from the splitting of a two-celled zygote (From Carlson, n above 13, pp 38-74). This is the point at which the embryo acquires significant moral status or value according to jurisdictions including Belgium, (*Law on Research on Embryos in Vitro*, 11/05/2003, at <http://www.eshre.eu>) which allow research to take place on embryos up to day 14 post-fertilisation, and the UK. The regulations contained in the UK’s *Human Fertilisation and Embryology Act 1990*, (as amended recently by the *Human Fertilisation and Embryology Act 2008*), allow experimentation on human embryos up to the appearance of the primitive streak. In their 2005 report, the Commission on Assisted Human Reproduction in Ireland (CAHR) recommended that research would be allowed in the Irish Republic on supernumerary IVF embryos up to this point (*Report of the Commission on Assisted Human Reproduction* (2005) Dublin: Government of Publications Office). This position has also received support from the Irish Council for Bioethics (ICB), which has proposed that the moral value afforded to embryos be based on recognition of their potential to develop into human persons, and from their representation of human life in its earliest stages (ICB (2008) *Ethical, Scientific and Legal Issues Concerning Stem Cell Research*. Dublin: ICB).

³⁸ Mahoney, J (1990) Religion and Assisted Conception. In Bromham, DR, Dalton, ME and Jackson, JC *Philosophical Ethics in Reproductive Medicine. Proceedings of the 1st International Conference*. Manchester: Manchester University Press, pp 84-104.

³⁹ Ford, N (1988) *When Did I Begin? Conception of the Human Individual in History*. Cambridge: Cambridge University Press, pp 102-132.

⁴⁰ Farley, n above 35, at p 116.

⁴¹ Devolder, K (2005) Human Embryonic Stem Cell Research: Why the Discarded-Created-Distinction Cannot Be Based on the Potentiality Argument. *Bioethics* 19: 167-186.

become actual under certain conditions'.⁴² Potentiality may also be regarded as a matter of degree—the more probable it is that an embryo will become a person, the greater the protection it should be afforded.

An examination of the potentiality argument by Outka, however, has lead him to claim that it is a 'double-sided' argument which allows conservatives to claim that it 'nullifies a serious commitment to foetuses and embryos,' while liberals deem it to be 'too indeterminate ever to be permitted to trump decisions to abort or to conduct research on embryos'.⁴³ In relation to embryo research, Outka argues that as embryos in reproductive clinics are bound either to be discarded or frozen in perpetuity, 'nothing is lost' if there are 'third parties with diseases such as Alzheimer's and Parkinson's whose lives 'may be saved by virtue of research on such embryos'.⁴⁴ Nothing more is lost effectively if the embryos are used in research, as such use determines how the embryo will die and not whether death will occur as 'they are destined to die in any case'.⁴⁵

A variant of the potentiality argument is the gradualist approach. This approach to the moral value of the embryo expresses what 'many people feel intuitively' and so may 'open up the way to consider a broader consensus on the issue of hESC research'.⁴⁶ Within the gradualist framework early embryos are regarded as having a moral value which is lesser than that of older or post-primitive streak formation embryos. The acquisition of moral status is proposed to be as continuous a process as biological development, with embryos gradually gaining moral value. From this viewpoint, a 20-week old foetus, for example, would have more moral value than a 6-week-old one. The assignation of significant moral value to embryos, however, does not exclude their use in research which may benefit those with full moral status since, as Holm contends, the 'reduction of human suffering and death in many cases outweigh the sacrifice of a (small) number of human embryos'.⁴⁷ It is argued by McGee and Caplan that whatever its moral status, the destruction of an embryo would only occur under 'the most scrupulous conditions and for the best communal

⁴² Ibid, at p 176.

⁴³ Outka, G. H (2002) The Ethics of Human Stem Cell Research. *Kennedy Institute of Ethics Journal* 12: 175-213, at p 188.

⁴⁴ Ibid, at p 193.

⁴⁵ Ibid, at p 194.

⁴⁶ Devolder, n above 41, at p 179.

⁴⁷ Holm, S (2002) Going to the Roots of the Stem Cell Controversy. *Bioethics*, 16: 493-507.

reasons'.⁴⁸ Since 'compassion for the sick and vulnerable' is one of the 'deepest moral habits of human life', they stress that it may actually be considered a moral imperative that stem cell research be carried out and overall that 'stem cell research is a pursuit of known and important moral goods'.⁴⁹ Devolder argues that although there are, and should be 'feelings of respect towards each created embryo because of their intrinsic potentiality', this respect does not preclude its use as a resource for 'a goal which is believed to be important'.⁵⁰ The overall conclusion to be ascertained from an examination of the potentiality argument is that the moral value and respect afforded to embryos due to their potential should only be trumped when a legitimate scientific or medical goal cannot be achieved by any other means. This should be implicitly acknowledged within any future regulatory framework for hESC research in Ireland.

6.4 The Legal Position of hESC Research in Ireland

As stated in the introduction, Ireland currently has no legislation either permitting or prohibiting hESC research. An examination of relevant Irish case law pertaining to the position of the embryo in the Irish Constitution may go some way to explaining why there is a legislative lacuna in this area.

Ireland has a written Constitution, *Bunreacht na hÉireann*, enacted in 1937. The legal and philosophical basis of *Bunreacht na hÉireann* was the natural law theory of Thomas Aquinas, popular at the time in the social philosophy of the Catholic Church, while the 'dominant political and social discourse of 1930's Ireland was conservative and irredentist'.⁵¹ Natural law theories are generally concerned with evaluating 'human laws in the light of higher sources, identified in the Preamble to *Bunreacht na hÉireann* as the Holy Trinity'.⁵² However, the Irish Constitution also acknowledges notions of liberal constitutionalism and in its fundamental rights articles guarantees the individual citizen freedom, equality and justice. According to

⁴⁸ McGee, G and Caplan, A (1999) The Ethics and Politics of Small Sacrifices in Stem Cell Research *Kennedy Institute of Ethics Journal* 9: 151-158.

⁴⁹ Ibid, at p 152.

⁵⁰ Devolder, n above 41, at p 182.

⁵¹ Hanafin P (2001) *Constituting Identity: Political Identity Formation and the Constitution in Post-Independence Ireland*. Aldershot: Ashgate, pp 10-25; see also Hanafin, P and Williams, MS (1999) *Identity, Rights and Constitutional Transformation*. Aldershot: Ashgate, p 74.

⁵² Byrne, R and McCutcheon, J (2001) *The Irish Legal System* (4th ed.). Dublin: Tottel Publishing Ltd, pp 13-15.

Binchy, while *Bunreacht na hÉireann* is ‘rooted in a philosophical perspective which embraces a concept of God’ it is:

‘premised on rejection of legal positivism, respect for universalism and an understanding of human beings as entities of equal dignity and value, each with an unique worth.’⁵³

In the early days of the Irish State, legislation was passed to bring the law into line with Catholic teaching on a wide range of moral issues. The Oireachtas Committee on the Constitution in 2006 found that the laws of the Irish State in the areas of marriage, contraception, abortion and homosexuality strongly mirrored those of the Catholic Church until reforms were introduced in the latter part of the 20th century.⁵⁴ Although there is no specific legislation, a number of constitutional provisions potentially affect the delivery of AHR services in Ireland, and the possibility of embryonic stem cell research taking place. These include the rights to privacy and bodily integrity, custody of a child, and equality before the law. However, in relation to embryonic and stem cell research, the most important article in the Constitution is Article 40.3.3, which guarantees the right to life of the ‘unborn’.

Following the enactment of *Bunreacht na hÉireann* in 1937, despite there being no explicit constitutional provisions protecting the ‘unborn child’, a number of judicial statements had indicated a willingness on the part of the judiciary to interpret the Constitution as affording rights, although unenumerated, to the individual foetus, in the same way as it afforded rights to the individual adult.⁵⁵ In *McGee v. Attorney General*⁵⁶ the Supreme Court through Walsh J, while recognising the constitutional right to marital privacy and limitation of family size, emphasised that it must not come at the cost of endangering or destroying human life.⁵⁷

⁵³ Binchy, W (2008) Article 40.3.3 of the Constitution: Respecting the Dignity and Equal Worth of Human Beings. In Schweppe J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, p189.

⁵⁴ *Report of the All-Party Oireachtas Committee on the Constitution* (2006). Dublin: Government of Ireland Publications.

⁵⁵ Cox, n above 5, at p 97.

⁵⁶ *McGee v. Attorney General* [1974] IR 284, (1975) 109 ILTR 29. In *McGee*, a woman suffered a stroke during a pregnancy and wished to import barrier contraceptives (spermicidal jelly) for her own use as advised by her doctor.

⁵⁷ Walsh J in *McGee* at 41-2.

There was concern following *McGee* that this right to marital privacy might be used in a manner similar to that used by pro-choice campaigners in the United States (US) to successfully invoke a comparable right to privacy, thereby invalidating statutes criminalising abortion, *Roe v. Wade*.⁵⁸ By re-iterating that privacy is a fundamental personal right, the US Supreme Court effectively granted American women the right to choose to have an abortion. This decision provided a significant example of the possibilities of judicial action in the area of reproductive rights. To prevent the possibility of a *Roe v. Wade*-type judgment in Ireland, the Pro-Life Amendment Campaign (PLAC), formed in 1981, proposed that an amendment be made to the Constitution, which it argued would protect unborn life. PLAC were ultimately successful in their campaign to have the unborn protected within the framework of the Constitution, but the effect of the amendment was to extend far beyond its specific intent to prevent the courts from introducing legal abortion in Ireland.

6.4.1 Article 40.3.3

The 8th Amendment to the Constitution of Ireland 1983 inserted a new article, Article 40.3.3, into the Constitution which stated:

‘The State acknowledges the right to life of the unborn and, with due respect to the equal right of life of the mother, guarantees in its laws to respect, and as far as is practicable, by its laws to defend and vindicate that right.’⁵⁹

What is interesting about Article 40.3.3 is that despite being regarded as ‘the anti-abortion amendment’ it does not actually mention the term abortion at all, as, according to Binchy, ‘it is entirely philosophical in character’.⁶⁰ In terms of constitutional interpretation the Irish text is the authoritative one. Consequently, the Irish language version of the word unborn, *beo gan breith*, introduces an element of uncertainty into the law with *beo* translated principally as ‘living being’, with the secondary sense of ‘life’, while *gan breith* can mean ‘without birth’.⁶¹ The

⁵⁸ *Roe v. Wade* (1973) 410 U.S.113.

⁵⁹ *Bunreacht na hÉireann* Constitution of Ireland, Dublin: Government of Ireland Publications, p 150.

⁶⁰ Binchy, n above 53, at p 195.

⁶¹ Ó Cearúil, M (1999) *Bunreacht na hÉireann: A Study of the Irish Text*. Dublin: Government of Ireland Publications, pp 548-549.

ambiguous nature of this wording was noted by both the then Attorney General, Peter Sutherland, who warned that the term ‘unborn’ could be interpreted to mean either that abortion was prohibited from conception or that it was permitted up to the point of viability.⁶² It was also noted by Senator Mary Robinson, who observed that:

‘The basic flaw in this amendment is that it is so uncertain in its scope and so potentially contradictory in its meaning and so potentially damaging to existing practices in the area of family planning and medical treatment.’⁶³

Determining at what stage the guarantee ‘to defend and vindicate the right to life’ applies is important given its implications for the potential research use of spare embryos from AHR in hESC research. In 1983 it was felt that Article 40.3.3 gave the individual foetus constitutional protection from the time of conception/ fertilisation, despite the amendment not defining with any precision the actual time frame involved.⁶⁴ Although this issue did not directly arise for consideration by the courts there was some judicial support for this interpretation.⁶⁵

Several commentators have examined this uncertainty in the law in relation to embryo research and arrived at different conclusions. Shercock argued it was likely that:

‘the courts would hold the *in vitro* embryo to come within the protection of [Article 40.3.3] and if this is the case, it would appear to rule out embryo research in Ireland, certainly in cases involving the destruction of the embryo. It would also appear to have implications for fertility treatments involving IVF as it would undoubtedly require that all embryos produced would have to be placed in the woman’s uterus. Presumably, this would have to

⁶² McAvoy, S (2008) From Anti-Amendment Campaign to Demanding Reproductive Justice: The Changing Landscape of Abortion Rights Activism in Ireland, 1983-2008. In Schweppe, J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, p 24.

⁶³ Foley, AJ and Lalor, S (1995) *Annotated Constitution of Ireland 1937- 1994*. Dublin: Gill and McMillan, p 235.

⁶⁴ Cox, n above 5, at p 97.

⁶⁵ *Attorney General (SPUC) v. Open Door Counselling* [1988] IR 593, at 598.

include the placing in the uterus of embryos even if they were known to be defective.’⁶⁶

The Constitutional Review Group in 1996 also addressed this difficulty in the state of the law and concluded that a clearer legal definition is needed as to when the unborn acquire the protection of the law. They were undecided as to the effect of this uncertainty in constitutional terms, concluding that if:

‘it were specified within a definition that the protection of Article 40.3.3 extended to *in vitro* fertilisation, legal problems could arise in relation to some practices in this area. If, as an alternative it was decided to specifically exclude *in vitro* fertilisation from the protection of Article 40.3.3 the result could appear anomalous.’⁶⁷

In the Green Paper on Abortion published in 1999, an attempt was also made to address this issue. It was suggested that in trying to change the law on abortion should an *in vitro* embryo come within the protection of Article 40.3.3 embryo research would be ruled out in Ireland.⁶⁸ Kingston also agreed with the Constitutional Review Group in concluding that, due to the great uncertainty around Article 40.3.3, it is difficult to identify if the protection offered by it to the ‘unborn applies from the moment of fertilisation, the moment of implantation, or from some later date’.⁶⁹

In contrast, Madden has argued that such an interpretation may not be strictly accurate.⁷⁰ She claims that for the purposes of *in vitro* fertilisation (IVF), if the word ‘unborn’ is interpreted as meaning ‘not yet born’ or ‘with the potential to be born’, then:

‘in light of the biological development of the early embryo and the absence of potential in the pre-implantation embryo it is likely that

⁶⁶ Sherock, A (1989) The Right to Life of the Unborn and the Irish Constitution *Irish Jurist* XXIV:24.

⁶⁷ The All-Party Oireachtas Committee on the Constitution (1996) *Report of the Constitutional Review Group*, Articles 40-44: Introduction to Fundamental Rights, pp 250-256. Dublin: Stationary Office. Available at <http://www.constitution.ie/reeports/crg.pdf>. (Accessed on 12/4/2011).

⁶⁸ The All Party Committee on the Constitution (1999) *5th Progress Report: Abortion*. Dublin: Government of Ireland Publications, Appendix: *Green Paper on Abortion*, p 125 at paras 7.05-7.13. Available at: <http://www.constitution.ie/reports/crg.pdf>. (Accessed on 12/4/2011).

⁶⁹ Kingston, J, Whelan A and Bacik I (1997) *Abortion and the Law*. Dublin: Round Hall Sweet and Maxwell, pp 23-36.

⁷⁰ Madden, D (2002) *Medicine, Ethics and the Law*. Dublin: Tottel Publishing Ltd, p 276.

the Constitutional protection extends only to the embryo after implantation in the uterus.’⁷¹

In line with this argument Madden appears to favour a gradualist/potentiality approach where she proposes that the acquisition of moral status and, by extension, constitutional protection, should be linked to the stage of biological development. She contends that the pre-implantation embryo is not sentient, and therefore the constitutional provision has no application. I would agree with the assertion that the full extent of the protection afforded by Article 40.3.3 should not apply to the early embryo prior to implantation. This should not mean, however, that no protection is afforded to such entities.

6.4.2 Recent Legal Developments

Over the last 20 years, no effort was made on the part of the legislators to reduce the uncertainty surrounding the term ‘unborn’. Hence the implications of this uncertainty remained for both AHR and hESC research. It seemed that this anomalous situation would continue indefinitely until the case of a separated couple (who were disputing the future of three frozen embryos from an IVF cycle) came before the Irish High Court.⁷² The Court had to examine firstly the private law issue of contract and consent to the procedures involved in IVF, and secondly the constitutional law question of the status of the frozen embryos in relation to Article 40.3.3.⁷³ In the High Court, McGovern J examined the legislative history of the Constitution and the Eighth Amendment in particular. In *The State (Healy) v. Donoghue*, O’Higgins CJ stated that the Preamble to the Constitution:

‘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

⁷¹ Madden, D (2008) Article 40.3.3 and Assisted Human Reproduction. In Schweppe, J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, p 310.

⁷² *R. (M) v. R (T) & Ors* [2006] IEHC 359 (15 November 2006). Available at <http://www.bailii.org/ie/cases/IEHC/2006/359.html>. (Accessed on 12/4/2011).

⁷³ For a fuller discussion of this case see Gough, F (2010) Ireland and the Frozen Embryo: A Slight Thawing? *Medical Law Review* 18: 239-247.

and develops, and which fall to be interpreted from time to time in accordance with prevailing ideas.⁷⁴

McGovern J claimed that these views affirmed that changing values in society meant that rights not previously acknowledged under the Constitution could now be firmly established. They were, however, not authority for the proposition that the word ‘unborn’ should be given a different meaning than that intended in 1983 when the Eighth Amendment was introduced, as the clear purpose of that amendment was to deal with the issue of abortion.⁷⁵ The court noted that in all previous cases pertaining to Article 40.3.3, no consideration was given as to whether or not the word ‘unborn’ included embryos *in vitro*. Referring to the English High Court case of *Smeaton*, he agreed with Munby J, the presiding judge in that case, that:

‘the question of when human life begins as a matter of morality, or indeed biology, is not the same as the question of when pregnancy begins for the purposes of the law.’⁷⁶

McGovern J went on to state that despite the various definitions offered by the many witnesses called in this case, it was not possible in his opinion for ‘this Court to state when human life begins’.⁷⁷ He concluded that there was no evidence that it was ever in the mind of the people voting on the Eighth Amendment to the Constitution in 1983 that ‘unborn’ meant anything other than a foetus or child within a woman’s uterus and that to infer otherwise and extend the term unborn to include ‘embryos outside the womb or embryos *in vitro* would be to completely ignore the circumstances giving rise to Article 40.3.3’.

McGovern J found that the word ‘unborn’ did not include embryos *in vitro* and therefore did not include the three frozen embryos at the heart of the dispute in this case, although such embryos are deserving of special respect. As a consequence, such embryos would not be afforded constitutional protection. He further suggested that given this, in the absence of any legislation or precedent, ‘embryos outside the

⁷⁴ *The State (Healy) v. Donohue* [1976] I.R.325 at 347.

⁷⁵ *Roche*, n above 72.

⁷⁶ *The Queen on the Application of Smeaton v. Secretary of State for Health* [2002] FLR 146 (2002) 66 BMLR 63; see *ibid* - judgement of McGovern J, paragraph 2 - ‘The Issues’.

⁷⁷ *Roche*, n above 72, from judgment of McGovern J, paragraph 2, subparagraph – ‘Are the frozen embryos unborn within the meaning of Article 40.3.3 of the Constitution of Ireland?’

womb have a very precarious existence’ and that as the proper function of the Courts at the end of the day is ‘to implement and apply the law, not morality, it should not be a matter for the Courts to decide whether the word ‘unborn’ should or should not include embryos *in vitro*. It should be up to the Oireachtas or the people through the process of a Constitutional Amendment to make such decisions.⁷⁸ Unlike many of his predecessors, McGovern J in his judgment did not allude to the role of natural law within the Irish Constitution but attempted to avoid using the law to enforce a moral judgment by separating the roles of ‘law’ and ‘morality’, and to strictly interpret the Constitution in a positivist manner. This High Court judgment was appealed to the Supreme Court, on grounds of both the private and constitutional law issues, and came before the Supreme Court early in February 2009.

The judgment in this case was finally handed down in December 2009.⁷⁹ McGovern J’s judgment was upheld unanimously by the five judges of the Supreme Court. According to Denham J, this case ‘was ‘not about the wonder and mystery of human life’, but simply a matter of construing the word ‘unborn’ in the Constitution to determine its constitutional meaning.⁸⁰ She emphasised that the main issue was a determination if the three frozen embryos fell under the protection of Article 40.3.3 or not. However, Denham J did not acknowledge that in practical terms these issues are not necessarily quite as distinct as she asserted, as any future policy reform would necessitate addressing and compromising on moral issues as well as hermeneutics. In her elegant judgment she explained that the original aim of the constitutional amendment was to strengthen the protection afforded to the embryo by s.58 of the Offences Against the Persons Act (OAPA) 1861,⁸¹ thus concurring with McCarthy J in *Attorney General v. X* who stated that:

‘The [Amendment’s] purpose can be readily identified—it was to enshrine in the Constitution the protection of the right to life of the

⁷⁸ Roche, n above 72, at paragraph on ‘Other Issues’.

⁷⁹ Roche, n above 72.

⁸⁰ Unreported judgment of Denham J at paragraph 45, p 24. Available at www.supremecourt.ie/Judgments.nsf/1b0757edc371032e802572ea0061450e/12. (Accessed on 15/11/2010).

⁸¹ Every woman, being with child who, with intent to procure her own miscarriage, shall unlawfully administer to herself poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent, and whosoever, with intent to procure a 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, shall be guilty of felony, and be convicted thereof shall be liable. *Offences against the Persons Act 1861*, s.58.

unborn thus precluding the legislature from an unqualified repeal of s.58 of the Act of 1861 [which prohibits abortion] or otherwise in general, legalising abortion.’⁸²

Both Hardiman J and Geoghegan J agreed that the purpose of Article 40.3.3 was to prevent the decriminalisation of abortion, and that the appellants had failed to establish that frozen embryos were ‘unborn’ within the meaning of the Article. Fennelly J supported this statement and declared his concern ‘at the total absence of any form of statutory regulation of in vitro fertilisation in Ireland’.⁸³ Hardiman J also noted in dismissing the appeal that there has been a ‘marked reluctance on the part of the legislature actually to legislate on these issues’. He warned that:

‘If the legislature does not address such issues, Ireland may become by default an unregulated environment for practices which may prove controversial or, at least, to give rise to a need for regulation.’⁸⁴

The decision of Supreme Court to dismiss the appeal, by unambiguously ruling that frozen embryos were not unborn within the meaning of Article 40.3.3 has important implications beyond the confines of this case. It would appear that as a consequence of this judgment, there is no legal prohibition to hESC research, since surplus embryos from IVF should now be available, and no legal impediment to other related therapeutic applications (such as pre-implantation diagnosis) taking place in Ireland. As confirmed by Hardiman J, the ruling also removes any threat to the legality of contraceptive methods which rely on the prevention of implantation, such as the IUD and post-coital pill.⁸⁵

Although providing clarity in one aspect of the law, the *Roche* case fails to define what protection should be afforded to a frozen embryo. It did, however, highlight the urgent need in Ireland to address the many issues that have arisen as a result of medical and scientific advances in the areas of hESC research and AHR, because

⁸² *Attorney General v. X* [1992] IR 1, [1992] ILRM 401, [1992] CMLR 277.

⁸³ Unreported judgment of Fennelly J, at p 40.

⁸⁴ Unreported judgment of Hardiman J, at paragraph on Article 40.3.1.

⁸⁵ *Ibid.*

‘scientific developments in the areas of embryology and the culturing of stem cells’, according to Hardiman J, ‘will not stand still’ waiting for Ireland to update its laws.⁸⁶

6.5 hESC Research Policy in Ireland

In its report on hESC research, the European Commission found that there is no consensus across the EU about what the limits and conditions for hESC research should be, nor what protections are afforded to the human embryo.⁸⁷ However, no jurisdiction, no matter how permissive its regime, has produced legislation denying human embryos some moral status.⁸⁸ There has been some attempt to develop policy in Ireland on hESC research despite the lack of legislation. The Irish Government established the Commission on Human Reproduction (CAHR) in March 2000, asking it to 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.’⁸⁹

The achievement of *in vitro* fertilisation was acknowledged by the Commission to raise a dilemma for both doctors and society as to the fate of those embryos surplus to requirements in reproductive terms.⁹⁰ The Commission’s report, published in 2005, contained 40 recommendations, with the main recommendations addressing regulatory issues. The first of these proposed that ‘a regulatory body should be established by an Act of the Oireachtas to regulate AHR services in Ireland’.⁹¹ In establishing such a body, the Oireachtas would be following international best practice. Ideally, the regulatory body, though independent would advise the government on all matters relating to AHR and associated procedures including hESC research. A provision would be made within the legislation for a regular

⁸⁶ Ibid.

⁸⁷ Harris, J, Bortolotti, L and Irving, L (2005) An Ethical Framework for Stem Cell Research in the European Union. *Health Care Analysis* 13: 157-162.

⁸⁸ Halliday, S (2004) A Comparative Approach To The Regulation Of Human Embryonic Stem Cell Research In Europe. *Medical Law Review* 12: 40-69.

⁸⁹ CAHR (2005) *Report of the Commission on Assisted Human Reproduction*. Dublin: Stationary Office, p v. Available at <http://www.dohc.ie/publications/cahr.html>.

⁹⁰ Ibid, *foreward*.

⁹¹ Ibid, at p 8.

review to accommodate any scientific or medical advances and take cognisance of social changes.⁹²

A public consultative process was undertaken by the Commission to fulfil its remit. Public attitudes towards AHR and embryo research were measured through a questionnaire, the staging of a public conference, and telephone interviewing of a representative sample of the population. The data so obtained was noted in the executive summary of the report, and suggested that public opinion ‘ranges from total opposition to all forms of AHR on the one hand to uncritical acceptance of any assistance that science can give to infertile people on the other’.⁹³

In considering the arguments for and against embryo research the Commission recognising the existence of three basic positions:

- (i) research should not be permitted;
- (ii) research should be permitted but only on surplus embryos; and
- (iii) research should be permitted on surplus embryos and on embryos specifically generated for research.⁹⁴

Position (ii) that research should be permitted on surplus embryo, was ultimately the position recommended by the Commission, although one member demurred from this conclusion. It was also proposed by a majority of CAHR members that embryo research, including embryonic stem cell research, should be permitted on surplus embryos that are donated for research. This would only be allowed up to 14 days post-fertilisation under stringently controlled conditions and for specific purposes only. These conditions and specific purposes would be stipulated by the new regulatory body. Probably the most important recommendation of a majority of the Commission was that:

‘the embryo formed by IVF should not attract the legal protection until it is placed in the human body, at which stage it should attract the same level of protection as the embryo formed *in vivo*.’⁹⁵

⁹² Ibid, at pp 67-72.

⁹³ Ibid, at p *xiii*.

⁹⁴ Ibid, at p 57.

⁹⁵ CAHR, n above 89, at p 34.

The creation of IVF embryos for research was ruled out by the CAHR, as was reproductive cloning and the generation and use of interspecies or hybrid embryos. Despite it being more than 5 years since the Commission reported, there has been no attempt to enact any of its recommendations in legislation.

Notwithstanding the failure of the legislature to act on the report of the CAHR, another report was commissioned into the ethical, scientific and legal issues in stem cell research. This was published by the Irish Council on Bioethics in 2008.⁹⁶ In their report the ICB presented a thorough summary of the current scientific and legislative debate about the generation and use of embryos and stem cells in research, and of the ethical issues central to these debates. The lack of a legal impediment to the importation into Ireland of embryonic stem cell by scientists was particularly noted by the ICB. Unlike doctors who may be working in the same field, scientists are not prohibited from importing stem cells due to the absence of specific legislation or professional constraints. Medical doctors are restricted as they are bound by guidelines from the Medical Council of Ireland.

The Irish Medical Council currently provides the only recommendations pertaining to this area of research in Ireland in their ‘Guide to Professional Conduct and Ethics for Registered Medical Practitioners.’⁹⁷ A practicing medical doctor must adhere to these guidelines or risk censure or even removal from the register of medical practitioners. In 2004 the Medical Council’s guidelines stated that ‘any fertilised ovum must be used for normal implantation and must not be deliberately destroyed’.⁹⁸ It further asserted that to create ‘new life forms for experimental purposes’ or to deliberately destroy ‘*in vitro* human life already formed’ would be considered to be professional misconduct.⁹⁹ These comments were revised in the new edition to simply state that a doctor ‘should not participate in creating new life forms solely for experimental purposes’ and should not ‘engage in human reproductive cloning.’¹⁰⁰ There is no repetition of the statement in the 2004 guidelines that destroy

⁹⁶ Irish Council for Bioethics (2008) *Ethical, Scientific and Legal Issues concerning Stem Cell Research*. Dublin: ICB.

⁹⁷ Medical Council of Ireland (2009) *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (7th ed.). Available at <http://www.medicalcouncil.ie>.

⁹⁸ Medical Council of Ireland (2004) *A Guide to Ethical Conduct and Behaviour*. Dublin: MCI, Section F – Genetic Testing and Reproductive Medicine, para 24.5, p 36.

⁹⁹ Medical Council of Ireland, n above 98, para 24.1, p 35.

¹⁰⁰ Medical Council of Ireland, n above 97, para 20.4, p 21.

or generate an embryo would constitute professional misconduct. When questioned as to this omission Prof Kieran Murphy, the President of the Medical Council, stated the Council was ‘exercised’ by the lack of legislation in this area and was thus unable to take up a position.¹⁰¹ The conclusion could be drawn, therefore, that there are no legal restrictions to carrying out embryonic and stem cell research by researchers who are not registered medical practitioners. The ICB does however note that:

‘Notwithstanding the lack of specific legislation pertaining to stem cell research in Ireland, within Europe there are a number of overarching regulatory frameworks in existence, which have implications for the legislative and regulatory processes for stem cell research that are adopted in Ireland. The European Convention on Human Rights and Biomedicine (1997) makes a number of references to research involving embryos and cloning. Article 18.1 of the Convention permits research on embryos *in vitro* where National legislation allows, provided the embryos are afforded sufficient protection.’¹⁰²

Unfortunately, Ireland has yet to ratify this convention.¹⁰³ The Report of the Bioethics Council concedes that research involving human embryos is regarded by some people as providing an opportunity to gain important scientific knowledge, but a significant number of people in Ireland are very strongly opposed to it.¹⁰⁴ The lack of political will to date, to initiate legislative action according to the ICB has allowed a certain level of anxiety to develop around these issues and ‘undermines the moral value of the human embryo’. The construction, however, of a cohesive and comprehensive regulatory structure would, in all likelihood, put pay to these anxieties, as it is generally recognised that systems which:

‘acknowledge and respond to public fears and doubts provide a sense of control, offer public access and influence and offer a

¹⁰¹ Ganty, D (2009) Cracking the Code of Ethics. *Irish Medical Times* November 27th, p 26.

¹⁰² ICB, n above 96, at p 64.

¹⁰³ CETS No. 164. Protocol to *Convention on Human Rights and Biomedicine*. Status as of 15 July 2010. Available at Council of Europe (<http://www.coe.int>).

¹⁰⁴ ICB, n above 96, at p. *ii*. (Foreword).

forum and time for discussion and education in that space between knowledge and ignorance that trust must occupy.’¹⁰⁵

The ICB also noted that the failure by Ireland to provide a system governing stem cell research and its applications is hindering the development of hESC research in Ireland, and the consequences of this may be felt in economic terms.¹⁰⁶

In recent years some academic institutions which have been involved in stem cell research have themselves attempted to introduce regulations. The governing body of University College Cork (UCC) recommended in November 2008, by a very slim majority (16 to 15), that the University’s Academic Council would allow hESC research to take place at UCC ‘under strict guidelines drawn up by the University Research Ethics Board (UREB)’.¹⁰⁷

UCC verified that it had taken the two expert independent reports published in this context in recent years, the CAHR Report (2005) and the Irish Bioethics Council Opinion (2008), into consideration when drawing up its guidelines. The statement from UCC confirmed that the university ‘in the absence of either national legislation or policy’, had sought to impose ‘the strictest internal control over research in this area.’¹⁰⁸ According to these guidelines, the importation of hESC lines would only be permitted once the scientific merit of the proposed research had been established. Before permission to use hESC lines would be given, the feasibility of using alternative research methods not requiring hESCs must be scrutinised, while approval of all research projects must be by majority of UREB members after full consideration of the scientific and ethical issues. No destructive research on living human embryos would be allowed under these proposals. It was the absence of national legislative measures to guide future hESC research within the university that compelled UCC to draw up and approve such proposals, and in doing so they do not

¹⁰⁵ The ICB itself has felt the impact of the downturn in the Irish economy. It was disbanded by the Government in December 2010, with ‘savings’ being the reason given for its demise. Ireland is now the only country in the EU not to have a national advisory body on bioethics. Some staff were seconded to the Department of Health but the new bioethics body will no longer publish its reports-see <http://www.icb.ie>, 1 December 2010 and Barron, D (2011) Staff from ICB Seconded to Department of Health. *Irish Medical News* February 2nd. Available at <http://www.IMN.com>.

¹⁰⁶ Johnston, MH & Petersen, K (2008) Public Interest or Public Meddling? Towards an Objective Framework for the Regulation of Assisted Reproductive Technologies *Human Reproduction* 23: 713-728.

¹⁰⁷ Culliton, G (2008) UCC’s Code of Practice for Stem Cells. *Irish Medical Times* November 16th.

¹⁰⁸ Ibid.

appear to be violating any existing constitutional provisions. This situation would appear to provide another cogent reason why national regulations should be introduced - there is no guarantee that another institution would take as stringent an approach to regulating hESC research as UCC.

Shortly after UCC's proposals were launched, a 'Stem-Cell Research (Protection of Human Embryos) Bill' was introduced into Seanad Éireann in November 2008 by Senator Rónán Mullen, an independent senator representing the National University of Ireland, Galway (NUIG). The aims of this Bill were set out in the explanatory memorandum. It seeks:

‘to regulate stem cell research in the State by prohibiting embryo-destructive research and related activities, such as the creation of human embryos, human clones or human-animal hybrids for research purposes.’¹⁰⁹

The Minister of State at the Department of Enterprise, Deputy Devins, spoke on behalf of the Government during the course of the debate and acknowledged that currently there is no legislation in Ireland ‘governing intervention in the natural process of creating human life’.¹¹⁰ The enactment of this Bill would also have effectively prohibited the use of any cell lines derived from embryos, even if the research from which the cell lines were obtained took place outside the jurisdiction. Despite speaking against this Bill, several senators emphasised that they were in agreement with Senator Mullen as to the need to legislate in this area. This particular proposal, they felt however, posed a difficulty in that it did not hold out any prospect of regulation; rather it simply banned hESC research altogether. By doing so they considered that the Bill, in this form, sent out a message that Ireland was not open to scientific research.¹¹¹ Despite vigorous debate, no vote was actually taken on this bill in the Seanad.

¹⁰⁹*An Bille um Thaighde Gaschille (Suthanna Daonna a Chosaint) 2008 Stem-Cell Research (Protection of Human Embryos) Bill* 2008. [No. 60 of 2008] Dublin: Government Publications Office.

¹¹⁰Deputy Devins. Available at <http://www.oireachtas.ie/SeanadDebates/> 26 November 2008. (Accessed on 12/4/2011).

¹¹¹ Senator Ivana Bacik. Available at <http://www.oireachtas.ie/SeanadDebates/> 26 November 2008. (Accessed on 12/4/2011).

6.6 The Future Enabled?

The current ‘Irish solution’ to the many issues surrounding hESC research - i.e. simply failing to address them - is no solution at all. A range of regulatory regimes exists in most of the Western world which aim to protect the interests of not only the *in vitro* embryo but also patients and society as a whole.¹¹² These regimes have been accepted as falling into one of four possible positions: A, B, C and D.¹¹³ In position A, all human embryo research, including the derivation of hES cells, is prohibited.¹¹⁴ Research is allowed to proceed on hES cells extracted before a specific dead-line in position B but no research is permitted on embryos¹¹⁵ Position C allows the isolation of, and research on hESCs obtained from embryos which are surplus to requirement of clinical IVF programmes, governed by the 14-day embryo research limit. Position D additionally allows research on embryos produced specifically for research by somatic cell nuclear transfer (SNCT) into human ova.¹¹⁶

Through the *Human Fertilisation and Embryology Act 1990*, the UK was one of the first countries in the world to introduce legislation regulating embryo research. The Human Fertilisation and Embryology Authority (HFEA) was established by the act to oversee all aspects of ART in the UK, and to provide the government with information and advice.¹¹⁷ Several revisions of the original 1990 Act means that the UK currently applies Policy Position D to hESC research. As a consequence of the adoption of this policy position, the UK has become the most productive country in Europe in terms of publications in the area of hESC research. It has also benefitted from significant investment being directed to hESC research within the UK.¹¹⁸

Responsible regulation in this area faces many challenges, including the complexity of the actual science involved, engagement with strongly held moral values, and not

¹¹² Gough, F (2010) *Public Policy and Human Embryonic Stem Cells Research. A Policy Document for The Irish Stem Cell Foundation*. Available at <http://www.irishstemcellfoundation.org/news>.

¹¹³ Knoepffler, N (2004) Stem Cell Research: An Ethical Evaluation of Policy Options. *Kennedy Institute of Ethics Journal* 14: 55-74; also Walters, L (2004) Human Embryonic Stem Cell Research: An Intercultural Perspective. *Kennedy Institute of Ethics Journal* 14: 3-38.

¹¹⁴ Jones, DG and Towns, CR (2006) Navigating the Quagmire: The Regulation of Human Embryonic Stem Cell Research. *Human Reproduction* 21: 1113-1116.

¹¹⁵ Heinemann, T and Honnefelder, L (2002) Principles of Ethical Decision Making Regarding Embryonic Stem Cell Research In Germany. *Bioethics*, 16: 530-543.

¹¹⁶ Mason JK and Laurie, GT (2006) *Mason and McCall Smith's Law and Medical Ethics* (7th ed.). Oxford: Oxford University Press, pp 71-119.

¹¹⁷ *Human Embryology and Fertilisation Act 1990*, s.13 (U.K.).

¹¹⁸ Winston, R (2007) Does Government Regulation inhibit Embryonic Stem Cell Research and Can it be Effective? *Cell Stem Cell* 1: 27-34.

least the polarising effect of the abortion debate in Ireland in the past. It can be difficult to conduct a debate on an issue of public policy where opposing sides are separated by an ‘apparently unbridgeable chasm of moral disagreement’, as evidenced by the on-going debate over legalising abortion in Ireland.¹¹⁹ Most people recognise that the debate about the status of the embryo, whether *in vitro* or *in vivo* does involve a confrontation with one’s conscience. And if after such a struggle, another individual comes to a different moral judgment than that which one may hold, it must be acknowledged that the other person has made a moral decision and has the right to hold that belief, and to act on that belief.¹²⁰

As Archard says, ‘granting the legal permission to do what others may deem immoral but acknowledge to be conscientiously determined is a mark of a civilised and tolerant society’.¹²¹ Archard explains that rights-based constitutionalism requires respect for the holding of different moral values and religious beliefs within a society, and this means that it is wrong for any government to enforce, through its policies or laws, any one particular moral or religious viewpoint.¹²² Jurists such as Dworkin endorse the view that decisions about reproductive matters are properly private in the sense of being matters over which the individual should be sovereign.¹²³ In this sense Dworkin’s arguments are in accordance with the findings of the US Supreme Court in *Roe v. Wade* and of the Irish Supreme Court in *McGee v. AG* which viewed choices about reproductive issues as protected by a constitutional right to privacy. However, in this era of AHR, hESC research and the benefits which may accrue from potential therapies developed from such research, the question remains whether procreation can or should still be regarded as essentially a private and individual matter.

Given that it is most unlikely that a consensus on the moral status of the *in vitro* embryo will be reached in the near future, the question becomes one of how a political compromise might be reached which would legally permit hESC research in certain circumstances. The present failure to resolve the ‘Law vs. Morality’ conundrum has led to problems managing scientific research. The question of what a

¹¹⁹ Archard, D (1995) *Legal Theory in Ireland*. Dublin: Oak Tree Press, pp 72-83.

¹²⁰ Ibid, at p 80.

¹²¹ Ibid, at p 81.

¹²² Ibid, at p.76.

¹²³ Dworkin, R (1993) *Life’s Dominion. An Argument about Abortion and Euthanasia*. London: Harper Collins. p 105.

lack of legislation means for the future of hESC research in Ireland was answered recently when two of Ireland's leading science funding agencies, the Health Research Board (HRB)¹²⁴ and Science Foundation Ireland (SFI), stated that they will not fund research projects using hESCs in the absence of legislation that specifically provides for such research.¹²⁵ The embargo came from the Government through the Department of Health. This 'regulation 'by default' will do nothing to improve Ireland's international reputation as a centre for scientific research. There is also the question of what the absence of legislation in Ireland renders permissible. According to the Irish Medicines Board (IMB), in the absence of national legislation prohibiting the use of medicinal products derived from embryos, once authorised by the European Medicines Agency, such a therapy could be supplied into Ireland on a named-patient basis.¹²⁶

The current legal uncertainty that exists in Ireland in relation to the appropriate use of non-implanted embryos or the importation of stem cell lines by scientists has led Dr Dolores Dooley, former chairperson of the Irish Council for Bioethics, to call on behalf of the Council for the Oireachtas to establish an independent regulatory authority.¹²⁷ This authority could be charged with clarifying the ambiguity in the meaning of the term 'unborn', and legislating for the registration, licensing and inspection of persons and premises working with human embryos. She has strongly supported the call to bring to an end the 'legal vacuum' that currently exists in this area in Ireland as it undermines the moral value of the human embryo but also because it 'undermines people working in the field of infertility treatment, and the thousands of couples availing of IVF'.¹²⁸

In the adoption of a regulatory scheme an acknowledgment must be made of the lack of social consensus regarding the potential 'harms' and potential therapeutic 'benefits' for many AHR procedures and hESC research. There must, however, also be a weighing of the moral value of human embryos against the moral value of

¹²⁴ HRB, available at <http://www.hrb.ie>. (Accessed on 12/4/2011).

¹²⁵ Burke-Kennedy, E (2010) Funding Ban on Research Using Human Stem Cells. *The Irish Times Health Supplement* October 12th, p 2.

¹²⁶ Personal communication with the Blood and Tissues Manager of the Irish Medicines Board (<http://www.imb.ie>).

¹²⁷ Barron, D (2011) Staff from ICB Seconded to Dept. of Health *Irish Medical News* February 2nd. Available at <http://www.imn.com> (Accessed on 12/4/2011).

¹²⁸ Dooley, D (2008) Head to Head: Should the State Legislate for Embryonic Stem Cell Research? *The Irish Times*, May 12th.

human welfare, in an attempt to balance an acceptance of the value of human life against the obligation to care for existing human kind generally.¹²⁹ In the near future it is clear that Ireland will have to face up to the difficult challenge of defining at which point the constitutional protection of the unborn, specified by Article 40.3.3, begins. It must be acknowledged that finding an appropriate policy will involve serious moral debate, and a willingness to be open to compromising policy solutions. A political decision must be made. The result of the recent election, however, has made this unlikely in the near future, as the main coalition partner, Fine Gael, is opposed to allowing stem cell research which uses human embryonic stem cells to take place in Ireland,¹³⁰ while the junior coalition partner, the Irish Labour Party, went as far as including a commitment to legislate in favour of hESC research in its manifesto.¹³¹ This dilemma has not gone unnoticed by the international scientific community.¹³²

The recommendation of both the Report of the Commission on Assisted Human Reproduction and the Opinion of the Irish Bioethics Council is that hESC research be allowed on donated ‘spare’ embryos from IVF cycles up to a maximum of 14 days. In addition, they recommend that the generation of embryos for research should not be allowed nor should cloning be permitted.

I would support these recommendations and propose that the carefully regulated use of supernumerary IVF embryos—embryos that are otherwise destined to be destroyed—for the purposes of embryonic stem cell research aimed at alleviating human suffering is morally acceptable. The current absence of a regulatory regime creates confusion and could potentially allow improper research to take place.

A greater openness and transparency in stem cell policy in Ireland is urgently needed. This would be best realised through the establishment of a regulatory regime to set out the limits, as well as the opportunities, for hESC research in Ireland.¹³³ It is

¹²⁹ McClean, MR (2001) Stem Cells: Shaping the Future in Public Policy. In Holland, S Lebacoz, K and Zoloth, L (eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*. Cambridge, MA: MIT Press, pp197-207.

¹³⁰ Available at <http://www.prolifecampaign.ie/pages.php?id=175>.

¹³¹ Available at <http://www.labour.ie/manifesto>. One Ireland: Jobs, Reform, Fairness. p 78.

¹³² Abbott, A (2011) Irish Election Raises Question for Stem Cell Research. *The Great Beyond* February 28th. Available at <http://www.go.nature.com/ftx2hu>.

¹³³ Caulfield, T (2004) Law and Policy in the Era of Reproductive Genetic *Journal of Medical Ethics* 30: 414-471.

essential that Ireland develops a flexible regulatory scheme that allows the public/professional dialogue in this area to continue while respecting the ethical and moral values of 21st century Irish citizens.

CHAPTER 7

7. PAPER 2: ‘SOMETHING MUST BE DONE’: A STUDY OF STAKEHOLDER ATTITUDES TOWARDS THE IRISH LEGAL VACUUM IN RELATION TO HESC RESEARCH.

7.1 ABSTRACT

There is no legal framework for human embryonic stem cell (hESC) research in the Republic of Ireland. This paper aims to make an empirically-informed contribution to the nascent Irish debate on hESC research legislation through an exploration of the attitudes of stakeholders. Drawing on data obtained from 12 semi-structured interviews, the effect of the absence of legislation is explored. It is shown that, despite not agreeing on the content of potential legislation, there is a consensus amongst the participants that it is essential that this regulatory lacuna should not continue. It is proposed that the continuing absence of such a framework stifles research at the scientific and clinical level ultimately harming patients, the potential beneficiaries of such research. It is further proposed the continuance of this legal vacuum, despite the existence of a Constitutional provision protecting in vivo embryos, demonstrates there is little regard for in vitro embryos in Ireland.

7.2 Introduction: Stem Cell Research and Ireland

Human embryonic stem cells (hESCs) are pluripotent, with the capability to become many cell types, and are thought to have the potential to revolutionise medical treatment by replacing individual cells and tissue types in a number of different degenerative diseases. They are currently being used as disease models for Parkinson’s disease by inducing genetic changes associated with Parkinson’s in hESC-derived neuronal cells,¹ and in a similar fashion in research into motor neuron disease,² to test new drugs for the treatment of other neurodegenerative diseases such as Alzheimer’s disease,³ to create 3-D tissue constructs with stem-cell derived

¹ Smith, K (2010) Treatment Frontiers. *Nature* 466: S15-S18.

² In 2005 the UK Human fertilisation and Embryology Authority (HFEA) granted Professor Ian Wilmut at the Roslin Institute a licence to perform research into motor neuron disease using somatic cell nuclear transfer (SCNT) to produce hES cell lines. See HFEA press release at <http://www.hfea.gov.uk/PressOffice/Archive/1107861560>.

³ Goldstein, L (2010) Why Scientific Details are Important When Novel Techniques Encounter Law, Politics and Ethics. *Journal of Law, Medicine and Ethics* 38: 204-211.

cardiomyocytes which may be used to screen for life-threatening arrhythmias,⁴ and more recently for the treatment of acute spinal injuries⁵ and macular dystrophy.⁶

Such advances in science often compel societies to determine whether ‘morally contentious issues require consensus, compromise and political convictions’.⁷ The contention arises from the acceptability, or not, that the derivation of hESCs from an embryo results in the destruction of that embryo. This in turn prompts an assessment of the moral and scientific ‘value’ of this entity to that particular society. In this way the boundaries between ethics, religion and politics can become blurred, with the result that hESC research has the potential to present a significant public policy and regulatory challenge for any government.

To date the challenge to balance the therapeutic potential of hESC research (hESCR) with the complex socio-ethical and moral issues involved has been one that successive Irish governments have been reluctant to take up. In the Republic of Ireland there is no law directly prohibiting or allowing research to take place using human embryonic stem cells.⁸ When a law is absent in a particular area it does not mean that everything is allowed but instead a situation of legal uncertainty is created.⁹ This can have negative implications for those working in a particular area and for those hoping to benefit practically or financially from advances in the area in question.

When the Irish Supreme Court decided in the case of a separated couple disputing the future of three frozen embryos from an *in vitro fertilisation* (IVF) cycle, *R v. R*

⁴ Daley, GQ and Scadden, DT (2008) Prospects for Stem Cell-Based Therapy. *Cell* 132: 544-548. (This article reviews a number potential stem cell-based therapies).

⁵ Strauss, S (2010) Geron Trial Resumes but Standards for Stem Cells Remain Elusive. *Nature Biotechnology* 28: 989-990.

⁶ Vogel, G (2011) UK Approves Europe’s First Embryonic Stem Cell Clinical Trial. *Science* (September 29th). Available at <http://news.sciencemag.org/scienceinsider/2011/09/uk-approves-europes-first-embryonic.html>. A clinical trial for the treatment of Stargardt’s Macular Dystrophy using retinal pigment epithelium derived from human embryonic stem cells, a leading cause of retinal juvenile blindness had been given approval in the UK.

⁷ Isasi, RM and Knoppers, BM (2009) Towards Commonality? Policy Approaches to Human Embryonic Stem Cell Research in Europe. In Plomer, A and Torremans, P (eds.) *Embryonic Stem cell Patents: European Law and Ethics*. Oxford: Oxford University Press, pp 29-56.

⁸ Mills, S (2007) *Clinical Practice and the Law*. Dublin: Tottel Publishing Ltd, pp 287-310.

⁹ European Group on Ethics in Science and Technology (2000) *Avis No.15: Ethical aspects of Human Stem Cell Research and Use*. Brussels: European Commission. Available at www.ec.europa.eu/european_group_ethics_archives.

(2009),¹⁰ that frozen or pre-implantation embryos did not come under the protection of Article 40.3.3 of the Irish Constitution, which protects the right to life of the ‘unborn’, this legal vacuum was highlighted and an inconsistency in the law’s approach to the embryo identified.¹¹ Prior to the *Roche* case it was assumed that the remit of the constitutional provision to protect unborn life extended to all embryos and hence prohibited embryonic and embryonic stem cell research.¹² As a result of the Supreme Court’s judgment, however, it would appear that there is no legal prohibition to hESCR taking place in Ireland, since surplus embryos from IVF cycles could potentially become available with no legal impediment.

Although this decision has been identified as a ‘landmark decision in the Irish bioethical landscape,’¹³ what the judgment failed to do was to provide clarity as to the actual protection afforded under Irish law to *in vitro* embryos. This has led to numerous calls for the enactment of appropriate legislation to bring a degree of certainty as to what may and may not be done with these embryos.¹⁴

The need for clarifying legislation has in particular been mooted by two leading Irish organisations; both the government-funded Commission on Assisted Human Reproduction (CAHR) and the Irish Council for Bioethics (ICB) recommended that hESC research should be allowed to take place in Ireland under strict guidelines overseen by an appropriate regulatory body.¹⁵ Although the ICB acknowledged that:

¹⁰ *Roche v. Roche & Ors* [2009] IESC 82; *R (M) v. R (T) & Ors* [2006] IEHC359 (15 November 2006). Available at: <http://www.bailii.org/ie/cases/IEHC/2006/359.html>. Referred to hereafter as the *Roche* case.

¹¹ Article 40.3.3 of *Bunreacht Ná hÉireann* states that:

‘The State acknowledges the right to life of the unborn and, with due respect to the equal right of life of the mother, guarantees in its laws to respect, and as far as is practicable, by its laws to defend and vindicate that right.’ *Bunreacht na hÉireann* Constitution of Ireland. Dublin: Government Publications Office, p 150.

¹² This outcome demonstrates once again in Ireland that ‘constitutional amendments cannot be judge-proofed particularly if the legislature, happy to have passed the buck, avoids the introduction of clarifying legislation’. See Fox, M and Murphy, T (1992) Irish Abortions: Seeking Refuge in a Jurisprudence of Doubt and Delegation. *Journal of Law and Society* 19: 454-455.

¹³ McGuinness, S and Ui Chonnachtaigh, S (2011) Implications of Recent Developments in Ireland for the Status of the Embryo. *Cambridge Quarterly of Healthcare Ethics*, 20: 396-408.

¹⁴ Culliton, G (2008) Doctor Urges Stem Cell Clarity. *Irish Medical Times* April 24th.

¹⁵ Irish Council for Bioethics (ICB) (2008) *Ethical, Scientific and Legal Issues Concerning Stem Cell Research*. Dublin: ICB, p 45. Also see CAHR (2005) *Current and Future Developments in Assisted Human Reproduction*. Dublin: Government Publications Office, recommendation 34, p 58.

‘Societal attitudes in relation to these questions vary greatly, with some people fundamentally opposed to research involving nascent human life, while others take the view that research on human embryos offers a legitimate opportunity to garner new scientific knowledge.’¹⁶

Both the ICB and the CAHR recommended that:

‘the embryo formed by IVF should not attract legal protection until it is placed in the body, at which stage it should attract the same protection as the embryo *in vivo*.’¹⁷

Unfortunately, the CAHR report may be interpreted as not providing any protection to the *in vitro* embryo. This assumption was effectively supported by the decision of the Supreme Court in *Roche* not to apply Constitutional protection to pre-implantation embryos, leaving the *in vitro* embryo unprotected by Irish law in its Petri dish.¹⁸

The empirical study presented in this paper was devised to attempt to provide some insight into both the issues behind the Irish failure to develop a regulatory mechanism and the legal, social and scientific implications of this failure. The need to develop a regulatory system providing the certainty required to facilitate hESC research in Ireland was further underlined by the decision by two major Irish universities, University College, Cork, and Trinity College, Dublin, to introduce their own guidelines to allow hESC research to be carried out within their science faculties in the absence of national regulations. It would seem obvious that a legislative initiative in this area is long overdue to avoid the potential for any abuse of this lacuna in Irish law.¹⁹

¹⁶ ICB, *ibid*, p *ii*.

¹⁷ CAHR, n above 15, recommendation 16: ‘The Commission with the exception of one member recommends that the embryo formed by IVF should not attract legal protection until placed in the human body, at which stage it should attract the same level of protection as the embryo formed *in vivo*’, at p 34.

¹⁸ Donnellan, E and Allstrom, D (2008) UCC Debate to Fuel Calls for National Stem Cell Policy. *The Irish Times* October 28th; also see Culliton, n above 14, and Gartland, F (2008) UCC Ethics Board Calls for Debate on Stem Cell Research. *The Irish Times* November 13th.

¹⁹ Hardiman, J warned in his judgment in *Roche* that without a legislative framework Ireland could become home to ‘unregulated practice that may be controversial’. For further discussion of this case see Gough, F (2010) Ireland and the Frozen Embryo: A Slight Thawing? *Medical Law Review* 18: 239-247; also see Jackson, E (2001) *Regulating Reproduction*. Oxford: Hart Publishing, p 170.

7.3 Empirical Methods

The questions being evaluated in this study relate to hESC research in Ireland. In bioethics a growing number of publications have examined empirical findings.²⁰ The aim in an empirical bioethics study should be to produce ‘a contextualised ethical analysis, which is both sensitive to the lived experiences of stakeholders and yet still critically normative’.²¹ Research in this area has significantly contributed both to the process of ethical clarification and to decision-making in other jurisdictions.²² It was hoped that this study could provide a distinctive Irish perspective on this area through identification of the problems, and exploration of the experiences of individuals in Ireland with a link to hESC research.

Qualitative methods, such as unstructured or semi-structured interviews, have advanced bioethical enquiry. The integration of structured and unstructured exchanges in these interviews allows a focus on the crucial issues of the study but lets the participants respond in their own words, with the interviewer prompting for clarification or more detail in an answer as necessary. This method is noted to be particularly well suited to areas of exploratory research with associated moral issues like hESC research, as these types of interviews are not concerned with the objective truth but with the truth as the participant sees it.²³

Sankar and Jones have championed them as ‘an adaptable and reliable means to gather the kind of data needed to conduct empirical bioethics research’, with this type of data substantially contributing to the understanding of complex ethical issues and hence to decision-making and policy formation.

Having obtained University ethical approval, stakeholders were identified.

In this Emily Jackson argues that ‘a more logical approach response to these sort of concerns (around hESCR) would be to construct an effective and comprehensive regulatory structure that might be better able to police undesirable practices than an unworkable blanket ban.’

²⁰ For example, see *American Journal of Bioethics* (2009) Vol.9, Issues 6 & 7.

²¹ Ives J (2008) Encounters with Experience: Empirical Bioethics and the Future. *Health Care Analysis* 16: 1-6.

²² Borry, P Schotsmans, NS and Dierickx, K (2004) What is the Role of Empirical Research in Bioethical Reflections and Decision-making? An Ethical Analysis. *Medicine, Health Care and Philosophy* 7: 41-53.

²³ Sankar, P and Jones, NL (2008) Semi-Structured Interviews in Bioethical Research. In Jacoby, L and Siminoff, L *Empirical Methods in Bioethics: A Primer*, pp 117-136.

Their selection was based on their contribution to the ethical discussion in this area, either in favour or against allowing hESC research to take place in Ireland, or because in their professional capacity the legal lacuna could potentially impact on their work.²⁴ Of the stakeholders initially identified as potential participants, contacted and invited to participate, one-third did not respond to canvassing. Anonymity was offered but requested by only one participant. The range of participants included scientists, clinicians, ethicists and politicians. An attempt was made to include approximately equal numbers of participants who were in favour of, or opposed to, hESC research. The interview guide was designed to permit the emergence of themes which might demonstrate some of the ways in which the 'normative structures of medicine and science produce different ethical positions.'²⁵ This exploration is important as by investigating how moral problems are 'perceived and constructed by those whom they effect and how these individuals handle those problems' it may be possible to discover 'the disparate forms of moral rationality' among key stakeholders in the Irish stem cell debate.²⁶

Questions were e-mailed to participants in advance of interviews. Consent for the taping of interviews was obtained. All participants were asked the questions in the same sequence with the interviewer probing inductively on key responses. After interviews were completed they were transcribed. The transcript were then analysed for the purposes of identifying emergent themes.²⁷

7.4 Results

Twelve interviews were carried out.²⁸ The participants included three clinicians who also engage in scientific research,²⁹ two politicians,³⁰ four academic ethicists,³¹ one

²⁴ This effectively was a purposive sample group where participants are selected according to pre-determined criteria relevant to the research objective. Bernard, HR (2000) *Social Research Methods: Qualitative and Quantitative Approaches*. London: Sage Publications Ltd, p 61.

²⁵ Cribb, A et al (2008) Towards the Applied: The Construction of Ethical Positions in Stem Cell Translational Research. *Medicine Health Care and Philosophy* 11: 351-361, at p 353.

²⁶ Hoffmaster, B (1992) Can Ethnography Save the Life of Medical Ethics? *Social Science and Medicine* 35: 1421-1431.

²⁷ Content analysis was undertaken. This is based on deductive coding. This technique is often used when there is evidence of social conflict or cultural contradictions. This thematic or content analysis is a flexible process which involves the identification of prominent or recurrent themes in data and may allow for the emergence of unanticipated ideas. From Bernard, n above 24, at p 444. Also Dixon-Woods, M et al (2005) Synthesising Qualitative and Quantitative Evidence: A Review of Possible Methods. *Journal of Health Services Research & Policy* 10: 45-53.

²⁸ Guest, G Bunce, A and Johnson, L (2006) How Many Interviews are Enough? An Experiment with Data Saturation and Variability. *Field Methods* 18: 59-82. This paper proposes that data

scientist who uses only adult stem cells, and two scientists who undertake research using both adult and embryonic stem cells.³²

There were a number of prominent themes identified from analysis of the data. In order to make an empirically-informed contribution to the understanding of the issues or nuances particular to the stem cell research debate in Ireland, the following will be discussed:

- (1) the moral and legal status of the embryo in Ireland,
- (2) the need for a legal framework around hESC research
- (3) the lack of political will-power to broach this subject, and
- (4) the economic and scientific impact of a lack of legislation in Ireland.

7.5 The Moral and Legal Status of the Embryo in Ireland

In order to do human embryonic stem cell research, embryos are destroyed. Most of the ethical debates around hESC research focus on the moral value of an embryo and on the morality of destroying one life to benefit another.

The use of human embryonic stem cells was acknowledged by all participants in this study to be the major ethical issue in stem cell research as far as the public was concerned and this was most likely driven by religious sensibilities in Ireland. The responses showing greatest diversity of views was in reply to the question:

‘Are there ethical problems associated with hESC research?’

The scientists, who have to deal with this issue as a practical reality in their work, showed differing approaches to this problem:

‘The difficulty obviously is that in order to make them you have to destroy human embryos so you are effectively terminating the life of an

saturation occurs within the first twelve interviews, with the basic elements for metathemes present as early as six interviews.

²⁹ Referred to in text as C1, C2 and C3.

³⁰ Referred to in text as P1 and P2.

³¹ Referred to in text as E1, E2, E3, and E4.

³² Referred to in text as S1, S2, and S3.

individual in order to generate material for research and possibly eventually for therapy but not yet. I suppose that's the fundamental ethical issue I think; that the only way you can get human embryonic stem cells is to destroy one or more human embryos.' (S1)

This scientist hoped that induced pluripotent stem (iPS) cells, derived from the re-programming of somatic or adult cells, would in the near future eliminate the major ethical issues related to the use of hES cells:

'Most people would now, I think, agree that since the discovery of iPS cells that there really is not going to be a therapeutic future for embryonic stem cells anyway. There are still a few technical hurdles to overcome because most people are still making iPS cells with retroviruses and there are certain safety issues there but there are other methods coming in. I would be fairly confident that in terms of the clinical applications anything that could have been done with the embryonic cells you will probably be able to do with the iPS cells.' (S1)

This attitude has been found in other studies where opponents of embryonic stem cell research stress the potential therapeutic benefits from research using adult or iPS cells, while advocates of hESC research tend to emphasise the possible advances that may only come about through working with embryonic cells.³³ However, there was also an awareness on the part of S1 that, in general, the public were unclear about the distinction between hES cells and iPS, and so public concern as to the providence of hES cells could in the public's mind 'taint' research done using only adult stem cells. He acknowledged that more work needs to be done to address the technical problems associated with iPS cells at the moment, such as their propensity to provoke an immune response and potential tumorigenicity.³⁴

Some scientists have no personal ethical concerns about harvesting or working on hES cells.³⁵ This was evident in this study amongst the scientists who worked with

³³ Longstaff, H et al (2009) Scientists' Perspectives on the Ethical Issues of Stem Research. *Stem Cell Review and Reports* 5 : 89-95.

³⁴ Regenbreg, AC et al (2009) Medicine on the Fringe: Stem Cell-Based Interventions in Advance of Evidence. *Stem Cells* 27: 2312-2319.

³⁵ Longstaff, n above 33.

both embryonic and adult stem cells. Contrast this opinion on the moral status of an embryo with that of the previous scientist:

‘All research has important ethical considerations. In relation to hESCR, the metaphysical status of a clump of cells against that of a patient with a certain condition? There’s no argument for me.’(S2)

In 2005 the Irish Council for Bioethics found that 57% of Irish people surveyed believed that human life begins at conception.³⁶ According to the 2008 survey by the private global foundation, Banco Bilbao Vizcayan Argentaris (BBVA) ‘citizens are influenced in their acceptance or otherwise of the use of embryos to obtain stem cells by the views they hold on the moral condition of an embryo that is a few days old, which are influenced in turn by religious beliefs (being a believer or non believer)’.³⁷ In general, a strictly biological view of the embryo, as expounded by the scientist S2, has been found to predominate among non believers, while the religious population, whether Protestant or Catholic, tends to see the embryo's moral status as being equivalent to that of a human being. Despite a considerable waning of the influence of the Catholic Church in Ireland in the last decade, this view would still have strong support among the general population.³⁸

Previous studies have shown that scientists appear to be uncertain about how to address the perceived widespread public misperceptions regarding hESC research.³⁹ This was also apparent in this study with the scientists differing in their views about whether they had a responsibility to communicate with the public to clarify these

³⁶ Irish Council for Bioethics (2005) TNS / MRBI Bio Ethics Research p 34. Available at www.bioethics.ie/uploads/docs/129171-Bioethics%20Research.pdf. (Accessed on 18/4/12). In research carried out by the ICB in 2005 82% of the people surveyed agreed that surplus embryos should be used for medical research into disease even if this meant they would be destroyed in the process.

³⁷ Fundación BBVA, Second BBVA Foundation International Study on Biotechnology (2008) *Attitudes to Stem Cell Research and Hybrid Embryos*. Available at www.fbbva.es/TLFU/dat/international_study_biotechnology_08. (Accessed on 18/4/12).

³⁸ While the percentage of the Irish population describing themselves as Catholic has fallen from 88.39 in the 2002 Census to 87.37 in the 2006 Census (www.cso.ie) and regular (weekly) attendance at Mass has fallen from 64% in the late 1990s to 51.6% in 2009/10 (according to ESS data- From ‘Practice and Belief among Catholics in the Republic of Ireland – A summary of data from the European social Survey Round 4 (2009/10) and the International Social Science Programme Religion III (2008/9) www.irishcatholicbishops.ie/practice-and-belief-among-catholics) a recent poll conducted by Red C on behalf of the Pro-Life Campaign found that 68% of those surveyed supported the current constitutional protection for the unborn. See Irish Examiner (2011) Feb 17th. The ICB also found in its report that 69% believe that an embryo acquires full moral status at fertilisation. ICB, n above 15.

³⁹ Longstaff, n above 33.

issues, but they seemed generally suspicious of, and hesitant to engage with, the media. It has been shown in relation to hESC research in Austria that media representation of this field of science rarely focuses on the actual details of the technology involved but rather on the context of the use of the technology and its potential to lead to moral disaster.⁴⁰

Scientists also voiced uncertainty as to whether, and how, they ought to address public concerns about the moral status of the embryo:

‘The challenge there is to make that balanced where there are controversial issues. Some people see the whole science communication as the scientist telling the public what they should do, whereas I think you need to listen to all voices and then let people make a balanced decision.’ (S1)

One of the clinicians expressed a gradualist opinion about the moral status of the embryo:

‘I hold a view on the status of the embryo in that I don’t see it as a progenitor human being, I see it as an embryo and so I don’t feel ethically conflicted when I think about cells being derived from embryos because I think that the position of the embryo is not the same as the position of a foetus or a human life yet.’ (C2)

Another of the clinicians, tried to examine the problem from both sides of the ethical argument:

‘I’m sure there are ethical difficulties in working with embryonic stem cells. From the perspective of the opposing view- for example, the good that would come out of hESC research is such that it should be the primary driver as opposed to the people who would feel that no matter what good comes out of something that is initially an evil act, or an immoral or unethical act, cannot justify the initial act. So you’ve got those two schools of thought I suppose and then you’ve got many people

⁴⁰ Prainsack, B and Gmeiner, R (2008) Clean Soil and Common Ground : The Biopolitics of Human Embryonic Stem Cell Research in Austria. *Science as Culture* 17: 377-395, at p 378.

who are in-between, who would have concerns about the destruction of the embryo and who would want a lot of regulation around that if it were to happen but that the potential good that might come out of it would justify that.’(C3)

The notion of stem cell research having the potential to do some ‘good’ is often central to the ethical justification for stem cell research, along with the need to improve scientific knowledge of basic cell biology.

As can be seen from the preceding paragraphs there was no overall consensus among the participants in this study as to the moral status of the embryo, but there was a consensus that there should be a clear legal definition of an embryo, as in any society ‘the law must define what it intends to protect’.⁴¹

However, some participants expressed concern over the Irish Supreme Court’s decision to exclude pre-implantation embryos from the legal protection offered by Article 40.3.3:

‘I think that it doesn’t make much sense to give it, the same entity, a different value outside the womb as inside the womb, given that in both cases you are dealing with something that is biologically human, biologically alive and growing’. (S1)

One of the politicians in the study emphasised that:

‘there is a prior issue of justice to be determined which is whether human embryos ought to attract the protection of the law, whether it be constitutional protection or in the light of the recent Supreme Court decision, whether it be legislative protection and for me that’s a prior issue to be determined’. (P1)

This politician felt strongly that:

⁴¹ All-Party Oireachtas Committee on the Constitution 1996-1997 (1996) *Report of the Constitutional Review Group, Articles 40–44*, Dublin: Stationary Office, pp 250-256. Available at <http://www.constitution.ie/reeports/crg.pdf>. (Accessed on 18/4/12). Also see Latham, SR (2009) Between Public Opinion and Policy: Human Stem Cell Research and Path-Dependency. *Journal of Law, Medicine and Ethics* 37:800-806.

‘there is an issue of principle here which is that a human embryos ought to attract in my view the protection of the law and therefore that we should encourage every possible avenue of medical research but subject to that overriding consideration’. (P1)

The need to ensure that research takes place within a legal framework was acknowledged by all participants, but there was disagreement as to how to protect the pre-implantation or frozen embryo. The level of protection proposed seemed to be based on the moral value afforded to these embryos by the participants.

7.6 Implications of a Lack of a Legal Framework

There was a general agreement among the study participants, irrespective of whether the participant was in favour or against allowing embryonic stem cell research to take place in Ireland, that there is an urgent need for a legal framework concerning hESCR, although there were different reasons cited for this need. One of the reasons identified was scientific and economic development. According to Perrin,⁴² the growth of the United Kingdom (UK) as a major centre for hESC research can be primarily attributed to the supportive regulatory framework that exist in the UK since the introduction of the Human Fertilisation and Embryology Act (HFEA) in 1990. The HFE Act, described as a ‘legislative tour de force’, has created a ‘legal framework for embryo research in the absence of moral consensus,’⁴³ and it is acknowledged both by academics and industry in the UK, that it has been this framework which has allowed researchers to work with hES cells within clearly defined parameters by optimising the scope of research and by providing a moral justification for the research framework.⁴⁴ This policy has enabled and encouraged world-class research, and UK scientists currently have developed significant expertise in the area of hESC research.⁴⁵

⁴² Perrin, NMR (2005) *The Global Commercialisation of UK Stem Cell Research*. London: UK Trade and Investment. Available at

http://chrismason.com/industry_library/assets/UKTI%20Stem%20Cell%20Res.pdf.

⁴³ Klotzko, AJ (1997) The Debate about Dolly. *Bioethics* 11: 427-438.

⁴⁴ Perrin, n above 42.

⁴⁵ Winston, R (2007) Does Government Regulation Inhibit Embryonic Stem Cell Research and Can it be Effective? *Cell Stem Cell* 1: 27–34.

The ethicists in this study seemed concerned about the implications of the lack of certainty as to what can and cannot be done in Ireland at the moment given the present unusual situation where, although embryonic stem cell research is not illegal, neither is it legal.⁴⁶ On the impact of lack of regulation and of the need to regulate in this area of hESC research one ethicist had this to say:

‘I think that at the very least the lack of law or lack of legislation has created an uncertainty and I think it extends beyond the stem cell research area, but just the whole area of reproductive technology and fertility treatments. The whole area has had this uncertainty.’(E1)

Another ethicist agreed that not having legislation had negative connotations as:

‘If we knew exactly where we stood well then we could say we approve of this or we don’t approve of that.’(E2)

This ethicist emphasised that although regulation was needed in the whole area of reproductive technology :

‘It doesn’t have to be a total re-invention of the wheel. There is some excellent legislation around that we could use or could refer to.’(E2)

A third ethicist felt that:

‘In any legislation there is going to have to be compromise. You are not going to keep everybody happy but I think you have to bite that bullet. Once you have legislation in place then it’s for people within society to use the political system, if they want to, to change, to add to, to subtract from, to advance on or whatever, like they do in other countries.’ (E4)

They emphasised that the debate on legislation was a very important one, but in Ireland:

⁴⁶ Yuko, E (2011) *Bioethical Regulations in Ireland: Where are They?* Available at www.gleube.eu/polemics-3/bioethical-regulations-in-Ireland-where-are-they-38.htm. (Accessed on 18/4/12).

‘debate is thwarted and portrays us as a society as not having any kind of moral fibre, and that our politicians are not prepared to engage in moral debate.’(E4)

Another ethicist felt Ireland’s position meant that:

‘Ireland is piggy-backing on other countries for their governance- we’re relying on them to have developed the stem cell lines within an ethical framework.’
(E3)

This ethicist deemed Ireland to be behaving like a moral “free-rider”, relying on the good governance developed in other jurisdictions in relation to stem cell research regulations.

Most of the ethicists acknowledged that the proposals made by the Commission on Assisted Human Reproduction in its 2005 report would be a good starting point for a legislative framework:

‘I would agree with some of the proposals they made;⁴⁷ I wouldn’t agree with others about the contents of legislation but that’s another day’s work. Certainly there has to be legislation’..... ‘International colleagues find it quite extraordinary that there are no regulations.’(E4)

The construction of a cohesive and comprehensive regulatory structure in Ireland would, in all likelihood, put pay to at least some of the anxieties voiced by the ethicists, as it is generally recognised that systems which ‘acknowledge and respond to public fears and doubts provide a sense of control, offer public access and influence and offer a forum and time for discussion and education’.⁴⁸

There is also some anecdotal evidence of young researchers leaving Ireland to pursue their interest in stem cell research abroad primarily because they are not comfortable

⁴⁷ The participant is referring to the proposals of the Commission on Assisted Human Reproduction (CAHR) in relation to legislating in the areas of IVF and stem cell research. The Commission made 40 recommendations in this area covering the establishment of a regulatory body, guidelines around the practice of IVF, allowing embryo research, including embryonic stem cell research, under stringently controlled conditions, but it recommended that reproductive cloning be prohibited.

⁴⁸ Caulfield, T (2004) Law and Policy in the Era of Reproductive Genetics. *Journal of Medical Ethics* 30: 414-471.

working in an unregulated environment.⁴⁹ In addition, they find that they cannot attract funding for their research because of the reluctance of funding agencies, particularly European-based agencies, to invest in Ireland as long as this uncertainty prevails despite the drive from the European Commission for Research, Innovation and Science to integrate European research programmes.⁵⁰

Scientists, in response to the question on the need for regulation, stated that the idea of a regulatory body was good as long as it operated within fairly strict parameters, and despite the perception internationally that Ireland was a conservative country, the fact that there is no law prohibiting stem cell research effectively means :

‘it could be the most liberal country in the world in practice if somebody decided to do it – there is nothing to stop them which is completely crazy.’(S2)

The scientist was referring here to the possibility that reproductive cloning could take place in Ireland as there is no law to prohibit it.⁵¹ In practice, however, this does not seem to be happening as none the scientists in the study group were aware of any research related to cloning being undertaken in Ireland. This scientist felt it is the job of those in Government, not the Judiciary, to remedy the problem:

‘I don’t think there is much point in wasting energy on criticising the Supreme Court; they had a job to do, they looked at the wording.’⁵² Their view is that the Constitution is silent on embryos pre-implantation, and therefore it is now up to the legislator to either cover that by law or a Constitutional amendment, whichever.’(S2)

⁴⁹ One of the scientists who participated in this study has subsequently left Ireland to work in the California Institute for Regenerative Medicine.

⁵⁰ Sullivan, S (2011) Stem Cell Research in the Emerald Isle. *Bioengineered Bugs* 2: 69-70. Available at www.landesbioscience.com. (Accessed on 18/4/12).

⁵¹ The scientist is referring to reproductive cloning of a human embryo where an embryo is produced by somatic cell nuclear transfer (SCNT). Therapeutic cloning has been permitted in the UK since 2004 under the HFEA. The embryo produced would be genetically identical to the donor of the somatic cell and could theoretically be used to produce new tissue or complete organs for the donor.

⁵² The participant is referring to the Supreme Court’s judgment in *Roche* which concluded that frozen embryos are outside the protection of Article 40.3.3 of the Irish Constitution which protects the right to life of the ‘unborn.’

Another scientist felt that any potential legislation should reflect good medical and scientific practice, while the lack of legislation marginalised certain parts of society. They emphasised that, although many Irish people would not be overly familiar with the minutia of IVF or hESC research, they:

‘.....don’t want it brought up again and again- if there was strong legislation this would not happen. Legislation is not just a set of do’s and don’t’s - it’s a reflection of how important the citizens of the country regard the matter. We need a commission of Irish and international experts to look at legislation and draft it in light of international best practices. Something must be done!’ (S3)

The politicians emphasised the role of the Irish Constitutional position on embryos:

‘The Supreme Court made its decision about no more and no less than what the Constitution has to say about the meaning of the ‘unborn’ and clearly it doesn’t cover human embryos at this stage of their existence that we are talking about, so all the more reason now for us to decide now as a community through our legislator what will and will not be permissible.’(P1)

One of the clinician/researchers had a different emphasis in that they felt that the legal lacuna and lack of definition meant:

‘that we now have the bizarre situation of being able to destroy but not research discarded embryos. It’s a nonsense!’(C1)

They were also concerned as to the effect on clinical practice as:

‘the bizarre side of having no legislation is that anyone can set up a clinic. It also means that it is difficult to collect statistics from clinics and compare clinic outcomes. This lack of legislation is frustrating as it means that there cannot be pre-implantation diagnosis here, which means that patients are forced to go abroad. The whole area of ART and SC research should be legislated for and a regulatory policy developed, as scientists at the moment are left feeling vulnerable and that they could at

any time end up in the Supreme Court as happened in the *Roche* case.’
(C1)

Other clinician/researchers felt that the failure to regulate would ‘distort the areas of regulated science,’ and:

‘because of the societal issues and because of the emotive issues around, for example, embryonic stem cell research, I think the failure to regulate in Ireland is much more likely to lead to a stagnation of research’. (C2)

Clinician C2 also expressed the need to, at the very least, recognise the ‘potential benefit as research tools of embryonic stem cell lines and to permit their importation.’ Many scientists would agree that with this idea and that iPS and hES cell techniques should be use in tandem as comparative methods to allow an improved understanding of stem cell biology.⁵³

Clinician (C2) was acutely aware that cultural issues, a historically Catholic moral outlook, and use of emotive language have contributed to the current lacuna in the law in this area in Ireland, but felt strongly that:

‘clinical practice has to be regulated for the moral framework, and everything that we do is subject to a moral/ethical code and clearly the derivation of any tissue that derived from humans has to be regulated along an ethical and moral code in the same way as we would handle other tissues like DNA or cells from patients. There is an ethical framework in which we have to practice to utilise biological material of any sort. And from a clinical point of view in the way our interactions with people that we see professionally, there is a moral and ethical code that governs how we act and clearly a similar moral and ethical code governs how we deal with embryonic stem cells.’ (C2)

This clinician clearly articulated an acceptance that all clinical research involving human-derived material should take place within an appropriate ethical and legal framework. This is not currently the case in Ireland.

⁵³ Wobus, AM and Boheler, KR (2005) Embryonic Stem Cells: Prospects for Developmental Biology and Cell Therapy. *Physiological Reviews* 85: 635-678, at p 668.

7.7 Lack of Political Will-Power

Another area in which there was a strong consensus was the perceived reluctance of politicians in Ireland to become embroiled in the debate around stem cell research. This political inertia is widely acknowledged despite the fact that the Irish State has a strong interest in being recognised as a democratic state and should be seeking to position itself as such through its laws.⁵⁴ There was also a strong consensus as to the unlikelihood of any political initiative to resolve this dilemma in the near future. This reluctance to become involved in matters pertaining to the area of reproduction is a hang-over from the (often) vitriolic debates that took place in Ireland in the 1980's in relation to abortion, when 'an anti-abortion stance and foetal rights seemed to become regarded as symbols of the core values of Irish identity- Catholicism, family, patriarchal dominance, fear of sex and opposition to foreign (British) ideologies.'⁵⁵ Even the politicians were not hopeful about the intentions of their colleagues in this area:

'...given the government's record to date I wouldn't be particularly optimistic about them initiating a legislative response in the near future'.(P2)

There would appear to be reasonable justification for the pessimism expressed by this politician as since 1995, over 1,200 written or verbal questions have been posed in the Houses of the Oireachtas, both Dáil and Seanad, in relation to legislation pertaining to Assisted Human Reproduction (AHR) or stem cell research. Four successive Ministers of Health have failed over a 12-year period to respond conclusively as to when legislation will be put before the Dáil.⁵⁶

⁵⁴ Smyth, L (2005) *Abortion and Nation: The Politics of Reproduction in Contemporary Ireland*. Aldershot: Ashgate Publishing Company, pp 1-38.

⁵⁵ There is no facility for abortion in Ireland but there is legislation allowing information on abortion. For review of Ireland's continuing inertia in relation to the issue of abortion see McGuinness, S (2011) A, B, and C leads to D (for Delegation). *Medical Law Review* 19: 476-491. See also Healy, M (2008) 'I Don't Want to Get Into This, It's Too Controversial'. How Irish Women Politicians Conceptualise the Abortion Debate. In Schweppe, J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, pp 65-85; see also Hanafin, P (2001) *Constituting Identity: Political Identity Formation and the Constitution in Post-independence Ireland*. Aldershot: Ashgate Publishing, pp 26- 46.

⁵⁶ The Health Ministers concerned were Brian Cowen, T.D. 16th November 1999; Michéal Martin, T.D. 2nd March 2000; Mary Harney, T.D. 6th December 2005; James Reilly, T.D. 27th September 2011 Available from www.Oireachtas.ie/debates.

The scientists, in both the pro- and anti- hESC research camps, were very vocal in their criticism of politicians to deal with this issue:

‘It’s the government’s problem. They don’t have the gumption or the will to do something - to legislate for this area.’(S3)

They also emphasised the implications of this failure:

‘There is a massive lack of any sort of governmental attempt to deal with the area of stem cell research - they just want to keep it under the carpet and hopefully it will go away. It’s lacking foresight; it’s lacking any sort of proper research structure, infrastructure for patient research. It’s a big section world-wide, it’s a big section of research for a lot of diseases, yet the Irish government has chosen to do nothing about it. It’s quite backwards; it’s bad for the patients, it’s bad for science, it’s bad for industry in Ireland’. (S3)

The failure to regulate is already affecting Ireland in competitive terms internationally despite Ireland being regarded as a favourable location by life science industries.⁵⁷ The main sources of science funding within Ireland, the Health Research Board (HRB) and Science Foundation Ireland (SFI), have stated that they will not fund research projects using hESCs in the absence of legislation that specifically provides for such research.⁵⁸ It also means that Ireland is not in a position to become involved in international collaborative research projects involving hESCs. The international scientific community is becoming increasingly globalised with a concomitant improvement in the quality and quantity of research being produced,⁵⁹ but Irish researchers will be unable to benefit in this sharing of resources, ideas and expertise as long as they work in a regulatory vacuum.

This problem was expounded by one of the scientist who was forthright in his belief that the failure to regulate is having a negative effect on Ireland:

⁵⁷ Irish Export Agency (2009) *Annual Report*. Available at <http://www.irishexporters.ie/section/IEAYearendReview2009>.

⁵⁸ Burke-Kennedy, E (2010) Funding Ban on Research Using Human Stem Cells. *The Irish Times Health Supplement* October 12th, p 2.

⁵⁹ Luo, J et al (2011) International Stem Cell Collaborations: How Disparate Policies between the United States and the United Kingdom Impact Research. *PLoS* 6 (3). Available at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0017684>.

‘It’s cowardly and it’s bad for Irish patients and it’s bad for Irish science, and Irish industry. I mean, if you follow the logic about it, it’s just ridiculous.’(S3)

It was felt by some scientists that this approach did not only apply to hESC research but that:

‘The problem with the Irish government is that most decisions are made in reaction to something - most Irish politicians react.’(S2)

This effectively means that there is little in the way of long term strategic decisions regarding the funding or facilitating of any research in Ireland. The possible reasons for the delay in proposing legislation was hypothesised by another scientist:

‘I have heard from a number of sources that legislation has been almost ready in the Department of Health for several years, so I suspect it is waiting for when they think is a political expedient time to do it’..... ‘I think if they feel that legislation is going to be problematic, the time to do it would be after an election, while they are in a strong position and have maybe four years to go.’ (S1) ⁶⁰

The clinicians agreed that as ‘there’s always short-term political concern about raising these issues’, political fortunes would determine the legislative outcome:

‘Unfortunately, there will again be political attempt to avoid legislating but hopefully the Roche decision will force them to do something – vainglorious to hope something will happen!’(C2)

One of the ethicists felt that the level of political debate in Ireland in this area was particularly poor because politicians had other priorities:

‘I think that is part of the whole problem here - it’s that there isn’t a way to articulate political philosophy or political ideology, whether I agree with it or disagree with it. It is an opportunity to propose and articulate something, but unfortunately it seems at the moment to still be – “we’ll

⁶⁰ These interviews mostly took place in the eight months preceding the General Election of February 2011 in Ireland, following which there was a change of government from a Fianna Fáil/Green Party coalition to a Fine Gael/Labour Party coalition.

deal with the potholes and then we'll worry about these other little issues once we're in!" (E1)

Another expressed the view that they would be surprised if the government tried to introduce legislation as:

'It's my own personal view that I think it's such a political hot potato. I think even IVF is a political hot potato'. (E2)

A third ethicist felt that the politicians were exhibiting 'moral cowardice' by their inaction because they were:

'afraid of the negative impact on their own parties and their own political strings but to me it's completely abandoning the purpose of political life. I mean, the purpose political life is in some way to regulate society. There are important issues in terms of scientific research that need to be regulated but they have abandoned it completely. I mean there is no political party in the Dáil, even in Labour, who's going to bite the bullet.⁶¹ They are going to say they have too many things to do, the economy is going down the tubes and they don't have time for this. It will go on for another ten years.' (E4)

This ethicist attributed this moral cowardice to the fact that for the first fifty years of its existence:

'the State was thwarted by the power of the Church, completely and utterly.' (E4)

The participants would appear to be in accord as to the reluctance of politicians in Ireland to lead. In other countries politicians are not as inhibited as Irish politicians on this issue; in the USA it would appear in hESC research has assumed the position previously occupied for many years by abortion as *the* issue on which politicians are

⁶¹ The Lower House of the Oireachtas is the Dáil and is equivalent to the House of Commons in the UK.

expected to take a stand.⁶² Unfortunately, in Ireland no major party has been prepared to address the issue. Yuko has suggested that:

‘many politicians do not see the merit in initiating or supporting any sort of bioethics-related regulation, for fear that it may harm their electability’.⁶³

The general election in February 2011 did not, as the scientist (S1) suggested it might, improve this position as, despite having a clear overall majority there is no agreement within the coalition on this issue; the main coalition partner, Fine Gael, is opposed to allowing stem cell research which uses human embryonic stem cells to take place in Ireland, while the junior coalition partner, the Irish Labour Party, gave a commitment to legislate in favour of hESC research in its pre-election manifesto.⁶⁴ Economic woes, however, have pushed this issue on to the policy backburner.

Despite the obvious difficulties that will be encountered in instituting statutory regulations in the fields of AHR and hESC research, it should be a government’s role to be seen to manage this process, to introduce regulations that protect fundamental interests and ‘to ensure that science remains accountable to the society within which it is embedded’.⁶⁵ It was, in fact, acknowledged by an Irish Government spokesman following the judgement of the Supreme Court in *Roche* (2009) that:

‘The Government fully accepts its responsibility to put proposals to the Oireachtas for legislation to regulate Assisted Human Reproduction.’⁶⁶

It would seem, however, in Ireland there is an ‘inability to deal with bioethical regulations in an objective and open manner,’ and that the ‘political scene is filled

⁶² Dresser, R (2010) Stem Cell Research as Innovation: Expanding the Ethical and Policy Conversation. *Journal of Law, Medicine and Ethics* 38: 332-341.

⁶³ Yuko, n above 46.

⁶⁴ See www.prolifecampaign.ie/pages.php?id=175. (Accessed on 30/10 2011), and *One Ireland: Jobs, Reform, Fairness*. Available at www.labour.ie/manifesto. (Accessed on 18/4/2012). Also see Abbott, A (2011) Irish Election Raises Question for Stem Cell Research. *The Great Beyond* February 28th. Available at: <http://www.go.nature.com/ftx2hu>. (Accessed on 18/4/12).

⁶⁵ Szoke, H Neame L and Johnston, L (2006) Old Technologies and New Challenges. In Freckleton, I and Petersen, K (eds.) *Disputes and Dilemmas in Health Care Law*. Sydney: Federation Press, pp 187-208.

⁶⁶ Minihan, M and Coulter, C (2009) Harney to Propose Law on Assisted Human Reproduction. *The Irish Times* Decembe 16th.

with figures devoid of substance, seeing power without representation.’⁶⁷ Of particular note to these reluctant legislators, perhaps, should be the response to a question posed by the ICB in its report: ‘Do you think there is a need for specific legislation concerning stem cell research in Ireland?’ 84% of respondents gave an affirmative answer.⁶⁸ A further demonstration of the new government’s lack of willingness to take this area seriously is its’ failure to restore the Irish Council of Bioethics to its independent role, as funding for the ICB ceased in October 2010 and it was subsumed in to the Department of Health due to wide ranging ‘fiscal difficulties’ under the previous administration.⁶⁹ The ICB itself described this political decision as one:

‘that has all the hallmarks of an expediency that is rash rather than reflective, damaging rather than deliberative. While significant funding has been allocated to science and technology research during the last decade, with the exception of the establishment of the ICB, similar investments have not been made in the area of research governance.’⁷⁰

The continuing lack of a national bioethics review commission leaves Ireland as the only country in the EU without an effective bioethics forum.

7.8 Economic and Scientific Impact of a Lack of Legislation

An issue that is gaining in importance in Ireland due to its’ current financial difficulties are the implications of no framework on the development of research from an economic perspective. It has been noted by several commentators that ‘embryo research has massive economic implications’.⁷¹ Some of the economic implications of the legal lacuna have already been noted in the course of reviewing the themes of political inertia and implications of a lack of a framework.

⁶⁷ Hanafin, P (2007) *Conceiving Life: Reproductive Politics and the Law in Contemporary Italy*. Aldershot: Ashgate Publishing Ltd, p 81.

⁶⁸ ICB, n above 15, p 92.

⁶⁹ Lyons, B (2012) The Irish Council for Bioethics – An Unaffordable Luxury? *Cambridge Quarterly Healthcare Ethics* 21: 375-383. The Irish Council for Bioethics (Comhairle Bitheice na hÉireann) had been established in 2002 by the Royal Irish Academy as an independent, autonomous, non-statutory body charged with considering the ethical issues raised by developments in science and medicine.

⁷⁰ Irish Council for Bioethics (2010) *Compendium of Work 2002-2010*. Dublin: ICB, p 2.

⁷¹ Spar, D (2004) The Business of Stem Cells. *New England Journal of Medicine* 351: 211-213.

The economic benefits that may accrue from the existence of policies favouring the development of stem cell research are often cited as a key rationale for permissive policies and increased government funding.⁷² In a document prepared for the Texas Alliance for Medical Research in 2009 it was claimed, somewhat optimistically perhaps, that the stem cell research industry has the potential by 2014 to become a \$62.5 billion industry, which would contribute \$87.4 billion to state economic activity and support over 230,000 direct, indirect, and induced jobs.⁷³ It also warns however that if the State fails to provide a regulatory environment favourable to research that this potential revenue source and job prospects would go elsewhere.

In 2005 a report from the UK Stem Cell Initiative proposed changes to existing regulations which they claimed there would attract investment from the pharmaceutical and healthcare private sectors as it has been suggested that such companies have a considerable interest in permissive laws concerning embryo research.⁷⁴ According to Fink:

‘the economic actor that has the highest stake in embryo research is the pharmaceutical industry. If embryo research fulfils its projected potential, the market for pharmaceuticals could be completely transformed.’⁷⁵

Given the importance of the pharmaceutical industry to the British economy it is not surprising that many of the recommendations from the UK Stem Cell Initiative report, such as permitting the development of human-animal hybrids, were subsequently enacted in the revised Human Fertilisation and Embryology Act (2008).

The impact of the legislative lacuna on the future of research in Ireland was assessed negatively by some of the participants in this study but not by all. On the economic effect of no regulatory framework, the ethicists demonstrated divergent opinions:

‘It can either allow any type of research to take place and not be publically accountable or it may mean that no research will come here

⁷² Caulfield, n above 48.

⁷³ Weinstein, BL, Clower, TL. and Seman, M (2009) *Economic Impact of Stem Cell Research in Texas*. Available at www.unt.edu/cedr/StemCell.2009.pdf. (Accessed on 18/4/12).

⁷⁴ *UK Stem Cell Initiative Report & Recommendations* (2005). Available at www.advisorybodies.doh.gov.uk/uksci/uksci-reportnov05.pdf. (Accessed on 18/4/12).

⁷⁵ Fink, S (2008) Politics as Usual or Bring Religion Back in? The Influence of Parties, Institutions, Economic Interests and Religion on Embryo Research Laws. *Comparative Political Studies* 41: 1631-1656.

because any big funding agency will say well there is no regulation or guidelines in the country and we are not sure where we stand and unless we know exactly what is going to happen to us we can't actually fund this kind of research.'(E2)

This ethicist seems to be suggesting that Ireland's position means that scientists are being impacted on negatively in terms of international scientific co-operation and as collaborative research projects across diverse jurisdictions become more common, particularly within Europe, it will be important to ensure that equivalent standards for quality, safety and ethics are applied in Ireland.⁷⁶

However, they were also sceptical that there would be a direct economic gain from introducing regulations to allow hESC research:

'I think this goes back to the economic aspects that we have this uncertainty with our heritage and then we are scrambling for economic recovery and think that if we change some of these traditional views that might help to bring in some economic benefits, but then we are stuck in the middle not sure whether we want to go there or not.'(E2)

One of the ethicists felt that the function of regulations was not solely to limit research but that they also have an important role in protecting investors, and long-term the lack of legislation will deter investors from choosing Ireland because of the absence of economic guarantees. This in turn was leading to a conflict of interest in that:

'the Government wants to create jobs, companies want to find new products, return a profit, scientists want fame and fortune, patents and publications and I think there is this notion that we all like to believe that the Government is sitting and deciding that for the good of the public we will put our money here and yet there are just so many of these conflicts of interest involved as to who gets funding and why.'(E1)

⁷⁶ Isasi, RM and Knoppers, BM (2009) Towards Commonality? Policy Approaches to Human Embryonic Stem Cell Research in Europe. In Plomer, A and Torremans, P (eds.) *Embryonic Stem cell Patents: European Law and Ethics*. Oxford: Oxford University Press, pp 29-56.

One of the scientists agreed with this assessment of the long-term economic effects of no legislation on scientific development in Ireland:

‘In essence for research to be internationally competitive it needs funding and regulatory oversight - both from the point of view of the scientist, so the researchers know where they stand, but also economically from the point of view of people outside of Ireland who need to know what the system is like in Ireland.’ (S2)

This scientist also expressed concern that political expediency in Ireland dictated scientific priorities:

‘There is an unhealthy link between direct economic link and spin-off and the funding of science- it doesn’t permit the funding of more long-term scientific endeavours with no quick payback-economic gain.’ (S2)

However, another scientist felt that despite concern in government circles, both in Ireland and the UK, that:

‘There is a big potential industry here and if we push too much on the ethical side we might miss the opportunity’,

they felt that long term:

‘the success will go to countries that have maintained reasonable ethical standards as well as scientific standards. It’s a long game but I think if you cut corners, as we have seen on the economic side, if you cut corners for apparent short term gain it will come back and bite you at some point in the future and the same with the ethics’.(S1)

The politicians were not as convinced as others that:

‘economic factors play any significant role in the development of regulations’(P2)

But that:

‘while it would be a challenge for people in our society with all the new possibilities that exist’ to explore ‘every possible avenue in terms of economic progress, in terms of attracting investment’ this should be ‘subject to philosophical limits; we need to decide with the people within what framework we would allow that to proceed.’(P1)

This politician was anxious that whatever framework ultimately is introduced in Ireland it should reflect the ethical and moral outlook of the Irish people. In today’s more diverse and pluralist society this outlook may not be as homogenous or conservative as it once was.⁷⁷

7.9 Discussion

In this study, of the four main themes identified, there was a broad consensus on two, namely on the need to legislate in the area of assisted reproduction and associated technologies such as stem cell research, and the lack of political initiative in areas of bioethical regulation, irrespective of which political party was in government.

In relation to the first area of consensus, what was interesting about some of the responses of the participants was their emphasis on the distinctive nuances of the hESC research debate in Ireland. They expressed their belief that it is not possible to simply transplant an ethical argument acceptable in one society to a different cultural situation and proposed a different solution should be sought to that adopted by other European countries. Effectively, they were asking for an ‘Irish slant’ to be put on any new approach to regulation for hESC research in Ireland, because, as one of the ethicists, E4, put it in relation to the structure of any future framework:

‘it’s a very poor reflection of us as a people if we end up mimicking word for word, letter for letter what has gone on in some other jurisdiction, that we can’t create our own particular approach or nuance.’

They seem to be suggesting that it may be possible to legislate to allow limited embryo research, while maintaining some of the tradition Catholic ethos of the country.

⁷⁷ In research carried out by the ICB in 2005 82% of the people surveyed agreed that surplus embryos should be used for medical research into disease even if this meant they would be destroyed in the process. ICB, above n 36, at p 34.

As clinician (C2) stated, despite the fact that the legacy in Ireland:

‘with respect to our moral outlook, heavily informed by our upbringing, has meant the language used to discuss this issue is very emotive’,

it is still imperative that clinical practice is regulated ‘within a moral or ethical framework’. It is, however, generally acknowledged that Catholic-dominated societies tend to legislate more strictly in relation to embryo research laws, with the Catholic Church being an effective and influential political actor when it garners social support.⁷⁸ The 2004 Italian (*legge quaranta*) law on assisted reproduction is an example of this as it effectively bans embryo testing for research and experimental purposes, and the embryo is accorded symbolic legal recognition.⁷⁹ In practice, hESC research is significantly limited by this law.⁸⁰ However, the existence of a culturally-Catholic context does not always lead to a restrictive policy on assisted reproductive technologies as Spain and Belgium have both developed relative liberal legislation. In the case of Belgium this was achieved by compromise through ‘negotiating, and not by imposing the opinion of the majority’, to overcome opposition.⁸¹ In Spain a liberal framework for reproductive technologies was facilitated by a combination of a medical profession vocally in favour of regulation in the interests of scientific progress, a new Socialist government trying to throw off the conservatism of the (fascist) past and a weak opposition to the legislation by the Catholic Church.⁸²

Ireland is a country in flux at the moment. It has a history of traditional Catholic values and the traditional ethos still largely exists. It is often difficult to have a rational debate in Ireland in area of reproductive medicine; people, particularly politicians, are reluctant to be drawn into debates in this area.⁸³ Any attempt to develop policy in the area of hESC research in Ireland has been still-born. The Report of CAHR, 2005, proposed the introduction of a regulatory body which would be independent, and would have the function of advising the government on all matters relating to AHR and associated procedures including research. Seven years

⁷⁸ Fink, n above 75, at p 1645.

⁷⁹ Hanafin, n above 67, at pp 60-64.

⁸⁰ Prainsack, n above 40.

⁸¹ Schiffino, N and Varone, F (2004) Belgium: A Bioethical Paradise? In Bleiklie, I Goggin, M and Rothmayr, C (eds.) *Comparative Biomedical Policy: Governing Assisted Reproductive Technologies*. London: Routledge, p 21.

⁸² Hanafin, n above 67, at p 78.

⁸³ Healy, above n 45, at p 83; also see Yuko, n above 46.

after its publication this has not been implemented. Within the CAHR's report there was a provision for regular review within the legislation in order to accommodate medical, scientific and social development. An acknowledgement of the concept that a perfect ethical choice does not actually exist in this area and that ethical decisions cannot be made once and for all but should be continually reassessed and evaluated, was central to this report.

The second area of consensus identified in this study is the unwillingness of Irish politicians to 'engage in open deliberative consensus politics on issues of bioethical controversy'.⁸⁴ The approach that has been adopted to date in Ireland of not facing up to the need to legislate cannot be put on the 'backburner' for much longer. In 'Conceiving Life' Hanafin has stated in relation to AHR in Italy that 'the government views bioethical policy as the ultimate hot potato and has neither the courage nor the political will to act in a manner independent of the Church on these matters'.⁸⁵ This statement could just as easily be applied to successive Irish governments' attitudes to bioethical issues involving reproductive matters. This was the central area of consensus in this study.

Within a democracy law and policy should be a reflection of the society and the social context in which they arise. They are generally shaped by history and past policies. All participants in this study identified apparent political cowardice, an innate cultural aversion to legislation, and that there still very much exists an attitude of 'Don't know/Don't tell' prevailing in Ireland, as is demonstrated by the approach to issue of abortion.⁸⁶ Latham in his exploration of 'path dependency' in relation to hESC research suggests that Irish policy, or lack of one, in this area may be attributed to the long shadow cast by Article 40.3.3 and has not come about as:

'a result of any national interest calculation regarding the value of embryonic stem cell research, nor as a result of any clashes of interests in the Irish legislature, nor the result of any consultation with public values. It is entirely the creature of an institutional

⁸⁴ Hanafin, n above 67, at p 79.

⁸⁵ Ibid, at p 83.

⁸⁶ hESC research seems to have the potential to usurp the place of abortion as Ireland's most 'avoided' issue. Fox and Murphy could have been describing hESC research when, in 1992, they described political careers as 'lurching precariously' and that "'passing the buck' becomes the solution when the personal becomes political, especially if that issue is abortion". Fox, n above 12.

policy established decades before the first human stem cell was even identified.’⁸⁷

In effect, Latham is claiming that the current problem with hESC research in Ireland is a direct result of the confusion generated by an amendment which, in spite of the intentions of its proponents, has, in practical terms, done little to protect the unborn.⁸⁸

Despite the difficulties that will inevitably arise in attempting to institute regulation in this field, the Irish Government should be the body that facilitates dialogue, assists in resolving conflict and formulates a policy. Any policy initiative in this area should provide carefully reasoned and measured guidelines to fill the void left by years of the abdication of political responsibility.

The moral status of the embryo was a very definite area of dissensus in this study and it is unlikely that a consensus on the moral status of the *in vitro* embryo will be reached in the near future. The question becomes one of how a political compromise might be reached which would legally permit hESC research to take place in Ireland under certain well proscribed conditions.⁸⁹ As the law is ‘about what works, what seems appealing and appropriate in a given society’,⁹⁰ Ireland may have to introduce a framework while simply admitting that:

‘the law is not capable of divining any absolute truth about the moral status of the embryo, and the only certainty is probably the continued absence of any consensus’.⁹¹

Any new legislation, developed as in the Belgian example, through a deliberative, negotiated process, should adopted a moderate position, doing away with the current one which lies ‘between the polarities of permitting no research and providing no

⁸⁷ Latham, n above 41.

⁸⁸ Cox, N (2008) Foetal Personhood in Perspective. In Schweppe, J (ed.) *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, pp 89-112.

⁸⁹ Archard, D (1995) *Legal Theory in Ireland* Dublin, Oak Tree Press, pp 72-83. Also see Gough, F (2011) Human Embryonic Stem Cell Research in Ireland Ethical and Legal Issues. *Medical Law International* 11: 262-283.

⁹⁰ Whitman, JQ (2004) The Two Western Cultures of Privacy: Dignity vs. Liberty. *Yale Law Journal* 113: 151-1221, at p 1168.

⁹¹ Jackson, E (2001) *Regulating Reproduction*. Oxford: Hart Publishing, p 229.

protection’, but should not be based on ‘reasons whose force depends on the acceptance of a particular religious doctrine that many citizens reasonably reject’.⁹²

The economic impact of an absence of a legislative framework for stem cell research in Ireland did not produce a consensus opinion either. In order to recover from its current fiscal difficulties Ireland is attempting to drive its recovery through the fostering of a ‘knowledge economy’. Science Foundation Ireland (SFI), the State body charged with developing science in Ireland as a means to sustain long-term economic growth, proposed that by focusing on R&D and innovation Ireland should be able to attract potential investors to make use of its ‘human resource capital’.⁹³ However, as the ICB stated in its final report in 2010:

‘A smart economy cannot be achieved without a society built on strong ethics and values.’⁹⁴

It would seem unlikely that investors would want to invest in a country where biomedical science is largely unregulated, and where there is no legal certainty around some of the research they might undertake. In developing legislation Ireland needs to take into consideration not only the future development of scientific research within the State, the continuing difficulties for those dealing routinely with *in vitro* embryos but also how Ireland is viewed by other countries and potential investors. As the science in this area matures the pressure on Ireland to legislate in this area will most likely increase, as already there is a widespread demand for the kind of products that stem cells may eventually provide to treat degenerative diseases.⁹⁵ Even if the stakeholders of the kind that participated in this study do not push for changes in Ireland’s attitude to hESC research, when embryonic stem cell-derived therapies become available, there will inevitably be enormous pressure from patient groups to allow such therapies be administered in Ireland.⁹⁶

⁹² Fletcher, JC (1995). Ethics and Society: US Public Policy on Embryo Research: Two Steps Forward, One Large Step Back. *Human Reproduction* 10: 1875-1878.

⁹³ Science Foundation Ireland (2010) *Annual Report 2010*. Accessible at www.sfi.ie/news-events/publications/annual-reports.

⁹⁴ ICB, above n 70.

⁹⁵ Spar, n above 71.

⁹⁶ Robertson, JA (2004) Reproductive Technology in Germany and in the United States: An Essay in Comparative Law and Bioethics. *Columbian Journal of Translational Law*, p 225-6.

7.10 Conclusion

This study appears to have uncovered a broader consensus on several issues around human embryonic stem cell research in Ireland than had previously been appreciated. The implication for Irish policy makers in light of this growing consensus is that ‘something must be done’ to introduce legislation in this area, but it must be sufficiently flexible to allow both a continuing dialogue and the inclusion of much of the diverse views that are on display here as is practicable.⁹⁷ The now defunct Irish Council for Bioethics had strongly asserted that the:

‘continuing failure to provide a comprehensive regulatory system to govern stem cell research and its applications undermines the moral value of the human embryo’.⁹⁸

The situation which currently exists in Ireland, where effectively the embryo is legally protected once implanted in a uterus but is without safeguards if *ex utero*, surely cannot sit easily with the Irish legislature.

It is hoped that the empirical findings presented here may provide a greater understanding of the debate around hESC research in Ireland and of those issues peculiar to Ireland. Whether any Irish government will have the ability to seek out the required ‘consensus, compromise and hold the political convictions’ that will allow human embryonic stem cell research to develop in Ireland is a question unlikely to be resolved in the near future.

⁹⁷ Brock, DW (2006) Is Consensus Possible on Stem Cell Research? Moral and Political Obstacles *Journal of Medical Ethics* 32: 36-42.

⁹⁸ ICB Report, n above 15, at p 67.

CHAPTER 8

8. PAPER 3: DELIBERATING OR DITHERING? IRELAND AND HUMAN EMBRYONIC STEM CELL RESEARCH

8.1 ABSTRACT

Disagreement about matters of public policy concerned with moral issues is inevitable in pluralist democracies. One approach to the resolution of moral conflicts in society is the concept of deliberative democracy. In deliberative democracy there is an emphasis on the process or procedure which ultimately allows a political decision to be reached. The Republic of Ireland effectively has no legislative framework regulating human embryonic stem cell research (hESC research). This paper proposes that Irish policymakers establish a procedural framework, similar to that used in other European democracies to allow the development of appropriate regulations pertaining to hESC research in Ireland. In particular the paper will consider how a three-tier model of procedural regulation has been used to achieve certainty in the area of hESC research in the United Kingdom and Germany and how this model might be applied to Ireland.

8.2 Introduction

The question of the value attached by the law to pre-natal life and hence the level of protection afforded to it has often been the focus of extensive debate in Ireland,¹ where ‘...reproductive politics are at the heart of questions about citizenship, liberty, family and nation’.² Under Article 40.3.3 the Irish Constitution grants the implanted embryo full personhood status.³ It would, therefore, seem logical to assume that ‘from an Irish perspective ... unborn life is something which represents a most important social value.’⁴ Despite this there are no laws regulating human embryo and human embryonic stem cell research (hESC research) in Ireland, either permitting it or prohibiting it from taking place. The Irish Supreme Court ruling in *R v. R* (2009),

¹ *Attorney General v. X* [1992] IR 1, [1992] ILRM 401, [1992] CMLR 277; *R v. R* (2009) IESC 82.

² Haraway, D (1997) *Modest_Witness@Second_Millennium.FemaleMan_Meets_OncoMouse: Feminism and Technoscience*. New York: Routledge, p 189.

³ ‘The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and as far as is practicable, to vindicate that right’. *Bunreacht na hÉireann* 8th Amendment, 1983.

⁴ Cox, N (2008) Foetal Personhood in Comparative Perspective. In Schweppe, J (ed.) *The Unborn Child. Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, p 103.

a dispute over the future of frozen embryos from an IVF cycle, clarified that Article 40.3.3 does not in fact apply to embryos *in vitro*, and consequently these embryos are apparently not afforded any protection in Irish law.⁵

This paper will argue that at a time when ‘human embryos may be used for purposes other than human reproduction’,⁶ Ireland’s failure to be explicit in what *is* allowed, potentially allows everything because nothing is explicitly forbidden. Such abdication of regulatory responsibility may also ‘have highly corrosive consequences for the possibility of moral reason and responsibility as we know and value it’⁷ and leave Ireland, as Hardiman J in *Roche* warned, in danger of becoming ‘by default an unregulated environment for practices which may prove controversial’.⁸

Successive Irish governments have tended to avoid addressing issues of bioethical controversy, particularly where Catholic ethical values are at stake due to a fear of a conservative backlash and subsequent loss of political support.⁹ Ireland’s failure to define what is permissible and impermissible has also lead to problems with managing scientific research, particularly in the area of reproduction and has been detrimental to the development of research and biotechnology as an industrial force in Ireland.¹⁰ The question must therefore be asked as to how the impartial governance of such issues might be developed in a State that, despite much social transformation over the last twenty years, remains symbolically and culturally Catholic.¹¹

⁵ *R v. R* (2009) IESC 82, hereafter known as *Roche*.

⁶ Schiffino, N and Varone, F (2004) Belgium: A Bioethical Paradise? In Bleiklie, I Goggin, M and Rothmayr, C (eds.) *Comparative Biomedical Policy: Governing Assisted Reproductive Technologies*. London: Routledge, pp 21-41.

⁷ Brownsword, R (2004) Regulating Human Genetics: New Dilemmas for a New Millennium *Medical Law Review*, 12: 14-39.

⁸ Judgment of Hardiman J in *R v. R* (2009) IESC at 82.

⁹ Hanafin, P (2007) *Conceiving Life: Reproductive Politics and the Law in Contemporary Italy*. Aldershot: Ashgate, p 79.

¹⁰ The question of what a lack of legislation means for the future of hESC research in Ireland was answered recently when two of Ireland’s leading science funding agencies, the Health Research Board (HRB) and Science Foundation Ireland (SFI), stated that they will not fund research projects using hESCs in the absence of legislation that specifically provides for such research. See Gough, F (2011) Human Embryonic Stem Cell Research in Ireland: Ethical and Legal Issues. *Medical Law International* 11: 262-283.

¹¹ The percentage of the Irish population describing themselves as Catholic was 87.37 in the 2006 Census (www.cso.ie). Of those identifying themselves as Catholic, 51.6% claimed regular (weekly) attendance at Mass in 2009/10 (according to ESS data- From *Practice and Belief among Catholics in the Republic of Ireland – A summary of data from the European Social Survey Round 4 (2009/10) and the International Social Science Programme Religion III (2008/9)*). Accessed at www.irishcatholicbishops.ie/practice-and-Belief-among-Catholics). A more recent Irish Times/Ipsos

This paper proposes that Irish policymakers establish a procedural framework, similar to that used in other European democracies as an effective mechanism for the resolution of such conflict, to allow the development of appropriate regulations pertaining to hESC research in Ireland. In particular the paper will consider how a three-tier model of procedural regulation, as described by Capps, might be applied to Ireland.¹² This model has been used with varying degrees of effectiveness in other jurisdictions despite the existence of an inherent multiplicity of views on hESC research. How two of these countries, the United Kingdom and Germany, reached their own, different, resolutions to the hESC research issue will be discussed and some of the limitations to this procedural process identified.

8.3. hESC Research

Bioethical dilemmas pose challenges for democratic societies as they must arbitrate between incompatible views of fundamental beliefs.¹³ Those in favour of hESC research propound its potential to relieve suffering through the treatment of degenerative diseases such as diabetes mellitus and Parkinson's, and spinal injury,¹⁴ while opponents claim that research involving nascent human life affronts human dignity and commodifies the human body.¹⁵ hESC research has been described as a 'paradigmatic example of an issue of public policy that ought to be informed by serious ethical debate in a morally pluralistic society.'¹⁶ What has often been central to this debate is the status and kind of protection given to the embryo.¹⁷ Its moral value is often questioned, with Sarah Franklin describing the liminality of the embryo as being 'betwixt and between humanity and otherness, potentiality but not

MRBI poll found, however, the number claiming weekly Mass attendance has now dropped to 31%. From Sheridan, K (2012) Catholicism Now: Never Less Cause for Celebration with Just a Third of Catholics Attending Weekly Mass. *The Irish Times*, June 5th.

¹² Capps, B (2008) Authoritative Regulation and the Stem Cell Debate. *Bioethics* 22: 43-55; and Capps, B (2007) Bioethics, Procedural Ethics, and Misrepresentation in the Stem Cell Debate. In Gunning, J and Holm, S (eds.) *Ethics, Law and Society*. Aldershot: Ashgate, pp 25-38.

¹³ Parker, M (2009) Naked Regulators: Moral Pluralism, Deliberative Democracy and Authoritative Regulation of Human Embryonic Stem Cell (hESC) Research. *Journal of Law and Medicine* 16: 580-589.

¹⁴ Smith, K (2010) Treatment Frontiers. *Nature* 466: S15-S18; also see Strauss, S. (2010) Geron Trial Resumes But Standards for Stem Cells Remain Elusive. *Nature Biotechnology* 28: 989-990.

¹⁵ Keown, J (1993) The Polkinghorne Report of Fetal Research: Nice Recommendations, Shame about the Reasoning. *Journal of Medical Ethics* 19: 114-120.

¹⁶ Sulmasy, DP (2006) Deliberative Democracy and Stem Cell Research in New York State: The Good, the Bad and the Ugly. *Kennedy Institute of Ethics Journal* 19: 63-78, at p 76.

¹⁷ Richardt, N (2003) A Comparative Analysis of the Embryological Research Debate in Great Britain and Germany. *Social Politics* 10: 86-128, at p 88.

yet recognisably one of us'.¹⁸ It is this 'liminality' Franklin claims that 'makes of embryo research such a busy and impassioned field of contestation',¹⁹ with the dynamics structuring the ethical debate over hESC research traditionally made along the extremes of the deontological-utilitarian divide, and often reflect the particularities of national history and culture.²⁰

8.4. Role of Deliberative Democracy

Until the recent past there was little diversity in the approach to issues of ethical controversy in Ireland, with the Constitution generally reflecting the teaching of the Catholic Church, particularly in relation to issues pertaining to reproduction.²¹ However, as Irish society becomes more diverse and less compliant, the notion of 'Irishness' being strongly linked to Roman Catholicism is losing ground.²² If Ireland wants to be regarded on the world stage as a pluralist, liberal democracy,²³ there must be recognition of a *de facto* diversity of beliefs concerning activities such as hESC research, and allowances made by its institutions for religious and moral pluralism.²⁴ But how is any State 'confronted with competing claims of knowledge and faith', to refrain from 'prejudging political decisions in favour of one side or the other'?²⁵

¹⁸ Franklin, S (1995) Postmodern Procreation: A Cultural Account of Assisted Reproduction. In Ginsburg, FD and Rapp, R (eds.) *Conceiving the New World Order. The Global Politics of Reproduction*. Berkeley: University of California Press, pp 323-335.

¹⁹ Ibid.

²⁰ Halliday, S (2004) A Comparative Approach To The Regulation Of Human Embryonic Stem Cell Research In Europe *Medical Law Review* 12: 40-69; also see Harris, J, Bortolotti, L and Irving, L (2004) An Ethical Framework for Stem Cell Research in the European Union. *Health Care Analysis* 13: 157-162; also see Farrell, AM (2007) The Body Politic: Ethical Concerns, Regulatory Dilemmas and Human Embryonic Stem Cell Research in the European Union *German Journal of Law and Society* 28: 215-227, at p 221.

²¹ The last 20 years has seen the repeal of many of the early laws which had inserted Catholic social ideology into the Irish Constitution, such as those on contraception, homosexuality and divorce. These changes were brought about by both social movements prompting legal change and the introduction of social legislation promoting social change. See Hanafin, n above 9, at p 9.

²² The strong association of Irish-Catholicism with anti-abortion policies has been described as a 'post-colonial urge to mark Irishness distinctively by constructing it in 'pro-life' terms'. See Fletcher, R (2001) Post-colonial Fragments: Representations of Abortion in Irish Law and Politics. *Journal of Law and Society* 28: 568-589.

²³ For the purposes of this paper, this is assumed to be a state which would generally be considered desirable.

²⁴ Hannon, P (1992) *Church, State, Morality and Law*. Dublin: Gill and MacMillan, p 7.

²⁵ Habermas, J (2004) *The Future of Human Nature*. Cambridge: Polity, p 105.

One approach to the resolution of moral conflicts in society is the process of deliberative democracy.²⁶ Central to deliberative democracy is the 'idea that citizens and officials must justify any demands for collective actions by giving reasons that can be accepted by those who are bound by the action.'²⁷ Habermas suggests that 'when it comes to contentious political issues' in order to achieve social solidarity citizens are expected by liberal states to find 'rationally motivated agreement' and this is achieved by:

'First the equal participation of all citizens which guarantees that the addressees of the law can also understand themselves as the authors of these laws; - and second the epistemic dimensions of deliberation that ground the rationally acceptable outcomes.'²⁸

Habermas maintains that in order to be considered legitimate, the decisions of political law-makers are 'contingent on the outcome of an inclusive process of opinion-formation within the wide public sphere facilitated by media and within the discursively structured deliberations of democratically elected bodies.'²⁹

One of the important features of a deliberative democratic process is that it conceives 'communication about political issues as shaping and changing the interests and preferences of the actors taking part in the communication', while not claiming to have determined a solution to a particular policy issue for all time.³⁰ Those taking part in this process discuss, deliberate and learn about a particular topic with the intention of forming a policy recommendation. Its general aim is to provide 'the most justifiable conception for dealing with moral disagreements in politics', while attempting to promote 'mutually respectful processes of decision-making'.³¹ This connection of policy making to ethical considerations and deliberations aims to improve political decision making. This is achieved by optimising the deliberations

²⁶ See Chapter 3 for discussion on the theory of deliberative democracy and its role in helping to resolve areas of societal conflict.

²⁷ Gutmann, A and Thompson, D (1997) Deliberating about Bioethics. *Hastings Center Report* 27: 38-41.

²⁸ Habermas, J (2006) Religion in the Public Sphere *European Journal of Philosophy* 14(1), 1-25, at p 5.

²⁹ Habermas, J (2008) *Between Naturalism and Religion*. Cambridge: Polity Press, p 92.

³⁰ Moore, A (2010) Public Bioethics and Deliberative Democracy. *Political Studies* 58: 715-30, at p 717.

³¹ Gutmann, A and Thompson, D (2004) *Why Deliberative Democracy*. Princeton, New Jersey: Princeton University Press, pp 10-11.

between politicians and society members who discuss and analyse available relevant information and air their opinions. This allows the exploration of policy options. The Government is able to then make ‘an informed public declaration on a course of policy.’³² It is this ‘expansive definition’ of who is included in the deliberative process which makes deliberative democracy *democratic*.³³ As a result of the deliberative process being followed ‘morally complex decisions may enjoy public legitimacy’ if they are perceived as having come about through ‘such fair and public processes’.³⁴ Gutmann and Thompson describe such deliberative procedures as ‘helping those who do not get what they want or even what they need come to accept legitimacy of a collective decision’.³⁵

Whilst a moral consensus is not necessarily the end point of the deliberative process, the deliberation must end in a decision.³⁶ No single procedure, however, is specified by deliberative democracy for reaching the final position.³⁷ The principle of deliberative democracy, therefore, may be considered distinct in two ways being both morally and politically provisional - that is, the outcomes or decisions arrived at ‘may be subject to further moral argument’, and ‘may be subject to change through further political argument’.³⁸

However, deliberation alone cannot make incompatible views suddenly appear compatible, so inevitably some public deliberations must be demoted and others promoted if recommendations are to be made to policy-makers. For example, what some might regard as a potential harm from unregulated science is the commodification of the embryo,³⁹ while others see harm as the infringement of the human rights of those suffering from diseases that are potentially treatable through therapies derived from hESC research.⁴⁰ There can be anxiety and disagreement in a society when the various positions on an area of moral contention appear discordant,

³² Capps, n above 12, at p 29.

³³ Gutmann, n above 31, at p 9.

³⁴ Goold, SD, Damschroder, L and Baum, N (2008) Deliberative Procedures in Bioethics. In Jacoby, L and Siminoff, LA (eds.) *Empirical Methods for Bioethics: A Primer Advances in Bioethics*. Oxford: Elsevier, pp 183-201.

³⁵ Gutmann, n above 27, at pp 38-41.

³⁶ Moore, n above 30, at p 722.

³⁷ Gutmann n above 31, at p 18.

³⁸ Ibid.

³⁹ Doerflinger, RM (1999) The Ethics of Funding Stem Cell Research: A Catholic Viewpoint. *Kennedy Institute of Ethics Journal* 9: 137-150.

⁴⁰ Outka, GH (2002) The Ethics of Human Stem Cell Research. *Kennedy Institute of Ethics Journal* 12: 182-193.

and where this happens, ‘reliance on peaceful or orderly co-existence will not normally suffice.’⁴¹ Therefore, in addition to the democratic, public process of deliberation, there should be an implementation of rules which allows people to live together who fundamentally disagree on matters of ethical importance to reduce anxieties and uncertainties around the permissible and impermissible. The aim of this ‘authoritative regulation’ cannot be to eliminate harm on either side but to provide an acceptable minimal level - to limit controversial activities to those which are considered to be necessary and desirable.⁴² Optimum mechanisms of procedure must therefore be in place to minimise harm while allowing an individual the possibility of committing to such regulation through some degree of compromise.⁴³

Although such ‘rules’ may not always be compatible with what individual moral commitments ideally permit,⁴⁴ Capps has nonetheless asserted that this regulation of the activities of its members by liberal democracies is justified.⁴⁵ The establishment of procedural frameworks will allow the uncovering of ‘arguments that can justifiably determine public policy,’⁴⁶ hence binding individuals ‘to the larger political-legal regimes, often begrudgingly or against their better judgment’.⁴⁷ Although these procedural frameworks cannot promise each participant ‘an outcome he or she will consider valid, it can justify his or her presumption that the outcome will be acceptable at least on rational grounds.’⁴⁸ According to Black, however, such strategies or ‘proceduralization’ may actually only be concerned with ‘how to best design and implement policy rather than with normative concerns of what policy should be’.⁴⁹ Black proposes that those involved with the development of regulations should act primarily as facilitators, assisting the ‘wider negotiation of regulatory norms’,⁵⁰ and suggests that the process would be greatly assisted if the regulators were to re-translate the views of different groups and put ‘them in a language that the

⁴¹ Capps, n above 12.

⁴² Capps, B (2007) Bioethics, Procedural Ethics, and Misrepresentation in the Stem Cell Debate. In: Gunning, J and Holm, S (eds.) *Ethics, Law and Society*. Aldershot: Ashgate, pp 25-38.

⁴³ Capps, n above 12, at p 44.

⁴⁴ Ibid.

⁴⁵ Ibid, at p 43.

⁴⁶ Ibid, at p 52.

⁴⁷ Capps, n above 42, at p 28.

⁴⁸ Gregg, B (2002) Proceduralism Reconceived: Political Conflict Resolution Under Conditions of Moral Pluralism. *Theory and Society* 31: 741-776, at p 751.

⁴⁹ Black, J (2000) Proceduralizing Regulation: Part 1. *Oxford Journal of Legal Studies* 20: 597-614, at p 598.

⁵⁰ Black, J (1998) Regulation as Facilitation: Negotiating the Genetic Revolution. *Modern Law Review* 61: 621-660, at p 659.

others can understand'.⁵¹ Although Michelman has warned that proceduralism has its legitimating limits, ultimately it is through the establishment of procedural frameworks that disputes may be resolved.⁵² This is done by defining acceptable and unacceptable conduct, with agreement then found through 'overlapping consensus'. Gregg asserts that this process is effective in producing a consensus because for those 'open to rational argumentation, a political procedure that involves deliberation will elicit, better than any non-deliberative alternative, the willing compliance of all those whose compliance is sought and needed.'⁵³

Proceduralism, in part through its recognition of dissent, would seem to provide a mechanism by which those arguments that justifiably determine public policy may be uncovered, gives legitimacy to the effort to elucidate reasonable and practical solutions in contentious areas and contributes to the formation of frameworks for dispute resolution.⁵⁴

8.5 A Three-Tier Framework

Within the EU, no consensus was found by the European Commission in its report on hESC research as to what the limits and conditions for research should be, nor what protections are afforded to the human embryo. Procedural frameworks, however, have been used in several EU States to provide solutions to the issues around embryo-stem cell research. In general the establishment of a procedural framework or model requires that at least three interrelated levels are constructed.⁵⁵ According to Capps, the first level 'filters opinions and evidence to establish those arguments that are fit for policy consumption', while the second 'is responsible for the authorship of public policies' and facilitates critical debate and dissent.

A third and final level of adjudication is then applied to policies to incorporate appropriate mechanisms of review, amendment and oversight.⁵⁶ By consenting to such procedures, individuals are now in theory bound to support these

⁵¹ Ibid, at p 652.

⁵² Michelman, FI (2003) Constitutional Legitimation for Political Acts. *Modern Law Review* 66: 1-15.

⁵³ Black, n above 49.

⁵⁴ Capps, n above 12, at p 52.

⁵⁵ Capps, n above 42, at p 30.

⁵⁶ Ibid.

policies. The resultant policy should be coherent and not readily rejected due to the fact that in the course of its development there has been an acknowledgement of any reasonable disagreement on the matter, an incorporation of the important elements of any personal positions, and because this policy ‘respects as many different reasonable positions as any workable alternative.’⁵⁷ How such procedures were implemented to allow the development of policy in the area of hESC research in two jurisdictions with different cultural and historical backgrounds will now be examined.

8.6 Proceduralism in Practice

Since the birth in 1978 of the first baby from *in vitro* fertilisation there has been extensive public debate in most European countries as to how this new technology would be regulated. In the United Kingdom and Germany both governments ‘were certain that legislative provisions were necessary to set distinct limits and boundaries for embryological research and its application.’⁵⁸ Recommendations from committees of inquiry established by both governments in the early 1980’s in favour of embryological research, lead to the production of white papers based on the reports in 1986-87.⁵⁹ At this time the positions of the UK and Germany in relation to these recommendations were quite similar; the final policy positions, however, were very different.

The process leading to the development of the UK’s Human Fertilisation and Embryology Act (1990) is often cited as a model example of the successful deployment of proceduralism as the three levels central to an effective procedural framework,⁶⁰ as described by Capps, can readily be ascertained. A number of first level reports, such as the Warnock Report (1985), Donaldson Report (2000) and those from the Human Genetics Commission offered ‘scientific analysis,

⁵⁷ Ibid, p 31.

⁵⁸ Richardt, n above 17, at p 88.

⁵⁹ The Warnock Commission in the UK (1982) and the Benda Commission in Germany (1985).

⁶⁰ Harmon, SH (2008) Motivating Values and Regulatory Models for Emerging Technologies: Stem Cell Research Regulation in Argentina and the United Kingdom. In Freeman, M (ed.) *Law and Bioethics: Current Legal Issues*. Oxford: Oxford University Press, pp 147-176; and Richardt, n above 17.

philosophical appraisal and public consultation'.⁶¹ These were used to inform the second level policy makers in Parliament.⁶² Capps' third level is represented by the on-going monitoring of ethical and scientific developments provided by the statutory licensing body- the Human Fertilisation and Embryological Authority (HFEA) - created under the 1990 Act.⁶³ The HFEA is an independent authority with both a licensing and monitoring function, and is charged with advising the Government and the general public about advances in the science around assisted reproductive technologies (ART) and embryology.⁶⁴ Reform of the HFEA incorporated into the HFE Act 2008 has allowed it to be recognised as a regulator of both the ART providers and their services, and also as having responsibility for ethical evaluation and decision-making.⁶⁵

The effectiveness of the deliberative process in the UK which resulted in the creation of the HFEA has been tested by a number of challenges to the resultant policies through judicial review.⁶⁶ The outcome of this process is that in the UK hESC research is permitted on the grounds that it is 'necessary and desirable' for high-ranking goals,⁶⁷ and that the alternative ethical objections were not 'sufficiently compelling to outweigh the potential benefits'.⁶⁸ The HFEA effectively is 'mandated to licensed research on human embryos if, and only if, such research is judged to be necessary.'⁶⁹ Banchoff has stated that through the creation of a 'durable framework that allowed embryo research under certain conditions the HFE Act framed political responses to new technological developments.'⁷⁰ It is through its structures that the

⁶¹ Human Genetics Commission (2004) *Choosing the Future: Genetics and Reproductive Decision Making*, and Human Genetics Commission (2005) *Making Babies: Reproductive Decisions and Genetic Technologies*, Available from www.hgc.gov.uk.

⁶² Capps, n above 42, at p 31.

⁶³ HFE Act 1990, s 5.

⁶⁴ Callus, T (2011) Ensuring Operational Compliance and Ethical Responsibility in the Regulation of ART: The HFEA, Past, Present and Future. *Law, Innovation and Technology* 3: 85-111.

⁶⁵ HFEA (2009) *Code of Practice* (8th ed.). Enacted in October 2009, amended April states that the HFEA is: 'required to maintain a statement of the general principles which it considers should be followed in the carrying out of its functions.' [Its purpose is as] the 'UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. We set standards for, and issue, licences to centres. We provide authoritative information for the public, in particular for people seeking treatment, donor conceived people and donors. We determine the policy framework for fertility issues, which are sometimes ethically and clinically complex.'
Available from www.hfea.gov.uk.

⁶⁶ For example, in relation to the licensing cell nuclear transfer by the HFEA see *R (on the application of Quintavalle) v. Secretary of State for Health* [2003] UKHL 13.

⁶⁷ Schedule 2 (1)(3) of the HFE Act 1990.

⁶⁸ Capps, n above 42, at p 32.

⁶⁹ Brownsword, n above 7, at p 17.

⁷⁰ Banchoff, T (2003) *Embryo Politics: Ethics and Policy in Atlantic Democracies*. Ithaca, NY: Cornell University Press, p 193.

HFEA itself embodies Capps' first, second and third tier actions. Most importantly, in the context of comparison to the situation in Ireland, the HFEA through its remit provides 'a level of certainty to those who are regulated.'⁷¹ The procedural mechanisms used in the UK have, however, not been without criticism. It has been suggested that there was an intrinsic bias towards 'liberal policies and a permissive interpretation of the science' involved.⁷² This was felt to be achieved through a selective membership of the various advisory boards which contributed to the deliberative process, and effectively a 'stacking of committee membership' with those who implicitly accept the 'legitimacy of destroying embryos'.⁷³ In addition, with the HFEA now having both a policy-making and licensing role, concern has been expressed that the HFEA, in attempting to balance many interests within 'such a wide legislative framework', can prioritise one set of interests over another or act in a manner that is *ultra vires*.⁷⁴ The extension of the regulatory scope of the HFEA has at times required a purposive interpretation of the 1990 Act by the Courts.⁷⁵ However, ultimately in the UK hESC research policy was both scrutinised and justified on legal grounds.⁷⁶

What became apparent from the process undertaken in the UK to develop policy is that in order to be acceptable to the greatest number of participants, an 'emphasis should be placed on the use of wide and declared expertise' within the process, so that the analysis that led to the particular policy decisions is 'transparent, and supported by evidence that demonstrates the level of critical appraisal at that time and a willingness to utilise procedural mechanisms to review and amend policies in light of progress.'⁷⁷ The resultant regulatory framework may be considered as an example of 'responsive regulation' as it

⁷¹ Callus, n above 64, at p 90.

⁷² Capps, n above 42, at p 32.

⁷³ Ibid, at p 33.

⁷⁴ *R (Quintavalle) v. Secretary of State for Health* [2003] UKHL 13; *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Authority* [2003] 2 All ER 105; *Quintavalle (CORE) v. HFEA* [2005] UKHL 28.

⁷⁵ Hammond-Browning, N and Holm, S (2010) Hybrid Embryos - Ethics, Law and Rhetoric in the United Kingdom's Stem Cell Policy. In Capps, BJ and Campbell, AV (eds.) *Contested Cells: Global Perspectives on the Stem Cell Debate*. London: Imperial College Press, p 381.

⁷⁶ Callus, n above 64; e.g. *R (on the application of Quintavalle) v. HFEA* [2008] EWHC 3395 Admin.

⁷⁷ Capps, n above 42, at p 38.

‘knows its regulatees’, is ‘capable of deploying different and new regulatory logics coherently’ and ‘grasps what its shifting challenges are.’⁷⁸

Having considered the extensive procedural process undertaken in the UK in the development of its regulatory regime, a procedural approach which led to a very different regulatory regime will now be appraised. The approach taken by Germany in developing regulations in relation to stem cell research demonstrates a different but arguably no less successful application of the principles of deliberative democratic as described by Capps. The experiences of these countries support the argument that a deliberative democratic process could be utilised by Ireland to develop its own policies in this area.

8.7 The German Experience

It has been found that policies concerning life science often become enmeshed in ‘more or less self-conscious projects of nation building or, more accurately, projects of reimagining nationhood at a critical juncture in world history’.⁷⁹ In Ireland this has manifested itself as the construction of a ‘pro-life’ Irish culture in part as a response to the ‘pro-choice’ culture of the [British] coloniser.⁸⁰ In Germany deliberations on policies relating to hESC research have been ‘tied to two recurrent narratives of nationhood: the still unfinished project of reconstituting German identity after two world wars and the Holocaust, and more recent questions about how that identity should be articulated in the aftermath of reunification.’⁸¹

Habermas’ description of German nationalism as taking on ‘an excessive, social-darwinistic form’ and consequently as the ‘basis for a collective identity became drastically devalued’⁸² has meant that Germans have tried to re-establish their nationhood through an emphasis on the protection of human life and dignity.⁸³

⁷⁸ Baldwin R and Black, J (2008) Really Responsive Regulation. *Modern Law Review* 32: 59-94.

⁷⁹ Jasanoff, S (2005) *Designs on Nature: Science and Democracy in Europe and the United States*. Princeton: Princeton University Press, p 7.

⁸⁰ Fletcher, n above 22, at p 569.

⁸¹ Habermas has criticised German reunification as a ‘normative deficit’ as it did not involve democratic legitimisation along deliberative lines. See Habermas, J (1994) *The Past as Future* Cambridge: Polity Press.

⁸² Habermas, J (1992) The Limits of Neo-Historicism. In Dews, P (ed) *Autonomy and Solidarity: Interviews with Jurgen Habermas*. London: Verso, pp 237-243. See also Jasanoff, n above 79, at p 7.

⁸³ Ibid.

⁸³ Banchoff, n above 70, at p 105.

Despite initially similar approaches to the hESC research question through committees of inquiry and white papers, in contrast to the UK, German legislation on stem-cell research is comparatively restrictive. The production of hESC lines is currently illegal in Germany; the 1990 Embryo Protection Act (Embryonenschutzgesetz) prohibits any utilization of the embryo that does not serve its preservation.⁸⁴ However, although the act makes the use of human embryos for research purposes a punishable offence, it does not explicitly prohibit the import of hESCs. The German Parliament made use of this loophole to establish the 2002 Stem Cell Act, (Stammzellgesetz - StZG) which allows the import of hESCs for 'high priority' research objectives only and where there is no demonstrable alternative to the use of hESCs. These conditions, which must be evaluated by the Robert Koch Institute (RKI), a federal institute in Berlin, and its central ethics committee for stem-cell research (ZES),⁸⁵ result from 'balancing interests as is characteristic of deliberative democracies'.⁸⁶

Following the enactment of the Stem Cell Act, 2002, hESC lines produced from surplus embryos from *in vitro* fertilization (IVF) before 1 January 2002 could be legally imported into Germany. This key date was chosen to ensure that no hESC lines are directly produced for German research; as no human embryos are actually destroyed by German researchers, they can remain free of any 'guilt and responsibility'.⁸⁷ In effect, the purpose of the Stem Cell Act, as stated in section 1, StZG 2002, was 'to prevent demand in Germany from causing the derivation of embryonic stem cells or the production of embryos with the aim of deriving embryos'.⁸⁸ Thus according to the Stem Cell Act the utilisation of cells is not morally equivalent to the destruction required to acquire them.⁸⁹ The cut-off date of 1st January 2002 has since been revised to include cell lines produced before May

⁸⁴ Beckmann, JP (2004) On the German Debate on Human Embryonic Stem Cell Research. *Journal of Medicine and Philosophy* 29: 603-621.

⁸⁵ Oduncu, FS (2003) Stem cell research in Germany: Ethics of Healing v. Human Dignity. *Medicine, Health Care and Philosophy* 6: 5-16, p 10.

⁸⁶ Zenker, F (2010) Analysing social policy argumentation: A Case Study on the Opinion of the German National Ethics Council on an Amendment of the Stem Cell Law. *Informal Logic* 30: 62-69, at p 64.

⁸⁷ *Ibid*, at p 69.

⁸⁸ *Ibid*, at p 67.

⁸⁹ Heinemann, T and Honnefelder, L (2002) Principles of Ethical Decision Making Regarding Embryonic Stem Cell Research in Germany. *Bioethics* 16: 530-543.

2007.⁹⁰ This German approach to hESC research would on first glance appear to be somewhat morally inconsistent in that they have effectively banned ‘embryo research while promoting their ambitions for the import of embryonic cells from other jurisdictions.’⁹¹ How can hESC research be ‘legally permitted and ethically justified’ in Germany while any ‘manipulations of the human embryo which are detrimental to it remain legally forbidden and ethically unjustified?’⁹² Within this German approach to hESC research there are several issues that are potentially relevant to the Irish situation. The following questions are particularly pertinent:

- How did Germany develop its unusual position in relation to hESC research?
- What allowed Germany to navigate its way through what some called ‘the nation’s greatest moral dilemma of the post-war era’ and to reconcile the arguments into a policy approach which appears not to be provoking concerted opposition?⁹³
- Does Capps’ three-tier approach to a procedural process account for Germany’s apparent success in navigating this ‘moral dilemma’?
- What lessons can be drawn from the German experience that might be of use in another jurisdiction?

The following sections will attempt to answer these questions and highlight what Irish policy makers might learn from their German counterparts.

8.8 How Germany Developed its hESC Research Policy

Prior to 2002, a classical procedural approach was adopted in Germany to try to establish a coherent policy in this area. Firstly, the Benda Commission was established in 1984. This had a similar role to the Warnock Committee in the UK. The Commission weighed the ‘concerns about scientific freedom against the dangers of genetic engineering’⁹⁴ and recommended that research be allowed for ‘medical

⁹⁰ This time point was chosen as a way of increasing the supply of cell lines from abroad for German researchers given that both the number of cell lines and their quality (less viral contamination) had improved since 2002.

⁹¹ Capps, BJ and Campbell, AV (2010) *Contested Cells*. London: Imperial College Press, p 8.

⁹² Oduncu, n above 85.

⁹³ Sperling, S (2008) Converting Ethics into Reason: German Stem Cell Policy Between Science and the Law. *Science as Culture* 17: 363-375, at p 365.

⁹⁴ Banchoff, n above 70, at p 48.

findings of greater value'.⁹⁵ The embryo was described in the report as 'a human subject in its early form of development' that should be afforded legal protection and that it should not be 'made the object of arbitrary manipulation'.⁹⁶ The language used by the Commission was felt to be 'decidedly deontological' by some commentators in keeping its focus on the status of the embryo, but this moral status was not deemed absolute and could be weighed against research that could make 'a decisive contribution to the life of other human beings'.⁹⁷ The Commissions' findings were published in November 1985 and there followed both public and parliamentary debates.⁹⁸ Thus, in these early stages of policy development Germany fulfils the criteria for the first two of Capps' tiers in a procedural process through the sifting of opinions and instigation of arguments for policy consumption, and the subsequent facilitation of critical debate and dissent.

In general, attempts to reach a consensus with regard to an embryo's legal and ethical right to protection can be made difficult by opinions at a conscious or unconscious level being 'prejudiced by the desire to give researchers either more or less freedom of action, depending on one's point of view', as had been suggested in analysis of the procedural process in the UK.⁹⁹ There was no resultant consensus on the ethical and legal permissibility of hESC research in Germany even though the German Constitution in Article 5, paragraph 3, guarantees that research should be independent of political or social restriction.¹⁰⁰

In response to the horrors of the Nazi era the importance of human dignity is ardently expressed in the German Constitution (Grundgesetz).¹⁰¹ Article 1 of the 1949 Grundgesetz proclaiming that human dignity is inviolable, is in effect an endorsement of Kant's categorical imperative that no human being may ever be treated as a means alone, but also always as an end.¹⁰² According to Sperling this has

⁹⁵ Benda Commission (1985) *Working Group on In Vitro Fertilisation, Genom Analysis, and Gene Therapy Report*. Bonn: Federal Ministry for Research and Technology, pp 5-6.

⁹⁶ Ibid.

⁹⁷ Banchoff, n above 70, at p 48; see also Eser, A (1992) The Legal Status of the Embryo in Comparative Perspective. *International Journal of Medicine and Law* 11: 579-590.

⁹⁸ Benda Commission, n above 95.

⁹⁹ Eser, n above 97.

¹⁰⁰ Zenker, n above 86.

¹⁰¹ Article 1 [Human Dignity] of the German Basic Law states: "(1) Human dignity shall be inviolable ('unantastbar'). To respect and protect it shall be the duty of all state authority."

¹⁰² Dignity is also emphasised in the Preamble to the Irish Constitution which states: 'We, the people of Eire, Humbly acknowledging all our obligations to our Divine Lord, Jesus Christ, who sustained our fathers through centuries of trial, gratefully remembering their heroic and unremitting struggle to

become the ‘foundation of post-war Germany’s claim to moral legitimacy’¹⁰³ while the guiding principle of ‘absolute protection of human dignity has acquired an almost transcendent status in the German ethical and social imagination’.¹⁰⁴ This status attached to the notion of ‘dignity’ is somewhat similar to that ascribed to the ‘unborn’ in Ireland- something that is inviolable.¹⁰⁵

Following the Benda’s Commission’s report, it appeared that the protection of human dignity, as proclaimed by the first article of the Grundgesetz, was at variance with scientists’ freedom of inquiry, which was also protected by the Constitution. Commenting on this conflict, the influential philosopher Jurgen Habermas expressed his fear that research involving the ‘instrumentalization of pre-personal human life’ could lead down a ‘slippery slope’ toward experiments on more developed forms of human life.¹⁰⁶ It seemed that many Germans believed hESC research to be a threat ‘not merely to human embryos and, by extension, to society’s weakest, most defenceless members, but to humanity itself’, and in a country still severely affected by its role in the Holocaust, the idea that scientists might once again conduct experiments on ‘vulnerable’ entities was for many an unpalatable idea.¹⁰⁷ The scope of the protection afforded to these ‘vulnerable’ entities *in vivo* by Germany will now be examined as an example of how Germany has managed to navigate a path through a moral dilemma, in this case, that of abortion.

8.9 Protection of the Unborn in Germany

The social construction of the human embryo has been cited as being central to the framing of the debate on embryological research in Germany, where the fusion of legal and political styles of policy making has been apparent in the deliberative

regain the rightful independence of our Nation, and seeking to promote the common good, with due observance of Prudence, Justice and Charity, so that the *dignity* and freedom of the individual may be assured, true social order attained, the unity of our country restored, and concord established with other nations, Do hereby adopt, enact and give to ourselves this Constitution.’

¹⁰³ Sperling, n above 93, at p 364.

¹⁰⁴ Ibid.

¹⁰⁵ Binchy, W (2008) Respecting the Dignity and Equal Worth of Human Beings. In Schweppe, J (ed.) *The Unborn Child. Article 40.3.3 and Abortion in Ireland*. Dublin: Liffey Press, pp 189-212.

¹⁰⁶ Auf schiefer Ebene: Ein Gespräch mit Jurgen Habermas über Gefahren der Gentechnik und neue Menschenbilder’ *Die Zeit*, January 24th, 2002. Habermas also expressed his concerns that in developing a policy about stem cell research ‘the collective good of health and freedom of research’ did not take precedence over ‘the protection of the life of the embryo *in vitro*’. See n above 25. See also Banchoff, n above 70, at p 135.

¹⁰⁷ Sperling, n above 93.

process.¹⁰⁸ In German constitutional law strong protection of unborn life is equated with a level of discretion afforded to the legislature as to how best to protect this life. The question of the level of protection actually given to the embryo has been considered by the German Constitutional Court. The Court deems some degree of constitutional protection as covering all unborn life, as it is reluctant to devalue any category of human life or regard it as being outside the ambit of constitutional protection. It, however, adapts the fact of that protection to the particular entity in question.¹⁰⁹ This adaptation means that it does not afford absolute protection to the developing foetus, whose nascent moral status is uncertain at various points in the pregnancy, and which is not demonstrably capable of enjoying or exercising rights.¹¹⁰ It is the non-absolute nature of the protection offered to the embryo by the German Constitution which allows abortions to take place in Germany. A pregnancy may be legally terminated in Germany since 1975.¹¹¹ The current law is based on a 1993 Constitutional Court judgment, the key features of which are the acknowledgement that:

- (i) there can be no legal justification of abortion
- (ii) an abortion can be carried out under certain circumstances and
- (iii) women seeking abortion must attend counselling.¹¹²

In effect the Court concluded that in order to protect the right to life of the embryo the state must criminalise abortion but it then distinguishes between the illegality and the criminality of the abortion act. This means that a woman may have an abortion as long as she attends the mandatory counselling.¹¹³ In this model it is acknowledged that the unborn has full human dignity and an inviolable right to life that is not conditional on the mother accepting it but the mother cannot be forced to continue with a pregnancy against her wishes.¹¹⁴ The Constitutional Court says that this approach does not infringe on the German Constitutional protection of ‘unborn’ life because the unique nature of unborn life means that it need not and should not be

¹⁰⁸ Harmon, n above 6, at p 108.

¹⁰⁹ Cox, n above 4, at p 104.

¹¹⁰ Ibid, at pp 104-5.

¹¹¹ BVerfGE 39, 1 [FRG] decision of February 25 1975.

¹¹² BVerfGE 88, 203 decision of May 28 1993; See Heinemann, n above 89, at p 540.

¹¹³ Robertson, J (2004) Reproductive Technology in Germany and the United States: An Essay in Comparative Law and Bioethics. *Columbia Journal of Transnational Law* 43: 189-227.

¹¹⁴ Heinemann, n above 89, at p 540.

protected in the same way as the law which protects ‘born’ life. The Court does not suggest that the protection it affords is inferior to ‘that which would have arisen if individual rights were recognised.’¹¹⁵ This ruling, applied to embryos *in vivo*, means women could still gain access to abortion services.¹¹⁶

Usually the level of esteem afforded to a living entity, such as an embryo, by a legal system is what ultimately determines the protection it is given.¹¹⁷ For example, in the UK the Warnock Report proposed that ‘respect’ be afforded to the embryo. As a consequence of this, research is permitted in the UK on the *in vitro* embryo until day 14 post fertilisation when the primitive streak emerges.¹¹⁸ If the German Constitutional Court had undertaken to decide the difficult question of when life begins, it would have had to determine when legal protection of the embryo begins, and the embryo would have to be treated as a citizen. This problem has also been faced by the Irish Courts in a number of cases with the Court in Ireland deciding to interpret Article 40.3.3 of the Irish Constitution as protecting an individual foetus as a rights bearer.¹¹⁹ However, in the German context Richardt has asserted that the question of when life begins [to matter] should not be determined by the Constitutional Court because this is a moral question and the Court would have overstepped its competence by basing its decision on a moral judgment.¹²⁰ The Constitutional Court could, however, determine when Constitutional protection begins. This same issue was faced by the Irish Supreme Court in *Roche* but unlike its German counterpart, the judgment of the Irish Supreme Court was not followed by a legislative initiative. Once the German Constitution Court had determined when constitutional protection begins, the legislature, the Bundestag, could make the seminal decision as to what such protection would mean in the context of an embryo *in vitro*. The court considered two natural boundaries in making its decision:

¹¹⁵ Cox, n above 4, at p 105.

¹¹⁶ Richardt, n above 17, at p 109.

¹¹⁷ Eser, n above 97, at p 584; Richardt, n above 17, at pp 108-109.

In *Roche* Murray CJ also identified this problem “The moral status of the embryo and the respect or protection which society may feel are owed is a different issue to the question posed, as to when life begins, and I do not propose to comment on it further for the purposes of the judgment”.

¹¹⁸ HFE Act 1990 section 13:(3) A licence cannot authorise (a) keeping or using an embryo after the appearance of the primitive streak; (4) for the purposes of subsection (3) (a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of fourteen days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored.

¹¹⁹ *Attorney General (SPUC) v. Open Door Counselling* [1988] IR 593; *SPUC v. Grogan* [1989] IR 753; See Cox, n above 4, at p 105.

¹²⁰ Richardt, n above 17, at pp 108-109.

protection could begin 14 days after fertilisation when the primitive streak has just developed as this is considered to determine the individuality of life, or it could consider the moment before the fusion of the sperm and the egg is completed.¹²¹ The different time scale between these arguments, both founded on biologically determinable facts, serves to accentuate the difficulty with legal reasoning in this situation. Thus the value of proceduralism in determining reasonable and practicable policy solutions for the resolution of such contentious issues may come to be appreciated.

With advances in hESC research in the late 1990s the issue of whether such research should be permitted and if so in what circumstances, assumed a prominent place on the national political agenda in Germany. The political debate on the construction of the human embryo in relation to hESC research tried to concentrate on how much protection the embryo *in vitro* rather than *in vivo* requires as the possibility of an embryo being misused is higher *in vitro* than *in utero*, in order to distinguish hESC research from the abortion debate.¹²² The Embryo Protection Law of 1990 had allowed embryos legal protection based on their potential to develop into human beings. This approach to protection of unborn life is regarded by some commentators as being ‘innovative and issue-specific’.¹²³ In order to resolve the conflicting constitutional and moral positions it became apparent that a legislative initiative was required. Another Commission of Enquiry on Law and Ethics in Modern Medicine was established by the Bundestag to evaluate the ethics of stem cell research in 2001.¹²⁴ When it became apparent that this body would most likely come out against stem cell research, Chancellor Gerhard Schröder, who was strongly in favour of hESC research, appointed his own National Ethics Council, which he hoped would ‘provide a more positive assessment’.¹²⁵ The National Ethics Council delivered a report in late 2001 that was in favour of allowing the strictly controlled import of stem cell lines,¹²⁶ while the Enquiry Commission’s report was against allowing the

¹²¹ Ibid, at p 109.

¹²² Callus, n above 64, at p 616.

¹²³ Cox, n above 4, at p 108.

¹²⁴ Sperling, at n above 93, at p 366.

¹²⁵ Ibid, p 366. Such political interference with national bioethics committees is not uncommon- President Bush in the US removed two members of his own President’s Council on Bioethics after they publically criticised the administration’s stance on stem cell research. See Check, E (2004) Bush Sacks Outspoken Biologist from Ethics Council. *Nature* 428 (6978): 4.

¹²⁶ Nationaler Ethikrat (2001) *German National Ethics Council Opinion on the Import of Human Embryonic Stem Cells*. Berlin: German National Ethics Council.

import of stem cells.¹²⁷ These reports, as examples of first level opinion filtering and evidence gathering procedures, may also be deemed as meeting Capps' first criteria for a procedural process.

Shortly after the two ethics commissions delivered their reports, the Bundestag debated the regulation of stem cell research. The facilitation by the Bundestag of critical deliberation on this issue fulfils Capps' second criteria for a procedural process.

A compromise bill, the Stammzellgesetz or Stem Cell Act 2002, was eventually adopted. This bill attempted to include the concept that 'no embryo should die for German research',¹²⁸ by allowing the import of cell lines generated outside Germany; this would in turn permit scientists to continue doing their work in accordance with their constitutionally guaranteed right to free inquiry.¹²⁹ The Act stipulates that each application to import stem cells must be evaluated by two agencies, the Robert Koch Institute, (RKI) and the Central Ethics Commission for Stem Cell Research (ZES).¹³⁰ As in the UK in regard to the HFEA, there has been criticism of the composition of these bodies, with some critics objecting that the majority of trained natural scientists on the commission would naturally 'predispose the commission to being permissive, while proponents countered that those who have expertise in the field should decide matters of scientific research.'¹³¹

Through these bodies the German State, as protector of human life and human dignity, in effect controls the motivations and practices of scientists. The RKI and the ZES have become the public custodian of the conscience of the scientific community of stem cell scientists, ensuring that German research proceeds in an ethical and transparent manner.¹³² Thus, Capps' third and final level of adjudication needed to complete a procedural process is thereby achieved by incorporating appropriate mechanisms of review and on-going monitoring of ethical and scientific developments by these statutory bodies. It would appear that Germany has

¹²⁷ *Zweiter Zwischenbericht der Enquete-Kommission. Recht und Ethik der Modrnen Medizin, TeilberichtStammzellforschung* (2001). Berlin: Deutscher Bundestag.

¹²⁸ Sperling, n above 93, at p 373.

¹²⁹ Ibid, at p 367.

¹³⁰ Ibid, at p 368.

¹³¹ Ibid.

¹³² Ibid.

successfully utilised a procedural process to reconcile the arguments in this area into a policy approach.

Takala and Häyry, however, have questioned how the German legislative body can choose to overlook activities in other countries that it does not allow in Germany? They ask ‘Is this a case of hypocrisy, or is there a rational justification for the distinction’?¹³³ This is a reasonable question to ask as, on the one hand the German Constitutional Court says unborn life is constitutionally protected, while The Stem Cell Act endorses a situation where the destruction of unborn life is acceptable as long as it does not actually take place in Germany.¹³⁴ The law prohibits the importation of cell lines in principle, while defining several strictly circumscribed conditions under which existing stem cell lines may be imported for research. Concerns regarding the promotion of destruction of human embryos abroad by importing ESCs into Germany are assuaged by setting a date in the future after which newly generated cell lines cannot be imported – that is, from the date of the enactment of the law. This is rationalized by saying that such cell lines were neither initiated nor supported directly or indirectly by German scientists. In other words, the utilisation of cells is not morally equivalent to the destruction required to acquire them. There is disagreement among German ethicists as to whether this is or is not a normatively tenable position to adopt.

According to Oduncu, in so doing Germany is behaving with moral inconsistency and has given up a long tradition of upholding the value of human dignity,¹³⁵ and it might appear from the Stem Cell Act that in Germany it is considered that ‘human dignity will be protected only by preventing Germans from freely importing, much less using, human embryonic stem cells’. Sperling states that this Act was actually ‘an awkward compromise, but the plenary debate and the resulting Stem Cell Law were nevertheless celebrated as triumphs,’ and lauded as a demonstration of Germany’s commitment to responsible science and democratic decision-making.¹³⁶ Heinmann and Honnerfeld, however, claim that the German stance is not hypocritical as the moral principles which underpin the German Stem Cell Act are derived from those underlying the 1990 Embryo Protection Act, in that this Act considered the

¹³³ Takala, T and Häyry, M (2007) Benefitting From Past Wrongdoing: Human Embryonic Stem cells, and the Fragility of the German legal Position. *Bioethics* 21: 150-159.

¹³⁴ Cox, n above 4, at p 108.

¹³⁵ Heinemann, n above 89.

¹³⁶ Sperling, n above 93, at p 368.

destruction of early human life not to be in line with ‘the protection of human dignity guaranteed within the German Constitution’.¹³⁷

In fulfilling the criteria for Capps’ three-tiered process for a procedural framework through the establishment of commissions of inquiry and ethics commissions which developed arguments for policy consumption, the facilitation of critical debate and dissent, and the creation of appropriate mechanisms of review, amendment and oversight, Germany, through a culturally specific form of deliberation, appears to have arrived at a decision that can be supported in a deliberative democratic context. What this process has ultimately facilitated is the resolution of the dilemma that existed in Germany between a duty to protect human dignity, as espoused by the Constitution, and the need to provide its scientists with both the certainty and constitutional freedom they need to do research.¹³⁸

Whether or not this is coherent ethically or represents a robust substantive moral position does not have a bearing on the legitimacy of the deliberative democratic or procedural process which may be considered ethically justifiable due to the justifiable procedure undertaken in coming to this position. In addition, as an example of Germany’s commitment to responsible science and democratic decision-making, this process should be commended.

8.10 Irish Dithering

The question of whether anything might be learned from the German approach that could be applied to the current Irish situation of a legal and policy vacuum in relation to hESC research was asked earlier in this paper. There are a number of reasons for considering the example of the German approach to the development of policy in the area of stem cell research:

1. Both Germany and Ireland have Constitutional texts that were written in the 20th Century; in writing a constitution the authors were attempting to found a nation anew.¹³⁹

¹³⁷ Heinemann, n above 89, at p 541.

¹³⁸ Sperling, n above 93, at p 372.

¹³⁹ Hanafin, n above 21, at p 3.

2. Both Constitutions were framed in such a way as to be a positive expression of the aspirations of the emerging nation - Germany's attempted to put its past behind it in the post-war period, while Ireland's attempted to establish it as an independent nation with its own clear identity in the post-colonial period.

As discussed earlier, within its constitution Germany upholds the importance of human dignity. Article 1 of the 1949 Basic Law proclaims that human dignity is inviolable, and it is regarded as Germany's 'claim to moral legitimacy' and to be its guiding principle.¹⁴⁰ The legal and philosophical basis of the Irish Constitution was the natural law theory of Thomas Aquinas, and at the time of its authorship it reflected many of the teaching of the Catholic Church. The Preamble to the Irish Constitution proclaims that it is 'seeking to promote the common good'..... so that 'the *dignity* and freedom of the individual may be assured, true social order attained, the unity of our country restored, and concord established with other nations.' Within its Constitution Ireland, like Germany, offers protection to the unborn through the Eighth Amendment to the Constitution, Article 40.3.3.¹⁴¹ In Ireland this means that there is no provision for abortion services. In contrast to Germany where the Constitutional protection of the unborn is acknowledged as being somewhat conditional, the Constitutional protection offered by Article 40.3.3 was assumed to be absolute at all stages of pre-natal development until the Supreme Court's judgment in *Roche* determined that this protection did not apply to embryos *in vitro*.¹⁴²

One difference of note is that Ireland, unlike Germany, has 'no express protection for freedom of research or enquiry or for academic freedom in the Constitution of Ireland.'¹⁴³ Neither is such a right guaranteed by the European Convention on Human Rights. There is not the problem in Ireland, therefore, of two constitutionally protected rights being in conflict as had been the case in Germany prior to the resolution of this dilemma by Stem Cell Act. The freedom to carry out research, however, does come under the Charter of Fundamental Rights of the European Union

¹⁴⁰ Sperling, n above 93, at p 364.

¹⁴¹ Article 40.3.3 "The State acknowledges the right to life of the unborn and, with due regard to the equal 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."

¹⁴² Binchy, n above 105, at p 201.

¹⁴³ Hamilton, J (2009) *The Mackey Lecture: Freedom of Expression and Enquiry*. Available at www.tcd.ie/longroomhub/assets.

to which Ireland subscribes.¹⁴⁴ Where Ireland and Germany most obviously differ is in the commitment to concluding a process once begun - Ireland dithers where Germany acts.

It would appear that through the translation of moral questions into formal administrative questions the procedural framework that Germany followed played a significant role in the conclusion of the debate around hESC research to the satisfaction of the majority in Germany, and has allowed such research to be carried out 'ethically'.¹⁴⁵ Ireland has attempted to address the issue of embryo and embryonic stem cell research in a quasi-procedural manner. The establishment of the Commission on Assisted Human Reproduction (CAHR) in 2000 might be regarded as fulfilling Capps' first criteria for a procedural framework.¹⁴⁶ The Commission, consisting of scientists, clinicians, members of the legal profession and lay members, was asked to 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'.¹⁴⁷ As described earlier Capps considers that the first level 'filters opinions and evidence to establish those arguments that are fit for policy consumption'. The CAHR, acknowledging that for the first time society had to face the question whether 'human embryos may be used for purposes other than human reproduction', undertook an extensive consultative process and delivered a comprehensive report in 2005 which made a number of significant recommendations which, if they had been enacted, would have made a major contribution to the development of policy in the areas of assisted reproduction and embryo research in Ireland.¹⁴⁸

The Commission's main recommendations addressed regulatory issues. The first of these proposed that 'a regulatory body should be established by an Act of the Oireachtas to regulate AHR services in Ireland', which would follow international best practice by monitoring both ethical and scientific developments.¹⁴⁹ Ideally, the

¹⁴⁴ An interesting question in relation to freedoms available under this Charter relates to the right or lack of it, that Irish patients would have to access any therapeutic advances that might accrue from human embryonic stem cell research. See Article 13, www.europarl.europa.eu/charter/convent49-en.htm.

¹⁴⁵ Sperling, above n 93, at p 373.

¹⁴⁶ Capps, n above 42, at p 30.

¹⁴⁷ CAHR (2005) *Current and Future Developments in Assisted Human Reproduction*. Dublin: Government Publications Office, p v.

¹⁴⁸ Ibid, at pp v and xv-xvii.

¹⁴⁹ Ibid, at p 8.

regulatory body, though independent would advise the government on all matters pertaining to AHR and hESC research. This authority could be charged with clarifying the ambiguity in the meaning of the term ‘unborn’, and legislating for the registration, licensing and inspection of persons and premises working with human embryos.¹⁵⁰ This statutory licensing body would adequately fulfil Capps’ third and final criteria for a procedural process in that it would provide an appropriate mechanism of review, amendment and oversight to the developing policies.

Within the proposed legislation a provision would be made for regular review to accommodate any scientific or medical advances, and cognisance would be taken of social changes.¹⁵¹ The Commission recommended that research should be permitted on donated surplus embryos. This would only be allowed up to 14 days post-fertilisation under stringently controlled conditions and for specific purposes only, as specified by the new regulatory body. Probably the most important recommendation of a majority of the Commission was that the embryo formed by IVF should not come under the remit of Article 40.3.3 of the Irish Constitution and therefore should not attract legal protection until placed in the human body, at which stage it should enjoy the same level of protection as the embryo formed *in vivo*.¹⁵²

However, the failure of the legislature and executive to construct Capps’ second level, which ideally should be ‘responsible for the authorship of public policies’ and facilitate critical debate and dissent, has meant that the argument in Ireland has not progressed. Notwithstanding the fact that the recommendations within the report of the CAHR were ignored, a second report was commissioned specifically on the ‘Ethical, Scientific and Legal issues in Stem Cell Research’ from the Irish Council for Bioethics (ICB). This body delivered its report in 2008. In it the ICB presented a thorough summary of the current scientific and legislative issues around the generation and use of embryos and stem cells in research, and of the ethical issues central to the debates. The ICB identified a growing consensus among stem cell researchers that, as it is currently very difficult to predict which kind of stem cell ultimately will be of most value scientifically and for treating disease, it would be

¹⁵⁰ Ibid.

¹⁵¹ Ibid.

¹⁵² Ibid, at p *xvi*, Recommendation 16.

most prudent that research using all types of stem cells, adult, foetal, umbilical and embryonic, be allowed.¹⁵³

The ICB has called for an end to the ‘legal vacuum’ that currently exists in this area in Ireland because ‘the failure to provide a comprehensive and cohesive regulatory system to govern stem cell research and its applications undermines the moral value of the human embryo. It may also hinder developments in this field of research in Ireland’.¹⁵⁴ The Chair of the ICB has claimed that the failure to regulate also ‘undermines people working in the field of infertility treatment, and the thousands of couples availing of IVF’.¹⁵⁵

The reports of both the CAHR and the ICB, despite being comprehensive and clear in their recommendations, have languished on the shelves of the Department of Health for some time now. No member of the executive or legislature seems willing to advance them to the stage of serious, considered debate in the Oireachtas.

It may fall to the European Institutions or bodies, which have instigated much of the significant social change and advancement in Ireland over the last thirty years, to force Ireland to deliberate on these issues despite its reluctance to do so.¹⁵⁶ The European Group on Ethics in Science and New Technologies (EGE) published an opinion on the ‘Ethical Aspects of Research involving the use of Human Embryos’ in 1998. The EGE stated that the human embryo deserved legal protection and that such protection fell under the remit of national legislation. It recognised, however, that it would be inappropriate for the EU to impose one overall moral code on all the States in the EU. Under the EU Framework Programme [FP7 (2007-2013)] all research activities must respect fundamental human rights and it was not possible under FPs to fund research in a member State that was prohibited in that State.¹⁵⁷ In Ireland, due to the current uncertainty around the legal status of embryonic stem cell research, there is no public funding available to those doing hESC research. Although the Irish

¹⁵³ Irish Council for Bioethics (ICB) (2008) *Ethical, Scientific and Legal Issues Concerning Stem Cell Research*. Dublin: ICB, p 15.

¹⁵⁴ Ibid, at p 67.

¹⁵⁵ Dooley, D (2008) Head to Head: Should the State legislate for embryonic stem cell research? *The Irish Times*, May 12th.

¹⁵⁶ For example, it was a European court that forced Ireland to legalise homosexuality, *Norris v. Ireland* (1991) 13 EHRR 186; and recently Ireland has been censured for failing to provide abortion service in cases where a mother’s life is in danger, as this breaches Article 8 rights: *A, B and C v. Ireland* 25579/05 [2010] ECHR 2032.

¹⁵⁷ See www.fp7ireland.com and cordis.europa.eu/pub/fp7/doc/ethics-for-researchers/pdf; see also CAHR, n above 147, at p 66.

Government does not permit the funding of hESC research here it does not oppose its funding using EU money in other member states. It is somewhat inconsistent with Ireland's position on the 'unborn' that Irish taxpayers fund research in other countries that is not permitted in Ireland. In a similar manner through the EU Germany funds research it does not permit within its borders. This may be considered to be an example of the less laudable similarities between Ireland and Germany, in that when Germany allows the import of stem cell lines but not their production in Germany,¹⁵⁸ they appear to behaving in a manner similar to the Irish in their approach to the issue of abortion- 'it's acceptable as long as it doesn't happen on our territory'.

8.11 Conclusion

The failure to address the controversy around hESC research in Ireland highlights the 'difficulty in finding agreement when fundamentally opposing moral positions exist', and has lead to an uncertainty as to what is allowed and what is not. Manin has asserted that 'what is evident, simple and luminous does not need to be deliberated on in the strongest sense of that term. Deliberation is necessary for what is uncertain, when there may be reasons to decide one way but also reasons to decide another way.'¹⁵⁹ In order to translate 'democratically legitimate and justified decisions into policy, citizens must first engage in deliberation' to reach an agreement, as in pluralistic communities the resolution of conflict require rules of conduct to exist.¹⁶⁰

In this paper proceduralism has been proposed as an effective mechanism of resolution of such conflict available to policymakers as it 'conveys the range of opinions within a community, and is able to filter justifiable arguments' and even those who disagree with the outcome of the process should 'ideally be able to recognize as legitimate the methods by which their preferences and opinions were overruled by others'.¹⁶¹ There should, therefore, be an attempt in Ireland to construct Capps' procedural framework, a process tentatively begun but not appropriately concluded, so that the issue of a lack of social consensus regarding the potential

¹⁵⁸ Ibid, at p 67.

¹⁵⁹ Manin, B (1987) On Legitimacy and Deliberation. *Political Theory* 15: 338-368.

¹⁶⁰ Master Z and Crozier, GKD (2010) The Ethics of Moral Compromise for Stem Cell Research Policy. *Health Care Analysis*, 20: 50-65, at p 62.

¹⁶¹ Nagel, T (1995) Moral Epistemology. In Bulger, RE, Bobby, EM and Fineberg, HV (eds.) *Society's Choices: Social and Ethical Decision Making in Biomedicine*. Washington: IOM, pp 201-214.

‘harms’ and potential therapeutic ‘benefits’ for many AHR procedures and hESC research be appropriately addressed, and ultimately a suitable regulatory scheme adopted. As Sandel says ‘rather than ban ESCR and research cloning we should allow them to proceed subject to regulations that embody the moral restraint appropriate to the mystery of the first string of human life’.¹⁶²

It should be acknowledged, however, that in developing an appropriate policy, serious moral debate must be undertaken in Ireland and there must be a willingness to be open to compromise in reaching policy solutions- something that Ireland’s politicians have been decidedly unwilling to contemplate to date. There must also be an admission that, despite the constitutional protection given to the unborn, there has been a profound failure in Ireland to ‘give it effect or define its scope’.¹⁶³ Cox has asserted that far from providing effective protection of the embryo, Article 40.3.3 actually offers a reduced protection, and the form which it takes is defined much less clearly than that afforded to embryos in Germany.¹⁶⁴ This reduced protection was made apparent by the decision of the Supreme Court in *Roche* to exclude embryos *in vitro* from the protection of the unborn specified by Article 40.3.3. Ireland must confront this difficult challenge of defining at which point this constitutional safeguard actually begins, and acknowledge that ‘perfect’ ethical decisions cannot be made once and for all but must be continually reassessed. This idea was central to the development of ‘The Stem Cell Act’ in Germany. Cognisance was also taken of German sensibilities and history. This approach could be adopted by those seeking to progress the debate over hESC research in Ireland, acknowledging the particular nuances of the debate in Ireland and looking for a solution somewhat different to that adopted by other European countries as ‘ethical arguments cannot simply be transplanted to a different cultural situation and history,’¹⁶⁵ and if the law is a reflection of the social context in which it arises and of ‘the values which its

¹⁶² Sandel, MJ (2007) *The Case against Perfection: Ethics in the Age of Genetic Engineering*. Cambridge, MA: Harvard University Press, p 127.

¹⁶³ Cox, n above 4.

¹⁶⁴ Ibid, at p108.

¹⁶⁵ Borry, P, Schotsmans, NS and Dierickx, K (2004) What is the Role of Empirical Research in Bioethical Reflections and Decision-making? An Ethical Analysis. *Medicine, Health Care and Philosophy* 7: 41-53.

members profess to hold',¹⁶⁶ Irish patients, scientists and embryos deserve to know what value Irish society really attaches to pre-natal life.

¹⁶⁶ Hannon, P (2004) Law and Morality. In Murphy, T (ed.) *Western Jurisprudence*. Dublin: Round Hall, pp 269-290, at p 290.

CHAPTER 9

9. CONCLUSIONS

9.1 Stem Cells, Religion and Politics

This final chapter reviews the arguments developed in this thesis for allowing stem cell research in Ireland within well-defined parameters, such as the parameters proposed by the Irish Council for Bioethics.¹

This thesis initially identified a number of research questions pertinent to an exploration of the Irish legal lacuna in relation to hESC research. The contribution of ethical, legal and social factors to the extant position in Ireland regarding the permissibility of embryonic stem cell research was examined in the first part of this thesis and in Paper 1.

Paper 1 primarily addressed the first two research questions, an evaluation of ‘unborn’ life in Ireland and the background to some of the specific problems and legal difficulties encountered in attempting to advance hESC research in Ireland. Many of these difficulties are associated with Ireland’s traditional identity as a Catholic country. Its Constitution has in the past strongly reflected the ideology of the Catholic Church, particularly on reproductive matters. The contemporary values and norms of a society have often been shown to reflect the religious legacies of the past, with strong Christian democracies being associated with restrictive regulations on embryo research.²

Unlike Italy, another culturally-Catholic country, Ireland has no regulations which address hESC research. It could be considered that the absence of restrictive legislation in Ireland might have evolved out of a situation similar to that in Italy prior to the introduction of its very restrictive law in 2004.³ Here, the Catholic Church, afraid that any law the political system in Italy might produce would not be strict enough to meet its doctrines, blocked the introduction of comprehensive

¹ As discussed in Chapter 4. Irish Council for Bioethics (ICB) (2008) *Ethical, Scientific and Legal Issues Concerning Stem Cell Research*. Dublin: ICB.

² Fink, S (2008) Politics as Usual or Bring Religion Back in? The Influence of Parties, Institutions, Economic Interests and Religion on Embryo Research Laws. *Comparative Political Studies* 41: 1631-1656.

³ Ramjoué, C and Klöti, U (2004) ART Policy in Italy: Explaining the Lack of Comprehensive Regulation. In Bleiklie, I, Goggins, M and Rothmayr, C (eds.) *Comparative Biomedical Policy: Governing Assisted Reproductive Technologies*. London: Routledge, p 54.

legislation altogether.⁴ There is, however, no evidence of such active campaigning by the Catholic Church in this regard in Ireland today but according to Hanafin the ‘commonality between the two states is the persistence of a strain of conservative Roman Catholic opinion that values the sanctity of unborn life over reproductive freedom.’⁵

What is actually evident in Ireland is a great reluctance on the part of the political system to address this issue. The political system in any country should be able to devise collectively binding decisions about which kind of research shall be allowed within its jurisdiction and which shall be banned. Ireland has a lot of experience with attempting to address socially divisive ethical issues in the last thirty years, often to the satisfaction of no one in Irish society.⁶ Embryo research and its regulation is yet another ‘policy field where the fact that politics is a matter of conflicting interests and values becomes most obvious’.⁷

There is a risk that important political factors, such as the need to provide regulatory certainty to allow industry to develop, could be allowed to fade into the background,⁸ as the highly ethical nature of the particular problem of hESC research may mean that the decision to permit it or not may be influenced in Ireland by more basic cultural and societal forces. While Sommerville suggests that politicians should not be expected to condone what they believe is wrong or unethical, they should fulfil the requirement that they ‘act morally and ethically as politicians.’⁹ As it may be considered that ‘politics is in the first instance about action’¹⁰ Irish politicians are failing by avoiding addressing the issue of hESC research in any effective way.

The perspectives opened up by hESC research require a ‘profound debate’ to take place in Irish society. This thesis does not propose that a utilitarian conception of the human being as a means to an end should be allowed to prevail, but neither should

⁴ It further interfered with the Italian political system by encouraging a general abstentionist approach to a referendum on the issue of the repeal of the 2004 law proposed by the Radical Party so that the necessary quorum of 50% plus 1 voters would not be achieved, thereby undermining the deliberative democratic process in Italy. See Hanafin, P (2007) *Conceiving Life: Reproductive Politics and the Law in Contemporary Italy*. Aldershot: Ashgate Publishing Ltd., p 65.

⁵ Ibid, at p 80.

⁶ As per discussion in thesis in relation to abortion. See Chapter 4.

⁷ Fink, n above 2, at p 3.

⁸ Ibid.

⁹ Sommerville, M (2004) Commentary: Social Issues and Ethical Values in the Political Public Square: Principle vs. Packages International and Comparative Health Law and Ethics: A 25-year Retrospective. *Journal of Law, Medicine and Ethics* 32: 731-740, at p 735.

¹⁰ Geuss, R (2008) *Philosophy and Real Politics*. Princeton: Princeton University Press, p 11.

‘humanity be deprived of the possibility of further alleviating its suffering’ over time.¹¹ Banchoff holds that politicians should take decisions in this area and that wherever they ‘come down on the moral status of the embryo or the importance of research, citizens and leaders should ask big questions and assume responsibility for their stances.’¹² As the French President Jacques Chirac asserted, while addressing the World Life Science Forum, these questions are ‘a matter of political responsibility.’¹³

The embracing of political responsibilities in this area has not, however, occurred in Ireland; politicians seem unwilling or unable to make a decision in relation to legislating in the whole area of ART and hESC research despite entreaties from, amongst others, the Irish Supreme Court,¹⁴ medical fertility specialists, and patient advocate groups. This latter group will be particularly interested if hESC research derived therapies become available but there has still been no progress in relation to legislation in Ireland. While Quigley has argued that the ‘morally conscientious and consistent State would not import hESC-derived therapies for use within its borders where that State persists in maintaining that embryo destruction is morally impermissible,’ if a viable hESC research derived therapy became available to treat for example, Parkinson’s disease, the Irish Medicines Board has stated that there is no law that would prevent it becoming available on a named-patient basis in Ireland.¹⁵ This line of argument would suggest that by not having any legislation that Ireland is not a ‘morally conscientious and consistent State’ and is ‘morally free-riding’ on the research efforts of other countries. It also means that Irish citizens could, by availing of such therapies, be regarded as being indirectly complicit in what is deemed, by some, to be the immoral act of hESC research. Alternatively, it could be argued that to deny Irish patients access to treatment derived from stem cell

¹¹ Chirac, J (2001) *Opening Speech to Biovision World Life Sciences Forum*. Lyon, France, February 8th. Available at <http://www.ambafrance-uk.org/Biovision-World-Sciences-Forum>.

¹² Banchoff, T (2011) *Embryo Politics, Ethics and Policy in Atlantic Democracies*. New York: Cornell University Press, p 234.

¹³ Chirac, n above 11.

¹⁴ See *Roche v. Roche* [2009] IESC 82 for criticism of legislature’s failure to act, notably judgments of Hardiman, J: ‘*There has been a marked reluctance on the part of the legislature actually to legislate on these issues*’, and Geoghegan, J: ‘*Since most of these problems are of an ultra-modern nature, I rather doubt that there is a constitutional solution to them, but that does not mean that there cannot and indeed should not be regulation by the Oireachtas.*’

¹⁵ Personal communication with Blood and Tissues Manager of the Irish Medicines Board (<http://www.imb.ie>). See Paper 1: Gough, F (2011) Human Embryonic Stem Cell Research in Ireland: Ethical and Legal Issues. *Medical Law International* 11: 262-283.

research would be to ‘punish’ people who may well be strongly in favour of SC-derived treatments.

This thesis has argued that although hESC research presents a difficult public policy and regulatory challenge, the potential of stem cell-derived therapies to bring immense benefit to a great number of people through the treatment of chronic debilitating conditions is one of the fundamental reasons for allowing hESC research. Another is the increased understanding of cell biology, and hence the optimisation of the *in vitro* culture conditions to maximise the regenerative potential of stem cells. It is only through continued studies of embryonic, IPS and adult stem cells that this improved understanding will be achieved, and lead to the stage where actual therapeutic and industrial applications are realised. It will be important therefore that the design of the governance system is flexible enough that it can respond to changes in knowledge and information pertaining to the benefits and risks associated with hESC research as these emerge.¹⁶

Paper 1 ultimately concluded that, despite the policy and regulatory challenges it poses, hESC research should be permitted in Ireland. It argued that any regulatory framework adopted to bring certainty to this field, for scientists, industry and for patients in Ireland, should encompass the recommendations of both the CAHR and the ICB, which, in stating that pre-implantation embryos should not attract the constitutional protection of Article 40.3.3, hence allowing hESC research on donated supernumerary embryos up to day-14 post fertilisation, have offered an apposite solution to the current legal vacuum.

9.2 Stem Cells and Stakeholders

Chapter 7 of this thesis, (paper 2), looked at the views of stakeholders on Ireland’s existing position in relation to hESC research, as the current lack of regulation has impacted in a practical sense on some of those involved in stem cell research in Ireland. The spectrum of stakeholders interviewed for this paper offers some insight into the key contributors to the hESC research debate in Ireland. In addition these particular stakeholders have the potential to influence the future direction of this debate due to their roles as politicians, researchers and ethicists.

¹⁶ Mandel, GN (2009) Regulating Emerging Technologies. *Law, Innovation and Technology* 1: 75-92, at p78.

The most significant finding from this study was the call by all the stakeholders for a clear legal definition of an embryo, and for all clinical research involving human-derived material to take place within an appropriate ethical and legal framework. The importance of a legal standards for hESC research can be measured by the fact that it has been shown that scientists consider these standards when ‘making personal and professional choices about what kind of research to pursue and where to do it, just as private and public funding organisations consider these standards when making decisions about where to invest their research dollars.’¹⁷ It is noteworthy that one of the contributors to the empirical study left Ireland shortly after being interviewed. This was not by choice; they had attempted for more than two years to attract funding for their research, having made the decision to return to Ireland after several years training in this area at a number of international centres of excellence for stem cell research. They were unsuccessful in attracting funding, however, as the main science-funding agencies in Ireland, the Health Research Board (HRB) and Science Foundation Ireland (SFI), have stated that they will not fund research involving human embryonic stem cells as long as the uncertainty persist about the legality of this research.¹⁸

As was demonstrated from the response of the participants to the empirical research study, mutual concerns about uncertainty can provide normally opposed stakeholders an incentive to work together and could be exploited to produce agreement on a particular governance system.¹⁹ Scientific and regulatory uncertainty has been found to create ‘fear and concern among members of the public and public interest groups, regulatory challenges for and criticism of regulatory agencies and produces a problematic environment for industry plans for investment and development’.²⁰ It is critical, however, that the public should not lose faith in a technology or its risk-governance system at early stages of technological development.²¹ The development, therefore, of a protective and well-defined governance structure,²² providing assurance to the public and stability for industry, should be incentivised.²³ As it has been shown that the involvement of a wide and diverse stakeholder group is critical

¹⁷ Baylis, F and Krahn, T (2009) The Trouble with Embryos. *Science Studies* 22: 31-54, at p 31.

¹⁸ Burke-Kennedy, E (2010) Funding Ban on Research Using Human Stem Cells. *The Irish Times Health Supplement* October 12th, p 2.

¹⁹ Mandel, n above 16, at p 81.

²⁰ Ibid, at p 80.

²¹ Ibid, at p 81.

²² Ibid, at p 82.

²³ Ibid, at p 81.

to proposals for emerging technology governance,²⁴ stakeholders such as those who participated in this empirical study should be persuaded to work together on a new governance system.

As states compete for advantages both in terms of the funding they commit to stem cell research and the moral values and regulatory framework they consider should guide its development, synergies are being constructed between scientific governance and society.²⁵ A cohesive policy should be developed in Ireland to regulate hESC research, not only regulating this science in terms of risk and safety, but also taking cognisance of the sensibilities of Irish cultural values. There was, however, an acknowledgement by the all the stakeholders of the inevitable difficulties that will arise in attempting to institute regulation in this field in Ireland.

Within this paper it is argued that in light of the opportunities and challenges offered by stem cell research, the continuation of the legal lacuna in this area undermines the perception of Ireland, not only as a country where unborn life is valued, but also as one open to investment, since the lack of certainty around what is permitted and what is not, deters potential international investment in Irish biotechnology. However, the closure of this regulatory gap expeditiously would provide certainty for industry and comfort for the public.²⁶

This paper offers, through a rare qualitative study, a valuable insight into the current state of the debate in Ireland on hESC research. It concluded that, while taking cognisance of the sensibilities of Irish cultural values, the Irish Government should be the body making the policy choices, designing the laws and creating the institutions to allow stem cell research to flourish.²⁷

9.3 Biotechnology and Deliberative Democracy

The last research question addressed in this thesis was how a regulatory framework for hESC research might be introduced in Ireland. The latter part of Chapter 3 looked

²⁴ Ibid, at p 90.

²⁵ Salter, B and Salter, C (2010) Governing Innovation in the Biomedicine Knowledge Economy: Stem Cell Science in the USA. *Science and Public Policy* 37: 87-100, at p 94.

²⁶ Mandel, n above 16, at p 85.

²⁷ On its own website *Regulating Better* the Department of the Taoiseach states that:

‘Consistency in the regulatory process is important as it gives a degree of predictability and legal certainty to individuals and groups within society, and the economy.’

Available at www.betterregulation.ie/upload/Regulating_Better_html/consistency.html.

at the role of deliberative democratic theories in helping to resolve morally challenging bioethical issues. The practical application of such theories was examined in some detail in Paper 3. As democratic engagement with biotechnology has been ‘shaped and constrained by national approaches to representation, participation and deliberation,’²⁸ a comparison was made between the approaches adopted in resolving the issue of hESC research in the UK and Germany. These countries have used deliberative processes to facilitate the development of different but culturally tolerated hESC research policies. The question was asked as to what Ireland could learn from their experiences. It became apparent on examination of these different approaches that widely different policy responses to the same scientific and technological breakthroughs are possible, and that serious ethical reflection and contestation informed those responses.²⁹

An awareness of the choices made in other national contexts may help to enrich the policy debate in another country by suggesting a wider range of alternatives.³⁰ Jasanoff states that the aim of such comparisons is to ‘reveal, with critical detachment but epistemic charity, what gives significance to another culture’s distinctions and differences, not forgetting in the process to reflect on the commitments encoded in one’s own.’³¹ This suggests that Ireland’s politicians should not ‘simply look abroad for policy models’.³² They may learn from other countries experiences but the options at their disposal will be constrained by ‘their own national historical legacies, institutions, and electoral and interest group politics’. This concept is strongly reflected in the findings from the empirical study discussed earlier in Paper 2. The participants in this study were not prepared to simply adopt policies developed in other countries; they were looking for an Irish-nuanced approach to policy development in the field of hESC research, stating that it would be a poor reflection on Irish society if it cannot come up with regulations of its own.³³

There is generally a ‘dearth of meaningful debate on the metaphysical aspects of biotechnology: that is debate about the kinds of entities, and associated forms of life,

²⁸ Jasanoff, S (2005) *Designs on Nature: Science and Democracy in Europe and in the United States*. Princeton: Princeton University Press, p 287.

²⁹ Banchoff, n above 12, at p 257.

³⁰ Ibid.

³¹ Jasanoff, n above 28, at p 291.

³² Banchoff, n above 12, at p 257.

³³ See Paper 2 ‘Something Must be Done’, E4 speech.

that technology has sought to, or should seek to, create.’³⁴ Ireland, Germany and the UK all aspire to be deliberative democracies. The legitimacy of political action in all three countries depends not only on the amount of democratic participation but also on its quality. Mere voting, ‘empty of deliberative content, is regarded as insufficient for democratic governance.’³⁵

If there is any possibility of Irish society eventually reaching an accord on hESC research, a significant improvement in the Irish public’s understanding of this area is needed.³⁶ This could be achieved through a deliberative process of the kind undertaken in Germany and the UK. However, as ‘deliberative democracy’ has become a popular ‘sound bite’ the effectiveness of such undertakings in Ireland has been questioned. The recently announced constitutional convention could provide the opportunity Ireland needs to enhance the ‘nature and form of political participation as opposed to just increasing it.’³⁷ But will it be ‘a genuine attempt at deliberative democracy or a quasi-therapeutic encounter between a selection of politicians and a glorified focus group of citizens?’³⁸

In establishing the constitutional convention the government appears to be sincere in ‘seeking a discursive space in which reform of the 1937 constitution can be advanced.’³⁹ However, many commentators have accused politicians of not being willing to ‘take tough decisions and prefer to follow the path of least resistance’.⁴⁰ Often, when Irish politicians are in doubt or do not want to make a decision, they set up a committee or commission. Michael Clifford, a political journalist, scrutinises the most recent proposal for a ‘Constitutional Convention’ thus:

‘Down through the decades, it has been the great instrument of diversion for Irish governments. Whenever

³⁴ Jasanoff, n above 28, at p 85.

³⁵ Ibid, p 285.

³⁶ Kennedy, D (2006) Foreword. In Scott, CT *Stem Cell Now: From the Experiment that Shook the World to the New Politics of Life*. St Paul: Pi Press.

³⁷ The proposals for a constitutional convention in Ireland are discussed in Paper 3: ‘Deliberating or Dithering’. Also see Carney, G and Harris C (2011) *Deliberative Democracy and Political Reform: A forum for Discussion of Politics, Policy and Political Reform*. Available at <http://politicalreform.ie/2011/03/30/deliberative-democracy-and-political-reform/>.

³⁸ O’Connell, D (2012) *Constitution Could Benefit from Radical Reappraisal*. Available at www.irishtimes.com/newspaper/opinion/2012/0510/1224315844103_pf.html

³⁹ Ibid.

⁴⁰ Daly, P (2012) *Shadow Constitutional Convention: Referendumitis*. Available at Human Rights in Ireland Blog at <http://www.humanrights.ie/index.php/2012/07/18/shadow-constitutional-convention-9-paul-daly-on-referendumitis/>.

an unpalatable issue is raised, refer it to a committee to expand and expound, pushing the unpalatable onto the long finger, whereon it shall remain until the next election is done and dusted.

Now this government is gifting us with one of the all-time great committees, a super-duper talking shop so big it could scarcely be accommodated in any middling-sized committee room. The establishment of a constitutional convention was approved by cabinet last Tuesday. The convention is a committee with bells and whistles on.'.....

The constitutional convention is just the latest manifestation of their cynical attitude to governance; it would be laughable if it weren't so serious.'⁴¹

In order that it might succeed as a deliberative process there must be 'some clarity and consensus about what is expected of the convention without predetermining its deliberations.' Without this it will not achieve its laudable aims and may only add 'to the sense of futility and hopelessness felt by those who are open to the possibilities of political renewal by way of constitutional reform.'⁴² As the 'not-yet born intermittently press their demands with an unmistakable but invisible power, a power that exceeds our conventional formulations of agency,'⁴³ two questions remain unanswered by the Irish legislature: When does human life deserve protection? And can embryos be destroyed to advance biomedical knowledge that might alleviate human suffering?

How Ireland will manage to combine respect for the embryo and solidarity with the sick remains a 'moral quandary even if increasingly obscured by polemics and polarised policy debates.'⁴⁴ King has stated that it is not necessary or feasible to have a complete moral consensus on when life or personhood begins in order to formulate an ethically acceptable public policy for human embryo research.⁴⁵ Jurisdictions

⁴¹ Clifford, M (2012) Constitutional Talk Shop Proves State is in No Tearing Hurry to Create Reform. *Comment: The Sunday Times*, June 10th, p 16.

⁴² O'Connell, n above 38.

⁴³ Brown, W (2001) *Politics Out of History*. Princeton: Princeton University Press, p 149.

⁴⁴ Banchoff, n above 12, at pp 254-255.

⁴⁵ King, PA (1997) Embryo Research: The Challenge for Public Policy. *Journal of Medicine and Philosophy* 22: 441-455, at p 441.

which permit hESC research stipulate clear limits on the nature, scope and duration of legally permissible embryo research.⁴⁶ Paper 3 concluded that using deliberative processes it should be possible to develop an Irish-nuanced hESC research policy which encompasses a clear legal definition of the embryo and the protection offered to it by Irish law. This should be devised and implemented without delay to provide much needed certainty to those who are hindered in their work by the current legal lacuna, such as the stakeholders who contributed to Paper 2. The dilemma surrounding the moral status of the embryo will always exist but so also will ‘the imperative to alleviate suffering and promote human flourishing.’⁴⁷

9.4 Concluding Remarks

There is an unarguable imperative on the Irish Government to clarify its legal position in relation to matters of ethical controversy, such as abortion, ART and stem cell research and to define the protection offered by the Constitution to the ‘unborn’. The inability of Ireland’s legislature to act in an appropriate and timely manner on matters of ethical controversy was highlighted recently in the case of a maternal death in an Irish hospital due, apparently, to the uncertainty over the legal position in relation to the rights of the mother versus the rights of the foetus to life.⁴⁸ It has been suggested that the medical practitioners involved in the care of a woman, who was 17 weeks pregnant, were slow to act to terminate her inevitable miscarriage due to their uncertainty as to whose right to life was paramount in the Constitution – that of the ‘unborn’ or that of its mother. In response to this tragedy doctors organisations have yet again called for legislative clarity and for politicians to have the ‘courage of their convictions, and that Ireland needs to act like an adult state on this issue.’⁴⁹ As with other issues of ethical controversy Ireland’s claim to be considered a democratic,

⁴⁶ Baylis, n above 17, at p 33.

⁴⁷ Banchoff, n above 12 at p 258.

⁴⁸ Savita Halappanavar, 31, died following the miscarriage of her 17-week pregnancy in an Irish Hospital. See Cullen, P (2012) Tragic Case Demonstrates Moral Minefield Faced by Doctors. *The Irish Times* November 15th; McInerney, S and O’Brien, S (2012) Still the Burning Issue. *The Sunday Times* November 18th; Kay, JF (2012) Time for an Abortion Law to Stop Irish Women Suffering. *The Irish Times* November 22nd; Gantly, D (2012) Tragedy Highlights ‘Grey Area’ in Legislation. *Irish Medical Times* November 23rd.

⁴⁹ Gantly, n above 48.

pluralist society has been called into question.⁵⁰ It is essential that legal clarity is provided forthwith to ensure that this tragedy is not repeated.

Appropriate options exist for the Government in the form of the recently published recommendations of the expert group on abortion.⁵¹ However, Irish politicians have ignored similarly apposite reports and recommendations in the areas of ART and stem cell research. The importance of these issues is such that they can be ignored no longer, as they have the potential to both save lives and enhance its quality. Decisions must be made in the near future as to how best to allow the potential of stem cell research to flourish in Ireland.

The response of Irish society to stem cell science will ultimately necessitate difficult choices being made about how that response is negotiated both domestically and internationally. Ultimately ‘we may not make the right decisions. But we should make them our own’.⁵² It is only then that the Irish public may develop a sense of trust in the field and in those who undertake it.⁵³ It is hoped that this thesis provides an informed contribution to the discussion around human embryonic stem cell research in Ireland and that ultimately it has propounded a convincing argument for allowing human embryonic stem cell research to take place in Ireland.⁵⁴

⁵⁰ Cochrane, D (2012) Story of Galway Death Spreads Around the World. *The Irish Times* November 15th, Knight, I (2012) Death to Shame Even the Pope. *The Sunday Times* November 18th. Knight describes Ireland as a ‘rascist, sadistic society’.

⁵¹ *Report of the Expert Group on Judgment in A, B and C v. Ireland* (2012). Available at [www.dohc.ie/publications/Judgment ABC.html](http://www.dohc.ie/publications/Judgment%20ABC.html).

⁵² Banchoff, n above 12, at p 258.

⁵³ Salter, n above 25, at pp 87-100.

⁵⁴ The scope of this thesis is restricted in that it does not consider the ethical and legal issues around the donors who are the source of the ova used to produce hESCs or problems associated with stem cell tourism.

BIBLIOGRAPHY

- Abbott, A (2011) Irish Election raises question for stem cell research
28 February *The Great Beyond* Available at:
<http://www.go.nature.com/ftx2hu>. Accessed 18/4/12
- An Bille um Thaighde Gaschille (Suthanna Daonna a Chosaint) 2008 Stem-Cell Research (Protection of Human Embryos) Bill 2008. [No. 60 of 2008] The Stationary Office, Government Publications Sale Office, Molesworth Street, Dublin 2.
- Aquinas, T *Summa Theologiae* Volumes 23 and 28 Translated by Gilby, T (1966) Cambridge, Cambridge University Press
- Archard, D (1995) Law and Moral Disagreement: The Case of Abortion *Legal Theory in Ireland*. Dublin: Oak Tree Press. pp.72–83.
- Aristotle, *Complete Works* (1984) Volume II Barnes, J (ed.) Princeton: Princeton University Press
- Aristotle, *The Nicomachean Ethics* (1953) Translated by Thomson, JAK London Penguin Classics Penguin Books
- Askoy, S (2005) Making Regulations and Drawing up Legislation in Islamic Countries under Conditions of Uncertainty, with Special Reference to Embryonic Cell Research *Journal of Medical Ethics* 31(7) pp.399-403.
- Bachtiger, A, Steenbergen, MR and Tschentscher, A (2010) A Developing Deliberative Democracy: A Research Paper and a Research Agenda BIDS, University of Bern. Available from www.bids.unibe.ch/.../Bachtiger:Steenbergen:Tschentscher.pdf
- Baldwin, R and Black, J (2008) Really Responsive Regulation *Modern Law Review* 32(2)pp. 59-94.
- Banchoff, T (2011) *Embryo Politics: Ethics and Policy in Atlantic Democracies* Ithaca and London, Cornell University Press
- Banks, M (2008) Modern Ireland: Multinationals and Multiculturalism. *Information, Society and Justice* 2(1) December pp 63-93
- Barde, Y (2009) Caution urged in Trial of Stem Cells to treat Spinal Cord Injury *Nature*, Vol. 458, p.29
- Barden, G (1995) Two Versions of Natural Justice *Justice and Legal Theory in Ireland* Quinn, G and Ingram, A (eds.) Dublin, Oak Tree Press
- Barron, D (2011) Staff from ICB Seconded to Dept. of Health *Irish Medical News* 2 February [Online] Available at: <http://www.imn.com>

- Barry, F (2008) *The Irish Times* 28 October
- Battles, J (2009).Going it Alone: Is IVF in Safe Hands? *The Sunday Times (Irish Edition)* 27 September.
- Baylis, F and Krahn, T (2009) The Trouble with Embryos *Science Studies* 22 (2), pp 31-54
- Beckmann, JP (2004) On the German Debate on Human Embryonic Stem Cell Research *Journal of Medicine and Philosophy* 29(5) pp 603-621.
- Benda Commission (1985) *Working Group on In Vitro Fertilisation, Genom Analysis, and Gene Therapy Report*. Bonn: Federal Ministry for Research and Technology pp 5-6.
- Beqqali, A et al (2006) Genome-Wide Transcriptional Profiling of Human Embryonic Stem Cells Differentiating to Cardiomyocytes *Stem Cells* 24 pp 1956-1967.
- Bernard, HR (2000) *Social Research Methods: Qualitative and Quantitative Approaches* Sage Publications Ltd p444.
- Binchy, W (2008) Article 40.3.3 of the Constitution: Respecting the Dignity and Equal Worth of Human Beings *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Schweppe, J (ed.) Dublin: The Liffey Press. pp 89-212
- Black, J (2000) Proceduralizing Regulation: Part 1 *Oxford Journal of Legal Studies* 20(4) pp.597-614
- Black, J (1998) Regulation as Facilitation: Negotiating the Genetic Revolution *Modern Law Review* 61(5) pp.621-660
- Borry, P Schotsmans, NS and Dierickx, K (2004) What is the Role of Empirical Research in Bioethical Reflections and Decision-Making? An Ethical Analysis *Medicine, Health Care and Philosophy* 7 pp.41-53
- Boyle, J (1991) The Roman Catholic Tradition and Bioethics *Bioethics Year Book Theological Developments in Bioethics 1988-1990* Brody, B. A. (ed.) Dordrecht: Kluwer Academic Publishers pp 5-21.
- Brazier, M and Cave, E (2007) *Medicine, Patients and the Law* (4th Edition) London Penguin Books
- Brock, DW (2006) Is Consensus possible on Stem Cell research? Moral and Political Obstacles *J. Med Ethics* 32:pp.36-42
- Brown, W (2001) *Politics Out of History* Princeton: Princeton University Press

- Browne, V (1995) Will the Country be Run under Natural Law? *The Irish Times* 26 April
- Brownsword, R (2004) Regulating Human Genetics: New Dilemmas for a New Millennium *Medical Law Review* 12:pp.14-39
- Broxmeyer, H et al (1989) Human umbilical cord blood as a potential source of transplantable hematopoietic stem/progenitor cells *Proc. Natl. Acad. Sci.USA* Vol. 86, pp.3828-3832.
- Bunreacht na hÉireann* Constitution of Ireland Dublin Government Publications Office
- Burke-Kennedy, E (2010) Funding Ban on Research Using Human Stem Cells *The Irish Times Health Supplement*. 12 October
- Byrne, E (2010) Let the People Have Their Say on Type of Country They Want . Political Blog. Available at www.elaine.ie/2010/02/02/let-people-have-their-say-on-type-of-country-they-want/
- Byrne, R and McCutcheon, J (2001) *The Irish Legal System* (4th edition) Dublin: Tottel Publishing Ltd.
- Callus, T (2011) Ensuring Operational Compliance and Ethical Responsibility in the Regulation of ART: The HFEA, Past, Present and Future *Law, Innovation and Technology* 3(1) pp.85-111.
- Capps, B (2007) Bioethics, Procedural Ethics and Misrepresentation in the Stem Cell Debate *Ethics, Law and Society* Gunning, J and Holm, S (eds.) *Ethics, Law and Society* Chapter 3, Volume III Aldershot: Ashgate Publishing Ltd pp.25-38
- Capps, B (2008) Authoritative Regulation and the Stem Cell Debate *Bioethics* 22(1) pp 43-55
- Capps, B and Campbell, AV (2010) (eds.) *Contested Cells* London: Imperial College Press
- Carlson, BM (1999) *Human Embryology and Developmental Biology*, St. Louis, Mosby
- Carney, G and Harris, C (2011) Deliberative Democracy and Political Reform Available from www.political-reform.ie/2011/03/30/deliberative-democracy-and-political-reform
- Casey, J (2000) *Constitutional Law in Ireland* (3rd Edition) Dublin Round Hall Sweet and Maxwell
- Caspi, O et al (2007) Transplantation of Human Embryonic Stem Cell-Derived Cardiomyocytes Improves Myocardial Performance in Infarcted Rat Hearts *J Am Coll Cardiol* 50 (19) pp 1884-1893

- Caulfield, T (2004) Law and Policy in the Era of Reproductive Genetics *J Med Ethics* 30 pp 414-471
- Caulfield, T (2010) Stem Cell Research and Economic Promises. Law Science and Innovation: The Embryonic Stem Cell Controversy Summer 2010 *The Journal of Law, Medicine and Ethics* pp 303-313.
- CETS No. 164. Protocol to Convention on Human Rights and Biomedicine Status as of 15 July 2010. Council of Europe (<http://www.coe.int>)
- Chambers, S (2003) Deliberative Democratic Theory *Annu. Rev. Polit. Sc.* 6:307-26
- Check, E (2004) Bush Sacks Outspoken Biologist from Ethics Council *Nature* 428 (6978) p.4.
- Chirac, J (2001) Opening Speech to Biovision World Life Sciences Forum, Lyons, France. 8th February. Available from <http://www.ambafrance-uk.org/Biovision-World-Sciences-Forum>.
- Church of Ireland General Synod Church in Society Committee, Medical Ethics, Science and Technology Sub-Committee. Submission to the Irish Council for Bioethics – November 2006. Stem Cell Research. Available at: <http://www.Ireland.anglican.org>
- Clarke, DM (1993) The Constitution and Natural Law *Irish Law Times* 11
- Clifford, M (2012) Comment: Constitutional Talk Shop Proves State is in no Tearing Hurry to Create Reform *The Sunday Times* 10 June
- Clissmann, I (2012) The Embryo in vitro after *Roche v. Roche*: What Protection is now Offered? *Medico Legal Journal of Ireland* 13
- Cochrane, D (2012) Story of Galway death spreads around the world *The Irish Times* 15 November
- Commission on Assisted Human Reproduction (2005) *Report of the CAHR*. Dublin: Government Publications Office Molesworth Street
- Condorelli, G and Catalucci, D (2007) Human Stem Cells for Heart Failure Treatment *J Am Coll Cardiol* 50.(19) pp.1894-1895
- Constitutional Assembly-TD Student Submission Posted by Byrne E (2012) Available from <http://political.reform.ie/2012/03/06/constitutional-assembly-tcd-student-submission>
- Constitutional Review Group (1996) The All-Party Oireachtas Committee on the Constitution 1996–1997. Report of the Constitutional Review Group

Dublin: Stationary Office. Available at:
<http://www.constitution.ie/reports/crg.pdf>.

- Coppleston, F (1993) *A History of Philosophy Volume II: Medieval Philosophy* New York: Image Books, DoubleDay
- Corkery, P (2010) Assisted Human Reproduction *Bioethics and the Catholic Moral Tradition* Dublin: Veritas Publications.pp.41-58.
- Corkery, P (2007) Bio-Ethics and Contemporary Irish Moral Discourse *Contemporary Irish Moral Discourse* Fleming, A (ed.) Blackrock, Co Dublin The Columba Press
- Coughlan, D (1995) *The Irish Times* 13 May
- Cox, N (2008) Foetal Personhood in Perspective *The Unborn Child, Article 40.3.3 and Abortion in Ireland* Schweppe, J (ed.) Dublin The Liffey Press. pp.89-112
- Cribb, A et al (2008) Towards the Applied: the Construction of Ethical Positions in Stem Cell Translational Research *Med Health Care and Philos.* 11 pp.351-361
- Cullen, P (2012) Tragic case demonstrates moral minefield faced by doctors *The Irish Times* 15 November
- Culliton, G (2008) Doctor urges Stem Cell Clarity *Irish Medical Times* 24 April
- Culliton, G (2008) Tomorrow's research needs legislation today *Irish Medical Times* 5 September
- Culliton, G (2008) UCC's Code of Practice for Stem Cells *Irish Medical Times.* 16 November
- Daley, GQ and Scadden, DT (2008) Prospects for Stem Cell Based Therapy. *Cell* 132 Feb 22 pp.544-548
- Daly, P (2012) Shadow Constitutional Convention: Referendumitis. Available from Human Rights in Ireland www.humanrights.ie/.../shadow-constitutional-convention-9-paul-daly
- De Wert, G and Mummery, C (2003) Human Embryonic Stem Cells: Research, Ethics and Policy. *Human Reproduction*, 18, pp 672-682.
- Della Porta, D (2005) Deliberation in Movement: Why and How to Study Deliberative Democracy *Acta Politica* 40 (3) pp.336-350
- Deng, W (2010) *EMBO Reports* 11 pp.161–165. doi:10.1038/embor.2010.15
- Deputy Devins. [http://www.oireachtas.ie/SeanadDebates/26 November 2008](http://www.oireachtas.ie/SeanadDebates/26%20November%202008)

- Devolder, K (2005). Human Embryonic Stem Cell Research: Why the Discarded-Created-Distinction Cannot Be Based on the Potentiality Argument. *Bioethics*. 19 (2) pp.167-186.
- Dictionary of Public Health* (2007) Last, JM (ed) Oxford University Press
Oxford Reference Online OUP
<http://www.oxfordreference.com/views/ENTRY.html?subview=Main&entry-t235.e3017>>
- Dixon-Woods, M et al (2005) Synthesising qualitative and quantitative evidence: A review of possible methods *Journal of Health Services Research & Policy* Vol. 10 (1): 45-53
- Doerflinger, RM (1999) The Ethics of Funding Stem Cell Research: A Catholic Viewpoint *Kennedy Institute of Ethics Journal* 9(2) pp.137-150.
- Dolan, A (2008) UCC Lauded for Move on Stem Cell Research *The Irish Times* 25 November
- Donnellan, E and Allstrom, D (2008) UCC Debate to Fuel Calls for National Stem Cell Policy *The Irish Times* 28 October
- Donum Vitae* Respect for Human Life (1987) Congregation for the Doctrine of the Faith, 22 February Available at:
<http://www.vatican.va/roman/curia/congregations/cfaith/documents>
- Dooley, D (2008) Head to Head: Should the State legislate for Embryonic Stem Cell Research? *The Irish Times* 12 May
- Dresser, R (2010) Stem Cell Research as Innovation: Expanding the Ethical and Policy Conversation. Law, Science and Innovation: The Embryonic Stem Cell Controversy *The Journal of Law, Medicine and Ethics* pp.332-336
- Dunnett, SB and Rosser, AE (2004) Cell Therapy in Huntington's Disease. *The Journal of the American Society for Experimental Neurotherapeutics*. Vol.1, 394-405, October.
- Dunstan, GR (1984) The Moral Status of the Human Embryo: A Tradition Recalled. *J Med Ethics* 10: pp.38-44
- Dworkin, R (1993) *Life's Dominion. An Argument about Abortion and Euthanasia*. London: Harper Collins
- Eberl, J (2006) *Thomistic Principles and Bioethics* New York: Routledge
- Engeli, I (2009) The Challenges of Abortion and Assisted Reproductive Technologies Policies in Europe. *Comparative European Politics* 7 (1) pp.56-74

- Englund, MCO, Sartipy, P and Hyllner, J (2011) Human Embryonic Stem Cell *Regenerative Medicine: From Protocol to Patient* Steinhoff, G (ed) Chapter 7, pp 169-186,
- Eser, A (1992) The Legal Status of the Embryo in Comparative Perspective *International Journal of Medicine and Law* 11(8) pp.579-590.
- European Group on Ethics in Science and Technology (2000) Avis No. 15 Ethical Aspects of Human Stem Cell Research and Use. Brussels, Belgium: European Commission available at www.ec.europa.eu/european_group_ethics_archives
- European Consortium for Stem Cell Research (EuroStemCell) (2006) Regulations in EU Member States regarding hES Cell Research. Available at www.eurostemcell.org/Documents/Outreach/stemcell_hesc_regulations_2006feb.pdf
- Farley, MA (2001). Roman Catholic Views on Research Involving Human Embryonic Stem Cells, in *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*. Holland, S, Lebacqz, K. & Zoloth, L (eds.) Cambridge, MA: MIT Press pp.113-118.
- Farrell, AM (2007) The Body Politic: Ethical Concerns, Regulatory Dilemmas and Human Embryonic Stem Cell Research in the European Union *German Journal of Law and Society* 28 pp. 215-227.
- Ferriter, D (2007) *Judging Dev: A Reassessment of the Life and Legacy of Eamon de Valera* Dublin: Royal Irish Academy
- Fink, S (2005) Live and Let...? Measuring and Explaining the Strictness of Embryo Research Laws in 21 Countries. *A Paper prepared for the ECPR General Conference Budapest, 8-10 September Regulation of Life Sciences: Themes for Comparative Analysis*. Available from regulation.upf.edu/ecpr-05-papers/sfink.pdf
- Fink, S (2008) Politics as Usual or Bring Religion back in? : The influence of Parties, Institutions, Economic Interests and Religion on Embryo Research Laws. *Comparative Political Studies* 41 pp.1631-1656
- Finnis, J (1980) *Natural Law and Natural Rights* Oxford Clarendon Law Series, Clarendon Press
- Fitzgerald, MJT (1978) *Human Embryology* Harper International Edition. Harper and Row.
- Fletcher, JC (1995) Ethics and Society: US Public Policy on Embryo Research: Two Steps Forward, One Large Step Back. *Human Reproduction* 10 (7) pp.1875-1878

- Fletcher, R (2001) Post-colonial Fragments: Representations of Abortion in Irish Law and Politics *Journal of Law and Society* 28(4) pp.568-589
- Foley, JA & Lalor, S (1995) Eight Amendment Act – Oireachtas Debate *Annotated Constitution of Ireland 1937- 1994*. Dublin Gill and McMillan.
- Ford, N (1988) *When did I Begin? Conception of the Human Individual in History, Philosophy and Science*, Cambridge: Cambridge University Press
- Fox, M and Murphy, T (1992) Irish Abortions: Seeking Refuge in a Jurisprudence of Doubt and Delegation *Journal of Law and Society* 19, 454-455.
- Franklin, S (1995) Postmodern Procreation: A Cultural Account of Assisted Reproduction in Ginsburg, F.D. and Rapp, R (eds.), *Conceiving the New World Order. The Global Politics of Reproduction* Berkeley University of California Press pp.323-335.
- Fundación BBVA, Second BBVA Foundation International Study on Biotechnology (2008) *Attitudes to Stem Cell Research and Hybrid Embryos*. Available at www.fbbva.es/TLFU/dat/international_study_biotechnology_08.
- Gantly, D (2009) Cracking the Code of Ethics *Irish Medical Times* 27 November
- Gantly, D (2012) Tragedy highlights ‘grey area’ in legislation *Irish Medical Times* 23 November
- Gartland, F (2008) UCC Ethics Board Calls for Debate on Stem Cell Research *The Irish Times* 13 November.
- Gimmler, A (2001) Deliberative Democracy and the Internet *Philosophy and Social Criticism* 27: pp. 21-39
- Goldstein, L (2010) Why Scientific Details are Important When Novel Techniques Encounter Law, Politics and Ethics *Journal of Law, Medicine and Ethics*. Symposium Summer 2010, pp.204-211.
- Goold, SD Damschroder, L and Baum, N (2008) Deliberative Procedures in Bioethics in: Jacoby, L. and Siminoff, L.A. (eds.). *Empirical Methods for Bioethics: A Primer Advances in Bioethics* Oxford: Elsevier, pp.183-201.
- Gough, F (2011) Human Embryonic Stem Cell Research in Ireland: Legal and Ethical Issues *Medical Law International* 11 (4) pp.262-283
- Gough, F (2010) Ireland and the Frozen Embryo: A Slight Thawing? *Med Law Rev.* Spring.18.(2) pp.239-247.

- Gough, F (2010) *Public Policy and Human Embryonic Stem Cells Research*. A Policy Document for The Irish Stem Cell Foundation. Available at: <http://www.irishstemcellfoundation.org/news>
- Green Paper on Abortion* (1999) Government of Ireland Dublin, Stationery Office
- Gregg, (2002) Proceduralism Reconceived: Political Conflict Resolution under Conditions of Moral Pluralism *Theory and Society* 31(6) pp.741-776
- Guest, G Bunce, A, and Johnson, L (2006) How Many Interviews are Enough? An Experiment with Data Saturation and Variability *Field methods* 18 (1) pp.59-82.
- Guide to Ethical Conduct and Behaviour* (2004) Comhairle na nDochtúirí Leigis Medical Council of Ireland 6th Edition Dublin
- Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (2009) Comhairle na nDochtúirí Leigis, Medical Council of Ireland. 7th Edition Available at: <http://www.medicalcouncil.ie>.
- Gutmann, A and Thompson, D (1997) Deliberating about Bioethics *Hastings Center Report* 27 (3) pp. 38-41.
- Gutmann, A and Thompson, D. (2004) *Why Deliberative Democracy* Princeton University Press
- Habermas, J (1975) *Legitimation Crisis* Translated McCarthy T Boston Beacon Press; London Heinmann
- Habermas, J (1992) The Limits of Neo-Historicism in Dews, P (ed) *Autonomy and Solidarity: Interviews with Jurgen Habermas* London: Verso pp. 237-243.
- Habermas, J (1996) *Between Facts and Norms :Contributions to a Discourse Theory of Law and Democracy* Translated by Rehg, W Cambridge MA MIT Press
- Habermas, J (2003) *The Future of Human Nature* Cambridge, Polity Press
- Habermas, J (2006) Religion in the Public Sphere *European Journal of Philosophy* 14(1) pp 1-25,
- Habermas, J (2008) *Between Naturalism and Religion* Cambridge: Polity Press
- Habermas, J (2001) *The Postnational Constellation: Political Essay* . Translated by Pensky, M Cambridge MA, MIT Press
- Habermas, J (1994) *The Past as Future* Cambridge: Polity Press

- Halliday, S (2004) A Comparative Approach To The Regulation Of Human Embryonic Stem Cell Research In Europe *Medical Law Review* 12 :40-69;
- Hamilton, J (2009) *The Mackey Lecture: Freedom of Expression and Enquiry*. Trinity College, Dublin. November. Available from www.tcd.ie/longroomhub/assets.
- Hammond-Browning, N and Holm, S (2010) Hybrid Embryos - Ethics, Law and Rhetoric in the United Kingdom's Stem Cell Policy *Contested Cells: Global Perspectives on the Stem Cell Debate* Capps, B and Campbell, AV(eds.) London: Imperial College Press
- Hanafin, P (2001) *Constituting Identity: Political Identity formation and the Constitution in Post-Independence Ireland*. Aldershot, Ashgate Publishing Ltd.
- Hanafin, P (2007) *Conceiving Life: Reproductive Politics and the Law in Contemporary Italy* Aldershot, Ashgate Publishing Ltd.
- Hanafin, P. and Williams, M.S., (1999). Issues of Territoriality and Identity in the Irish Constitution in (eds.) *Identity, Rights and Constitutional Transformation*. Aldershot: Ashgate Publishing Company.
- Hanley, A and Smith, D (2005) *Quench not the Spirit : Theology and Prophecy for the Church in the Modern World* Blackrock, Co. Dublin The Columba Press
- Hannon, P (1992) *Church, State, Morality and Law*. Dublin, Gill and MacMillan
- Hannon, P (1998) Rights:Theological Resources *Milltown Studies* 42
- Haraway, D (1997) *Modest Witness at Second Millenium. FemaleMan_meets_OncoMouse* New York Routledge
- Harmon, SHE (2008) Motivating Values and Regulatory Models for Emerging Technologies: Stem Cell Research Regulation in Argentina and the United Kingdom *Law and Bioethics: Current Legal Issues* Freeman, M (ed.) Oxford: Oxford University Press pp.147-176
- Harris, J Bortolotti, L & Irving, L (2005) An Ethical Framework for Stem Cell Research in the European Union *Health Care Analysis*, 13, 157-162
- Harris, JW (1997) *Legal Philosophies* 2nd Edition. London Butterworth
- Healy, M (2008) 'I Don't Want to Get into This, It's Too Controversial': How Irish Women Politicians Conceptualise the Abortion Debate *The Unborn Child, Article 40.3.3 and Abortion in Ireland* Schweppe, J (eds.) Dublin: The Liffey Press pp 65-85

- Heaney, S (2004) *Burial at Thebes: Sophocles' Antigone*. Faber and Faber
- Heinemann, T & Honnefelder, L (2002) Principles of Ethical Decision Making Regarding Embryonic Stem Cell Research In Germany *Bioethics* 16(6) 530-543
- Henchy, S (1962) Precedent in the Irish Supreme Court *Modern Law Review* Vol. 25(5) pp 544-558
- Hoffmaster, B (1992) Can Ethnography Save the Life of Medical Ethics? *Social Science and Medicine* 35, pp.1421-31
- Holland, S Lebacqz, K & Zoloth, L (2001) *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*. Cambridge, MA: MIT Press
- Holm, S (2002) Going to the Roots of the Stem Cell Controversy *Bioethics*, 16, 493-507.
- Holmes, D (2011) Sound and fury after stem cell ruling *The Lancet* vol. 378, Issue 9803, p 1617
<http://www.childabusecommission.ie>
<http://www.hrb.ie>
<http://www.irishstemcellfoundation.org/ethicdebate>
- http://www.labour.ie/download/pdf/labour_election_manifesto_2011.pdf
 One Ireland - Jobs Reform Fairness
- <http://www.prolifecampaign.ie/pages.php?id=175>
- Human Fertilisation and Embryology Act (2008) Available from www.hfea.gov.uk/134.html or www.dh.gov.uk
- Human Fertilisation and Embryology Authority (2009) *Code of Practice* 8th Edition, Available from www.hfea.gov.uk
- Human Genetics Commission Reports *Choosing the Future: Genetics and Reproductive Decision Making* (2004), and *Making Babies: Reproductive Decisions and Genetic Technologies*, (2005). Available from www.hgc.gov.uk.
- Human Reproduction Bill *An Bille Um Atáirgeadh Daonna* A Green Paper (2001), (2003) Dublin, Government Publications Stationery Office
- Illes, J Raimer, JC and Kwon, BK (2011) Stem Cell Clinical Trials for Spinal Cord Injury: Readiness, Reluctance, Redefinition *Stem Cell Review and Reports*, Online First, doi: 10.1007/S12015-011-9259-1

- Indian Council of Medical Research New Delhi (2000) *Ethical Guidelines for Biomedical research on Human Subjects* Foreword by Justice M.N. Venkatachaliah. p.1 Available at www.scribd.com/doc/7218924/ICMR-Ethical-Guidelines-India.
- Instruction *Dignitas Personae* on certain Bioethical Questions. Congregation for the Doctrine of the Faith, 12 December 2008. Available at: http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_c_on_cfaith_do.
- Irish Council for Bioethics (Comhairle Bitheitice Ná hÉireann) (2005) TNS mrbi/129171/Bio Ethics Research/September, 2005 ICB www.bioethics.ie/uploads/docs/129171-Bioethics%20Research.pdf
- Irish Council for Bioethics (2008) *Ethical, Scientific and Legal Issues concerning Stem Cell Research* Published by The Irish Council for Bioethics, (Comhairle Bitheitice Ná hÉireann) Regus House, Harcourt Road, Dublin.
- Irish Council for Bioethics (2010) *Compendium of Work 2002-2010* Published by The Irish Council for Bioethics, (Comhairle Bitheitice Ná hÉireann) Regus House, Harcourt Road, Dublin.
- Irish Export Agency (2009) Annual Report. <http://www.irishexporters.ie/section/IEAYearendReview2009>
- Isasi, RM and Knoppers, BM (2009) Towards Commonality? Policy Approaches to Human Embryonic Stem Cell Research in Europe in *Embryonic Stem cell Patents: European Law and Ethics*. Plomer, A and Torremans, P(eds.) Oxford Oxford University Press. pp 29-56
- Isasi, RM and Knoppers, BM (2006) Mind the Gap: Policy approaches to Embryonic Stem Cell and Cloning Research in 50 countries *European Journal of Health Law* 13: 9-26
- Ives J (2008) Encounters with Experience: Empirical Bioethics and the Future *Health Care Analysis* 16(1) 1-6
- Jackson, E (2001) *Regulating Reproduction* Oxford Hart Publishing
- Jasanoff, S (2005) *Designs on Nature: Science and Democracy in Europe and the United States* Princeton, Princeton University Press
- Johnston, MH & Petersen, K (2008) Public Interest or Public Meddling? Towards an Objective Framework for the Regulation of Assisted Reproductive Technologies *Human Reproduction*, 23 pp.713-728.
- Jones, DG & Towns, CR (2006) Navigating the Quagmire: The Regulation of Human Embryonic Stem Cell Research *Human Reproduction* 21pp.1113-1116.

- Jonsen AR (1998) *O Brave New World : Ethics of Human Reproduction The Birth of Bioethics* Oxford University Press.
- Kant, I (1871) *Critique of Pure Reason* Translated by Max Muller, (2008) London: Penguin Classics
- Kavanagh, A (1997) The Quest for Legitimacy in Constitutional Interpretation *32 Irish Jurist* 195
- Kay, JF (2012) Time for an abortion law to stop Irish Women suffering *The Irish Times* 22 November
- Kelly, JM (2003) *The Irish Constitution* (4th Edition) Hogan, GW and Whyte, GF (eds) Dublin: Tottel Publishing
- Kennedy, H (2010) People Power Must Set New Parliamentary Agenda. Available from news.bbc.co.uk/democracylive/hi/comment/newsid
- Keogh, D (1994) *Twentieth-Century Ireland: Nation and State* Dublin, Gill and MacMillan.
- Keown, J (1993) The Polkinghorne Report of Fetal Research: Nice Recommendations, Shame about the Reasoning *Journal of Medical Ethics* 19 (2) pp.114-120
- Kerridge, IH et al (2009) Religious Perspectives on Embryo Donation and Research *Clinical Ethics*. 5: pp.35-45
- King, PA (1997) Embryo Research: The Challenge for Public Policy *Journal of Medicine and Philosophy*, 22 (5) pp.441-455
- Kingston, J, Whelan, A and Bacik, I (1997) *Abortion and the Law*. Dublin: Round Hall Sweet and Maxwell.
- Klotzko, AJ (1997) The Debate about Dolly *Bioethics*. 11 (5) pp.427-438
- Knight, I (2012) Death to shame even the Pope *The Sunday Times* 18 November
- Knight, J (1999) Constitutionalism and Deliberative Democracy in *Deliberative Politics: Essays on Democracy and Disagreement* Macedo, S (ed.) Oxford: Oxford University Press
- Knoepffler, N (2004) Stem Cell Research: An Ethical Evaluation of Policy Options. *Kennedy Institute of Ethics Journal*; March, 55-74
- Knoppers, BM, Bordet, S and Isasi, R (2009). The Human Embryo: Ethical and Legal Aspects *Human Embryogenesis: Methods and Protocols* Lafond, J and Vaillancourt, C (eds.) New York, Humana Press pp.281-305

- Korobin, R (2007) *Stem Cell Century: Law and Policy for a Breakthrough Technology* New Haven, Yale University Press
- Latham, SR (2009) Between Public Opinion and Policy: Human Stem Cell Research and Path- Dependency *Journal of Law, Medicine and Ethics* p800-806. Developing Oversight Approaches to Nanobiotechnology: The Lessons of History. Winter 2009
- Lee, P and George, R (2001) Reason, Science and Stem cells: Why Killing Human Beings is Wrong *National Review Online*. 20th July. Available at www.nationalreview.com/
- Lee, P (2005) Comment on John Finnis' 'Foundations of Practical Reason Revisited' *Am. J. Juris.* Vol. 50 p133
- Lee, S (1992) Abortion Law: The Tragic Choices *Abortion, Law and Conscience: A Special Issue of Doctrine and Life* May/June
- Lenoir, N (2000) Europe Confronts the Embryonic Stem Cell Research Challenge *Science* 287 (5457) pp 1425-1427.
- Lewis, VB (2001) Liberal Democracy, Natural Law and Jurisprudence: Thomistic Notes on an Irish Debate *Reassessing the Liberal State: Reading Maintains Man and State* Fuller, T and Hittinger, J (eds.). Washington American Maritain Association Catholic University of America Press pp 140-158
- Lindvall, O and Kokaia, Z (2006) Stem Cells for the Treatment of Neurological Disorders *Nature* Vol. 441 pp 1094-1096
- Longstaff, H et al (2009) Scientists' Perspectives on the Ethical Issues of Stem Research *Stem Cell Rev and Rep* 5 pp 89-95
- Lucas, R (1997) The Anthropological Status of the Human Embryo in *Identity and Statute of Human Embryo. Proceedings of Third Assembly of the Pontifical Academy for Life*. De Dios Vial Correa, J and Sgreccia, E (eds.) Vatican City, Published by Liberia Editrice Vaticana. pp 178-205
- Luo, J et al (2011) International Stem Cell Collaborations: How Disparate Policies between the United States and the United Kingdom Impact Research. PLoS www.plosone.org6 (3)
- Lyons, B (2012) The Irish Council for Bioethics – An Unaffordable Luxury? *Cambridge Quarterly of Healthcare Ethics*, 21 (3) pp.375-383
- Madden, D (2002) *Medicine, Patients and the Law* Dublin: Tottel Publishing
- Madden, D (2006) Assisted Reproduction in the Republic of Ireland – A Legal Quagmire *Ethics, Law and Society: Volume II* Gunning, J and Holm, S (eds) Chapter 4, pp 27-34

- Madden, D (2008).Article 40.3.3 and Assisted Human Reproduction *The Unborn Child, Article 40.3.3 and Abortion in Ireland* Schweppe, J (ed.) Dublin: The Liffey Press pp.310-318.
- Mahoney, J (1990) Religion and Assisted Conception. *Philosophical Ethics Reproductive Medicine. Society and Assisted Reproduction* Mahoney, J (ed). Manchester: Manchester University Press. pp.84-104.
- Mandel, GN (2009) Regulating Emerging Technologies *Law, Innovation and Technology*, Vol.1 pp.75-92
- Manin, B (1987) On Legitimacy and Deliberation *Political Theory* 15(3) pp. 338-368.
- Mansbridge, J (2008) What Does the Idea of Deliberative Democracy Demand? Theory Workshop Seminar Paper Available from politicalscience.stanford.edu/.../theory-workshop-jane-mansbridge
- Mason, JK & Laurie, GT (2006) *Mason and McCall Smith's Law and Medical Ethics* 7th Edition. Oxford: Oxford University Press
- Master, Z and Crozier, GKD (2012) The Ethics of Moral Compromise for Stem Research Policy Cell *Health Care Analysis* 20 pp. 50-65.
- McAvoy, S (2008) From Anti-Amendment Campaign to Demanding Reproductive Justice *The Unborn Child, Article 40.3.3 and Abortion in Ireland* Schweppe, J (ed.) Dublin The Liffey Press Chapter 1 pp.15-46
- McClean, MR (2001) Stem Cells: Shaping the Future in Public Policy *The Human Embryonic Stem Cell Debate:Science, Ethics and Public Policy*. Holland, S, Lebacqz, K & Zoloth, L (eds.) Cambridge, MA: MIT Press pp.197-207
- McGee, G & Caplan, A (1999) The Ethics and Politics of Small Sacrifices in Stem Cell Research *Kennedy Institute of Ethics Journal*, 9, 151-158.
- McGuinness, S (2011) A, B and C leads to D (for Delegation) Commentary *Medical Law Review* 19, pp.476-491
- McGuinness, S and Ui Chonnachtaigh, S (2011) Implications of Recent Developments in Ireland for the Status of the Embryo *Cambridge Quarterly of Healthcare Ethics* 20 pp. 396-408
- McGuinness, S (2012) The Construction of the Embryo and Implications for Law *Stem Cells: New Frontiers in Science and Ethics* Quigley, M, Chan, S and Harris, J (eds.) Singapore, World Scientific Publishing Ltd pp.51-83
- McInerney, R (1980) The Principles of Natural Law *Am. J of Juris* 25 (2)

- McInerney, S and O'Brien, S (2012) Still the Burning Issue *The Sunday Times* 18 November
- Michelmann, FI (1988) Law's Republic *Yale Law J.* 97
- Michelman, FI (2003) Constitutional Legitimation for Political Acts *Modern Law Review* 66(1) pp 1-15
- Mills, S (2007) *Clinical Practice and the Law* Dublin: Tottel Publishing Ltd.
- Minihan, M and Coulter, C (2009) Harney to Propose Law on Assisted Human Reproduction *The Irish Times* 16 December
- Mitchell, S (2011) Warning over Stem Cell Research in Ireland *The Sunday Business Post* March 6
- Moore, A (2010) Public Bioethics and Deliberative Democracy *Political Studies* 58(4) pp 715-730
- Murphy, T (2004) *Western Jurisprudence* Dublin: Thomson, Round Hall
- Nagel, T (1995) Moral Epistemology, *Society's Choices: Social and Ethical Decision Making in Biomedicine* Bulger, RE, Bobby, EM and Feinberg, HV (eds.) Washington, IOM, pp 201-214.
- Narsinh, KH, Plews, J and Wu, JC (2011) Comparison of Human Induced Pluripotent and Embryonic Stem Cells: Fraternal or Identical Twins? *Molecular Therapy* 19 (4) pp 635-638
- Nationaler Ethikrat, *German National Ethics Council Opinion on the Import of Human Embryonic Stem Cells* (2001) Berlin: German National Ethics Council
- Ó Cearúil, M (1999) *Bunreacht na hÉireann: A Study of the Irish Text* Dublin Government of Ireland Publications
- O'Connell, D (2012) Constitution could Benefit from Radical Reappraisal. Available www.irishtimes.com/newspaper/opinion/2012/0510/1224315844103_pf.html
- O'Hanlon, RJ (1993) Natural Rights and the Irish Constitution *Irish Law Times* 11 (8)
- O'Mahoney, C (2010) Societal Change and Constitutional Interpretation *Irish Journal of Legal Studies* 1 (2) pp 71-100
- Oduncu, FS (2003) Stem Cell Research in Germany: Ethics of Healing v. Human Dignity *Medicine, Health Care and Philosophy* 6 pp.5-16.
- Outka, GH (2002) The Ethics of Human Stem Cell Research *Kennedy Institute*

of Ethics Journal, 12(2)

- Oxford Dictionary of Law* (2006) Martin, E.A. and Law J (eds) Oxford University Press. Oxford Reference Online OUP
<http://www.oxfordreference.com/views/ENTRY.html?subview=Main&entry-t49.e2554>>
- Parker, C (2007) Ethics for Embryos *J Med Ethics* 33(1) 614-616
- Parker, M (2009) Naked Regulators: Moral Pluralism, Deliberative Democracy and Authoritative Regulation of Human Embryonic Stem Cell (hESC) Research *Journal of Law and Medicine* 16 (4) pp.580-589
- Perrin, NMR (2005) The Global Commercialisation of UK Stem Cell Research. *How can the UK's strengths in stem cell research be translated into commercial opportunities in a global market?* UK Trade and Investment
<http://www.hfea.gov.uk/PressOffice/Archive/1107861560>
- Plomer, A (2004) Embryonic Stem Cell Research: Human Dignity and the Right to Life *The Law and Ethics of Medical Research* Chapter 4 London. Cavendish
- Practice and Belief Among Catholics in the Republic of Ireland-A summary of Data from the European Social Survey Round 4 (2009/10) and International Social Science Programme and Religion III (2008/9) Available at www.irishcatholicbishops.ie/practice-and-Belief-among-Catholics
- Prainsack, B and Gmeiner, R (2008) Clean Soil and Common Ground:The Biopolitics of Human Embryonic Stem Cell Research in Austria *Science as Culture* 17 (4) pp.377-395
- Quigley, M (2012) Stem Cell Therapies and Benefitting from the Fruits of Banned Research *Stem Cells: New Frontiers in Science and Ethics* Quigley, M, Chan, S and Harris, J (eds.) Singapore, World Scientific Publishing Ltd pp. 163-186
- Ramjoué, C and Klöti, U (2004) ART Policy in Italy: Explaining the Lack of Comprehensive Regulation *Comparative Biomedical Policy: Governing Assisted Reproductive Technologies* Bleiklie, I, Goggins, M and Rothmayr, C (eds.) London: Routledge.
- Ramsey, P (1961) *War and the Christian Conscience: How Shall Modern War be Conducted Justly* Durham, NC: Duke University Press, p171-191
- Rawls, J. (1999) *The Laws of Peoples* Cambridge MA: Harvard University Press
- Regenberg, AC et al (2009) Medicine on the Fringe: Stem Cell-Based Interventions in Advance of Evidence *STEM CELLS* 27: pp.2312-2319

- Regling, K and Watson, M (2010) '*A Preliminary Report on the Sources of Ireland's Banking Crisis*' Available from Government Publications, Government Publications Sale Office, Molesworth Street, Dublin or www.bankinginquiry.gov.ie,
- Report of the Commission on Assisted Human Reproduction* (2005) CAHR
Dublin: Government Publications Office, Molesworth Street. Available at: <http://www.dohc.ie/publications/cahr.html>.
- Richardt, N (2003) A Comparative Analysis of the Embryological Research Debate in Great Britain and Germany *Social Politics: International Studies in Gender, State and Society* 10(1) pp. 86-128
- Robertson, J (1999) Ethics and Policy in ESCR *Kennedy Institute of Ethics Journal* 9 :109-136. The John Hopkins University Press
- Robertson, JA (2004) Reproductive Technology in Germany and the United States: An Essay in Comparative Law and Bioethics *Columbian Journal of Transnational Law* (43) pp.189-227
- Robinson, W (1992) European Dimension of the Abortion Debate *Abortion and Conscience A Special Issue of Doctrine and Life* May/June
- Salter, B and Salter, C (2010) Governing Innovation in the Biomedicine Knowledge Economy: Stem Cell Science in the USA *Science and Public Policy* 37(2) pp. 87-100
- Sandel, M (2005) *Public Philosophy: Essays on Morality in Politics* Cambridge MA: Harvard University Press
- Sandel, M (2007) *The Case against Perfection :Ethics in the Age of Genetic Engineering* Cambridge MA: The Belknap Press of Harvard University Press
- Sankar, P and Jones, NL (2008) Semi-Structured Interviews in Bioethical Research *Empirical Methods in Bioethics : A Primer* 11 pp 117-136
- Schenker, JG (2003) Ethical Aspects of Advanced Reproductive Technologies in *Annals New York Academy of Sciences November* Vol. 997, pp 11-21
- Schiffino, N and Varone, F (2004) Belgium : A Bioethical Paradise? *Comparative Biomedical Policy: Governing Assisted Reproductive Technologies* Bleiklie, I Goggin, M and Rothmayr, C (eds.). London, Routledge.
- Schweppe, J (2008) Introduction *The Unborn Child, Article 40.3.3 and Abortion in Ireland* Schweppe, J (ed.) Dublin: The Liffey Press
- Science Foundation Ireland Annual Report 2010* Accessible at www.sfi.ie/news-events/publications/annual-reports.

- Scott, CT (2006) *Stem Cell Now: A Brief Introduction to the Coming Medical Revolution* New York, Plume. Penguin Group
- Scott, R et al (2012) Donation of ‘Spare’ Fresh or Frozen Embryos to Research: Who decides that an Embryo is ‘Spare’ and How Can We Enhance the Quality and Protect the Validity of Consent? *Medical Law Review Advance Access* Published June 13, 2012
- Senator Ivana Bacik. <http://www.oireachtas.ie/SeanadDebates/> 26 November 2008
- Shercock, A (1989) The Right to Life of the Unborn and the Irish Constitution. *Irish Jurist*, 13; 24.
- Sheridan, K (2012) Catholicism Now: Never Less Cause for Celebrations with Just a Third of Catholics Attending Weekly Mass *The Irish Times* 5 June
- Simonstein, F (2008) Embryonic Stem Cells: the Disagreement Debate and Embryonic Stem Cell Research in Israel *Journal of Medical Ethics*, 43 pp.732-734.
- Skene, L (2012) Legal Regulation of Human Stem Cells *Stem Cells: New Frontiers in Science and Ethics* Quigley, M, Chan, S and Harris, J (eds.) Singapore, World Scientific Publishing.pp.85-105
- Smith, K (2010) Parkinson’s Disease Outlook: Treatment Frontiers S15-S18. Available from www.nature.com/outlooks
- Smyth, L (2005) *Abortion and Nation: The Politics of Reproduction in Contemporary Ireland* Aldershot, Ashgate Publication Ltd.
- Somerville, M (2004) Commentary: Social Issues and Ethical Values in the Political Public Square: Principle vs. Packages *International and Comparative Health Law and Ethics: A 25-year Retrospective. The Journal of Law, Medicine and Ethics*, 32 (4) pp 731-740
- Spar, D (2004) The Business of Stem Cells *New England Journal of Medicine* 351:(3) 211-213
- Sperling, S (2008) Converting Ethics into Reason: German stem cell policy between Science and the Law *Science as Culture* 17(4) pp. 363-375
- Strauss, S (2010) Geron Trial Resumes but Standards for Stem Cells Remain Elusive *Nature Biotechnology* 28. (10) pp.989-990
- Sullivan, S (2011) Stem Cell Research in the Emerald Isle. *Bioengineered Bugs* 2(2) 69-70 March/April 2011. www.landesbioscience.com
- Sullivan, S & Gough, F (2009) Crux of the Unborn *The Irish Examiner* 15

December

Sulmasy, DP (2009) Deliberative Democracy and Stem Cell Research in New York State: The Good, the Bad and the Ugly *Kennedy Institute of Ethics Journal* 19 (1) pp.63-78

Sunstein C (1994) *The Partial Constitution* Cambridge MA, Harvard University Press

Symposium on Un-enumerated Rights in the Irish Constitution
www.nuigalway.ie/law/GSLR

Szoke, H, Neame, L and Johnston, L (2006) Old Technologies and New Challenges *Disputes and Dilemmas in Health Care Law* Freckleton, I and Petersen, K (eds.) New South Wales: Federation Press pp187-208.

Takahashi, K and Yamanaka, S (2006) Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors *Cell* **126**: pp.663–676

Takashi, K et al (2007) Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors *Cell* 131: pp.861-872.

Takala, T and Häyry, M (2007) Benefitting from Past Wrongdoing: Human Embryonic Stem Cells, and the Fragility of the German Legal Position *Bioethics* 21 pp. 150-159.

The All Party Committee on the Constitution (1999) *5th Progress Report: Abortion. Appendix-Green Paper on Abortion.* Government of Ireland,. Dublin: Government Stationary Office. Available at: <http://www.constitution.ie/reports/crg.pdf>.

The All-Party Oireachtas Committee on the Constitution 1996-1997 *Report of the Constitutional Review Group (1996)* Dublin: Stationary Office. Available at: <http://www.constitution.ie/reports/crg.pdf>.

The Concise Oxford Dictionary of the Christian Church (2006) Livingstone, EA (ed) Oxford University Press. *Oxford Reference Online* OUP <http://www.oxfordreference.com/views/ENTRY.html?subview+Main&entry-t95.e3984>>

The Oxford Guide to the United States Government (2001) Patrick, JJ, Pious, RM and Richie, DA (eds.) OUP *Oxford Reference Online* OUP <http://www.oxfordreference.com/views/ENTRY.html?subview+Main&entry-t89.e596>>

The Report of the All-Party Oireachtas Committee on the Constitution (2006), Dublin Stationary Office. Available at: <http://www.constitution.ie/reports/crg.pdf>.

The Report of the Commission to Inquire into Child Abuse (CICA) 2009

- Available from www.childabusecommission.com/rpt/pdfs
- The Report of the Expert Group on Judgment in A, B and C v. Ireland*
Available from www.dohc.ie/publications/JudgmentsABC.html
- Thompson, D (2008) Deliberative Democratic Theory and Empirical Political Science *Annu. Rev. Polit. Sc.* 11: 497-520
- Thomson, JA et al (1998) Embryonic Stem Cell Lines Derived from Human Blastocysts *Science* 282: 1145-1147.
- Thompson, JS and Thompson, MW (1986) Immunogenetics *Genetics in Medicine*, 4th Edition, Chapter 8. Philadelphia, W.B Saunders Company
- UK Stem Cell Initiative (2005) *Report & Recommendations* Available at www.advisorybodies.doh.gov.uk/uksci/uksci-reportnov05.pdf
- Vogel, G (2011) UK Approves Europe's First Embryonic Stem Cell Clinical Trial *Science Insider* 22/09/11
<http://news.sciencemag.org/scienceinsider/2011/09/uk-approves-europes-first-embryo>.
- Von Prondzynski (1977) Natural Law and the Constitution *Dublin University Law Journal* 1
- Walters, L (2004) Human Embryonic Stem Cell Research: An Intercultural Perspective *Kennedy Institute of Ethics Journal* March, 3-38.
- Warnock, M (1987) Do Human Cells Have Rights *Bioethics* 1 (1) pp.1-14
- Warren, MA (1997) *Moral Status – Obligations to Persons and Other Living Things. Issues in Biomedical Ethics*. Oxford. Clarendon Press.
- Weinstein, BL, Clower, TL and Seman, M (2009) *Economic Impact of Stem Cell Research in Texas*. Prepared for The Alliance for Medical Research, Houston, Texas, January 2009. Available at www.unt.edu/cedr/StemCell.2009.pdf
- Weiss, ML et al (2006) Human Umbilical Cord Matrix Stem Cells: Preliminary Characterisation and Effect Transplantation in a Rodent Model of Parkinson's Disease *Stem Cells* 24: pp.781-792
- Werpehowski, W (1997) Persons, Practices and the Conception Argument *The Journal of Medicine and Philosophy*, 22: 479-494,
- Whitman, JQ (2004) The Two Western Cultures of Privacy: Dignity vs. Liberty 113 *YALE L.J.* p 1168

- Whyte, G (1992) Abortion and the Law *Abortion, Law and Conscience: A Special Issue of Doctrine and Life* May/June
- Winston, R (2007) Does Government Regulation Inhibit Embryonic Stem Cell Research and Can it be Effective? *Cell Stem Cell* 1 pp 27–34.
- Wobus, AM and Boheler, KR (2005) Embryonic Stem Cells: Prospects for Developmental Biology and Cell Therapy *Physiol Rev* Vol. 85 April pp.635-678
- Wolff, J (2011) *Ethics and Public Policy: A Philosophical Approach* London, Routledge
- World Medical Association Declaration of Helsinki: *Ethical Principles for Medical Research Involving Human Subjects*. Available at www.wma.net/en/20activities/10ethics/10helsinki.
- Yuko, E (2011) Bioethical Regulations in Ireland: Where are They? Available from www.gleube.eu/polemics-3/bioethical-regulations-in-Ireland-where-are-they-38.htm
- Zenker, F (2010) Analysing Social Policy Argumentation: A Case Study on the Opinion of the German National Ethics Council on an Amendment of the Stem Cell Law *Informal Logic* 30 (1) pp.62-91
- Zweiter Zwischenbericht der Enquete-Kommission Recht und Ethik der modernen Medizin, (2001) *Teilbericht Stammzellforschung* Berlin: Deutscher Bundestag

APPENDIX

PUBLISHED PAPERS

1. COMMENTARY

IRELAND AND THE FROZEN EMBRYO: A SLIGHT THAWING? *Med Law Rev* 2010, 18:239-247

2. HUMAN EMBRYONIC STEM CELL RESEARCH IN IRELAND: ETHICAL AND LEGAL ISSUES *Med Law International* 2011,11(4) 262-283

COMMENTARY

IRELAND AND THE FROZEN EMBRYO: A SLIGHT THAWING?

Roche v Roche & Ors

[2009] IESC 82

Introduction

In any society, the moral status or degrees of protection to be accorded to an embryo is constituted 'linguistically, culturally, scientifically, politically, and through its religious and secular beliefs'.¹ Within the European Union, the lack of consensus concerning the status of the embryo is reflected by the different national definitions given to this entity, although the ethical and legal questions resulting from advances in assisted reproductive technologies have produced a range of regulatory regimes aiming to protect the interests of the *in vitro* embryo, patients and society as a whole.² The UK was one of the first states in the world to introduce legislation regulating assisted human reproduction (AHR) and embryo research through the *Human Fertilisation and Embryology Act 1990*. The embryo is afforded 'respect' due to its potential under the Act, with the main aim of this Act being to establish an authority—the Human Fertilisation and Embryology Authority (HFEA) to oversee all aspects of AHR in UK.³

Although it has long been apparent that 'unborn' life is something which 'represents a most important social value' in Ireland,⁴ there is no Irish legislative framework regulating AHR or human embryonic stem cell research (hESCR) despite assisted reproductive technologies being available since 1987.⁵

¹ J Harris and others, 'An Ethical Framework for Stem Cell Research in the European Union' (2005) 13 Health Care Analysis 158.

² ESHRE Task Force on Ethics and Law, 'The Moral Status of the Pre-implantation Embryo' (2001) 16 Human Reproduction 1046.

³ K Mason and GT Laurie, *Mason and McCall Smith's Law and Medical Ethics* (7th edn OUP, Oxford 2006) 71–119.

⁴ N Cox, 'Foetal Personhood in Perspective' in J Schweppe (ed), *The Unborn Child, Article 40.3.3 and Abortion in Ireland* (Liffey Press, Dublin 2008) 89–112.

⁵ D Madden, *Medicine, Ethics and the Law* (Tottel Publishing Ltd, Dublin 2002) 241–92; S Mills, *Clinical Practice and the Law* (Tottel Publishing Ltd, Dublin 2007) 441–60; The Medical Council of Ireland currently provides the only recommendations pertaining to this area of practice in Ireland. See Medical Council of Ireland, *A Guide to*

The consequences of the legislature's failure to address the constitutional ambiguities, that have given rise to the uncertain legal position of AHR and human embryonic and stem cell (hESC) research, became all too apparent when the case of the 'frozen embryos' first came before the Irish High Court in 2006.

The 'Frozen Embryos' Case

This case concerned a separated couple who were disputing what was to happen to three frozen embryos from an *in vitro* fertilisation (IVF) cycle.⁶ In the case, which has some similarities with *Evans*,⁷ the appellant mother wished to have three frozen embryos implanted in an attempt to become pregnant again, despite the fact that the couple had separated following the birth of a daughter from the original IVF procedure. The father argued for his right not to reproduce and refused to give his consent to allow the embryos to be transferred. The appellant argued that she should be allowed to have the embryos implanted in her uterus as they (the frozen embryos) were 'unborn' for the purposes of Article 40.3.3 of the Irish Constitution.

Within the Irish Constitution, despite the legislative void, a number of provisions potentially affect the delivery of AHR and hESC research in Ireland. The most important of these is Article 40.3.3.⁸ This guarantees the right to life of the 'unborn' stating:

The State acknowledges the right to life of the unborn and, with due respect to the equal right of life of the mother, guarantees in its laws to respect, and as far as is practicable, by its laws to defend and vindicate that right.

Article 40.3.3 represents the 8th Amendment to the Constitution of Ireland, and was inserted in 1983 following a difficult referendum campaign. The popular view in 1983 was that Article 40.3.3 gave the individual foetus constitutional protection from the time of conception/fertilisation, although the actual timing of this was not precisely delineated.⁹ Defining at what stage the guarantee 'to defend and vindicate the right to life' applies is essential in determining whether assisted

Professional and Ethics for Registered Medical Practitioners (7th edn Medical Council, Dublin 2009) 20.1–4.

⁶ *Roche (M) v Roche (T), Walsh (A), Walsh (D) & Sims Clinic Ltd and Attorney General* [2006] IEHC 359.

⁷ *Evans v United Kingdom* [2007] 6339/05 ECtHR 2.

⁸ The Irish Constitution was formulated in 1937. The authoritative version is that in the Irish language, *Bunreacht ná hÉireann*.

⁹ Cox, above n 4.

reproduction can take place legally in Ireland, and also the lawfulness of the use of spare embryos from IVF for hESC research.¹⁰

As far back as 1996, the Constitutional Review Committee considered this difficulty in the state of the law and concluded that a clearer definition was needed as to when the ‘unborn’ acquired the protection of the law:

If it were specified within a definition that the protection of Article 40.3.3 extended to *in vitro* fertilisation, legal problems could arise in relation to some practices in this area. If, as an alternative it was decided to specifically exclude *in vitro* fertilisation from the protection of Article 40.3.3 the result could appear anomalous.¹¹

Despite this statement that it was imperative that the law should define what it intended to protect,¹² no effort was made on the part of the legislators to reduce the uncertainty as to the meaning of the term ‘unborn’.

Judgment at First Instance

The Court divided the case into two distinct parts. First, it looked at the private law issues that primarily were described as pertaining to contractual matters. The Court examined the standard clinic consent forms and other documentation executed by the parties in the context of their treatment and concluded that no agreement had been made between the couple as to the fate of any ‘spare’ frozen embryos in the event of their separation. It observed that as there was no evidence of an intention to create legal relations, there was no legally enforceable contract. It also concluded that as the father had withdrawn his consent, the transfer of the frozen embryos could not proceed. The second aspect of this case related to the constitutional law question of the status of the embryo—did the constitutional protection provided by Article 40.3.3 to the ‘unborn’ extend to the frozen embryos, giving them the right to life?

The presiding judge, Mr Justice McGovern, examined the legislative history of the Constitution and the 8th Amendment in particular. The court noted that in all previous cases pertaining to Article 40.3.3 no consideration was given as to whether the word ‘unborn’ included embryos *in vitro*. Mr Justice McGovern concluded that there was no evidence that it was ever in the mind of the people voting on the 8th Amendment to the Constitution in 1983 that ‘unborn’ meant anything other than ‘a foetus or child within a woman’s uterus’ and that to infer

¹⁰ *Report of Commission on Assisted Human Reproduction* (TSO, Dublin 2005) 58.

¹¹ *Report of Constitutional Review Group* (TSO, Dublin 1996) 275.

¹² Above n 11.

otherwise and extend the term unborn to include ‘embryos outside the womb or embryos *in vitro* would be to completely ignore the circumstances giving rise to Article 40.3.3’. He further suggested that given this, in the absence of any legislation or precedent, ‘embryos outside the womb have a very precarious existence’ and that it should not be a matter for the courts to decide whether the word ‘unborn’ should or should not include embryos *in vitro*. Rather it should be for the legislature (Oireachtas) or the people through the process of a Constitutional Amendment to so decide, as the proper function of the Courts at the end of the day is ‘to implement and apply the law, not morality’. He found that while embryos *in vitro* are deserving of special respect, the frozen embryos in the case in question were not ‘unborn’ as defined by the Constitution.

This judgment was appealed to the Supreme Court. The case was heard in February 2009 and the judgment handed down on December 15 2009.

Judgment on Appeal

The appellant’s case was resolved into a number of specific topics. On the private law issue, it was submitted that the appellant and first named defendant had agreed that the embryos would be returned to the appellant’s uterus and that the defendant was precluded and estopped from denying or revoking that consent as this agreement still bound the parties irrespective of their subsequent separation. On the constitutional law issue, it was submitted that the frozen embryos were ‘unborn’ for the purposes of Article 40.3.3 of the Constitution of Ireland and that the Court must vindicate that right by directing the second named defendants and the Sims Fertility Clinic, to facilitate the appellant in having the embryos inserted in her uterus.¹³

The five judges of the Supreme Court initially dealt with the private law issue of consent.¹⁴ In this matter, the Court held, having examined several consent forms, that there was no contract between the plaintiff and her husband as there was no ‘question of an offer or acceptance or consideration, or an intention to create a legal contract’¹⁵ and that the defendant did not give his express or implied consent to the implantation of the three frozen embryos in the plaintiff’s uterus. Murray CJ concluded that the appellant had not established the existence of a contractual agreement nor of implied consent that would oblige the father

¹³ Denham J at 15.1–15.2

¹⁴ Five judges normally sit in the Irish Supreme Court for cases involving constitutional issues with the number of judges ranging from three up to nine for other types of cases (communication with the Office of the Supreme Court).

¹⁵ Denham J at 20.2–21.

to consent to the implantation of the embryos.¹⁶ This was in agreement with the conclusions of Geoghegan J and Hardiman J. He agreed with Denham J that the plaintiff therefore was not entitled to succeed in her claim that her husband be estopped from refusing to withdraw his consent to implantation.¹⁷ Fennelly J also agreed in his judgment that the father was not bound ‘by contract or agreement or by the application of equitable principles to permit the frozen embryos to be implanted’.¹⁸

The Status of the ‘Unborn’

On the constitutional issues, the Court upheld the decision of the High Court, unanimously dismissing the appeal of the mother to allow the frozen embryos to be transferred to her uterus, ruling that the frozen embryos were not the ‘unborn’ within the meaning of Article 40.3.3, and the appellant was not entitled by virtue of this Article to the return of the embryos to her uterus.

In her detailed judgment, Denham J emphasised that the central issue in this case was whether ‘three embryos, which have been frozen and stored in a clinic, are the “unborn” and as such protected by Article 40.3.3. of the Constitution of Ireland’, and was not ‘about the wonder and mystery of human life, but simply a matter of construing the word “unborn” in the Constitution to determine its constitutional meaning’.¹⁹ She explained that through the introduction of Article 40.3.3, the State-guaranteed protection of the embryo began after implantation. The Amendment was introduced to copper-fasten the protection that already existed under s.58 of the Offences against the Person Act 1861. This effectively rendered it unconstitutional to ‘procure a miscarriage’, or effectively to prevent abortion being constitutionally permissible.²⁰ She expressed her satisfaction that ‘the mischief to which Article 40.3.3 was addressed was that of the termination of pregnancy’ only, as previously stated by Justice McCarthy in *Attorney General v X* [1992].²¹ Moreover, an interpretation of Article 40.3.3 as applying to ‘frozen embryos would necessitate the intervention of the State to facilitate their implantation’ even if this meant going

¹⁶ Murray CJ—paragraph on ‘Estoppel’.

¹⁷ Denham J at 32.

¹⁸ Fennelly J at 1.

¹⁹ At 45 (Denham J).

²⁰ At 53 (Denham J).

²¹ *Attorney General v X* 1 IR 1 [1992] ILRM 401, [1992] 2 CMLR 277. McCarthy J at 81: ‘[The Amendment’s] purpose can be readily identified—it was to enshrine in the Constitution the protection of the right to life of the unborn thus precluding the legislature from an unqualified repeal of s.58 of the Act of 1861 [which prohibits abortion] or otherwise in general, legalising abortion’.

against the parents' wishes.²² She found this to be an inappropriate construction of Article 40.3.3 as it would be inconsistent with the rights of the family under the Constitution.²³

Geoghegan J expressed his agreement with the opinion of Munby J, who, in the English case of *R (Smeaton) v Secretary of State for Health* (2002) related the importance of the expression 'being with child' to the offence of 'procuring a miscarriage' created by the Offences against the Person Act 1861 s.58.²⁴ He concluded that there could be no offence without a 'miscarriage' and there could be no 'miscarriage' without 'carriage'. He expressed his belief that Article 40.3.3 was not 'drafted or indeed voted on with IVF treatment in mind' and he was satisfied that the constitutional provision did not have the effect of 'overriding the objections of the father'. Similarly, Hardiman J stated that Article 40.3.3 was introduced to protect the legal position enshrined in the Offences against the Person Act 1861 s.58. He expressed his agreement with Geoghegan J in his analysis of the constitutional provision as primarily a means to prevent decriminalisation of abortion, and that 'it is manifest that the embryo undergoing cryogenic preservation is not implanted and is incapable of impinging on the right to life of the mother'. He therefore concluded that the frozen embryos were not 'unborn' within the meaning of Article 40.3.3 but he emphasised that this did not mean that 'such embryos should not be treated with respect as entities having the potential to become a life in being'. Fennelly J, though satisfied that the frozen embryos did not enjoy the protection of Article 40.3.3, did not think that the constitutional provision was intended only as a reinforcement of s.58 of the Offences against the Person Act 1861, believing that '[t]he people, in adopting the 8th Amendment to the Constitution employed distinct, new and independent language'.²⁵ Murray CJ, while agreeing with the conclusions of Denham, Geoghegan and Hardiman that the appellant had failed to establish that the frozen embryos constituted 'the unborn' within the meaning of Article 40.3.3, emphasised that it should not be within the remit of a Court of law to 'pronounce on the truth of when human life begins'.²⁶

The deliberate eschewing by all the judges of a literal interpretation of the Constitution in relation to the definition of the 'unborn' for a more purposive interpretation is not unusual in Irish Constitutional law when

²² At 56 (Denham J).

²³ At 67 (Denham J).

²⁴ *R (on the Application of Smeaton on behalf of the Society for the Protection of Unborn Children) v Secretary of State for Health* [2002] 2 FLR 146, at 99–103.

²⁵ Fennelly J at 2.

²⁶ Murray CJ—paragraph on 'Human Life and Article 40.3.3'.

the provision of the Constitution being examined relates to fundamental rights and public policy.²⁷ It is generally regarded as the approach which will allow the 'spirit' rather than the letter of the law to be favoured within the interpretation.²⁸

Discussion

It would appear, as a consequence of this judgment, that there is no legal prohibition to AHR, hESCR and other related therapeutic applications such as pre-implantation diagnosis taking place in Ireland. The seemingly unanimous view of the judges that the courts should not be called upon to state when life begins could be regarded as an abdication of their judicial responsibilities if a judge's role is regarded as one of interpretation of constitutional provisions. However, the Supreme Court through its judgment is effectively criticising the abdication of legislative responsibility by successive Irish governments in the area of AHR.²⁹ By ruling as they have, the Supreme Court has been forced to decide what is permissible and what is not. In most democratic societies, this is what politicians are elected to do.

Despite the lack of legislation to date in Ireland, there has been some attempt to develop policy in this area. In March 2000, the Irish Government established the Commission on Assisted Human Reproduction (CAHR) to report 'on the possible approaches to the regulation of all aspects of AHR and the social, ethical, and legal factors to be taken into account in determining public policy in the area'.³⁰ The Commission acknowledged that achievement of IVF presented 'the medical profession and through them society as a whole with the dilemma created by the existence of embryos that will not be used for their intended purpose'. One of the purposes of the Commission was to force Irish

²⁷ J Casey, 'Constitutional Interpretation' in *Constitutional Law in Ireland* (3rd edn Round Hall Press, Sweet and Maxwell, Dublin 2000) 7–13.

²⁸ G Hogan and G Whyte, 'Introduction: Constitutional Interpretation' in JM Kelly (ed), *The Irish Constitution* (4th edn Tottel Publishing, Dublin 2003) 3–46.

²⁹ Geoghegan J noted that 'Since most of these problems are of an ultra modern nature, I rather doubt that there is a constitutional solution to them but this does not mean that there cannot and indeed should not be regulation by the Oireachtas'. Hardiman J described the 'marked reluctance on the part of the legislature actually to legislate on these issues', and warned that if the 'legislature does not address such issues, Ireland may become by default an unregulated environment for practices which may prove controversial or, at least to give rise to a need for regulation'. Murray CJ agreed that 'it is for legislatures in the exercise of their dispositive powers to resolve such issues on the basis of policy choices'. Fennelly J also expressed concern at the lack of legislation in this area stating that 'it is disturbing to use no stronger word, that some 4 years after the publication of the Report of the Commission on Assisted Human Reproduction, no legislative proposal has even been formulated'.

³⁰ Above n 10, Foreword to Report, v.

society 'to face the question whether, for the first time in the history of mankind, human embryos may be used for purposes other than human reproduction'.³¹

The Commission published the report, referred to by Justice Fennelly in his judgment, in 2005. It contained forty recommendations. The main recommendations addressed regulatory issues, with the first of these being that 'a regulatory body should be established by an Act of the Oireachtas to regulate AHR services in Ireland'.³² This recommendation follows international best practice. The regulatory body would be independent and would have the function of advising the government on all matters relating to AHR and associated procedures including research. There would be provision within the legislation for regular reviews in order to accommodate medical, scientific, and social development.³³

The Commission also considered the arguments for and against embryo research recognising the existence of three basic positions: (i) research should not be permitted; (ii) research should be permitted but only on surplus embryos; and (iii) research should be permitted on surplus embryos and on embryos specifically generated for research.³⁴ With one exception, all members of the CAHR were in favour in principle of the second position. A majority of the CAHR members also recommended that embryo research, including embryonic stem cell research should be permitted on surplus embryos that are donated for research, for specific purposes only and under stringently controlled conditions up to 14 days following fertilisation. The conditions and purposes for which embryo research is permitted would be stipulated by the regulatory body.³⁵ Most importantly, a majority of the Commission recommended that 'the embryo formed by IVF should not attract the legal protection until it is placed in the human body, at which stage it should attract the same level of protection as the embryo formed *in vivo*'.³⁶ To date, none of the recommendations of the CAHR have been enacted in legislation by the current Government.

Conclusion

The legal position of the embryo under Irish law will almost certainly never rest on an agreed consensus as to its moral status. It should, however, be possible to acknowledge this while at the same time

³¹ Above n 10, v.

³² Above, n 10, 8 (Recommendation 1).

³³ Above, n 10, 70.

³⁴ Above n 10, 58 (Recommendation 34).

³⁵ Above n 10, 58 (Recommendation 34).

³⁶ Above n 10, 34 (Recommendation 16).

showing respect for all parties to the debate by introducing a system of regulation that allows such matters to be teased out.

If Ireland continues to avoid addressing the difficult legal and ethical issues thrown up by advances in reproductive technology, we may find that Ireland becomes the 'unregulated environment for practices that may be controversial' of which Hardiman J warned.

Fionnuala Gough
School of Law, University of Manchester

Human embryonic stem cell research in Ireland: Ethical and legal issues

Medical Law International

11(4) 262–283

© The Author(s) 2011

Reprints and permission:

sagepub.co.uk/journalsPermissions.nav

DOI: 10.1177/0968533211419124

mli.sagepub.com



Fionnuala Gough

University of Manchester, Manchester, UK

Abstract

The paper examines the ethical and legal background to the current debate in the Republic of Ireland on the use of human embryos and embryonic stem cells (hESC) for research. How should public policy be formed to balance the potential health benefits of such research against the moral values of 21st century Irish society? The legislature has failed to address the constitutional ambiguities that have contributed to the current uncertainty as to the legal position of hESC research in Ireland. In view of the challenges posed by hESC research, it is argued that an appropriate regulatory framework should be adopted in Ireland, which will bring a degree of certainty as to what is and is not permitted. In adopting such a framework, it is suggested that hESC research should be permitted on donated supernumerary embryos up to day-14 post fertilisation.

Introduction

Research involving human embryonic stem cells (hESCs) seems to have the potential to produce significant therapeutic benefits in many degenerative diseases, such as Diabetes Mellitus, Alzheimer's disease and Parkinson's disease, through the replacement of damaged cells with appropriately cultured stem cells. Although induced pluripotent stem cells (iPSCs)¹ may have important potential applications by allowing the reproduction of human diseases in culture and the exploration of their progression in different tissues,²

1. Takahashi, K. and Yamanaka, S., (2006). Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors. *Cell* 126: 663–676.
2. Deng, W., (2010). *EMBO reports* (2010) 11, p. 161–165. doi:10.1038/embor.2010.15

Corresponding author:

Fionnuala Gough, Doctoral programme in Bioethics and Medical Jurisprudence, School of Law, University of Manchester, Williams Building, Oxford Road, Manchester.

Email: Fionnuala.Gough@postgrad.manchester.ac.uk.

currently the most therapeutically promising stem cells are those derived from embryos, such as the hESC-derived oligodendrocyte progenitor cells,³ which have recently begun phase 1 trials on spinal injury patients in the United States (US).⁴

It has been evidenced for some time that in Ireland ‘unborn life is something which represents a most important social value’.⁵ Despite this, there has been no political response to the question of whether or not human embryonic and embryonic stem cell research should be permitted to take place within Ireland. Currently there is no Irish legislative framework regulating either research involving human embryos and human embryonic stem cells,⁶ or assisted human reproduction (AHR), the source of these cells, although assisted reproductive technologies have been available since 1987.⁷ The absence of legislation in this area is seen as extremely unsatisfactory by scientists involved in stem cell research in Ireland,⁸ in terms of their competitiveness internationally,⁹ as well as by clinicians involved in the provision of assisted reproductive services,¹⁰ as they are uncertain as to the legal standing of the services they provide.¹¹

In this paper, I argue that stem cell research presents unprecedented public policy and regulatory challenges, and as therapies derived from hESC research have the potential to deeply affect lives, I believe that the goal of policy makers should be to pursue a policy that promotes human health, while aiming to protect the interests of the *in vitro* embryo, patients and society as a whole.¹² It is essential, therefore, for the purposes of transparency as well as clarity, that a regulatory regime be adopted that would permit hESC research to take place in Ireland within very strict parameters. The parameters countenanced would limit permissible research to donated supernumerary embryos from *in vitro* fertilisation (IVF) up to 14 days post fertilisation, and prohibit cloning or the production of human-animal chimeras.¹³ These are the parameters which have been advocated by both

3. Oligodendrocytes are the cells responsible for the myelination of neuronal axons. Fitzgerald, M.J.T. (1978) *Human Embryology*. Harper International Edition. Harper and Row. p. 146.
4. Strauss, S., (2010). Geron trial resumes but standards for stem cells remain elusive. *Nature Biotechnology*. 28: 989–990.
5. Cox, N., (2008). Foetal Personhood in Perspective. In Schweppe, J., ed. *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: The Liffey Press. p. 89–112.
6. <http://www.irishstemcellfoundation.org/ethics> [Accessed 12 April 2011].
7. Mills, S., (2007). The Extremes of Life I: The Beginning. *Clinical Practice and the Law*. Dublin: Tottel Publishing Ltd. p. 287–310.
8. Sullivan, S. and Gough, F. (2009). Crux of the Unborn. *The Irish Examiner*. 15 December.
9. Culliton, G., (2008). Doctor urges stem cell clarity. *Irish Medical Times*. 24 April. p. 8.
10. Donnellan, E. and Allstrom, D., (2008). UCC debate to fuel calls for national stem cell policy. 28 October. *The Irish Times*. Gartland, F. (2008) UCC ethics board calls for debate on stem cell research. *The Irish Times*. 13 November.
11. Battles, J., (2009). Going it alone: Is IVF in safe hands? *The Sunday Times (Irish Edition)* 27 September. p. 10.
12. Holland, S., Lebacqz, K. and Zoloth, L., (2001). *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*. Cambridge, MA: MIT Press. p. 199.
13. A human-animal chimera is an organism composed of two genetically distinct populations of cells, e.g. a single cell is taken from an early cleavage-stage human embryo and injected into the blastocyst of a genetically different host such as a mouse. From Carlson, B. M., (1999) *Human Embryology and Developmental Biology*, St. Louis, Mosby. p. 38–74.

the Commission on Assisted Human Reproduction (CAHR) in their report of 2005,¹⁴ and the Opinion published by the Irish Council for Bioethics (ICB) in 2008.¹⁵

In order to support this position, the particular issues which have contributed to the current Irish policy vacuum will be identified, and local recommendations related to the governance of human embryo research will be examined.

The moral status of the embryo

The primary ethical issue associated with hESC research arises due to the way in which the embryonic stem cells are obtained. The inner cell mass of a blastocyst is the source of embryonic stem cells.¹⁶ The removal and placement in a suitable culture medium of the stem cells, however, disrupts the biological integrity of the blastocyst, rendering the embryo non-viable, as those elements necessary for successful implantation, the trophoblast cells and the extra-embryonic mesoderm, are no longer present.¹⁷ It is this destruction that has forced an examination of the moral status, or value of the *in vitro* human embryo and the uses to which it may be put.¹⁸

The status of the human embryo has continually changed throughout history in response to transformations of cultural values and the acquisition of scientific knowledge.¹⁹ The major monotheistic religions, Judaism, Islam, and Christianity, hold differing positions regarding the moral status of the human embryo.²⁰

Despite an acknowledged diversity of opinion within Judaism, the majority opinion holds that the Halakah's position on the moral status of the embryo is that no significant moral status is assigned to the embryo until 40 days after fertilisation. It is considered until this as 'mere water'.²¹ A foetus' moral position then develops

14. Report of the Commission on Assisted Human Reproduction (2005) Dublin, Government Publications Office.
15. Ethical, Scientific and Legal Issues concerning Stem Cell Research. Irish Council for Bioethics (Comhairle Bitheiteice Ná hÉireann) Opinion 2008.
16. When an oocyte is fertilised it becomes a zygote and undergoes cleavage or successive division to become a 2-celled, 4-celled, 8-celled etc cluster of cells known as a morula (from the Greek for mulberry). When the morula contains 50-60 cells a cavity forms in the centre, it is then known as a blastocyst. At the blastocyst stage the embryo consists of two types of cells: an outer superficial layer (the trophoblast) that surrounds a small inner group of cells called the inner cell mass. Cells of the inner cell mass give rise to the embryo proper as well as a number of extra-embryonic structures, whereas the cells of the trophoblast form only extra-embryonic structures, including the outer layers of the placenta. (From n. 11 above).
17. De Wert, G. and Mummery, C., (2003). Human Embryonic Stem Cells: Research, Ethics and Policy. *Human Reproduction*, 18: 672-682.
18. <http://www.irishstemcellfoundation.org/ethicdebate>. [Accessed 12 April 2011].
19. Lenoir, N., (2000). Europe confronts the Embryonic Stem Cell Research challenge. *Science*, 287: 1425.
20. n. 18 above.
21. Kerridge, I.H. et al., (2009). Religious perspectives on embryo donation and research. *Clinical Ethics*. 5: 35-45

gradually throughout a pregnancy until birth.²² Within Islam, although human life is considered valuable and deserving of protection,²³ the attainment of personhood does not occur until the body and soul subsist together. This ensoulment is thought to occur after the first trimester.²⁴ Little protection or rights are afforded to the pre-implantation embryo.

Within Christianity, Protestantism and Catholicism demonstrate a different emphasis on the moral status of the embryo. The Church of Ireland (Anglican) acknowledges the embryo as a potential human being but with some rights assigned from the moment of fertilisation. They distinguish morally between the adult human being and the embryo, that is, between actually 'being' in existence and 'potential'.²⁵ The Catholic Church has, however, consistently articulated the sanctity and dignity of human life, arguing that it should be revered and protected from the beginning of its existence,²⁶ as 'human corporeality begins at the very moment of conception'.²⁷ In both *Donum vitae* and *Dignitas personae*, despite the acknowledgment that personhood is a difficult and complex question,²⁸ the Church confirmed its position by arguing that an embryo has, the same intrinsic value as a fully developed human being and that it 'is to be respected and treated as a person from the moment of conception; and therefore from that same moment its rights as a person must be recognized, among which in the first place is the inviolable right of every innocent human being to life'.²⁹ In addition, the Catholic Church advocates that every human being should be respected for themselves, and they should not be commodified as the human embryo has 'from the very beginning the dignity proper to a

22. Simonstein, F., (2008). Embryonic Stem Cells: the Disagreement Debate and Embryonic Stem Cell Research in Israel. *Journal of Medical Ethics*, 43: 732–734.
23. Askoy, S., (2005). Making Regulations and Drawing up Legislation in Islamic Countries under Conditions of Uncertainty, with Special Reference to Embryonic Cell Research. *Journal of Medical Ethics*. 31(7): 399–403.
24. Kerridge, I. H. et al., (2009). Religious perspectives on embryo donation and research. *Clinical Ethics*. 5: 35–45
25. Church of Ireland General Synod Church in Society Committee, Medical Ethics, Science and Technology Sub-Committee. Submission to the Irish Council for Bioethics – November 2006. Stem Cell Research. Available at: <http://www.Ireland.anglican.org/index.php?do=information&id=20> [Accessed 12 April 2011]
26. Corkery, P. , (2010). Assisted Human Reproduction in Bioethics and the Catholic Moral Tradition. Dublin: Veritas Publications. p. 41–58.
27. Lucas, R. (1997) The Anthropological Status of the Human Embryo in *Identity and Statute of Human Embryo. Proceedings of Third Assembly of the Pontifical Academy for Life*. Ed. De Dios Vial Correa, J. and Sgreccia, E. Vatican City, Published by Libreria Editrice Vaticana. p. 178–205
28. *Donum Vitae* Respect for Human Life, Congregation for the Doctrine of the Faith, 22 February 1987. Available at: <http://www.vatican.va/roman/curia/congregations/cfaith/documents>, Chapter 1, Question 1. [Accessed 12 April 2011].
29. Instruction *Dignitas Personae* on certain Bioethical Questions. Congregation for the Doctrine of the Faith, 12 December 2008. First Part: Anthropological, Theological and Ethical Aspects of Human Life and Procreation. Available at: http://www.vatican.va/roman/curia/congregations/cfaith/documents/rc_con_cfaith_do. [Accessed 12 April 2011].

person'.³⁰ To treat it as 'the object or instrument of experimentation' violates its human dignity.³¹ Proponents of this view claim that the Catholic Church's stand against embryo research is not only based on the doctrine that life begins at conception but also on its particular interpretation of the biology of early human development.³² These views have strong support in Ireland despite a considerable waning of the influence of the Church in the last decade.³³

The Catholic Church's presumption that there is a new human individual from conception is a relatively recent one. For many centuries, the Church held a gradualist view of embryonic development with the 13th century writing of Thomas Aquinas on the question of embryonic development being influential. Drawing on Aristotle, Aquinas considered that the human embryo did not possess a rational soul and was not therefore a human being until day 40 of development.³⁴ Ensoulment was regarded, therefore, as one of the critical events in determining the attribution of moral status. This position, however, is not accepted by all Catholic philosophers. Farley has stated that as fertilisation has been shown by embryological studies to be a process rather than a one-off event, the embryo at the blastocyst stage 'is not sufficiently individualised to bear the moral weight of personhood'.³⁵ Similarly, Mahoney and Ford, although accepting the Church's position on abortion, contend that it is only at day 14 post-fertilisation, when the primitive streak appears,³⁶ that an embryo becomes 'an ontologically human individual'.³⁷

30. *Donum Vitae* Respect for Human Life, Congregation for the Doctrine of the Faith, 22 February 1987. Available at: <http://www.vatican.va/roman/curia/congregations/cfaith/documents>, Chapter 1, Question 4. [Accessed 12 April 2011].
31. Instruction *Dignitas Personae* on certain Bioethical Questions. Congregation for the Doctrine of the Faith, 12 December 2008. Second Part: New problems concerning Procreation. Paragraph 15. Available at: http://www.vatican.va/roman/curia/congregations/cfaith/documents/rc_con_cfaith_do. [Accessed 12 April 2011].
32. Boyle, J., (1991). The Roman Catholic Tradition and Bioethics. In Brody, B. A., (Ed.) *Bioethics year book Theological Developments in Bioethics 1988–1990*. Dordrecht: Kluwer Academic Publishers. p. 5–21.
33. This is due in part to the fallout from clerical abuse scandals (The Ryan Report, 20 May 2009. Available at: <http://www.childabusecommission.ie>, [Accessed 12 April 2011]) and increasing multiculturalism of Irish society, BANKS, M (2008) Modern Ireland: multinationals and multiculturalism. *Information, Society and Justice*. Vol.2.1 December. p. 63–93.
34. Dunstan, G.R., (1984). The Moral Status of the Human Embryo: A Tradition Recalled. *J Med Ethics* 10: 38–44.
35. Farley, M. A., (2001). Roman Catholic Views on Research Involving Human Embryonic Stem Cells, in *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*. eds. Holland, S., Lebacqz, K. and Zoloth, L. Cambridge, MA: MIT Press. p. 113–118.
36. The primitive streak forms the notochord, a cellular rod which lies ventral to the central nervous system.
37. Part of the development of a normal embryo is the individualisation of the embryo through the development of the primitive streak at 14 days post fertilisation; twinning can no longer take place and a new individual now exists. Most twins arise from the subdivision of the inner cell mass of a blastocyst, not from the splitting of a two-celled zygote (From Carlson, B. M.,

Prior to this Mahoney maintains that the early embryo should not be regarded as 'anything more than a human entity possessed of astonishing promise or potential'.³⁸ This more liberal position also asserts that 'conception' differs from 'individualisation', with Ford arguing that otherwise the possibility of twinning or fusion which can occur after conception cannot be accounted for, and therefore prior to the development of the primitive streak the moral status of the embryo is not that of a person,³⁹ thereby justifying its use in certain kinds of research.⁴⁰

Potentiality

When the moral status of the embryo is being examined, the potentiality argument is often cited as it expresses the view that because embryos have the potential to become fully developed human beings, the embryos are deserving of moral status, and by extension protection.⁴¹ The main difficulty with this argument, as identified by Devolder, is that the only point of agreement within the argument is the meaning of 'potentiality'—that is, it applies is to something 'that is potential, not actual but can become actual under certain conditions'.⁴² Potentiality may also be regarded as a matter of degree—the more probable it is that an embryo will become a person, the greater the protection it should be afforded.

(1999) *Human Embryology and Developmental Biology*, St. Louis: Mosby. p. 38–74). This is the point at which the embryo acquires significant moral status or value according to some jurisdictions including Belgium, ('Law on Research on Embryos in Vitro', 11/05/2003, <http://www.eshre.eu> [Accessed 12 April 2011] which allows research to take place on embryos up to day 14 post-fertilisation, and the UK. The regulations contained in the UK's *Human Fertilisation and Embryology Act 1990*, (as amended recently by the *Human Fertilisation and Embryology Act 2008*), allow experimentation on human embryos up to the appearance of the primitive streak. In their 2005 report, the Commission on Assisted Human Reproduction in Ireland (CAHR) recommended that research would be allowed in the Irish Republic on supernumerary IVF embryos up to this point (Report of the Commission on Assisted Human Reproduction (2005) Dublin, Government of Publications Office). This position has also received support from the Irish Council for Bioethics (ICB), which has proposed that the moral value afforded to embryos be based on recognition of their potential to develop into human persons, and from their representation of human life in its earliest stages (Ethical, Scientific and Legal Issues concerning Stem Cell Research. Irish Council for Bioethics (Comhairle Bitheiteice Ná hÉireann) Opinion 2008).

38. Mahoney, J. ed., (1990). *Religion and Assisted Conception. Philosophical Ethics in Reproductive Medicine. Society and Assisted Reproduction*. Manchester: Manchester University Press. p. 84–104.
39. Ford, N., (1988). *When did I begin? Conception of the Human Individual in History, Philosophy and Science*, Cambridge: Cambridge University Press. p. 102–132.
40. n. 35 above at p. 116.
41. Devolder, K., (2005). Human Embryonic Stem Cell Research: Why the Discarded-Created-Distinction Cannot Be Based on the Potentiality Argument. *Bioethics*. 19: 167–186.
42. n. 41 above at p. 176.

An examination of the potentiality argument by Outka, however, has lead him to claim that it is a 'double-sided' argument which allows conservatives to claim that it 'nullifies a serious commitment to fetuses and embryos,' while liberals deem it to be 'too indeterminate ever to be permitted to trump decisions to abort or to conduct research on embryos'.⁴³ In relation to embryo research, Outka argues that as embryos in reproductive clinics are bound either to be discarded or frozen in perpetuity, 'nothing is lost' if there are 'third parties with diseases such as Alzheimer's and Parkinson's whose lives 'may be saved by virtue of research on such embryos'.⁴⁴ Nothing more is lost effectively if the embryos are used in research, as such use determines how the embryo will die and not whether death will occur as 'they are destined to die in any case'.⁴⁵

A variant of the potentiality argument is the gradualist approach. This approach to the moral value of the embryo expresses what 'many people feel intuitively' and so may 'open up the way to consider a broader consensus on the issue of hESC research'.⁴⁶ Within the gradualist framework early embryos are regarded as having a moral value which is lesser than that of older or post-primitive streak formation embryos. The acquisition of moral status is proposed to be as continuous a process as biological development, with embryos gradually gaining moral value. From this viewpoint, a 20-week old foetus, for example, would have more moral value than a 6-week-old one. The assignment of significant moral value to embryos, however, does not exclude their use in research which may benefit those with full moral status since, as Holm contends, the 'reduction of human suffering and death in many cases outweigh the sacrifice of a (small) number of human embryos'.⁴⁷ It is argued by McGee and Caplan that whatever its moral status, the destruction of an embryo would only occur under 'the most scrupulous conditions and for the best communal reasons'.⁴⁸ Since 'compassion for the sick and vulnerable' is one of the 'deepest moral habits of human life', they stress that it may actually be considered a moral imperative that stem cell research be carried out and overall that 'stem cell research is a pursuit of known and important moral goods'.⁴⁹ Devolder argues that although there are, and should be 'feelings of respect towards each created embryo because of their intrinsic potentiality', this respect does not preclude its use as a resource for 'a goal which is believed to be important'.⁵⁰ The overall conclusion to be ascertained from an examination of the potentiality argument is that the moral value and respect afforded to embryos due to their potential should only be trumped when a legitimate scientific or medical goal cannot be achieved by any other means. This should be implicitly acknowledged within any future regulatory framework for hESC research in Ireland.

43. Outka, G.H., (2002) .The Ethics of Human Stem Cell Research. *Kennedy Institute of Ethics Journal*, 12, 175–213. p. 188

44. n. 43 above at p. 193.

45. n. 43 above at p. 194.

46. n. 41above at p. 179.

47. Holm, S., (2002.) Going to the Roots of the Stem Cell Controversy. *Bioethics*, 16, 493–507.

48. McGee, G. and Caplan, A., (1999). The Ethics and Politics of Small Sacrifices in Stem Cell Research. *Kennedy Institute of Ethics Journal*, 9, 151–158.

49. n. 48 above at p. 152.

50. n. 41above at p. 182.

The legal position of hESC research in Ireland

As stated in the introduction, Ireland currently has no legislation either permitting or prohibiting hESC research. An examination of relevant Irish case law pertaining to the position of the embryo in the Irish Constitution may go some way to explaining why there is a legislative lacuna in this area.

Ireland has a written Constitution, *Bunreacht na hÉireann*, enacted in 1937. The legal and philosophical basis of *Bunreacht na hÉireann* was the natural law theory of Thomas Aquinas, popular at the time in the social philosophy of the Catholic Church, while the ‘dominant political and social discourse of 1930’s Ireland was conservative and irredentist’.⁵¹ Natural law theories are generally concerned with evaluating ‘human laws in the light of higher sources, identified in the Preamble to *Bunreacht na hÉireann* as the Holy Trinity’.⁵² However, the Irish Constitution also acknowledges notions of liberal constitutionalism and in its fundamental rights articles guarantees the individual citizen freedom, equality and justice. According to Binchy, while *Bunreacht na hÉireann* is ‘rooted in a philosophical perspective which embraces a concept of God’ it is

premised on rejection of legal positivism, respect for universalism and an understanding of human beings as entities of equal dignity and value, each with an unique worth.⁵³

In the early days of the Irish State, legislation was passed to bring the law into line with Catholic teaching on a wide range of moral issues. The Oireachtas Committee on the Constitution in 2006 found that the laws of the Irish State in the areas of marriage, contraception, abortion and homosexuality strongly mirrored those of the Catholic Church until reforms were introduced in the latter part of the 20th century.⁵⁴ Although there is no specific legislation, a number of constitutional provisions potentially affect the delivery of AHR services in Ireland, and the possibility of embryonic stem cell research taking place. These include the rights to privacy and bodily integrity, custody of a child, and equality before the law. However, in relation to embryonic and stem cell research, the most important article in the Constitution is Article 40.3.3, which guarantees the right to life of the ‘unborn’.

-
51. Hanafin, P., (2001). Origi(N)ation: Problems of Constitutional Subjectivity in Constituting Identity. *Constituting Identity: Political Identity Formation and the Constitution in Post-Independence Ireland*. Aldershot: Ashgate Publishing Company. p. 10–25. Hanafin, P. and Williams, M.S., (1999). Issues of Territoriality and Identity in the Irish Constitution IN (Ed.) *Identity, Rights and Constitutional Transformation*. Aldershot: Ashgate Publishing Company. p. 74.
 52. Byrne, R. and McCutcheon, J., (2001). Introduction to the Irish Legal System. *The Irish Legal System*. 4th ed. Dublin: Tottel Publishing Ltd. p. 13–15.
 53. Binchy, W., (2008). Article 40.3.3 of the Constitution: Respecting the Dignity and Equal Worth of Human Beings. In Schweppe, J. ed., *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: The Liffey Press. p. 189
 54. The Report of the All-Party Oireachtas Committee on the Constitution, 2006, Dublin, Dáil Éireann.

Following the enactment of *Bunreacht na hÉireann* in 1937, despite there being no explicit constitutional provisions protecting the ‘unborn child’, a number of judicial statements had indicated a willingness on the part of the judiciary to interpret the Constitution as affording rights, although unenumerated, to the individual foetus, in the same way as it afforded rights to the individual adult.⁵⁵ In *McGee v. Attorney General*,⁵⁶ the Supreme Court through Mr Justice Walsh, while recognising the constitutional right to marital privacy and limitation of family size, emphasised that it must not come at the cost of endangering or destroying human life.⁵⁷

There was concern following *McGee* that this right to marital privacy might be used in a manner similar to that used by pro-choice campaigners in the United States (US) to successfully invoke a comparable right to privacy, thereby invalidating statutes criminalising abortion, *Roe v. Wade*.⁵⁸ By re-iterating that privacy is a fundamental personal right, the US Supreme Court effectively granted American women the right to choose to have an abortion. This decision provided a significant example of the possibilities of judicial action in the area of reproductive rights. To prevent the possibility of a *Roe v Wade*-type judgment in Ireland, the Pro-Life Amendment Campaign (PLAC), formed in 1981, proposed that an amendment be made to the Constitution, which it argued would protect unborn life. PLAC were ultimately successful in their campaign to have the unborn protected within the framework of the Constitution, but the effect of the amendment was to extend far beyond its specific intent to prevent the courts from introducing legal abortion in Ireland.

Article 40.3.3

The 8th Amendment to the Constitution of Ireland 1983 inserted a new article, Article 40.3.3, into the Constitution which stated

The State acknowledges the right to life of the unborn and, with due respect to the equal right of life of the mother, guarantees in its laws to respect, and as far as is practicable, by its laws to defend and vindicate that right.⁵⁹

What is interesting about Article 40.3.3, is that despite being regarded as ‘the anti-abortion amendment’ it does not actually mention the term abortion at all, as, according to Binchy, ‘it is entirely philosophical in character’.⁶⁰ In terms of constitutional

55. n. 5 above.

56. *McGee v. Attorney General* [1974] IR 284 (1975)109 ILTR 29. In *McGee*, a woman suffered a stroke during a pregnancy and wished to import barrier contraceptives (spermicidal jelly) for her own use as advised by her doctor.

57. Walsh, J., in *McGee v. Attorney General* [1974] IR 284 (1975)109 ILTR 29 at 41–2.

58. *Roe v. Wade* (1973) 410 U.S.113.

59. *Bunreacht na hÉireann* Constitution of Ireland, Government Publications Office. Dublin, p. 150.

60. n. 53 above at p. 195.

interpretation the Irish text is the authoritative one. Consequently, the Irish language version of the word unborn, *beo gan breith*, introduces an element of uncertainty into the law with *beo* translated principally as 'living being', with the secondary sense of 'life', while *gan breith* can mean 'without birth'.⁶¹ The ambiguous nature of this wording was noted by both the then Attorney General, Peter Sutherland, who warned that the term 'unborn' could be interpreted to mean either that abortion was prohibited from conception or that it was permitted up to the point of viability.⁶² It was also noted by the then Senator Mary Robinson, who observed that

The basic flaw in this amendment is that it is so uncertain in its scope and so potentially contradictory in its meaning and so potentially damaging to existing practices in the area of family planning and medical treatment.⁶³

Determining at what stage the guarantee 'to defend and vindicate the right to life' applies is important given its implications for the potential research use of spare embryos from AHR in hESC research. In 1983 it was felt that Article 40.3.3 gave the individual foetus constitutional protection from the time of conception/ fertilisation, despite the amendment not defining with any precision the actual time frame involved.⁶⁴ Although this issue did not directly arise for consideration by the courts there was some judicial support for this interpretation.⁶⁵

Several commentators have examined this uncertainty in the law in relation to embryo research and arrived at different conclusions. Shercock argued it was likely that,

the courts would hold the *in vitro* embryo to come within the protection of [Article 40.3.3] and if this is the case, it would appear to rule out embryo research in Ireland, certainly in cases involving the destruction of the embryo. It would also appear to have implications for fertility treatments involving IVF as it would undoubtedly require that all embryos produced would have to be placed in the woman's uterus. Presumably, this would have to include the placing in the uterus of embryos even if they were known to be defective.⁶⁶

The Constitutional Review Committee in 1996 also addressed this difficulty in the state of the law and concluded that a clearer legal definition is needed as to when the unborn acquire the protection of the law. They were undecided as to the effect of this uncertainty in constitutional terms, concluding that if

61. Ó Cearúil, M., (1999). *Bunreacht na hÉireann: A Study of the Irish Text*. Dublin, Government of Ireland Publications. p. 548–549.

62. McAvoy, S., (2008). From Anti-Amendment Campaign to Demanding Reproductive Justice: The Changing Landscape of Abortion Rights Activism in Ireland, 1983–2008, in Schweppe, J. ed., *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: The Liffey Press. p. 24.

63. Foley, J.A. and Lalor, S., (1995). Eight Amendment Act – Oireachtas Debate *Annotated Constitution of Ireland 1937–1994*. Dublin: Gill and McMillan. p. 235.

64. n. 5 above at p. 97.

65. *Attorney General (SPUC) v. Open Door Counselling* [1988] IR 593 (at 598).

66. Shercock, A., (1989). The Right to Life of the Unborn and the Irish Constitution. *Irish Jurist*, 13; 24.

it were specified within a definition that the protection of Article 40.3.3 extended to *in vitro* fertilisation, legal problems could arise in relation to some practices in this area. If, as an alternative it was decided to specifically exclude *in vitro* fertilisation from the protection of Article 40.3.3 the result could appear anomalous.⁶⁷

In the Green Paper on Abortion published in 1999, an attempt was also made to address this issue. It was suggested that in trying to change the law on abortion should an *in vitro* embryo come within the protection of Article 40.3.3, then embryo research would be ruled out in Ireland.⁶⁸ Kingston also agreed with the Constitutional Review Group in concluding that due to the great uncertainty around Article 40.3.3, it is difficult to identify if the protection offered by it to the 'unborn applies from the moment of fertilisation, the moment of implantation, or from some later date'.⁶⁹

In contrast, Madden has argued that such an interpretation may not be strictly accurate.⁷⁰ She claims that for the purposes of *in vitro* fertilisation (IVF), if the word 'unborn' is interpreted as meaning 'not yet born' or 'with the potential to be born', then

in light of the biological development of the early embryo and the absence of potential in the pre-implantation embryo, it is likely that the Constitutional protection extends only to the embryo after implantation in the uterus.⁷¹

In line with this argument Madden appears to favour a gradualist/potentiality approach where she proposes that the acquisition of moral status and, by extension, constitutional protection, should be linked to the stage of biological development. She contends that the pre-implantation embryo is not sentient, and therefore the constitutional provision has no application. I would agree with the assertion that the full extent of the protection afforded by Article 40.3.3 should not apply to the early embryo prior to implantation. This should not mean, however, that no protection is afforded to such entities.

Recent legal developments

Over the last 20 years, no effort was made on the part of the legislators to reduce the uncertainty surrounding the term 'unborn'. Hence the implications of this uncertainty

67. The All-Party Oireachtas Committee on the Constitution 1996–1997. Report of the Constitutional Review Group, 1996. Articles 40–44. Introduction to Fundamental Rights, p. 250–256. Dublin: Stationary Office. Available at: <http://www.constitution.ie/reeports/crg.pdf>. [Accessed 12 April 2011].
68. The All Party Committee on the Constitution. 5th Progress Report: Abortion. Appendix-Green Paper on Abortion. Government of Ireland, 1999, p. 125 – at paragraph 7.05–7.13. Dublin: Government Stationary Office. Available at: <http://www.constitution.ie/reports/crg.pdf>. [Accessed 12 April 2011]
69. Kingston, J., Whelan, A. and Bacik, I., (1997). Constitution Law on Abortion. *Abortion and the Law*. Dublin: Round Hall Sweet and Maxwell. p. 23–36.
70. Madden, D., (2002). In Vitro Fertilisation. *Medicine, Ethics and the Law*. Dublin: Tottel Publishing Ltd. p. 276.
71. Madden, D., (2008). Article 40.3.3 and Assisted Human Reproduction. In Schweppe, J. ed., (2008) *The Unborn Child, Article 40.3.3 and Abortion in Ireland*. Dublin: The Liffey Press. p. 310.

remained for both AHR and hESC research. It seemed that this anomalous situation would continue indefinitely until the case of a separated couple (who were disputing the future of three frozen embryos from an IVF cycle) came before the Irish High Court.⁷² The Court had to examine firstly the private law issue of contract and consent to the procedures involved in IVF, and secondly the constitutional law question of the status of the frozen embryos in relation to Article 40.3.3.⁷³ In the High Court, Mr Justice McGovern examined the legislative history of the Constitution and the Eighth Amendment in particular. In *The State (Healy) v. Donoghue*, Chief Justice O'Higgins stated that the Preamble to the Constitution

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.⁷⁴

Mr Justice McGovern claimed that these views affirmed that changing values in society meant that rights not previously acknowledged under the Constitution could now be firmly established. They were, however, not authority for the proposition that the word 'unborn' should be given a different meaning than that intended in 1983 when the Eighth Amendment was introduced, as the clear purpose of that amendment was to deal with the issue of abortion.⁷⁵ The court noted that in all previous cases pertaining to Article 40.3.3, no consideration was given as to whether or not the word 'unborn' included embryos *in vitro*. Referring to the English High Court case of *Smeaton*, he agreed with Mr Justice Munby, the presiding judge, that

the question of when human life begins as a matter of morality, or indeed biology, is not the same as the question of when pregnancy begins for the purposes of the law.⁷⁶

Mr Justice McGovern went on to state that despite the various definitions offered by the many witnesses called in this case, it was not possible in his opinion for 'this Court to state when human life begins'.⁷⁷ He concluded that there was no evidence that it was ever in the mind of the people voting on the Eighth Amendment to the Constitution in 1983 that 'unborn' meant anything other than a foetus or child within a woman's uterus

72. *R. (M) v. R (T) & Ors* [2006] IEHC 359 (15 November 2006). Available at: <http://www.bailii.org/ie/cases/IEHC/2006/359.html>. [Accessed 12 April 2011].

73. For a fuller discussion of this case see Gough, F., (2010). Ireland and the Frozen Embryo: A Slight Thawing? *Medical Law Review*. Spring. Vol.18. No.2. p. 239–247.

74. *The State (Healy) v. Donoghue* [1976] I.R.325 at 347

75. n. 72 above – paragraph on 'Principles of Constitutional Interpretation'.

76. *The Queen on the application of Smeaton v. Secretary of State for Health* [2002] FLR 146 (2002) 66 BMLR 63. n. 68 above- Judgement of Mr Justice McGovern, paragraph 2 – 'The Issues'.

77. n. 72 above from Judgment of Mr J. McGovern, paragraph 2, subparagraph – 'Are the frozen embryos unborn within the meaning of Article 40.3.3 of the Constitution of Ireland?'

and that to infer otherwise and extend the term unborn to include 'embryos outside the womb or embryos *in vitro* would be to completely ignore the circumstances giving rise to Article 40.3.3'.

Mr Justice McGovern found that the word 'unborn' did not include embryos *in vitro* and therefore did not include the three frozen embryos at the heart of the dispute in this case, although such embryos are deserving of special respect. As a consequence, such embryos would not be afforded constitutional protection. He further suggested that given this, in the absence of any legislation or precedent, 'embryos outside the womb have a very precarious existence' and that as the proper function of the Courts at the end of the day is to implement and apply the law, not morality, it should not be a matter for the Courts to decide whether the word 'unborn' should or should not include embryos *in vitro*. It should be up to the Oireachtas or the people through the process of a Constitutional Amendment to make such decisions.⁷⁸ Unlike many of his predecessors, Mr Justice McGovern in his judgment did not allude to the role of natural law within the Irish Constitution but attempted to avoid using the law to enforce a moral judgment by separating the roles of 'law' and 'morality', and to strictly interpret the Constitution in a positivist manner. This High Court judgment was appealed to the Supreme Court, on grounds of both the private and constitutional law issues, and came before the Supreme Court early in February 2009.⁷⁹

The judgment in this case was finally handed down in December 2009. Mr Justice McGovern's judgment was upheld unanimously by the five judges of the Supreme Court. According to Mrs Justice Denham, this case 'was 'not about the wonder and mystery of human life', but simply a matter of construing the word 'unborn' in the Constitution to determine its constitutional meaning.⁸⁰ She emphasised that the main issue was a determination if the three frozen embryos fell under the protection of Article 40.3.3 or not. However, Mrs Justice Denham did not acknowledge that in practical terms these issues are not necessarily quite as distinct as she asserted, as any future policy reform would necessitate addressing and compromising on moral issues as well as hermeneutics. In her elegant judgment she explained that the original aim of the constitutional amendment was to strengthen the protection afforded to the embryo by s.58 of the Offences Against the Persons Act (OAPA) 1861,⁸¹ thus concurring with Justice McCarthy in *Attorney General v X* who stated that

78. n. 72 above at paragraph on 'Other Issues'.

79. *Roche v. Roche & Ors* [2009] IESC 82.

80. Unreported judgment of Denham J., at paragraph 45, p. 24. Available at: www.supremecourt.ie/Judgments.nsf/1b0757edc371032e802572ea0061450e/12. [Accessed 12 April 2011].

81. 'Every woman, being with child who, with intent to procure her own miscarriage, shall unlawfully administer to herself poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent, and whosoever, with intent to procure a 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, shall be guilty of felony, and be convicted thereof shall be liable. s.58 Offences against the Persons Act 1861.

The [Amendment's] purpose can be readily identified—it was to enshrine in the Constitution the protection of the right to life of the unborn thus precluding the legislature from an unqualified repeal of s.58 of the Act of 1861 [which prohibits abortion] or otherwise in general, legalising abortion.⁸²

Both Mr Justice Hardiman and Mr Justice Geoghegan agreed that the purpose of Article 40.3.3 was to prevent the decriminalisation of abortion, and that the appellants had failed to establish that frozen embryos were 'unborn' within the meaning of the Article. Mr Justice Fennelly supported this statement and declared his concern 'at the total absence of any form of statutory regulation of in vitro fertilisation in Ireland'.⁸³ Mr Justice Hardiman also noted in dismissing the appeal that there has been a 'marked reluctance on the part of the legislature actually to legislate on these issues'. He warned that

If the legislature does not address such issues, Ireland may become by default an unregulated environment for practices which may prove controversial or, at least, to give rise to a need for regulation.⁸⁴

The decision of Supreme Court to dismiss the appeal, by unambiguously ruling that frozen embryos were not unborn within the meaning of Article 40.3.3 has important implications beyond the confines of this case. It would appear that as a consequence of this judgment, there is no legal prohibition to hESC research, since surplus embryos from IVF should now be available, and no legal impediment to other related therapeutic applications (such as pre-implantation diagnosis) taking place in Ireland. As confirmed by Justice Hardiman, the ruling also removes any threat to the legality of contraceptive methods which rely on the prevention of implantation, such as the IUD and post-coital pill.⁸⁵

Although providing clarity in one aspect of the law, the Roche case fails to define what protection should be afforded to a frozen embryo. It did, however, highlight the urgent need in Ireland to address the many issues that have arisen as a result of medical and scientific advances in the areas of hESC research and AHR, because 'scientific developments in the areas of embryology and the culturing of stem cells', according to Mr Justice Hardiman, 'will not stand still' waiting for Ireland to update its laws.⁸⁶

hESC research policy in Ireland

In its report on hESC research, the European Commission found that there is no consensus across the EU about what the limits and conditions for hESC research should be, nor

82. *Attorney General v. X* [1992] IR 1, [1992] ILRM 401, [1992] CMLR 277.

83. Unreported judgment of Fennelly, J., p. 40.

84. Unreported judgment of Hardiman J., paragraph on Article 40.3.1.

85. n. 84 above.

86. n. 84 above.

what protections are afforded to the human embryo.⁸⁷ However, no jurisdiction, no matter how permissive its regime, has produced legislation denying human embryos some moral status.⁸⁸ There has been some attempt to develop policy in Ireland on hESC research despite the lack of legislation. The Irish Government established the Commission on Human Reproduction (CAHR) in March 2000, asking it to 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.⁸⁹

The achievement of *in vitro* fertilisation was acknowledged by the Commission to raise a dilemma for both doctors and society as to the fate of those embryos surplus to requirements in reproductive terms.⁹⁰ The Commission's report, published in 2005, contained 40 recommendations, with the main recommendations addressing regulatory issues. The first of these proposed that 'a regulatory body should be established by an Act of the Oireachtas to regulate AHR services in Ireland'.⁹¹ In establishing such a body, the Oireachtas would be following international best practice. Ideally, the regulatory body, though independent would advise the government on all matters relating to AHR and associated procedures including hESC research. A provision would be made within the legislation for a regular review to accommodate any scientific or medical advances and take cognisance of social changes.⁹²

A public consultative process was undertaken by the Commission to fulfil its remit. Public attitudes towards AHR and embryo research were measured through a questionnaire, the staging of a public conference, and telephone interviewing of a representative sample of the population. The data so obtained was noted in the executive summary of the report, and suggested that public opinion 'ranges from total opposition to all forms of AHR on the one hand to uncritical acceptance of any assistance that science can give to infertile people on the other'.⁹³

In considering the arguments for and against embryo research the Commission recognising the existence of three basic positions:

(i) research should not be permitted; (ii) research should be permitted but only on surplus embryos; and (iii) research should be permitted on surplus embryos and on embryos specifically generated for research.⁹⁴

87. Harris, J., Bortolotti, L. and Irving, L., (2005). An Ethical Framework for Stem Cell Research in the European Union. *Health Care Analysis*, 13, 157–162.

88. Halliday, S., (2004). A Comparative Approach To The Regulation Of Human Embryonic Stem Cell Research In Europe. *Medical Law Review*, 12, 40–69.

89. Report of the Commission on Assisted Human Reproduction (2005) p. v (foreword). Dublin: Government Publications Office, Molesworth Street. Available at: <http://www.dohc.ie/publications/cahr.html>.

90. n. 89 above (foreword).

91. Report of the Commission on Assisted Human Reproduction (2005) p. 8.

92. n. 89 above, chapter 9, p. 67–72.

93. n. 89 above at p. xiii

94. n. 89 above at p. 57

Position (ii), that research should be permitted on surplus embryo, was ultimately the position recommended by the Commission, although one member demurred from this conclusion. It was also proposed by a majority of CAHR members that embryo research, including embryonic stem cell research, should be permitted on surplus embryos that are donated for research. This would only be allowed up to 14 days post-fertilisation under stringently controlled conditions and for specific purposes only. These conditions and specific purposes would be stipulated by the new regulatory body. Probably the most important recommendation of a majority of the Commission was that

the embryo formed by IVF should not attract the legal protection until it is placed in the human body, at which stage it should attract the same level of protection as the embryo formed *in vivo*.⁹⁵

The creation of IVF embryos for research was ruled out by the CAHR, as was reproductive cloning and the generation and use of interspecies or hybrid embryos. Despite it being more than 5 years since the Commission reported, there has been no attempt to enact any of its recommendations in legislation.

Notwithstanding the failure of the legislature to act on the report of the CAHR, another report was commissioned into the ethical, scientific and legal issues in stem cell research. This was published by the Irish Council on Bioethics in 2008.⁹⁶ In their report the ICB presented a thorough summary of the current scientific and legislative debate about the generation and use of embryos and stem cells in research, and of the ethical issues central to these debates. The lack of a legal impediment to the importation into Ireland of embryonic stem cell by scientists was particularly noted by the ICB. Unlike doctors who may be working in the same field, scientists are not prohibited from importing stem cells due to the absence of specific legislation or professional constraints. Medical doctors are restricted as they are bound by guidelines from the Medical Council of Ireland.

The Irish Medical Council currently provides the only recommendations pertaining to this area of research in Ireland in their 'Guide to Professional Conduct and Ethics for Registered Medical Practitioners'.⁹⁷ A practicing medical doctor must adhere to these guidelines or risk censure or even removal from the register of medical practitioners. In 2004 the Medical Council's guidelines stated that 'any fertilised ovum must be used for normal implantation and must not be deliberately destroyed'.⁹⁸ It further asserted that to create 'new life forms for experimental purposes' or to deliberately destroy '*in vitro*

95. n. 89 above at p. 34

96. Ethical, Scientific and Legal Issues concerning Stem Cell Research. Irish Council for Bioethics (Comhairle Bitheitice Ná hÉireann) Opinion 2008. Published by The Irish Council for Bioethics, Dublin.

97. Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2009). 7th ed. Medical Council of Ireland. Available at: <http://www.medicalcouncil.ie>. [Accessed 12 April 2011].

98. A Guide to Ethical Conduct and Behaviour (2004) Medical Council of Ireland. March. Section F – Genetic Testing and Reproductive Medicine. Paragraph 24.5, p. 36.

human life already formed' would be considered to be professional misconduct.⁹⁹ These comments were revised in the new edition to simply state that a doctor 'should not participate in creating new life forms solely for experimental purposes' and should not 'engage in human reproductive cloning.'¹⁰⁰ There is no repeat of the statement in the 2004 guidelines that destroy or generate an embryo would constitute professional misconduct. When questioned as to this omission Prof Kieran Murphy, the President of the Medical Council, stated the Council was 'exercised' by the lack of legislation in this area and was thus unable to take up a position.¹⁰¹ The conclusion could be drawn, therefore, that there are no legal restrictions to carrying out embryonic and stem cell research by researchers who are not registered medical practitioners. The ICB does however note that,

Notwithstanding the lack of specific legislation pertaining to stem cell research in Ireland, within Europe there are a number of overarching regulatory frameworks in existence, which have implications for the legislative and regulatory processes for stem cell research that are adopted in Ireland. The European Convention on Human Rights and Biomedicine (1997) makes a number of references to research involving embryos and cloning. Article 18.1 of the Convention permits research on embryos *in vitro* where National legislation allows, provided the embryos are afforded sufficient protection.¹⁰²

Unfortunately, Ireland has yet to ratify this convention.¹⁰³ The Report of the Bioethics Council concedes that research involving human embryos is regarded by some people as providing an opportunity to gain important scientific knowledge, but a significant number of people in Ireland are very strongly opposed to it.¹⁰⁴ The lack of political will to date, to initiate legislative action according to the ICB has allowed a certain level of anxiety to develop around these issues and 'undermines the moral value of the human embryo'. The construction, however, of a cohesive and comprehensive regulatory structure would, in all likelihood, put pay to these anxieties, as it is generally recognised that systems which,

acknowledge and respond to public fears and doubts provide a sense of control, offer public access and influence and offer a forum and time for discussion and education in that space between knowledge and ignorance that trust must occupy.¹⁰⁵

99. n. 98 above, paragraph 24.1, p. 35.

100. n. 97 above, paragraph 20.4, p. 21.

101. Ganty, D., (2009). Cracking the Code of Ethics. *Irish Medical Times*. 27 November. p. 26.

102. n. 96 above at p. 64.

103. CETS No. 164. protocol to Convention on Human Rights and Biomedicine Status as of 15 July 2010. Council of Europe (<http://www.coe.int>) [Accessed 12 April 2011].

104. n. 96 above at p. ii. (foreword)

105. The ICB itself has felt the impact of the downturn in the Irish economy. It was disbanded by the Government in December 2010, with 'savings' being the reason given for its demise. Ireland is now the only country in the EU not to have a national advisory body on bioethics. Some staff were seconded to the Department of Health but the new bioethics body will no longer publish its reports- see <http://www.icb.ie>, 1 December 2010 and BARRON, D., (2011). Staff from ICB seconded to Department of Health in *Irish Medical News* 2 February 2011. Available at: <http://www.imn.com>. [Accessed 12 April 2011].

The ICB also noted that the failure by Ireland to provide a system governing stem cell research and its applications is hindering the development of hESC research in Ireland, and the consequences of this may be felt in economic terms.¹⁰⁶

In recent years some academic institutions which have been involved in stem cell research have themselves attempted to introduce regulations. The governing body of University College Cork (UCC) recommended in November 2008, by a very slim majority (16 to 15), that the University's Academic Council would allow hESC research to take place at UCC 'under strict guidelines drawn up by the University Research Ethics Board (UREB)'.¹⁰⁷

UCC verified that it had taken the two expert independent reports published in this context in recent years, the CAHR Report (2005) and the Irish Bioethics Council Opinion (2008), into consideration when drawing up its guidelines. The statement from UCC confirmed that the university 'in the absence of either national legislation or policy', had sought to impose 'the strictest internal control over research in this area'.¹⁰⁸ According to these guidelines, the importation of hESC lines would only be permitted once the scientific merit of the proposed research had been established. Before permission to use hESC lines would be given, the feasibility of using alternative research methods not requiring hESCs must be scrutinised, while approval of all research projects must be by majority of UREB members after full consideration of the scientific and ethical issues. No destructive research on living human embryos would be allowed under these proposals. It was the absence of national legislative measures to guide future hESC research within the university that compelled UCC to draw up and approve such proposals, and in doing so they do not appear to be violating any existing constitutional provisions. This situation would appear to provide another cogent reason why national regulations should be introduced—there is no guarantee that another institution would take as stringent an approach to regulating hESC research as UCC.

Shortly after UCC's proposals were launched, a 'Stem-Cell Research (Protection of Human Embryos) Bill' was introduced into Seanad Éireann in November 2008 by Senator Rónán Mullen, an independent senator representing the National University of Ireland, Galway (NUIG). The aims of this Bill were set out in the explanatory memorandum. It seeks

to regulate stem cell research in the State by prohibiting embryo-destructive research and related activities, such as the creation of human embryos, human clones or human-animal hybrids for research purposes.¹⁰⁹

106. Johnston, M. H. and Petersen, K., (2008). Public Interest or Public Meddling? Towards an Objective Framework for the Regulation of Assisted Reproductive Technologies. *Human Reproduction*, 23, 713–728.

107. Culliton, G. (2008). UCC's code of practice for stem cells. *Irish Medical Times*. Dublin. 16 November.

108. n.107 above.

109. An Bille um Thaighde Gaschille (Suthanna Daonna a Chosaint) 2008 Stem-Cell Research (Protection of Human Embryos) Bill 2008. [No. 60 of 2008] The Stationary Office, Government Publications Sale Office, Molesworth Street, Dublin 2.

The Minister of State at the Department of Enterprise, Deputy Devins, spoke on behalf of the Government during the course of the debate and acknowledged that currently there is no legislation in Ireland ‘governing intervention in the natural process of creating human life’.¹¹⁰ The enactment of this Bill would also have effectively prohibited the use of any cell lines derived from embryos, even if the research from which the cell lines were obtained took place outside the jurisdiction. Despite speaking against this Bill, several senators emphasised that they were in agreement with Senator Mullen as to the need to legislate in this area. This particular proposal, they felt however, posed a difficulty in that it did not hold out any prospect of regulation; rather it simply banned hESC research altogether. By doing so they considered that the Bill, in this form, sent out a message that Ireland was not open to scientific research.¹¹¹ Despite vigorous debate, no vote was actually taken on this bill in the Seanad.

The future enabled?

The current ‘Irish solution’ to the many issues surrounding hESC research—i.e. simply failing to address them—is no solution at all. A range of regulatory regimes exists in most of the Western world which aim to protect the interests of not only the *in vitro* embryo but also patients and society as a whole.¹¹² These regimes have been accepted as falling into one of four possible positions: A, B, C and D.¹¹³ In position A, all human embryo research, including the derivation of hES cells, is prohibited.¹¹⁴ Research is allowed to proceed on hES cells extracted before a specific dead-line in position B but no research is permitted on embryos.¹¹⁵ Position C allows the isolation of, and research on hESCs obtained from embryos which are surplus to requirement of clinical IVF programmes, governed by the 14-day embryo research limit. Position D additionally allows research on embryos produced specifically for research by somatic cell nuclear transfer (SCNT) into human ova.¹¹⁶

110. Deputy Devins. [http://www.Oireachtas.ie/SeanadDebates /26 November 2008](http://www.Oireachtas.ie/SeanadDebates/26%20November%202008) [Accessed 12 April 2011].
111. Senator Ivana Bacik. [http://www.Oireachtas.ie/SeanadDebates/26 November 2008](http://www.Oireachtas.ie/SeanadDebates/26%20November%202008) [Accessed 12 April 2011].
112. Gough, F., (2010). Public Policy and Human Embryonic Stem Cells Research. A Policy Document for The Irish Stem Cell Foundation. Available at: [http://www.irishstemcellfoundation.org /news](http://www.irishstemcellfoundation.org/news) [Accessed 12 April 2011]
113. Knoepffler, N., (2004). Stem Cell Research: An Ethical Evaluation of Policy Options. *Kennedy Institute of Ethics Journal*; March, 55–74. WALTERS, L., (2004). Human Embryonic Stem Cell Research: An Intercultural Perspective. *Kennedy Institute of Ethics Journal*; March, 3–38.
114. Jones, D. G. and Towns, C. R., (2006). Navigating the Quagmire: The regulation of human embryonic stem cell research. *Human Reproduction* 21, 1113–1116.
115. Heinemann, T. and Honnefelder, L., (2002). Principles of Ethical Decision Making Regarding Embryonic Stem Cell Research In Germany. *Bioethics*, 16, 530–543.
116. Mason, J. K. and Laurie, G. T.(2006) The Management of Infertility and Childlessness. *Mason and McCall Smith's Law and Medical Ethics*. 7th ed. Oxford: Oxford University Press. p. 71–119

Through the *Human Fertilisation and Embryology Act 1990*, the UK was one of the first countries in the world to introduce legislation regulating embryo research. The Human Fertilisation and Embryology Authority (HFEA) was established by the act to oversee all aspects of ART in the UK, and to provide the government with information and advice.¹¹⁷ Several revisions of the original 1990 Act means that the UK currently applies Policy Position D to hESC research. As a consequence of the adoption of this policy position, the UK has become the most productive country in Europe in terms of publications in the area of hESC research. It has also benefitted from significant investment being directed to hESC research within the UK.¹¹⁸

Responsible regulation in this area faces many challenges, including the complexity of the actual science involved, engagement with strongly held moral values, and not least the polarising effect of the abortion debate in Ireland in the past. It can be difficult to conduct a debate on an issue of public policy where opposing sides are separated by an ‘apparently unbridgeable chasm of moral disagreement’, as evidenced by the ongoing debate over legalising abortion in Ireland.¹¹⁹ Most people recognise that the debate about the status of the embryo, whether *in vitro* or *in vivo* does involve an confrontation with one’s conscience. And if after such a struggle, another individual comes to a different moral judgment than that which one may hold, it must be acknowledged that the other person has made a moral decision and has the right to hold that belief, and to act on that belief.¹²⁰

As Archard says, ‘granting the legal permission to do what others may deem immoral but acknowledge to be conscientiously determined is a mark of a civilised and tolerant society’.¹²¹ Archard explains that rights-based constitutionalism requires respect for the holding of different moral values and religious beliefs within a society, and this means that it is wrong for any government to enforce, through its policies or laws, any one particular moral or religious viewpoint.¹²² Jurists such as Dworkin endorse the view that decisions about reproductive matters are properly private in the sense of being matters over which the individual should be sovereign.¹²³ In this sense Dworkin’s arguments are in accordance with the findings of the US Supreme Court in *Roe v. Wade* and of the Irish Supreme Court in *McGee v AG* which viewed choices about reproductive issues as protected by a constitutional right to privacy. However, in this era of AHR, hESC research and the benefits which may accrue from potential therapies developed from such research, the question remains whether procreation can or should still be regarded as essentially a private and individual matter.

117. Human Embryology and Fertilisation Act 1990, s.13, U.K.

118. Winston, R., (2007). Does Government Regulation inhibit Embryonic Stem Cell Research and can it be effective? *Cell Stem Cell*, 1, 27–34.

119. Archard, D., (1995). Law and Moral Disagreement: The Case of Abortion. *Legal Theory in Ireland*. Dublin: Oak Tree Press. p. 72–83.

120. n. 119 above at p. 80.

121. n. 119 above at p. 81.

122. n. 119 above at p. 76.

123. Dworkin, R., (1993). *Life’s Dominion. An Argument about Abortion and Euthanasia*. London: Harper Collins. p. 105.

Given that it is most unlikely that a consensus on the moral status of the *in vitro* embryo will be reached in the near future, the question becomes one of how a political compromise might be reached which would legally permit hESC research in certain circumstances. The present failure to resolve the 'Law vs. Morality' conundrum has led to problems managing scientific research. The question of what a lack of legislation means for the future of hESC research in Ireland was answered recently when two of Ireland's leading science funding agencies, the Health Research Board (HRB)¹²⁴ and Science Foundation Ireland (SFI), stated that they will not fund research projects using hESCs in the absence of legislation that specifically provides for such research.¹²⁵ The embargo came from the Government through the Department of Health. This 'regulation 'by default' will do nothing to improve Ireland's international reputation as a centre for scientific research. There is also the question of what the absence of legislation in Ireland renders permissible. According to the Irish Medicines Board (IMB), in the absence of national legislation prohibiting the use of medicinal products derived from embryos, once authorised by the European Medicines Agency, such a therapy could be supplied into Ireland on a named patient basis.¹²⁶

The current legal uncertainty that exists in Ireland in relation to the appropriate use of non-implanted embryos or the importation of stem cell lines by scientists has led Dr Dolores Dooley, former chairperson of the Irish Council for Bioethics, to call on behalf of the Council for the Oireachtas to establish an independent regulatory authority.¹²⁷ This authority could be charged with clarifying the ambiguity in the meaning of the term 'unborn', and legislating for the registration, licensing and inspection of persons and premises working with human embryos. She has strongly supported the call to bring to an end the 'legal vacuum' that currently exists in this area in Ireland as it undermines the moral value of the human embryo but also because it 'undermines people working in the field of infertility treatment, and the thousands of couples availing of IVF'.¹²⁸

In the adoption of a regulatory scheme an acknowledgment must be made of the lack of social consensus regarding the potential 'harms' and potential therapeutic 'benefits' for many AHR procedures and hESC research. There must, however, also be a weighing of the moral value of human embryos against the moral value of human welfare, in an attempt to balance an acceptance of the value of human life against the obligation to care for existing human kind generally.¹²⁹ In the near future it is clear that Ireland will have to

124. <http://www.hrb.ie> [Accessed 12 April 2011].

125. Burke-Kennedy, E., (2010). Funding Ban on Research Using Human Stem Cells. *The Irish Times Health Supplement*. 12 October. p. 2.

126. Personal communication with the Blood and Tissues Manager of the Irish Medicines Board (<http://www.imb.ie>)

127. Barron, D., (2011). Staff from ICB Seconded to Dept. of Health. *Irish Medical News*. 2 February [Online] Available at: <http://www.imn.com> [Accessed 12 April 2011].

128. Dooley, D., (2008). Head to Head: Should the State legislate for embryonic stem cell research? *The Irish Times*, 12 May,

129. McClean, M. R., (2001). Stem Cells: Shaping the Future in Public Policy. from *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*, eds. Holland, S., Lebacqz, K. and Zoloth, L., Cambridge, MA: MIT Press, p. 197–207

face up to the difficult challenge of defining at which point the constitutional protection of the unborn, specified by Article 40.3.3, begins. It must be acknowledged that finding an appropriate policy will involve serious moral debate, and a willingness to be open to compromising policy solutions. A political decision must be made. The result of the recent election, however, has made this unlikely in the near future, as the main coalition partner, Fine Gael, is opposed to allowing stem cell research which uses human embryonic stem cells to take place in Ireland,¹³⁰ while the junior coalition partner, the Irish Labour Party, went as far as including a commitment to legislate in favour of hESC research in its manifesto.¹³¹ This dilemma has not gone unnoticed by the international scientific community.¹³²

The recommendation of both the Report of the Commission on Assisted Human Reproduction and the Opinion of the Irish Bioethics Council is that hESC research be allowed on donated 'spare' embryos from IVF cycles up to a maximum of 14 days. In addition, they recommend that the generation of embryos for research should not be allowed nor should cloning be permitted.

I would support these recommendations and propose that the carefully regulated use of supernumerary IVF embryos—embryos that are otherwise destined to be destroyed—for the purposes of embryonic stem cell research aimed at alleviating human suffering is morally acceptable. The current absence of a regulatory regime creates confusion and could potentially allow improper research to take place.

A greater openness and transparency in stem cell policy in Ireland is urgently needed. This would be best realised through the establishment of a regulatory regime which sets out the limits, as well as the opportunities, for hESC research in Ireland.¹³³ It is essential that Ireland develops a flexible regulatory scheme that allows the public/professional dialogue in this area to continue while respecting the ethical and moral values of 21st century Irish citizens.

130. <http://www.prolifecampaign.ie/pages.php?id=175> [Accessed 12 April 2011].

131. <http://www.labour.ie/manifesto> One Ireland: jobs, reform, fairness. p. 78 [Accessed 12 April 2011].

132. Abbott, A., (2011). Irish Election raises question for stem cell research. 28 February. The Great Beyond. Available at: <http://www.go.nature.com/ftx2hu> [Accessed 12 April 2011].

133. Caulfield, T.; (2004). Law and Policy in the Era of Reproductive Genetic. *J Med Ethics*, 30, 414–471.