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Legislating Science and Morality:

Statutory Schemes for the Regulation of Reproductive Technology in Australia, Canada and the United Kingdom

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February 1997

A thesis submitted to the department of Graduate Studies and Research in partial fulfilment of the requirements of the degree of Master of Laws, specialisation in Bioethics.

Abstract

Reproductive and genetic technologies ("RGTs") raise many complex social, legal and ethical issues. Several jurisdictions have perceived a need for government intervention and regulation of the conduct of RGTs, and consequently have enacted legislation to this end. In three states in Australia (Western Australia, Victoria and South Australia) and in the United Kingdom, legislation has been introduced which imposes a regulatory scheme according to which RGTs must be practised in each jurisdiction. Legislation based on the recommendations of the Royal Commission on New Reproductive Technologies is currently before the Canadian parliament.

This thesis examines from a comparative perspective the proposed legislation in Canada and legislation enacted in the United Kingdom and the Australian states to govern the conduct of RGTs. Particular emphasis is given to the manner in which the legislation seeks to deal with the rapid pace of scientific development and with moral pluralism. The focus of the thesis is on the effectiveness of the legislation in these jurisdictions in light of the relationships between law and science and law and morality.

Résumé

Les techniques de reproduction et la technologie génétique ("les TRG") soulèvent de multiples questions sociales, juridiques et morales. Plusieurs juridictions ont ressenti le besoin d'une intervention gouvernementale et d'une réglementation de la conduite des TRG. En Australie, dans les états d'Australie-Occidentale, d'Australie-Méridionale et de Victoria, ainsi qu'au Royaume-Uni, des lois ont été promulgués à cet effect. Au Canada, un projet de loi basée sur les recommendations de la Commission royale sur les nouvelles techniques de reproduction est actuellement à l'étude devant le parlement.

Cette thèse examine, d'un point de vue comparatif, la législation régissant les TRG telle qu'elle est proposée au Canada et la législation correspondant en vigueur en Australie et au Royaume-Uni. Une attention particulière est accordée à la façon dont ces différentes lois traitent des difficultés engendrées par la rapidité des développements scientifiques et le pluralisme moral. Cette thèse se concentre sur l'effectivité de la législation de chaque juridiction à la lumière des relations entre le droit et la science et le droit et la moralité.

Acknowledgments

I would like to thank my supervisor, Professor Patrick Healy, for his support and guidance in writing this thesis. I would also like to thank Professors Alison Harveson-Young and Margaret Somerville for their assistance and helpful advice, Keven Richard for lending me his computer during the 1996 summer in Montreal, Vincent Laroche for assistance on the French translation of the abstract, Dennis Koutoulogenis for proofreading and Lesley Haysom for obtaining materials for me back home in Australia. Finally, I would like to thank my teachers and classmates for providing me with the intellectual stimulation during my year at McGill that enabled me to undertake and complete this thesis.

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I INTRODUCTION

On 14 June 1996, the Canadian Health Minister David Dingwall introduced legislation into the Canadian Parliament prohibiting several unacceptable uses of new reproductive and genetic technologies.[1] This legislation is to be supplemented by a regulatory scheme to be enacted as an amendment to the first piece of legislation following further public and government consultation. To this end, the Health Minister has released a discussion paper for public comment, and is initiating consultations with Canadian provinces and territories.[2]

The government's proposal follows the controversial Canadian Royal Commission on New Reproductive Technologies, which reported in November 1993.[3] Seen as an opportunity to do something different from the various national and international commissions that came before it, particularly from a feminist perspective,[4] the outcome of the Royal Commission and the process by which it was achieved were generally disappointing. The Commission's report was criticised on several grounds, including that all decisions concerning the operation of the Commission were made unilaterally by the Chair, a member of

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1 Bill C-47, *An Act respecting human reproductive technologies and commercial transactions relating to human reproduction*, 2nd sess., 35th Parl., 1996 (1st reading, 14 June 1996) [hereinafter Canadian Bill].

2 Government of Canada *New Reproductive and Genetic Technologies Setting Boundaries, Enhancing Health* (Ottawa: Minister of Supply and Services, June 1996).

3 Canada, Royal Commission on New Reproductive Technologies *Proceed with Care Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Government Services, 1993) (Chair: Dr P Baird) [hereinafter Royal Commission Report]. The controversy surrounding the Royal Commission is described in Basen G, Eichler M & Lippman A, eds, *Misconceptions* (Hull: Voyageur Publishing, 1993) [hereinafter Basen et al] Volume 1, Part III; see also Gray C "The report on new reproductive technologies: Will it lead to change, or gather dust" *CMAJ* 1994; 150: 266-268 at 267; Mickleburgh R "Panel was mired in controversy" *The [Toronto] Globe & Mail* (30 November 1993) A6.

4 See generally Anonymous "Inside the Royal Commission" in Basen et al, *supra* note 3 223 at 233, 236.

the scientific community,[5] and that its public consultation process was less than adequate.[6] When compared with the reports of other commissions, the Royal Commission report is not only superficial, but discloses nothing substantially new in terms of its approach to the issues raised by reproductive and genetic technologies. Despite these and other criticisms, the Canadian government has seen fit to base its legislative approach on the recommendations of the Royal Commission.

Less than two months later, in August 1996, technicians at fertility clinics in Britain began thawing more than 3000 unclaimed frozen human embryos stored at the clinics as part of their IVF programs.[7] This action was required under British legislation passed in 1991 which prohibits clinics from keeping frozen embryos longer than five years without the consent of the "parents".[8] This too was steeped in controversy, attracting strong opposition from various pro-life organisations as well as last minute legal bids by people seeking to prevent the destruction of embryos held on their behalf in fertility clinics.[9] The controversy arose despite the fact that the legislation has been on the statute books since 1991, and that these issues have been discussed in Britain at least since the establishment in 1982 of the

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5 See generally Eichler M "Frankenstein meets Kafka: The Royal Commission on New Reproductive Technologies" in Basen et al, *supra* note 3 196-222.

6 See generally Massey C "The Public Hearings of the Royal Commission on New Reproductive Technologies: An Evaluation" in Basen et al, *supra* note 3 237-252.

7 McCabe A "A very black day for civilization" *The [Montreal] Gazette* (2 August 1996) A13; Laurence J "Plea to couples to save 3,300 embryos from destruction" *The [London] Times* (23 July 1996); Moyes J "A world of anguish in an inch of glass 'Blanket' legislation that is causing despair" *The [London] Independent* (3 August 1996) 1.

8 *Human Fertilisation and Embryology Act 1990* (UK) 1990 c.37.

9 Monmaney T "Death Sentence for human embryos" *The [Montreal] Gazette* (30 July 1996) B1, B14; McCabe *supra* note 7; Kennedy D "Childless woman wins reprieve by serving injunction" *The [London] Times* (3 August 1996); Moyes *supra* note 7.

Warnock Committee, upon whose recommendations the legislation was largely based.

Meanwhile, in May 1995, the government in the Australian state of Victoria passed comprehensive legislation to govern the conduct of reproductive technologies in that state. This legislation replaced earlier legislation enacted in 1984, which shortly thereafter was shown to be inadequate to deal with many of the issues raised by reproductive technologies.

These experiences raise the broad issue of the adequacy of the responses of governments to the issues raised in circumstances, such as those surrounding the use of reproductive technologies, in which there is substantial moral controversy and where scientific developments are occurring at a pace that challenges the law's attempts to deal with them. Within this context, this thesis analyses, from a comparative perspective, proposed legislation in Canada and legislation enacted in the United Kingdom and the Australian states of South Australia, Western Australia and Victoria, to govern the conduct of reproductive and genetic technologies.

This legislation is, respectively, Bill C-47, to be known as the *Human Reproductive and Genetic Technologies Act* if enacted,[10] the *Human Fertilisation and Embryology Act 1990* (UK),[11] the *Reproductive Technologies Act 1988* (SA),[12] the *Infertility Treatment Act 1995* (Vic),[13]

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10 *supra* note 1. As noted above and discussed further below, Bill C-47 as it currently stands contains only criminal prohibitions on unacceptable conduct. Unlike the legislation in the other jurisdictions considered here, the Canadian Bill does not contain a regulatory component, although one has been proposed in general terms by Health Canada: see further Government of Canada *supra* note 2 generally.

11 *Human Fertilisation and Embryology Act 1990* (UK) 1990 c.37.

12 *Reproductive Technologies Act 1988* (SA) No.10 of 1988.

13 *Infertility Treatment Act 1995* (Vic) No.63 of 1995 repealing *Infertility (Medical Procedures) Act 1984* (Vic) No. 10163.

and the *Human Reproductive Technology Act 1991* (WA).[14] This legislation has been chosen because of the similarities in legal systems in each of the jurisdictions, yet different approaches to the regulation of reproductive and genetic technologies revealed in the legislation.

The enactment of legislation in Victoria, Western Australia, South Australia and the United Kingdom and proposals for legislation in Canada follows a gradual increase in state intervention into the practice of medicine over the last thirty years. This intervention stems from a recognition that many issues arising out the practice of medicine are not simply matters of private morality, but have wider implications for society. The state, as protector of the public interest, may be justified in intervening to prevent potential adverse consequences in matters that extend beyond the confines of the private doctor-patient relationship into the realm of public morality.

The political climates in the jurisdictions under consideration support this vision of the role of the state. In contrast to the cultural climate in the United States, which places great emphasis on the exercise of individual rights and views government interference with suspicion, intervention by the state is seen as appropriate and effective in Canada, the United Kingdom and Australia.[15]

That the state has a role to play in the regulation of activities that affect the public interest is assumed in this thesis. It is also assumed that reproductive and genetic technologies are activities that do affect the

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14 *Human Reproductive Technology Act 1991* (WA) No. 22 of 1991. In this thesis the Western Australian, South Australian, Victorian and United Kingdom legislation is collectively referred to as "the legislation".

15 Harvison Young A "New Reproductive Technologies in Canada and the United States: Same Problems, Difference Discourses" [unpublished] at 3-4.

public interest, and that legislation is an appropriate form of state intervention in the context of reproductive and genetic technologies.[16]

The central question that arises for consideration here is what sort of legislative regulatory scheme can be implemented that produces meaningful public policy in circumstances of wide-ranging moral opinion and rapid scientific change. The focus of this thesis is therefore on the effectiveness of reproductive technology legislation in the United Kingdom, Australia and Canada in light of the relationships between law and science and law and morality.

This thesis is largely descriptive of the legislative schemes within this context. Its objective is not to provide a jurisprudential analysis of the substantive issues raised, nor to examine the practical operation of the schemes described. Rather, it aims to identify the legislative schemes in the jurisdictions under consideration and several of the substantive issues that must be dealt with in legislation that aims to govern the conduct of reproductive and genetic technologies.

The background to the British and Australian statutes and the Canadian Bill is considered in Part II. Essentially a literature review, this Part describes the commissions of inquiry preceding the legislation in each jurisdiction, as well as the major ethical and legal issues that arise and must be grappled with by any regulatory scheme in this area. This examination demonstrates the current lack of consensus concerning not only the morality of reproductive and genetic

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16 All of the inquiries that preceded the legislation under consideration here concluded that regulation by way of legislation was needed to deal with the far-reaching social, ethical and legal implications of reproductive and genetic technology to protect the public interest. The appropriateness of state intervention to control the conduct of reproductive and genetic technologies is considered in detail in Law Reform Commission of Canada *Medically Assisted Procreation* Working Paper 65 (Ottawa: The Commission, 1992) [hereinafter *Medically Assisted Procreation*].

technologies but also what constitutes the central moral controversy surrounding their use. Indeed, if there were moral consensus there would be little if any need for legislation since those involved in RGTs would be expected to act morally.[17]

The legislative approaches to the regulation of reproductive and genetic technologies in each jurisdiction are described in Part III. Although superficially similar in terms of the overall regulatory scheme, the legislation in the United Kingdom and the Australian states contains several differences which impact upon decision-making and public policy formation in those jurisdictions. Each statute may be characterised according to its approach to two issues: morally questionable conduct, and the formation of public policy. Broadly speaking, the legislation illustrates two approaches to each of these issues. In the case of morally questionable conduct, the legislation may be either prohibitive or regulatory, while the approach taken to the formation of public policy may be described as prescriptive or facilitative.[18] Each of the statutes contains elements of all of these approaches to some extent. Nevertheless, each tends to reflect a dominant approach to these issues, and this forms the basis of the characterisations made in this study.

Part IV examines the relationship between science and law in more detail. The institution of law and the institution of science do not fit easily together, proceeding on different bases and with different objectives. Science is constantly progressing and accumulating knowledge in order to predict and control the behaviour of natural

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17 Wellman C "Moral consensus and the law" in Bayertz K, ed, *The Concept of Moral Consensus The Case of Technological Interventions in Human Reproduction* (Dordrecht: Kluwer Academic Publishers, 1994) 109-121 at 110.

18 These characterisations are described below in Part III at pp.75-76.

phenomena and to use these phenomena for social purposes. This is typified by the field of reproductive technology, in which scientists seek to understand and then control the processes of conception and embryonic development according to society's reproductive objectives. Law, and in particular legislation, remain fairly static, providing a normative framework within which legitimate social activities, including reproductive and genetic technologies, can take place. Legislation generally applies to relevant situations that may arise in the future. This is problematic when the subject of the regulation is science, since legislation is necessarily dependent on scientific knowledge as it exists at the time the legislation is enacted, and any predictions as to the future will tend to be speculative.[19] Furthermore, as discussed further in Part IV, legislation draws lines and distinctions on policy grounds which are often meaningless from a scientific perspective. The challenge is to produce legislation that recognises and adequately deals with the differences between science and law, so that public policy formed within the legislative framework is applicable to situations as they arise.

The legislation is examined against this background. The difference between law and science is illustrated by the distinction made in the legislation between clinical practice and research. This distinction, which is by no means unique to the legislation but is common in ethics and in law, is analysed in light of the way in which medical progress occurs in practice. Although the distinction is arbitrary and difficult to

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19 Problems of predicting future conduct were raised in the California Supreme Court case of *Tarasoff v Regents of University of California* 17 Cal 3d 425, 551 P 2d 334, 131 Cal Rptr 14 (Ct App 1976) [cited to Cal Rptr] in the context of whether a psychiatrist had a duty to warn a third party that his patient may threaten her with violent behaviour, including killing her. The duty depended, at least in part, on the ability of the psychiatrist to predict future violent conduct on the part of the patient: see in particular at 23-26.

make both in theory and in practice, it is nevertheless necessary. The legislation is also examined in terms of the mechanisms, if any, by which the regulatory bodies in each jurisdiction keep apprised of scientific developments and incorporate these developments into the decision-making process.

Legislation is also problematic when it relates to matters upon which the community is deeply divided. Modern Western society is characterised by moral pluralism: a wide variety and diversity of views exist on morality and on what constitutes "the good life".[20] Canada, Australia and Great Britain reflect this view of modern society. Canada and Australia in particular pride themselves on significant immigrant populations, and multiculturalism and pluralism are generally encouraged. This state of affairs presents a challenge for legislation concerning reproductive and genetic technologies: how to facilitate the formation of public policy that is acceptable to, and binding on, a community that is characterised by moral pluralism. A related concern is how to provide a regulatory scheme that allows disparate interests to be taken into account in the formation of policies and norms of conduct in the area of reproductive and genetic technology.

These issues are examined in Part V. Who decides on the appropriateness of the norms of conduct and policy in the area is important because of the wider implications reproductive and genetic technologies have for society. The elitist model of the British legislation, which tends to place decision-making power in the hands of the scientists and clinicians is compared with the Australian

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20 See further the discussion below at pp.100-101. The political philosophy of liberal pluralism is assumed in this thesis.

legislation which takes an approach based on community representation. The extent to which the community should and can be involved in decision-making under the statutes is examined.

In Part VI conclusions are drawn concerning the appropriate legislative model for regulating morally controversial conduct and producing meaningful public policy in the context of the rapid progression of science and the different interests and moral positions existing in the community.

The recent events outlined at the beginning of this chapter indicate that the analysis in this thesis is timely. While comparative reviews have been carried out in respect of the way in which legislation in several jurisdictions deals with the substantive moral and legal issues arising out of the conduct of reproductive and genetic technologies,[21] none of these examines the legislation in terms of the particular difficulties faced when the law attempts to regulate science and morality. This thesis thus supplements existing reviews by examining these important issues. With the regulatory component of the Canadian system still to be formulated, this study hopes to provide some useful insights into the relative strengths and weakness of the regulatory schemes in operation in comparable jurisdictions.

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21 See for example Knoppers B & Sloss E "Recent Developments: Legislative Reforms in Reproductive Technology" (1986) 18 Ottawa Law Review 663; Knoppers & Le Bris S "Recent Advances in Medically Assisted Conception: Legal, Ethical and Social Issues" (1991) 17 Am J Law & Med 329; and Williams L "Legislation, Inquiries and Guidelines on Infertility Treatment and Surrogacy/Preconception Contracts: A Review of Policies in Seven Countries" in Royal Commission on New Reproductive Technologies *Treatment of Infertility: Assisted Reproductive Technologies* Research Studies Volume 9 (Ottawa: Royal Commission on New Reproductive Technologies, 1993) 279-368. See also Gunning J & English V *Human In Vitro Fertilisation A Case Study in the Regulation of Medical Innovation* (Aldershot: Dartmouth, 1993) at 143-179.

This study may also have broader appeal beyond the field of reproductive and genetic technologies. The bioethics movement, among other things, has challenged traditional notions of the way in which medicine and science should be practised, particularly in the area of biomedical research. As a result, both the state and the community is playing a greater role in the formation of policies concerning the conduct of medicine and science. In addition, the continued rapid pace of scientific development means that unforeseen circumstances will arise in many areas of science that require the scrutiny of the community and/or regulation by the state. While the precise circumstances may be incapable of accurate prediction, the same basic questions concerning the regulation of science and morality will arise. In this respect, the way in which reproductive technology legislation in the jurisdictions considered here have dealt with these issues may be considered a paradigm for similar issues arising in other areas in science and medicine.

II THE CONTEXT OF REPRODUCTIVE AND GENETIC TECHNOLOGY

A. *Introduction*

This chapter provides the context for consideration of the legislation in the balance of this thesis. First, the background to the legislation is described by reference to the commissions of inquiry preceding the legislation in each jurisdiction. Next, several of the ethical and legal complexities surrounding the use of reproductive and genetic technologies are described.

B. *Terminology*

Before turning to the background to the legislation, it is necessary to deal with terminology. The phrase "reproductive technologies" is commonly understood to refer solely to techniques such as *in vitro* fertilisation, artificial insemination and the like, which may be used to assist individuals to conceive a child.[22] However, reproductive technologies are broader than that, and extend to what may be collectively termed "genetic technologies", such as preimplantation and prenatal genetic diagnosis and sex selection, which aim to assist individuals to have a healthy or "good quality" child. What one author has termed "non-reproductive uses of reproductive technology",[23] such as the use of fetal tissue for transplantation purposes, may also fall within the scope of the term "reproductive technologies". The term also contemplates techniques used to prevent

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22 Royal Commission Report *supra* note 3 at 4 and 5.

23 Robertson J A *Children of Choice* (Princeton: Princeton University Press, 1994) at 11.

reproduction - contraception and abortion - as well as research in all of the areas mentioned above.

In this thesis, the phrase "reproductive and genetic technologies" ("RGTs")[24] is used to refer generally to the range of procedures, outlined briefly above, which are associated with reproduction. However as will be seen, not all of the techniques and activities encompassed within the term were examined by the respective commissions, nor fall within the scope of the legislation that was subsequently enacted.

C. *Background to the legislation*

The birth of the world's first "test-tube" baby, Louise Brown, in England in 1978 gave rise simultaneously to wonder and to anxiety. As noted by the Warnock Committee,

> [t]here was a sense that events were moving too fast for their implications to be assimilated. Society's views on the new techniques were divided between pride in the technological achievement, pleasure at the new-found means to relieve, at least for some, the unhappiness of infertility, and unease at the apparently uncontrolled advance of science, bringing with it new possibilities for manipulating the early stages of human development.[25]

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24 This phraseology is adopted from the Canadian government's proposals which uses the phrase "new reproductive and genetic technologies" or "NRGTs"; see Government of Canada *supra* note 2. The word "new" is not used in this thesis because many of the techniques are not in fact new, and to that extent the word is misleading. Artificial insemination, for example, is reported to have been first attempted in 1790: Corea G *The Mother Machine* (New York: Harper & Row, 1985) at 35; Edwards R & Brody S *Principles and Practice of Assisted Human Reproduction* (Philadelphia: WB Saunders Co., 1995) at 479. Similarly, the Biblical story of Sarah and Abraham suggests that surrogacy has been practised since Biblical times: see *Good News Bible* (New York: American Bible Society, 1976) Genesis 16.1-4.

25 United Kingdom, Committee of Inquiry into Human Fertilisation and Embryology *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (London: Her Majesty's Stationery Office, 1984) (Chair: Dame Mary Warnock) [hereinafter Warnock Report] at 4.

Throughout the Western world, the medical profession, national governments and non-governmental organisations alike have reacted by carrying out surveys and inquiries, and producing reports and position papers in an attempt to grapple with the difficult ethical, social and legal questions posed by RGTs, and the appropriate means of dealing with them.[26]

The Waller Committee in the Australian state of Victoria, and the Warnock Committee in Great Britain, established in May 1982[27] and July 1982[28] respectively, were two of the earliest inquiries.[29] Appropriately, these committees were set up in the jurisdictions in which the medical profession was leading the way in *in vitro* fertilisation.[30] The content and interpretation of the terms of reference of these inquiries reflect the fact that they were set up relatively early in the development of reproductive techniques. The terms of reference of the Waller Committee were limited to considering "whether the process of in vitro fertilisation (IVF) should be conducted in Victoria, and, if so, the procedures and guidelines that should be implemented

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26 There are too many reports and position papers on the issues surrounding the use of reproductive and genetic technology to be listed exhaustively here. Several of the major ones are as follows: Germany, Federal Ministry of Justice and Federal Ministry for Research and Technology *Report of the Working Group on In Vitro Fertilization, Genome Analysis, and Gene Therapy* (Bonn, 1985); France, Comité consultatif national d'éthique pour les sciences de la vie et de la santé *Avis sur les problèmes éthiques nés des techniques de reproduction artificielle* (Paris, 1985); United States, The American Fertility Society "Revised minimum standards for in vitro fertilisation, gamete intrafallopian transfer, and related procedures" *Fertility and Sterility* 1990; 53: 225-226; New York State Task Force on Life and Law *Surrogate Partnering: Analysis and Recommendations for Public Policy* (Albany, 1988). For several of the Canadian reports see *infra* note 50. For a more comprehensive list of reports issued since 1986, see Knoppers & Le Bris *supra* note 21 at note 2.

27 Victoria, Committee to consider the social, ethical and legal issues arising from in vitro fertilisation *Report on Donor Gametes in IVF* (August 1983) (Chair: Professor L Waller) [hereinafter Waller Committee *Report on Donor Gametes*] at 1.

28 Warnock Report *supra* note 25 at 4.

29 An earlier inquiry in the United Kingdom in 1960 considered artificial insemination: see Home Office and Scottish Home Department *Departmental Committee on Human Artificial Insemination Report* (London: Her Majesty's Stationery Office, 1960) Cmnd 1105 (Chair: The Earl of Feversham).

30 See Gray C "Studying Reproductive Technologies: 'We'll never please everybody'" *CMAJ* 1989; 141: 1258-1259 at 1258; Royal Commission Report *supra* note 3 at 508.

in respect of such processes in legislative form or otherwise."[31] In comparison with the range of activities encompassed within the term reproductive and genetic technology, these terms of reference are narrow.

The Warnock Committee's terms of reference were wider, calling for the Committee to consider the social, ethical and legal implications of recent and potential developments related to "human fertilisation and embryology".[32] Although this reference would include all techniques falling within the scope of the term "reproductive and genetic technologies" as understood today, the Committee confined the scope of its inquiry to "new processes of assisted reproduction" including surrogacy and artificial insemination, and human embryo experimentation.[33] Genetic technologies such as parthenogenesis, cloning and nucleic substitution were considered in passing as "possible future developments in research."[34] The Waller Committee reported in 1983[35] and in 1984.[36] The Warnock Committee reported in 1984.[37] Both recommended that legislation be enacted to govern the conduct of reproductive technologies.

In Victoria, legislation was enacted almost immediately. The *Infertility (Medical Procedures) Act 1984* [38] was the first legislation enacted in the world that attempted to deal with the issues surrounding the practice of RGTs. As a result of the narrow terms of reference of the inquiry

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31 Victoria, Committee to consider the social, ethical and legal issues arising from in vitro fertilisation *Report on Disposition of Embryos Produced by In Vitro Fertilisation* (August 1984) (Chair: Professor L Waller) [hereinafter Waller Committee *Report on Disposition of Embryos*] at 2.

32 Warnock Report *supra* note 25 at 4.

33 *ibid* at 4-5 and generally.

34 *ibid* at 70-74.

35 Waller Committee *Report on Donor Gametes supra* note 27.

36 Waller Committee *Report on Disposition of Embryos supra* note 31.

37 Warnock Report *supra* note 25.

38 (Victoria) No.10163.

that preceded it, it only governed IVF and artificial insemination. The Act contained provisions relating to the conduct of IVF and research, and also established the Standing Review and Advisory Committee ("SRACI") which approved human embryo research (where permissible under the legislation) and provided advice to the Minister on reproductive technology. During the years following its enactment, the legislation was shown to be deficient in a number of respects.[39] Amending legislation was passed in 1987,[40] but this was insufficient to overcome many of the deficiencies of the legislation. In 1991, the SRACI recommended substantial amendments including establishing a licensing system. Its recommendations were adopted by the Victorian government, and the current legislation was passed in May 1995.[41]

The rapid enactment of legislation in Victoria can be contrasted with delay in the United Kingdom before legislation based on the Warnock Committee's recommendations was enacted. Following the Warnock Report, the government produced a consultation document for public comment in 1986.[42] Following this, a White Paper was produced outlining the features of the proposed legislation.[43] The subsequent Bill was unique in that it contained alternate provisions with respect to human embryo research, one which prohibited it and one which

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39 When it was first enacted the Act did not include gamete intrafallopian transfer (GIFT) and other related procedures, and later, as outlined below at pp.90-91, it ran into interpretation difficulties which impacted upon whether certain research was legal: Gunning & English *supra* note 21 at 145.

40 *Infertility (Medical Procedures) Amendments Act 1987* (Vic) No.86 of 1987.

41 See Victoria, Office of the Minister for Health, News Release "Minister Details New IVF Legislation" (4 May 1995).

42 Montgomery J "Rights, Restraints and Pragmatism: The Human Fertilisation and Embryology Act 1990" (1991) 54 Modern LR 524 at 524.

43 United Kingdom, Department of Health and Social Security *Human Fertilisation and Embryology: A Framework for Legislation* (London: Her Majesty's Stationary Office, 1987) [hereinafter DHSS *Framework*].

permitted it. The *Human Fertilisation and Embryology Act 1990* that was subsequently enacted adopted the permissive provision.[44]

In the meantime, in South Australia a working party was set up in October 1983 with the fairly narrow mandate to examine the issues surrounding IVF and artificial insemination by donor.[45] The major focus of the Working Party's report was on the status of children born as a result of these procedures, and it recommended that legislation be enacted to clarify the status of children and to deal with the donation of gametes. Following this report, a select committee of the Legislative Council in South Australia was established.[46] The Committee had broader terms of reference than those of the Working Party, including human embryo experimentation, the eligibility of participants, privacy and confidentiality.[47] The Committee reported in 1987.[48] Its recommendations formed the basis of the legislation subsequently enacted in South Australia in 1988.

Finally, in Western Australia, a Committee of Inquiry was appointed by the Western Australian government to consider the issues relating to the conduct of IVF and related procedures. It reported in 1986,[49] following which a working party was set up in 1988 to further consider the issues. Legislation was passed in 1991.

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44 See further below at pp.34, 67.

45 South Australia, Working Party on In Vitro Fertilization and Artificial Insemination by Donors *Report of the Working Party on In Vitro Fertilization and Artificial Insemination by Donor* (January 1984) [hereinafter South Australian Working Party] at 1.

46 The Committee was first appointed in October 1984 but lapsed prior to the State election in December 1985, and was reappointed in February 1986.

47 South Australia, Select Committee of the Legislative Council *Report of the Select Committee of the Legislative Council on Artificial Insemination by Donor, In Vitro Fertilisation and Embryo Transfer Procedures and Related Matters in South Australia* (Adelaide: Government Printer SA, 1987) [hereinafter Select Committee Report] at 4-5.

48 *ibid*.

In Canada, the most recent examination of the issues was undertaken by the Canadian Royal Commission on New Reproductive Technologies. The Commission was established on 25 October 1989 and released its report in November 1993. Prior to the Royal Commission, several provincial commissions had been set up to consider the issues.[50] In addition, in one of its last projects, the Law Reform Commission of Canada produced a report which was published in 1992 which recommended that legislation be enacted.[51]

The Royal Commission was established as a result of lobbying by a nationwide coalition of women's groups, individuals, and health and other groups concerned about the potential lack of uniformity in provincial approaches to the problems posed by RGTs.[52] The terms of reference are significantly wider than those of the earlier inquiries. The Commission's general mandate to examine the implications of "new reproductive technologies" was followed by a list of particular issues to be considered, which included:

> pre-natal screening and diagnostic techniques, genetic manipulation and therapeutic interventions to correct genetic abnormalities, sex selection techniques, embryo experimentation and fetal tissue transplants.[53]

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49 Western Australia, Committee of Inquiry *Report of the Committee appointed by the Western Australian Government to Inquire into the Social, Legal and Ethical Issues Relating to In Vitro Fertilization and its Supervision* (Perth: The Committee, 1986).

50 See for example British Columbia Royal Commission on Family and Children's Law *Artificial Insemination* (Vancouver, May 1975), Ontario Law Reform Commission *Report on Human Artificial Reproduction and Related Matters* (Toronto: Queen's Printer, 1985), Law Reform Commission of Saskatchewan *Proposals for a Human Artificial Insemination Act: Report to the Minister of Justice* (Saskatoon, 1987), Ministère de la santé et des Services Sociaux du Québec *Rapport du Comité de travail sur les nouvelles technologies de reproduction humaine* (Quebec, 1988).

51 *Medically Assisted Procreation supra* note 16. The Law Reform Commission of Canada was abolished in 1992.

52 Delacourt S "Ottawa plans to study reproductive issues" *The [Toronto] Globe & Mail* (15 March 1989) A8. See also Eichler *supra* note 5 at 196 and Delacourt S "Inquiry to look at reproductive technology" *The [Toronto] Globe & Mail* (4 April 1989) A12.

53 Order in Council extracted in Royal Commission Report *supra* note 3 at 3.

There were high expectations for the work of the Royal Commission. When the Royal Commission was established, it was hoped that it would provide the most up-to-date and comprehensive examination in the world on the issues surrounding the conduct of RGTs,[54] with particular emphasis on feminist views.[55] It was also proposed that empirical work would be undertaken which would provide a perspective - the views of Canadians - that was missing from previous work. Over twenty eight million dollars later,[56] both the result and the process by which it was achieved are disappointing.[57] When compared with existing reports, the Royal Commission's report is not only superficial, but discloses nothing substantially new or progressive in terms of its approach to the moral and social issues raised by reproductive technologies.[58]

A comparison of the terms of reference and the scope of the recommendations made by the various inquiries demonstrates the rapid pace of scientific development that has taken place since the birth of Louise Brown in 1978. Genetic technologies in particular were only considered superficially, if at all, by the earlier inquiries. The predominant focus of these inquiries was assisted reproduction techniques used in overcoming the inability to conceive at all. The notion of genetic infertility appears only to have arisen later with the rise of prenatal diagnosis for genetic disorders, and the possibility of

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54 Gray *supra* note 30 at 1258; Mickleburgh *supra* note 3 at A6.

55 Anonymous *supra* note 4 at 223, 226, 227, and 233; "Royal Commission on Reproductive Technology welcomed by CMA" *CMAJ* 1989; 140: 1188 at 1188.

56 Mickleburgh *supra* note 3 at A6.

57 Basen G, Eichler M & Lippman A "The Royal Commission on New Reproductive Technologies: A Costly Failure?" in Basen et al, *supra* note 3 193-195 at 193 and the articles in Part III of this book; see also Gray *supra* note 3 at 266.

58 The first stage of the Canadian government's legislative response, which is based on the Royal Commission's recommendations, discloses an approach that is both prescriptive and coercive in its prohibition of unacceptable conduct through criminal sanctions. See further discussion below at p.70ff.

preimplantation diagnosis through embryo biopsy. The force behind the availability of these procedures is the Human Genome Project, which officially commenced in 1990.[59] It is only since then that the techniques used in genetic technology, as applied for both reproductive and non-reproductive purposes, have been feasible and have started to be used in practice.

Little attention was given in the reports to the problems posed by the rapid pace of scientific development. Several of the reports contain statements concerning the need to keep up to date with developments, but with little discussion about how this might be achieved. The focus of the reports is clearly and understandably on technologies that were feasible at the time the reports were written or which could become feasible in the foreseeable future. Absent a crystal ball, unforeseen technologies are obviously by their very nature unpredictable, which merely highlights the difficulties of legislating the conduct of science.

D. Moral, Social and Legal Issues

The anxiety and concern that followed the reports of the world's first test tube babies gave rise to widespread public debate about the morality of IVF and associated activities, such as embryo research, and the impact these techniques could have on social institutions such as parenthood and the family. Despite the many inquiries established to consider these issues,[60] this debate continues. Not only does there exist a wide variety of positions in society with respect to the morality of RGTs, but there is no consensus on what constitutes the central moral controversy in this area. Furthermore, as research and practice

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59 "HUGO Statement on the Principled Conduct of Genetic Research" *Genome Digest* (May 1996) at 2.

60 See for example the references at *supra* notes 25-27, 29, 31, 45, 47 and 49.

continues, additional information is discovered about the processes involved in human conception and embryological development which may impact upon the morality aspects of RGTs.

In order effectively to evaluate and analyse the way in which the legislation deals with scientific developments and community participation, it is necessary to outline some of the important moral and legal issues that arise from the conduct of RGTs. The following review of some of these issues is by no means exhaustive, nor is it meant to be. Rather its aim is to provide a context for the analysis in later chapters. Positions taken in the legislation in respect of these issues are described in this chapter.

The Medical Perspective

Reproductive technology is justified broadly by the medical establishment and other proponents on the basis of the goals of medicine. Two of these goals are the alleviation of suffering or beneficence, and the acquisition of knowledge for the advancement of medical science.[61] Procedures are acceptable where they assist in alleviating human suffering or result in the acquisition of knowledge either for its own sake or for future clinical application.

IVF is thus justified on the basis that it can assist infertile individuals to conceive a child where they might otherwise have been unable to do so. Infertility is seen as a medical problem and IVF a cure or treatment

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61 Engelhardt H T *Foundations of Bioethics* 2nd ed (New York: Oxford University Press, 1996) [hereinafter Engelhardt *Foundations*] at 292. These goals lie beneath several of the principles contained in professional codes of ethics: see for example The Canadian Medical Association *Code of Ethics* April 1990; Australian Medical Association *Code of Ethics* 1 February 1996.

for this problem.[62] In its Preamble, the Western Australian legislation expressly recognises the benefits of the technology it seeks to regulate:

> In enacting this legislation Parliament is seeking to give help and encouragement to those eligible couples who are unable to conceive children naturally or whose children may be affected by a genetic disease.[63]

Similarly, the Victorian legislation recognises in its guiding principles that "infertile couples should be assisted in fulfilling their desire to have children".[64] IVF and associated procedures are viewed, particularly by the medical profession, as something people - and women in particular - want and need. And it is this need, according to proponents, that justifies the continued use of IVF, despite its low success rate and the physical and psychological risks associated with it.[65]

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62 The idea that infertility is a medical problem has been challenged particularly by feminist groups who see infertility primarily as a psychosocial problem: see for example discussion in Birke L, Himmelweit S & Vines G *Tomorrow's Child Reproductive Technologies in the 90s* (London: Virago Press, 1990) [hereinafter Birke et al] at 65. See also Basen et al *supra* note 3 Volume II Part IV and Shanner L "The Right to Procreate: When Rights Claims Have Gone Wrong" (1995) 40 McGill LJ 823 at 856-858.

63 WA Act, Preamble paragraph A.

64 Victorian Act s.5(1)(d). This principle comes fourth in a list of guiding principles to be applied in order. Thus, higher ranking principles are (a) the welfare and interests of any person born as a result of a treatment procedure; (b) human life should be preserved and protected; and (c) the interests of the family should be considered.

65 Success rates are measured and reported in a variety of ways, such as the number of pregnancies or the number of live births: see Royal Commission Report *supra* note 3 at 538 and Edwards & Brody *supra* note 23 at 656ff. The Royal Commission found that success rates of IVF in terms of live births were the most useful from the patient's perspective: *ibid* at 541. Edwards & Brody note that an analysis of more than 2900 cycles of treatment led to 767 clinical pregnancies and 500 births. More than 20% of patients under 39 and 17.5% overall who were given three embryos delivered one or more babies. See also Stanley F & Webb S "The Effectiveness of In Vitro Fertilisation: An Epidemiological Perspective" in Stephenson P & Wagner M, eds, *Tough Choices* (Philadelphia: Temple University Press, 1993). Different success rates apply to different infertility treatments. In one of its reports, the Australian National Bioethics Consultative Committee reports a success rate measured in terms of live births for IVF of 8.1%, while a success rate for GIFT (gamete intrafallopian transfer) of 18.4%: Australia, National Bioethics Consultative Committee *Access to Reproductive Technology* (Canberra: March 1991) at 10.

The medical indications for IVF have gradually expanded since it first began to be practiced in the mid 1970s. First introduced as a technique for the treatment of women with blocked fallopian tubes, IVF is now used in a range of situations which constitute "infertility". Although there is no agreed standard definition of infertility,[66] the notion of infertility has expanded to include what may be described as "genetic infertility" - the inability to conceive a genetically "normal"[67] child. This is reflected in provisions in the Australian legislation which allow those who appear to be at risk of having a child with a genetic disorder access to assisted conception procedures.[68]

From the medical perspective, IVF and associated procedures are viewed as standard medical treatments for infertility ("[i]nfertility seems to be a clinical defect to be remedied if possible by medical attention")[69] and research is justified to increase knowledge of infertility and ways to overcome it, and to improve clinical practice in the field. This medical perspective of RGTs permeates the reports of the inquiries, and is perpetuated by the ensuing legislation. It is generally assumed without discussion that infertility is a medical problem, a disease or disorder to be cured. The focus is on attempting to cure and treat infertility, rather than on preventing infertility occurring in the first place or on non-medical alternatives to infertility such as adoption or childlessness.

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66 Wagner M & Stephenson P "Infertility and In Vitro Fertilisation: Is the Tail Wagging the Dog?" in Stephenson & Wagner *ibid* 1-22 at 3.

67 The concept of what is "normal" or "abnormal" is a relative one, particularly in the context of genetic traits. Some commentators have argued that genetic abnormality is a social construction: see for example Draper E *Risky Business* (Cambridge: Cambridge University Press, 1991) at 43-45; Wolf S "Beyond 'Genetic Discrimination': Toward the Broader Harm of Geneticism" (1995) 23 J Law, Medicine & Ethics 345 at 347.

68 SA Act s.13(3)(b), Victorian Act s.8, WA Act s.23(a).

69 Edwards R & Sharpe D "Social Values and Research in Human Embryology" *Nature* 1971; 231: 87-91 at 87.

The medical perspective also assumes that technology is neutral and value-free, and that decisions are made on objective clinical grounds.[70] But clinical decisions are never value-free, particularly decisions in the context of IVF which are often based on moral or social preconceptions about the role of women in society[71] or what constitutes an acceptable family in which to raise a child.

The Pursuit of Scientific Knowledge

The science and medicine of RGTs are rapidly progressing. One of the major issues is the extent to which limits should be placed on the freedom of scientific inquiry. The unlimited pursuit of science proceeds on the grounds that the acquisition of knowledge is the ultimate good. On this view, scientific knowledge is valuable for its own sake, and scientists' liberty to pursue knowledge is absolute. The application of this knowledge is a matter for society, not scientists,[72] and consequently scientists do not have a moral duty to consider the implications of their research.

Calls for the restraint of scientific inquiry are commonly made on utilitarian grounds. Thus, it has been argued that scientific inquiry should be limited if the long and short term costs outweigh any enduring benefits (in terms of the minimisation of suffering and the maximisation of the social good) to society.[73] In this case, such inquiry would be unreasonable and should therefore be subject to restraint.[74] Another, similar view is that scientists have a duty to exercise self-

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70 Brody E "Reproduction Without Sex - But With the Doctor" (1987) 15 Law, Med & Health Care 152 at 152, 155.

71 *ibid* at 155.

72 Stone J "Knowledge, Survival and the Duties of Science" (1973) 23 The American University LR 231 at 234-5, 240.

73 Smith G "The Province and Function of Law, Science and Medicine: Leeways of Choice and Patterns of Discourse" (1987) 10(2) UNSWLR 103 at 124.

74 *ibid*.

restraint where activities are found "likely to produce dangers of cataclysmic physical or psychological proportions for mankind"[75] and "where the scientists are aware of this likelihood as a proximate outcome of their work."[76] In the context of RGTs, scientists recognised the complexity of the issues surrounding their use, and were amongst the first to call for guidance.[77]

The rapid pace of science in the field of RGTs is outstriding society's ability to deal with its potential consequences. Time is needed to reflect on the likely consequences,[78] yet the academic climate of "publish or perish", funding that is increasingly difficult to obtain and the possibility of commercial applications count against reasoned reflection on these issues. The problems of reconciling scientific development with the need for legislative limitations is considered in more detail in Part IV.

Procreative Freedom

The medical perspective generally supports unrestricted access to reproductive technologies to those who could benefit from them on the basis of an individual's right to reproduce. A similar position is taken by Robertson in his recent book *Children of Choice*.[79] Robertson views the issues presented by reproductive technology primarily as a question of "the scope and limits of procreative freedom",[80] and analyses the gamut of reproductive technologies in the context of

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75 Stone *supra* note 72 at 240.
76 *ibid*.
77 See for example Edwards & Sharpe *supra* note 67, Edwards R "Fertilization of Human Eggs in Vitro: Morals, Ethics and the Law" *Quarterly Review of Biology* 1974; 49: 3-26.
78 Kennedy I "Emerging Problems of Medicine, Technology, and the Law" in Kennedy I, ed, *Treat Me Right Essays in Medical Law and Ethics* (Oxford: Clarendon Press, 1989) 1-18 at 5.
79 *supra* note 23.
80 *ibid* at 4.

reproductive liberty. Procreative freedom consists of both a right to reproduce and a right not to reproduce, and the right to reproduce includes a right to use "noncoital techniques".[81] For Robertson, procreative liberty is such a deeply held value in society that it should only be limited where there is "substantial harm to the tangible interests of others".[82] "Speculation or mere moral objections alone" will be insufficient, and the burden of showing substantial harm is on those who wish to impose limitations.[83] He analyses various reproductive technologies, concluding that none of them demonstrate harm sufficient to warrant government restriction.

Robertson's approach, consistent with the individualistic philosophy of modern Western society, particularly in the United States, is a typical liberal rights-based approach.[84] As Robertson himself recognises, this approach may be criticised on the basis that it fails to take into account broader societal and community implications.[85] Thus it is argued that "a rights-based perspective tends to view reproduction as an isolated individual act without effects on others", although it "clearly implicates community and other persons."[86] The rights-based approach disregards the needs of community and fails to recognise that reproduction is not a private matter, and "cannot be completely accounted for in the language of individual rights".[87] The implications of the conduct of medical practice and research in the field of RGTs, some of which are discussed below, extend the matter beyond the

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81 *ibid* at 34.
82 *ibid* at 35.
83 *ibid* at 35, 41.
84 For a general critique of the rights-based approach to reproductive technology see Shanner *supra* note 62.
85 Robertson *supra* note 23 at 223.
86 *ibid*.
87 *ibid*.

private realm of the doctor-patient relationship to the public realm, and raise issues of public morality and community interests. It was in recognition of the wider implications for society of RGTs that regulation was recommended by the various inquiries.

Another criticism is that the rights-based approach "ignores the social and economic context in which exercise of rights is embedded."[88] The rights-based approach thus ignores issues concerning resource allocation and social justice. In the United States, only those who have sufficient wealth can take advantage of reproductive technology. Those in lower socio-economic groups who lack sufficient financial resources are denied the opportunity to use these technologies. In countries such as Canada, Great Britain and Australia, where there are socialised health care systems, the issue of resource allocation translates into a question of whether the government should use public funds to finance reproductive services, and if so, how much of the health care budget ought to be spent on these services.[89]

Status of the Embryo

The status of the embryo is considered by many to be at the heart of the moral controversy surrounding reproductive technologies, and in particular, human embryo experimentation. There are three main positions concerning the moral status of the embryo. The first, held by the Right to Life organisation and some religious groups, such as the Roman Catholic Church, proceeds on the basis of the sanctity of human life and holds that life begins at fertilisation. According to this view,

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88 *ibid* at 225.

89 In Australia, Medicare funds up to six cycles of treatment using assisted reproductive technology services: Medicare, Personal Communication, 25 September 1996. In Canada, Ontario is the only province that covers IVF under its health insurance plan: Royal Commission Report *supra* note 3 at 383.

the sanctity of human life is absolute, so that from the moment of fertilisation, the human embryo has the same moral status as a person and is entitled to the same legal protection as a person.

The Right to Life organisation, whose motivating principle is that human life should be protected at all stages, totally rejects all *in vitro* human embryo experimentation and IVF for any purpose.[90] The Vatican's *Instruction in Respect for Human Life and its Origin and on the Dignity of Procreation* from 1987 states that "the human being must be respected - as a person - from the very first instant of his [sic] existence."[91] According to the Vatican, life begins from the time the ovum is fertilised, which as used in the teaching means from complete syngamy.[92] The Instruction further states that

> [m]edical research must refrain from operations on live embryos unless there is moral certainty of not causing harm to the life and integrity of the unborn child and the mother, and on condition that the parents have given their free and informed consent to the procedure. ... If the embryos are living, whether viable or not, they must be respected, just like any other human persons; experimentation on embryos which is not directly therapeutic is illicit.[93]

Despite the present official position of the Roman Catholic Church, there are a number of positions held within Catholicism about both assisted reproductive procedures and human embryo experimentation.[94] Many Catholic theologians argue, for example, that

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90 Australia, National Bioethics Consultative Committee *Embryo Experimentation* NB 16 (Canberra: National Health and Medical Research Council, c.1991) [hereinafter NBCC Report] at 24.

91 Vatican, Congregation for the Doctrine of the Faith *Instruction on Respect for Human Life it its Origin and Dignity of Procreation* extracted in Alpern K, ed, *The Ethics of Reproductive Technology* (New York: Oxford University Press, 1992) 83-97 at 85.

92 NBCC Report *supra* note 90 at 28. For the definition of syngamy see *infra* note 118 and text accompanying.

93 Vatican, Congregation for the Doctrine of the Faith *supra* note 91 at 85, 86.

94 NBCC Report *supra* note 90 at 26-27.

an embryo is not a human being until 14 days after fertilisation, while others argue that a new human individual is formed prior to syngamy.[95]

At the other end of the spectrum is the view that a human embryo is no different from other human tissue. Accordingly, it does not deserve any special legal protection. The only limits on its use, as with other human tissue, is that the consent of those having decision-making authority should be obtained, and no consideration may be given in exchange for the embryos.[96] A more extreme version of this position is that human embryos should be treated as property. As discussed below, this view has been assumed by several courts in the United States in decisions involving human embryos.[97]

The intermediate position on the moral status of the embryo recognises that while the human embryo is not a "person", it is nevertheless is entitled to "special respect" because of its potential to develop into a person.[98]

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95 See further *ibid* at 26-31.

96 The use of human tissue requires consent of the donor, or, in the case of post-mortem where there is no prior consent of the deceased, by the next of kin. In Canada, in all provinces except Quebec, provisions for tissue donation are based on the *Uniform Human Tissue Donation Act* (1989 Uniform Law Conference of Canada, *Consolidation of Uniform Acts* (Fredricton, New Brunswick: The Conference, 1990) at 22-1). In Quebec, see Civil Code Book 1 Title 1 art. 43, 44. The sale of human tissue is prohibited in Canada: Law Reform Commission of Canada *Procurement and Transfer of Human Tissues and Organs* Working Paper 66 (Ottawa: The Commission, 1992) at 133; see *Uniform Human Tissue Donation Act* 1989 ss.15-1 (except blood). In South Australia, Western Australia and Victoria, legislation requiring consent and prohibiting commercial trade is *Transplantation and Anatomy Act 1983* (SA) No. 11 of 1983 ss.5, 9, 10 & 35, *Human Tissue Act 1982* (Vic) No. 9860 of 1982 ss.3, 7, 8 & 38 and *Human Tissue and Transplant Act 1982* (WA) No. 116 of 1982 ss.3, 8, 9 & 29 respectively. In the United Kingdom s.1 of the *Human Tissue Act 1961* (UK) 1961 c.54 requires consent for the removal of tissue , and s.1 of the *Human Organ Transplants Act 1989* (UK) 1989 c.31 prohibits commercial dealings in human organs.

97 See below pp.30-31.

98 Robertson *supra* note 23 at 102.

The controversy surrounding the moral status of the human embryo is reflected in the uncertainty as to its legal status. According to the common law, a fetus (and therefore an embryo) is not a legal person until it is born alive.[99] A fetus does not therefore have any legal rights until birth, although it may have certain contingent interests subject to being born alive.[100] These interests include, for example, those concerning the inheritance of property from a testator who dies leaving property to an heir which at the time of the testator's death is a fetus *en ventre sa mere*.[101]

Inheritance of property provided the context for one of the first sets of proceedings in which the legal status of extracorporeal embryos created by *in vitro* fertilisation was considered. In 1984, an American couple died leaving two frozen embryos at an IVF clinic in Victoria, Australia, raising the issue of whether the embryos were entitled to inherit the couple's estate. The matter was dealt with by a California court without considering whether the embryos had any rights, but the theoretical question was nevertheless considered.[102] More recently, the Supreme Court of the Australian state of Tasmania held that frozen

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99 Sneiderman B, Irvine J, Osborne P *Canadian Medical Law* 2nd ed (Scarborough: Ontario, 1995) [hereinafter Sneiderman et al] at 314; New South Wales Law Reform Commission *In Vitro Fertilisation Report* (Sydney: New South Wales Law Reform Commission, 1988) at 7. In the United Kingdom see *Paton v British Pregnancy Advisory Service Trustees* [1979] QB 276 at 279 and *Re F* [1988] 2 All ER 193; in Australia see *Attorney-General (Qld) (Ex rel Kerr) v T* (1983) 46 ALR 275 at 277; and in Canada see for example *Dehler v Ottawa Civic Hospital* (1979) 25 OR (2d) 748, 14 CPC 4, 3 L Med Q 141, 101 DLR (3d) 686 (HC). In Canada the common law position is codified in s.223 of the Criminal Code which states that a child becomes a human being when it has completely proceeded in a living state from the body of the mother. By contrast, the state of Louisiana in the United States has passed legislation which states that an embryo is a juridical person: La Rev Stat Ann §9:123, 124 (West 1996).

100 Seymour J *Fetal Welfare and the Law* (A Report of an Inquiry Commissioned by the Australian Medical Association) (Canberra: Australian National University, 1994) at 43; Sneiderman et al, *supra* note 99 at 319.

101 *Wallis v Hodson* (1740) 2 Atk 114; 26 All ER 472.

102 Robertson *supra* note 23 at 111-112.

embryos, like fetuses, had rights of inheritance, contingent upon them being implanted and born alive.[103]

As noted above,[104] an alternative approach to the question of the status of the human embryo is to treat it as property. This approach has been considered in the context of the issue of who has decision-making authority in respect of extracorporeal embryos.[105] These issues have been considered in the following three cases in the United States. In the first case, *Del Zio v Columbia Presbyterian Hospital*, in 1978, a couple was awarded US$50,000 for emotional distress when a doctor deliberately destroyed the contents of the petri dish in which *in vitro* fertilisation was being attempted with the wife's egg and her husband's sperm.[106] The decision may be interpreted as implicitly recognising the couple's ownership of the incubating embryo.[107]

The issue was considered next by the courts in the United States in *York v Jones*.[108] In this case, the plaintiffs sought the release and transfer of frozen embryos from storage at the defendants' facility to another facility in a different jurisdiction where the plaintiffs wished to continue their IVF attempts. The defendants refused to consent to the transfer. The court held that the plaintiffs had dispositional authority over the embryos on the basis of an agreement they had signed with

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103 *Estate of K v Public Trustee* (22 April 1996) No. M25/1996 [unreported] (Tas SC).

104 See p.28 above.

105 Robertson *supra* note 23 says that the question of decision-making authority is really a question of who "owns" or has a "property interest" in the embryo: at 104. An alternative interpretation was adopted by the Australian Senate Select Committee on the Human Embryo Experimentation Bill 1985, which stated that the question of decision-making authority is one of the legal principle of guardianship: Australia, Senate Select Committee on the Human Embryo Experimentation Bill 1985 *Human Embryo Experimentation in Australia* (Canberra: AGPS, 1986) [hereinafter Senate Select Committee] at 30.

106 The decision is unreported (No. 74-3558, (SDNY filed April 12, 1978)), but is summarised in footnote 25 in *Davis v Davis* 842 SW 2d 588 (Tenn 1992) at 602.

107 Robertson *supra* note 23 at 105.

108 717 F Supp 421 (ED Va 1989).

the defendants. This agreement created a bailment relationship with the consequence that the defendants as bailors had an obligation to return the embryos to the plaintiffs. Failure to do so gave rise to action for detinue. Thus, without discussing it, the court assumed that the embryos were property.

Davis v Davis[109] involved a battle between divorced spouses as to who had "custody" of seven frozen embryos stored in a fertility clinic that the couple had attended while married. At the time proceedings were commenced, Mrs Davis wanted custody of the embryos so that she could have them implanted notwithstanding the divorce. Her ex-husband wanted to leave the embryos frozen until he decided whether he wanted to be a parent out of marriage. Proceeding on the basis that the embryos were human beings from the moment of fertilisation, the trial court applied the best interests of the child test and awarded custody to Mrs Davis. On appeal, the Court of Appeals, relying on *York v Jones*, awarded joint control to Mr and Mrs Davis on the basis of an undefined shared interest in the embryos. Mrs Davis appealed to the Supreme Court of Tennessee, by which time the circumstances had changed. She no longer wanted to use the embryos herself, but wanted to donate them to a childless couple. Mr Davis opposed the donation, preferring to have the embryos discarded.

The Supreme Court held that the embryos were neither persons nor property, but fell into an intermediate category (consistent with the intermediate moral position described above) that entitled them to special respect because of their potential for human life.[110] It further held that the interest of the Davises in the embryos was in the nature of

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109 *supra* note 106.
110 *ibid* at 597.

ownership to the extent that they had decision-making authority concerning disposition of the embryos.[111] "Custody" was awarded to Mr Davis, whose interest in avoiding procreation was found to prevail over Mrs Davis' wishes when the competing interests of the parties were balanced.[112]

The common law in the United States is unclear. While the first two cases suggest that embryos are property, such a conclusion is probably only sustainable within the specific context of determining who has decision-making authority over frozen embryos. That embryos are property is clearly at odds with the United States common law of abortion, according to which a woman's right to terminate pregnancy is not absolute, but may be limited by the state's interest, among other things, in protecting potential human life.[113]

The common law position in Australia, Canada and the United Kingdom is similarly unclear. Were the issue to come before the court in these jurisdictions, it would likely be determined in a similar manner as has been done in the United States courts, with ill-fitting analogies being drawn from property law. The resulting middle ground, where the embryo is considered neither person nor property simply highlights the inadequacy of the common law and, judicial creativity notwithstanding, the need for legislation to deal with the issues surrounding RGTs.

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111 *ibid*.

112 *ibid* at 604. *Davis v Davis* was applied in *Hecht v Superior Court* 20 Cal Rptr 2d 275; 16 Cal App 4th 836 (Ct App 1993), althought in *Hecht* the court considered the status of frozen sperm rather than frozen embryos.

113 *Roe v Wade* 410 US 113;93 S Ct 705, 35 L Ed 2d 147 (1973) (cited to US) at 150 per Blackmun J; *Planned Parenthood v Casey* 112 S Ct 2791, 120 L Ed 2d 674 (1992) (cited to L Ed 2d) at 694.

All of the inquiries recommended against treating the human embryo either as a person or as property.[114] They adopted instead the position which mirrors that taken in *Davis v Davis*, being the intermediate moral position that the embryo deserved a "special status" because of its potential to become a human person.[115] Although a human embryo is not entitled to the full legal rights attributed to a person, its special status means that it is entitled to some protection under the law.

The legislation under consideration in this study takes various positions on the issue. The Western Australian legislation reflects the view that human life begins at fertilisation, and assumes that the moral status of the human embryo is such that it requires legal protection from this point. The Preamble specifically states that the legislation should "respect the life created" by the process of fertilisation.[116] Human embryos should be given "all reasonable opportunities" to implant and only research that will benefit the embryo is permitted. Research does not appear to be permitted on "spare embryos".[117]

The Victorian legislation may also be considered to reflect the view that life begins at fertilisation with fertilisation considered to take place at

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114 The wider implications of characterising the embryo as a person or as property counted against either of these positions. For example, the embryo as a person has implications for the status of the fetus and could lead to the criminalisation of abortion and the legitimation of judicial intervention into pregnancy and other fetal protection policies. On the other hand, characterisation of the embryo as property discounts its symbolic human nature and may lead to commercialisation. For a more detailed discussion of these issues see for example Seymour *supra* note 100.

115 See for example Warnock Report *supra* note 25 at 63; Waller Committee *Report on Disposition of Embryos supra* note 31 at 45.

116 WA Act Preamble paragraph B.

117 Section 26 of the WA Act provides for the control, dealing and disposal of embryos. Among other things it provides that surplus embryos no longer required by the couple on whose behalf they are held may be donated with the consent of the couple to specific recipients. There is no mention of what is to be done with the embryos if such donation is not desired. Given the general tenor of the rest of the legislation it would appear that research on surplus embryos, except where therapeutic and where the embryo is to be donated, is not permitted by the legislation.

the point of syngamy.[118] Embryos are protected from this point, a position that is consistent with the Vatican's view noted above.[119] Embryos may not be created for research purposes, although research that is not "destructive" may be carried out on "spare" embryos up to 14 days after fertilisation. In this respect, the Victorian legislation may be considered to reflect the intermediate moral position described above.

In the United Kingdom embryos may be created pursuant to a licence for the purpose of research, including non-therapeutic or destructive research prior to the appearance of the primitive streak (deemed in the legislation to be 14 days after fertilisation).[120] Although the Warnock Committee said that this was a manifestation of the "special status" of the embryo, suggesting the intermediate moral position described above, the view of the embryo taken in the legislation is more accurately characterised as the human tissue view. Legal protection starts from day 14, rather than before this,[121] and there are no restrictions on the type of research that may be carried out before day 14. As with other human tissue, no money or other consideration is to

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118 "Syngamy" is defined in the legislation as "that stage of development of a fertilised oocyte where the chromosomes derived from the male and female pronuclei align on the mitotic spindle.": Victorian Act s.4; compare the definition in the Royal Commission on New Reproductive Technology: "the process through which the 23 chromosomes of an egg cell and the 23 chromosomes of a sperm cell combine so that the new cell has 46 chromosomes.": Royal Commission Report *supra* note 3 at 1171.

119 See p.27 above.

120 See UK Act s.3(3). Destructive research is not prohibited in the legislation which suggests that it is (legally) permitted. This proposition is not as self-evident as it might seem on its face, and raises several interesting questions concerning the relationship between ethics and law (is conduct that is legally permissible always ethically permissible and vice versa) which are beyond the scope of this thesis.

121 The lack of protection afforded to the human embryo prior to the 14 day mark has also been noted in Kennedy I "The Moral Status of the Embryo" in Kennedy *supra* note 78 119-139 at 133.

be given for embryos,[122] and consent of the individuals supplying gametes used to create an embryo *in vitro* must be obtained.[123]

The legislation in South Australia adopts the intermediate position. Research is permitted on human embryos prior to the 14 day mark, but not "detrimental" research. Embryos are protected by the law to the extent that only therapeutic research may be performed on them. Similarly, the Canadian legislation prohibits the creation of embryos for research purposes and the maintenance of embryos outside the body after the 14 day mark.[124]

Feminist Perspectives

Feminists in general disagree with the notion that the central moral controversy surrounding RGTs is the moral status of the embryo.[125] They argue that the locus of the debate ought to be shifted from the narrow focus of the embryo to the wider focus of the impact of RGTs on women. Infertility should not be narrowly construed as a purely medical problem, but as a psychosocial problem which should be considered within the wider context of the perceived role of women in society.[126] As pointed out by a number of commentators,[127] despite

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122 UK Act s.12(e).

123 UK Act Schedule 3 paragraph 6. The consent must be specific in the sense that it must outline that the gametes and embryos will be used for the purposes of research. Provisions requiring consent and prohibiting consideration are also contained in the legislation in Victoria (s.57 (consideration), ss.13, 14, 27, 28, 34 and Part 4 (consent)) and Western Australia (s.7(1)(j) (consideration), s.22 (consents generally). Consideration and consent is dealt with in the codes of practice in South Australia: see *Reproductive Technology (Code of Ethical Research Practice) Regulations 1995* Schedule para.13 and paras.14-21 and *Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995* Schedule para.10 and paras.15-27. The Canadian Bill prohibits buying and selling of gametes, zygotes, embryos and fetuses: cl. 6.

124 Canadian Bill cl. 4(1)(j) and (k).

125 Overall C *Ethics and Human Reproduction* (Boston: Unwin Hyman, 1987) at 10.

126 See references at *supra* note 62.

127 See generally Sherwin S *No Longer Patient* (Philadelphia: Temple University Press, 1992) at 27-34; Overall *supra* note 125 at 10; Wolf S "Introduction: Gender and Feminism in Bioethics" in Wolf S, ed, *Feminism and Ethics Beyond Reproduction*

general agreement on these points, feminist perspectives on RGTs (as on other issues) are not homogeneous.[128]

Liberal feminists approach the issue of reproductive technology within the framework of procreative choice and reproductive freedom. Thus, a woman's right to choose whether or not to have children and the timing of that choice is of paramount importance. Reproductive technologies are seen as a means of liberating women from "the tyranny of their biological nature",[129] and should not be limited, since to do so would restrict women's choice, hence restricting their reproductive freedom.[130] On this view, research which may lead to techniques to enhance women's reproductive choice is acceptable.

The radical feminist view holds that in utilising reproductive technology such as IVF, women are not in fact exercising a choice but are succumbing to patriarchal notions of the role of women in society, that is as "breeders".[131] The predominance of men in the medical profession which encourages women to seek "treatment" for their infertility may lead to the perpetuation of the oppression of women in society. Reproductive technologies are seen as a means by which the

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(New York: Oxford University Press, 1996) 3-43 at 5; and Charlesworth M "Whose Body? Feminist Views of Reproductive Technology" in Komesaroff P, ed, *Troubled Bodies* (Durham: Duke University Press, 1995) at 126.

128 *ibid*. Feminism is often criticised for its failure to produce an overarching feminist approach to this and many other issues. But see Charlesworth *ibid* who says that this should not be considered as a sign of weakness or incoherence but as "an index of maturity, a sign of vitality and strength": at 126.

129 Charlesworth *supra* note 127 at 127.

130 This approach was particularly popular in the early 1970s, with the work of Firestone S *The Dialectic of Sex The Case for Feminist Revolution* (New York: Morrow, 1970).

131 This term is used by Corea *supra* note 24 to refer to the perception of women that she considers to be perpetuated by reproductive technologies. It is interesting to note Margaret Atwood's futuristic novel *The Handmaid's Tale* was first published the same year as Corea's book. The book recounts the story of a woman trapped in an authoritarian society in which certain women in the society are allocated to childless couples to act as (in Corea's terms) "breeders": "We are two-legged wombs, that's all: sacred vessels, ambulatory chalices." Atwood M *The Handmaid's Tale* (Toronto: Seal Books, 1986) at 128.

patriarchy can further control and exploit women.[132] Women become slaves of the technology that is supposed to free them. Human embryo experimentation is objected to on the basis that "the abuses of women's bodies that are required to allow such experimentation far outweigh any benefits that the experimentation might yield."[133] Many radical feminists, such as those who are members of FINRRAGE[134] consequently totally reject all reproductive technologies.[135]

A middle position between the two positions described so far recognises the dangers of exploitation, but at the same time realises that reproductive technologies may be used to liberate women.[136] Reproductive policies based solely upon reproductive rights on the one hand, or the domination and oppression of women by the patriarchy on the other are insufficient.[137] According to this view, what is needed is not prohibition of these technologies, nor an increased and unrestricted range of choices, but rather more control of RGTs by women themselves.[138]

Feminist concerns are either omitted from the reports and legislation, or if addressed, are given symbolic or passing consideration. For example, the Canadian Royal Commission's purported reliance on the "ethic of care", which is widely associated with feminism although having broader appeal as a moral theory, does not support its core recommendations.[139] The report of the South Australian Working

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132 See for example Corea *supra* note 24.

133 NBCC Report *supra* note 90 at 35.

134 Feminist International Network of Resistance to Reproductive and Genetic Engineering.

135 Charlesworth *supra* note 127 at 127.

136 *ibid* at 131; Birke at al *supra* note 62.

137 See Birke at al, *ibid* at 18-20, 282.

138 *ibid* at 306.

139 See Healy P "Statutory Prohibitions and the Regulation of New Reproductive Technologies under Federal Law in Canada" (1995) 40 McGill LJ 905 at 910-914.

Party focuses on the welfare of the child to be born, while little attention is given to the concerns of the woman who will carry and rear that child.[140]

The Family

The impact of RGTs on the family is another important issue.[141] RGTs challenge the traditional notion of parenthood, that is a child being the genetic offspring of a mother and a father who also rear the child. As a consequence of RGTs, a child may have different genetic, gestational and social mothers, and/or different genetic and social fathers. Accordingly, the welfare of children born as a result of assisted conception procedures is one of the main issues surrounding the use of RGTs.

This concern is taken up by the Australian statutes in particular. The Victorian legislation lists five principles, in order of importance, which are to guide the conduct of activities under the Act.[142] The first of these is that "the welfare and interests of any person born or to be born as a result of a treatment procedure are paramount." Similarly, in South Australia, the welfare of any child "is to be treated as of paramount importance, and accepted as a fundamental principle."[143]

Counselling requirements in the Victorian legislation reflect this concern. Donors of gametes and those wishing to make use of assisted conception procedures must have received counselling from a

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140 South Australian Working Party *supra* note 45.

141 This issue was considered in detail by the Australian Family Law Council. See Australia, Family Law Council *Creating Children A Uniform Approach to the Law and Practice of Reproductive Technology in Australia* (Canberra: AGPS, 1985).

142 Victorian Act s.5.

143 SA Act s.10(2).

counsellor approved under the legislation.[144] Provisions allowing children access to information about their genetic parentage goes some way to addressing concerns regarding the psychological impact being born of reproductive technologies may have on a child.

In the United Kingdom and Western Australia the welfare of children is to be taken into consideration, but is not of paramount importance as it is in the other jurisdictions.[145] Interestingly, the requirement in the Western Australian legislation that the welfare of any future child be taken into account comes after the requirement that the welfare of participants be properly promoted. Western Australia is the only jurisdiction of the ones considered here that specifically requires that the welfare of those undergoing assisted conception procedures be taken into account as well as the welfare of the child.

All of the legislation, at least initially, assumed a traditional notion of the acceptable family, and this is evidenced in provisions concerning access to RGTs. Until recently, in all Australian jurisdictions, only heterosexual couples who were married or in long term stable relationships were entitled under the legislation to make use of RGTs.[146] The provision to this effect in the South Australian legislation was recently struck down by the Supreme Court of South Australia as being contrary to federal anti-discrimination legislation.[147] In Victoria,

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144 Victorian Act ss.11 and 16.

145 WA Act s.4(d)(iv): the welfare of any child is to be "properly taken into consideration"; UK Act s.25(2): the code of practice must include "guidance ... about the account to be taken of the welfare of children who may be born as a result of treatment services." The code does not consider the needs of the child or those of people seeking treatment as paramount over the other: Gunning & English *supra* note 21 at 117.

146 SA Act s.13(3), Victorian Act s.8, WA Act s.23.

147 *Pierce v South Australian Health Commission* (10 September 1996) SCGRG-96-114 [unreported] (SA SC). Section 6 of the Australian *Sex Discrimination Act 1984* (Cth) No.4 of 1984 prohibits discrimination on the grounds of marital status. According to s.109 of the Australian Constitution, where state legislation is inconsistent with Commonwealth legislation, the Commonwealth legislation prevails

where donor gametes are used, the consent of the donor's spouse is also required.[148] The assumption is made in the Australian jurisdictions that a traditional family is in the best interests of the child. Thus, if it can be said that there is a right to reproduce, according to the Australian legislation, that right may only be exercised by heterosexual married or de facto couples. The interests of the child are favoured over the interests or right of individuals to have children. However, as a result of the recent South Australian Supreme Court case, the equivalent provisions in the Western Australian and Victorian statutes would also likely be struck down for the same reason.

The British legislation is less directive and does not specifically limit access to couples, permitting the possibility of treatment services being provided to single or homosexual women. Nevertheless, the legislation does imply the propriety of the traditional two-heterosexual-parent norm in its requirement that when deciding to treat a woman, a clinician must take account of the need for the future child to have a father.[149]

The common law is based on traditional notions of the family and parenthood. Its inadequacy to deal with the consequences of RGTs is typified by the manner in which it deals with artificial insemination by donor ("AID"). Legitimacy at common law depended on a child's (genetic) mother and father being married. Children born out of marriage or as a result of adultery were illegitimate. Such children had no claims on their fathers' property, and fathers had no legal rights or duties in respect of their illegitimate children.

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and the state legislation is invalid to the extent of the inconsistency: *The Constitution Act 1900* (Cth), 63 & 64 Victoria, c.12.

148 Victorian Act s.13.

149 UK Act s.13(5).

Early cases in Canada, for example, ruled that the practice of AID amounted to adultery, thus constituting grounds for divorce and criminal prosecution.[150] The British courts took a different view, finding that AID was not adultery.[151] Nevertheless, as the Warnock Committee report stated, in the British common law:

> ... a child born as a result of AID ... is illegitimate. ... In theory the husband of the woman who bears an AID child has no parental rights and duties in law with regard to that child; these in principle lie with the donor, who could be made liable to pay maintenance, and who could apply to a court for access or custody.[152]

In recognition of the inadequacies of the common law to deal with these issues, status of children legislation, which, among other things, outlines who are to be considered the legal parents of a child where donor gametes are used, has been passed in several jurisdictions.[153]

The Natural Order and the Nature of Humankind

RGTs are objected to on the basis that they interfere with nature, and that in using them, scientists and clinicians are "playing God". This objection often proceeds on the basis of slippery slope arguments that herald the moral and/or physical destruction of the human race.[154]

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150 *Orford v Orford* (1921) 49 OLR 15, 58 DLR 251 (HC Ont.); see also Corea *supra* note 24 at 39.

151 *MacLennan v MacLennan* (1958) SC 105 cited in Warnock Report *supra* note 25 at 20.

152 Warnock Report *supra* note 25 at 20.

153 See for example in Australia *Family Law Act 1975* (Cth) No. 53 of 1975 as amended by the *Family Law Reform Act 1995* (Cth) No. 167 of 1995 which provides for the status of children born of artificial conception procedures which is narrowly defined as including artificial insemination and the implantation of an embryo into the body of a woman (s.60D). This would seem to exclude, for example, GIFT using donor eggs. In the United Kingdom see *Human Fertilisation and Embryology Act 1990* ("HFE Act") ss. 27-30.

154 As a personal aside, in reading the literature, both scientific and non-scientific, the interventionist nature of the technologies was striking, particularly in their apparent attempts to "unravel the mysteries of life" (although this is not to say that consequently I disagree with RGTs). Despite all the fascinating aspects, there is something counterintuitive about taking the beginning of new life outside its natural

The official view of the Roman Catholic Church reflects this position in holding that IVF and other forms of reproductive technology are unacceptable because they separate the conjugal act in marriage from its procreative functions, which in nature coexist.[155]

Genetic technologies, such as genetic manipulation, raise the possibility of artificial, non-natural selection of those traits that society (or scientists) deem to be less desirable. The technology used to artificially select traits in agriculture such as tastier tomatoes[156] may be transferred to humans with similar goals: the enhancement of beneficial features and the elimination of unwanted ones.[157] The possibility that these technologies may be used for eugenic purposes is horrifying to most in the community, particularly in the light of the abuses that occurred earlier this century as a consequence of eugenics movements in the United States and Canada, as well as its common association with the Nazi regime in Germany.[158]

Huxlian images of fetuses developing outside the body in incubators, and scientists producing armies of clones genetically engineered to undertake menial tasks for the rest of society are frequently associated

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birthplace. Similarly, the possibility of sex determination and genetic manipulation takes the mystery out of conception and birth.

155 NBCC Report *supra* note 90 at 27.

156 Miller S "Genetic first upsets food lobby" *New Scientist* 1994; 142(1927): 6.

157 IVF and embryo transfer technology in human stemmed from its use in cattle. See further Corea *supra* note 24, chapters 4, 5 and 6 for a discussion of this technology and its transfer from animals to humans.

158 Eugenics programs requiring the forced sterilisation of "mental incompetents" and "mental defectives", for example, existed in Canada and the United States. In Canada, eugenic sterilisation laws were enacted in Alberta in 1928, and British Columbia in 1933. Both were repealed in the early 1970s. In the United States, by the 1930s, 29 states had passed eugenic sterilisation laws. See Sneiderman et al, *supra* note 99 at 297-299. For a detailed account of the eugenics movement in Canada see McLaren A *Our Own Master Race Eugenics in Canada 1885-1945* (Toronto: McClelland & Stewart, 1990).

with RGTs.[159] While these visions remain in the realms of science fiction at least for the time being,[160] they have a strong hold on the minds of the public. With each announcement of a new development in the field comes a barrage of objections based on these types of claims. Such claims, which are speculative at best, highlight the need for those involved in the debate to be well informed about the current state of knowledge, and the direction and likelihood of future developments.

Broadly speaking, this objection formed the basis of the recommendation contained in most of the inquiries to outlaw certain practices in the area of RGTs, although the rationale for doing so was not considered in detail. The Canadian Royal Commission on New Reproductive Technologies considered the rationale for prohibitions to the greatest extent of all the inquiries. Thus, the Royal Commission recommended that certain practices be criminalised on the grounds that they "conflict so sharply with the values espoused by Canadians" and are "so potentially harmful to the interests of individuals and of society, that they must be prohibited..."[161] However, as recognised by Healy,[162] the jurisprudence of criminal prohibitions in this context is considered only superficially, if at all. Statements such as those quoted above tend to be merely proposed, rather than being supported by any comprehensive jurisprudential analysis. The extent to which practices are "so potentially harmful" and "conflict so sharply" with commonly

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159 See Huxley A *Brave New World* (London: Flamingo, 1994) [first published 1932]. Fay Weldon's *The Cloning of Joanna May* (London: Flamingo, 1993) is another fictitious examination of the world of genetic engineering and cloning.

160 But see a recent newspaper report that a team of British and Japanese announced that they were experimenting with "a hi-tech tank" in which a fetus could grow to full term: Popham P "And man became God" *The [London] Independent* (15 August 1996) 14.

161 Royal Commission Report *supra* note 3 at 1022.

162 *supra* note 139 at 920. See also Dickens B "Do Not Criminalize New Reproductive Technologies" (1996) 17(2) Policy Options 11.

held values is not developed in detail. The other inquiries do no better. The Warnock Committee, for example, merely recommended the criminal prohibition of various practices without considering the underlying rationale.[163]

163 See Warnock Report *supra* note 25 at 71, 72.

III LEGISLATIVE REGULATION OF REPRODUCTIVE AND GENETIC TECHNOLOGIES

A. *Introduction*

This section describes the approaches taken to the regulation of RGTs in the legislation that has been enacted in the United Kingdom (the *Human Fertilisation and Embryology Act 1990*), and the Australian states of South Australia (the *Reproductive Technologies Act 1988*), Victoria (the *Infertility Treatment Act 1995*) and Western Australia (the *Human Reproductive Technology Act 1991*). The first stage of the Canadian government's proposals for regulation of RGTs, Bill C-47, to be known as the *Human Reproductive and Genetic Technologies Act* if enacted, is also discussed. The Canadian legislation does not yet contain a regulatory component, although a discussion paper has been released by the federal government which proposes a regulatory scheme similar to that in Britain and the Australian jurisdictions.[164] The regulatory component of the Canadian proposals is therefore not discussed in detail here, although features of the proposed scheme are referred to where relevant.

The discussion in this Part focuses on the framework of the respective regulatory schemes. Accordingly, positions, if any, taken in the respective statutes in relation to substantive moral issues, some of which have been noted in Part II, are not considered. Those aspects of

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164 See further Government of Canada *supra* note 2.

the regulatory schemes relevant in particular to issues of scientific progress and community participation are highlighted.

B. Regulatory Scheme

RGTs are regulated in each jurisdiction by means of a licensing and monitoring system overseen by a statutory body established under the legislation. On a superficial level, the regulatory systems established in each jurisdiction are similar. Thus, in each jurisdiction assisted conception procedures,[165] research, and storage of gametes and embryos[166] must be licensed. In South Australia, a person wishing to carry out assisted conception procedures[167] (except artificial insemination in certain circumstances)[168] or research involving gametes

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165 Assisted conception procedures include artificial insemination ("AI"), *in vitro* fertilisation ("IVF"), embryo transfer ("ET"), gamete intrafallopian transfer ("GIFT") and other less well known procedures such as direct ovum and sperm transfer ("DOST") and pronuclear oocyte salphingo transfer ("PROST"). As discussed *infra* at notes 167, 172, 177 and 183, each statute uses different terminology to refer collectively to these procedures. In general, terms are defined broadly so as to allow techniques that are developed in the future to fall within the purview of the legislation. The term "assisted conception procedures" is used in this thesis to refer generally to techniques used to assist individuals to conceive a child.

166 The legislation in each jurisdiction uses different terms ("zygote", "embryo", "egg in the process of fertilisation") to describe the entity at different points in development. In this thesis, for the sake of convenience, "embryo" is used to refer to the entity from the point at which the sperm and egg first meet, although this definition is not scientifically accurate. Even amongst scientists, the understanding of the definition of "embryo" is not unanimous: Australia, National Health and Medical Research Council *In Vitro Fertilisation Centres in Australia Their Observance of the National Health and Medical Research Council Guidelines* (Canberra: AGPS, 1987) at 3.

167 The term "artificial fertilization procedure" is used in the legislation, the definition of which is "any medical procedure directed at fertilisation of a human ovum by artificial means", and specifically includes IVF and associated activities such as storage of ovum and embryos: see SA Act s.3.

168 A licence is not required if artificial insemination is carried out by a registered medical practitioner who is registered with the Commission and has made an undertaking to the Commission to observe the code of practice, *or* it is carried out gratuitously: s.13(7). This operates as an exemption from licensing requirements. This provision is rather curious since it suggests that if AI is carried out gratuitously it does not have to be carried out by a registered medical practitioner, nor does the person carrying out the procedure need to comply with the code of practice. This conflicts with s.13(8) which says the exemption may be withdrawn if there is a suspicion of breach of the code of practice. None of the statutes in the other jurisdictions contain a similar provision, although in WA AI may be exempted from licensing requirements: s.28(1).

or embryos must be licensed.[169] A person wishing to carry out assisted conception procedures must have appropriate staff and facilities,[170] but the premises themselves do not have to be specifically approved. Licences for artificial conception procedures are only to be granted to fulfil a "genuine and substantial social need" that cannot be filled by existing licences.[171] No such requirement exists in relation to research. There are no statutory limits on the duration of a licence.

In the United Kingdom, a person wishing to create, keep or use embryos for assisted conception procedures[172] or for research must be licensed.[173] Activities authorised by a licence may only be carried out at premises named in the licence and under the supervision of "the person responsible" named in the licence.[174] Premises must be inspected before a licence is granted.[175] Licences for storage and therapy are granted for up to five years, while research licences are granted for up to three years.[176]

In Victoria, both the doctor carrying out assisted conception procedures (excluding artificial insemination)[177] and the premises at which procedures are carried out must be approved or licensed.[178]

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169 SA Act ss.13, 14.

170 SA Act s.13(2)(b).

171 SA Act s.13(2)(a).

172 Assisted conception procedures, referred to broadly in the legislation as "treatment services" that must be licensed, do not include artificial insemination using a husband's sperm. In other words, only artificial insemination using donor sperm requires a licence: see UK Act s.4(1)(b).

173 UK Act s.3, Schedule 2.

174 UK Act s.12.

175 UK Act s.9(7).

176 UK Act Schedule 2.

177 The term "fertilisation procedure" is used in the legislation, and it includes *in vitro* fertilisation, embryo transfer, gamete intrafallopian transfer, etc but not artificial insemination: Victorian Act s.3.

178 Victorian Act ss.6, 7, 22, 97 and 101. This is different from the *Infertility (Medical Procedures) Act 1984* according to which only hospitals at which assisted conception procedures were carried out needed to be approved: s.7. See also Office of the Minister for Health *supra* note 40.

Premises at which donor insemination is performed need not be licensed.[179] A person wishing to undertake research must be an approved doctor or scientist or be supervised by an approved doctor or scientist at premises that have been licensed for the purpose of research.[180] Premises at which gametes or embryos are stored must also be licensed.[181] The duration of licences is determined by the Infertility Treatment Authority which grants the licences.[182]

Finally, in Western Australia, a person wishing to carry out assisted conception procedures,[183] storage of gametes or embryos, or research must be licensed.[184] A licence must specify the premises to which the licence relates and "the person responsible" in charge of ensuring that the licence is complied with.[185] Artificial insemination may be exempted from licensing requirements in certain circumstances.[186] Licences operate for up to five years.[187]

Carrying out activities without a licence is a criminal offence in the United Kingdom,[188] Victoria,[189] and Western Australia.[190] In South Australia, carrying out licensed activities without a licence attracts a penalty but is not stated to be an offence.[191]

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179 Victorian Act s.7.
180 Victorian Act ss.22 and 23.
181 Victorian Act s.54.
182 Victorian Act s.111.
183 The term "artificial fertilization procedure" is used in the legislation and includes artificial insemination and IVF: WA Act s.3.
184 WA Act ss. 6 and 7.
185 WA Act s.27.
186 WA Act s.28.
187 WA Act s.27(4).
188 UK Act s.41.
189 Victorian Act ss. 6, 7, 22 and 163.
190 WA Act ss. 6, 7.
191 SA Act ss. 13(1) and 14(1).

Contravention of or non-compliance with licence conditions[192] is an offence in South Australia[193] and Victoria,[194] but can also result in suspension or cancellation of a licence in these jurisdictions.[195] In Western Australia and the United Kingdom, failure to comply with licence conditions does not constitute an offence but may result in the revocation or variation of a licence. Additional administrative sanctions such as a reprimand or the payment of a monetary penalty to the Crown may be imposed in Western Australia for breach of a licence.[196]

C. Statutory Agencies

Establishment and Functions

Regulatory agencies are established in each jurisdiction.[197] These are: in South Australia, the South Australian Council on Reproductive Technology ("the SA Council"); in the United Kingdom, the Human Fertilisation and Embryology Authority ("HFEA"); in Western Australia, the Western Australia Reproductive Technology Council ("the WA Council"), and in Victoria, the Infertility Treatment Authority ("ITA"). [198]

Specific functions of the agencies differ from jurisdiction to jurisdiction,[199] but all have the basic function of overseeing the

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192 See further pp.58 & 59 below for brief discussion of licence conditions.
193 SA Act ss.13(6) and 14(4).
194 Victorian Act s.110.
195 SA Act s.15, Victorian Act s.115.
196 WA Act ss. 39 and 40.
197 See SA Act s.5; UK Act s.5; WA Act s.8 and Victorian Act s.121.
198 The ITA is new to Victoria. Under the previous Act, the *Infertility (Medical Procedures) Act supra* note 13, there was no licensing agency. Approval of hospitals at which assisted conception procedures were carried out were granted by the Minister for Health: s.7.
199 See SA Act s.10(1), UK Act ss. 8 and 25, Victorian Act s.122, and WA Act ss. 5, 12 and 14.

licensing system by granting licences and formulating licence conditions. In all jurisdictions except Victoria, these bodies also have a role in the formation of public policy on research and practice in reproductive and genetic technology. In Victoria an additional body, the Standing Review and Advisory Committee ("SRACI") is established under the legislation, and has advisory and policy formation functions, particularly in relation to research.[200]

In South Australia, licences for artificial fertilisation procedures are granted by the South Australian health department, with the SA Council providing advice on licence conditions. Research licences are granted by the SA Council, which also formulates the conditions that are to apply to them.[201] In addition, the SA Council is charged with carrying out and promoting certain research and advising the Minister on RGTs.[202]

In Western Australia, the head of the State health department, the Commissioner of Health, is ultimately responsible for administering the licensing scheme, although the WA Council advises the Commissioner generally on licensing and related matters.[203] The WA Council has additional functions similar to those of the SA Council noted above.[204] In South Australia and Western Australia, the respective Councils are not independent from the government, but work with the health departments in each state to administer the regulatory scheme.

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200 Victorian Act ss.140 and 141. The SRACI must also advise the Minister on matters relating to infertility and the use of procedures to avoid genetic abnormality or disease: s.141. The SRACI was established under the previous Act, the *Infertility (Medical Procedures) Act supra* note 13 and had the same functions: see s.29.

201 SA Act ss. 13 and 14 respectively.

202 SA Act s.10(1).

203 WA Act ss. 5 and 14.

In Victoria, the ITA is charged with administering the licensing and approval system, including maintaining a central register of information, and advising the Minister for Health about several aspects of RGTs and the operation of the legislation.[205] Licences for research are granted on the advice of the SRACI.[206]

In Britain, the HFEA is in charge of overseeing the regulatory scheme, including the establishment and operation of a licensing committee to carry out licensing functions, and reviewing and advising the Secretary of State for Health on practice and research using human embryos.[207] The HFEA is expressly stated to be independent from the government.[208]

The Canadian government's discussion paper envisages the establishment of an agency with similar functions to oversee the conduct of RGTs in Canada.[209] While a detailed examination of the constitutional foundations of such an agency is beyond the scope of this thesis, it is worth noting that the constitutional basis for a federal agency in Canada is complex. Health matters are generally within the legislative jurisdiction of the provinces, although the federal government may have authority to legislate in relation to health where the legislation seeks to address a national issue.[210] The Royal Commission on New Reproductive Technologies claimed that the federal government had authority to legislate in this respect on the basis of the peace, order and good government power in the

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204 WA Act s.14.
205 Victorian Act s.122.
206 Victorian Act s.141.
207 UK Act ss. 8(a) and 9(1).
208 UK Act Schedule 1 para. 1.
209 Government of Canada *supra* note 2 at 27.
210 *R v Schneider* [1982] 2 SCR 112 at 141.

Constitution,[211] although doubts have been raised about the ability of this power to support such legislation in light of the relevant jurisprudence.[212]

Membership

The statutes in the Australian jurisdictions envisage a multidisciplinary regulatory agency composed of members from varied backgrounds, and having equal numbers of men and women. The South Australian Council on Reproductive Technology consists of eleven members, representing a broad range of interests. Of these members, two are nominated by institutions involved in research (the University of Adelaide and Flinders University), two are representatives of associations of medical professionals (the Royal Australian College of Obstetricians and Gynaecologists and the Royal Australian College of General Practitioners). One is a representative of the Heads of Churches in South Australia, and one is nominated by the Law Society of South Australia.[213] The associations and organisations from which these members are drawn have sole discretion in respect of who is nominated to membership of the Council, thus decreasing the influence that the government may have on the Council's composition.

The remaining five members are to be nominated by the Minister for Health. In nominating these members, the Minister must endeavour to ensure that the Council has available to it expertise in the various facets of reproductive technology, that other relevant disciplines and backgrounds are adequately reflected, and that the Council's

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211 Royal Commission Report *supra* note 3 at 19.
212 See further Healy *supra* note 139 at 919-919.
213 SA Act s.5(1).

membership is sufficiently representative of the general community.[214] The legislation is silent on what constitutes "other relevant backgrounds and disciplines", or "sufficiently representative of the general community". Other relevant backgrounds could include, for example, philosophy, bioethics, counselling, those with expertise in child welfare matters, and people born as a result of fertilisation procedures.[215]

In Victoria the ITA is comprised of members nominated by the Minister for Health. The Minister has a fairly wide discretion in making nominations for appointments to the ITA, although under the legislation the Minister must "have regard to the need for diversity of expertise and experience and to the need to appoint persons who have the expertise to carry out functions of the Authority or to ensure that these functions are carried out."[216]

While several of the ITA's functions may be described as administrative,[217] others would appear to require a broad range of expertise. Functions such as advising the Minister on developments in the treatment of infertility which the Authority considers "of major importance" would require both scientific expertise (so that developments can be evaluated for their scientific importance) and non-scientific expertise (to evaluate the wider social implications of developments).

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214 SA Act s.5(4).

215 See for example the Victorian Act s.142(2) which calls for people with these backgrounds to be members of the SRACI.

216 Victorian Act s.123.

217 Administrative functions include administering the central register and keeping records about programs carried out under the Act. See Victorian Act s.122.

The SRACI is more diverse. It is comprised of a maximum of 14 members nominated by the Minister for Health who must be mindful of the need for the SRACI to have a diverse membership in making those nominations. In contrast to provisions relating to the ITA, the legislation lists fourteen categories of people from which members may be drawn. The categories include doctors and scientists, members of religious bodies, people from non-scientific disciplines such as philosophy, law, social work, and health education, people who have participated in infertility programs, people with experience in child welfare matters, and people born as a result of assisted reproductive techniques.[218]

The major impact of this Committee is on research approval. All research proposals will be subject to the scrutiny of a range of people from different backgrounds, disciplines and interest groups. The same scrutiny is not given to applications for licences for treatment procedures, which are considered by the ITA alone.

The Western Australian Reproductive Technology Council established under the WA legislation consists of 10 nominated members and an ex officio member who is the Council's Executive Officer. Members are appointed by the Governor on the recommendation of the Minister for Health. Seven of these members are to be drawn from panels of individuals nominated by different professional organisations including the Royal Australian College of Obstetricians and Gynaecologists, the Australian Medical Association, and the Law Society of Western Australia. One member is to be nominated by the

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218 Victorian Act s.142(2).

Minister for Community Services, and three other members are to be nominated by 3 other prescribed bodies.[219]

In making nominations to the Minister, professional bodies should consider the need for the Council to be comprised of individuals with special knowledge and experience in the areas that the Council is required to deal with under the Act, but still be reasonably representative of the general community.[220]

The remaining three members are selected by the Minister.[221] In recommending persons for membership of the Council, whether nominated by professional groups or selected by the Minister, the Minster must endeavour to ensure a wide variety of interests are represented. Thus, the Council must have available to it adequate representation of the interests of women, parents, children born of reproductive technology, and participants in reproductive technology, experts in reproductive technology, experience in public health matters, and ethical guidance.[222] In so far as practicable, the Minister should consider any other appropriate discipline, experience or background is adequately reflected in the Committee's membership. No more than one member of the Council at any time can be a licensee or can have pecuniary or other beneficial interests in the practice of a licensee. The Council should consist of equal numbers of men and women and no one person is to be the sole representative of disparate interests.[223] There may be some difficulty given the size of this Council in complying with this last requirement.

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219 WA Act s.8(2)(i).
220 WA Act s.9(1).
221 WA Act s.8(2)(ii).
222 WA Act s.9(2)(a).
223 WA Act s.9(2).

If the members nominated by professional bodies have sufficient expertise in reproductive technology, more members of the Council may come from non-scientific backgrounds. The Council is therefore not weighted towards scientific or technical expertise. It has sufficient non-scientific representation to balance any scientific interests, and to allow wider social implications to be taken into account in decision-making.

By contrast, the United Kingdom legislation gives a broad discretion to the Secretary of State for Health with respect to the composition of the Human Fertilisation and Embryology Authority. The legislation does not specify a precise number of members, although the minimum is six,[224] nor is there a requirement that there be representatives from the general community.[225]

At least one member of the HFEA must be a medical practitioner, and at least one other member must be a person who is experienced in keeping or using gametes or embryos outside the body. At least one third but not more than one half of the members must represent scientific interests.[226] The remaining members would presumably represent non-scientific interests.[227] The legislation does not give any indication as to the sorts of interests that should be represented, except

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224 Two members are specified - one medical practitioner and one scientist. At least one third of the members must represent scientific interests, and with two mandatory scientific members, the minimum size of the Authority is six.

225 Membership of the HFEA is dealt with in paragraph 1 of Schedule 1 to the UK Act.

226 The legislation specifically calls for medical practitioners, people concerned with keeping or using gametes or embryos outside the body or people who have been directly concerned with commissioning or funding research involving gametes or embryos or who have actively participated in any decision to do so: UK Act Schedule 1 para.4. The Warnock Committee reasoned that a "significant representation of scientific and medical interests" was necessary because of the need to have access to expert medical and scientific advice: Warnock Report *supra* note 25 at 75-76.

227 This is consistent with the recommendation of the Warnock Committee that there should be "substantial lay representation" on the statutory authority to regulate research: Warnock Report *supra* note 25 Recommendation A2 at 80.

that in exercising his or her discretion, the Secretary of State must have regard to the desirability of ensuring that the Authority is informed by the views of both men and women.[228] The Chair is to be a lay person.[229]

At least on its face, the HFEA appears to be weighted toward scientific and medical interests, in contrast to the Australian agencies which are expressly required by the legislation to be multidisciplinary. These alternate approaches to agency composition are examined in detail in Part V, together with the impact agency composition has on the formation of public policy in the area of RGTs.

D. Standards of Practice

One of the rationales for the enactment of legislation to regulate the conduct of RGTs is to provide guidance to doctors and scientists on the proper standards of conduct in the field. The legislation overall evidences two approaches to achieving this aim. According to the first approach standards of practice are set out in detail in the legislation. This approach is adopted in the Victorian Act which lists detailed requirements concerning, for example, indications for treatment,[230] consent of participants and donors and information that must be provided to them,[231] and counselling by approved counsellors.[232] Requirements relating to the provision of information and consent are also listed in relation to research.[233] These requirements are imposed on licensees by way of licence conditions.[234] Licence conditions may

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228 UK Act Schedule 1 para. 4(2).
229 UK Act Schedule 1 para. 4(3).
230 Victorian Act s.8
231 Victorian Act ss. 10, 17 and 21.
232 Victorian Act ss. 11 and 16.
233 See Victorian Act Part III Divisions 2, 3 and 4.
234 Victorian Act s.106.

also deal with matters such as the manner in which research, storage and treatment procedures may be carried out.[235] Licence conditions may be varied at any time during the duration of the licence.[236]

As a consequence of these statutory norms, the ITA in Victoria has a significant amount of control over the practices of licensees. However, the ITA has little input into the content of these norms, which have been predetermined in the legislation. This applies to what may be described as "procedural" norms such as those concerning consent and the maintenance of records, and to substantive matters which were previously within the clinical judgment of doctors, such as the provision of information to patients and counselling. In essence, public policy has been made by the legislature and the role of the ITA is to interpret and implement it.

The SRACI appears to have a more extensive role in the formation of policy than the ITA. Its role in advising the Minister on matters relating to infertility has in the past included advising the Minister in relation to the operation of the legislation. Indeed, it was the advice of the SRACI that lead to the previous legislation being replaced by the current Act. Nevertheless, because the Victorian legislation lays down rules concerning both procedural and substantive matters, within the framework of the legislation, the SRACI has little scope to make policy in relation to proper standards of practice in RGTs.

By contrast in Western Australia, South Australia and the United Kingdom, standards of practice are left to be determined by the regulatory agency, and are either imposed as licence conditions or

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235 Victorian Act s.106(2). In other jurisdictions, these types of matters are dealt with in a code of practice compiled by the regulatory authority. See further pp.59-61 below.

236 Victorian Act s.108.

directions by the agency, or outlined in a code of practice compiled under the legislation.[237] The code of practice is to be kept under review by the regulatory agency,[238] and can be amended to take into account new developments, thus providing greater flexibility to the regulatory scheme.[239] Licence conditions may be varied at any time during the duration of the licence.[240]

The South Australian Council has a wide discretion concerning what is to be dealt with in the code of practice, which is to be promulgated in the form of subordinate legislation.[241] Apart from four matters that the legislation expressly states must be dealt with in the code,[242] it is up to the Council to decide the content of the code. Two codes have been compiled, one relating to research,[243] and the other relating to clinical practice.[244]

The HFEA in the United Kingdom has a similarly broad discretion under the Act in relation to the content of the code of practice. The legislation simply states that the code must give "guidance about the proper conduct of activities carried on ... under [the] Act and the proper discharge of functions" of persons to whom licences apply.[245]

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237 WA Act ss. 15, 27(4) and 31-33, SA Act ss. 10(1)(a), 13(3) and 14(2), UK Act ss. 12-15, 23-25. .

238 SA Act s.10(1)(a), UK Act s.25(4), WA Act s.14(1)(c).

239 Flexibility of the scheme in relation to the manner in which the legislation deals with scientific developments is considered in more detail in Part IV.

240 SA Act ss. 13(5) and 14(3); UK Act s.18; WA Act s.27(4).

241 SA Act s.10.

242 The code of practice must prohibit embryo flushing and the culture of an embryo beyond the point at which implantation would normally occur, and must state that the persons on whose behalf embryos are held have decision-making authority in respect of those embryos, and that an embryo must not be stored for longer than 10 years: SA Act s.10(3).

243 The *Reproductive Technology Code of Ethical Research Practice 1995* is found in the Schedule to the *Reproductive Technology (Code of Ethical Research Practice) Regulations 1995* No.188 of 1995.

244 The *Reproductive Technology Code of Ethical Clinical Practice 1995* is found in the Schedule to the *Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995* No.189 of 1995.

245 UK Act s.25(1).

The only prescribed element relates to access to treatment services: the code must include "guidance for those providing treatment services about the account to be taken of the welfare of children who may be born of a result of treatment services (including a child's need for a father) ...".[246] The code of practice provides guidance on a wide range of matters such as the qualifications of staff at facilities providing treatment services and carrying out research, the standard of research and treatment facilities, the assessment of participants (including donors), the welfare of the child, the provision of information and counselling to participants, consent, the use and storage of gametes and embryos, research, records and complaint procedures.[247]

The Western Australian legislation provides an extensive list of matters that may be dealt with in the code of practice, thus providing more guidance to the licensing body as to the content of the code than in other jurisdictions.[248] The only mandatory prohibitions to be contained in the code are those preventing the use of multiple sources of gametes and embryos in the same assisted conception procedure, and preventing the development of an embryo other than for the purposes of implantation into a woman.[249]

In these three jurisdictions, standards for scientific and medical practice in the field of RGTs are thus not imposed by the legislation, but rather are to be determined by the regulatory agency and outlined in the code of practice or imposed by way of licence conditions. Consequently, the agencies have a significant role in public policy formation. However, the apparently wide discretion of the regulatory

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246 UK Act s.25(2).
247 Gunning & English *supra* note 21 at 117-121.
248 See WA Act s.18(1).
249 WA Act s.17.

agencies in this respect is limited to the extent that the code must not be contrary to prohibitions contained in the legislation. Where those prohibitions are extensive, as is the case in Western Australia, the apparent permissiveness of the legislation and the extent of the agency's decision-making power may be compromised. Similarly, the composition of the regulatory agency will also affect the decisions made by the agency. This is considered in more detail in Part V.

E. Monitoring

In each jurisdiction, the licensing scheme is supported by a system of monitoring, reporting requirements and inspection powers.

Monitoring Licensed Activities

Only the British and Victorian agencies have express monitoring functions. Thus, the HFEA in Britain has a broad function to review information relating to activities governed by the Act, including the development of embryos.[250] The HFEA is entitled to inspect the premises to which an application for a licence relates before it considers the application.[251] Annual inspections are to made of licensed premises, and it is a mandatory condition of all licences that authorised persons be permitted to enter and inspect premises.[252] The Victorian ITA has among its functions to monitor compliance with licences, to keep approved research under regular review, and to keep records about activities carried out under the Act.[253] Functions of this nature are not specifically imposed on the Western Australian and South Australian Councils, despite the presence of a fairly extensive list

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250 UK Act s.8(a).
251 UK Act s.9(7).
252 UK Act s.9(8), and 12(b).
253 Victorian Act s.122(1)(c).

of functions in the respective pieces of legislation. However, monitoring of licensed activities is required for the effective operation of the legislation, otherwise the agency will be unable to obtain evidence for alleged breaches of licence conditions or prohibitions under the Act, nor will there be any incentive for licensees to comply. Monitoring functions are implied by the presence of reporting requirements and inspection powers.

Reporting Requirements

In all jurisdictions, detailed records must be kept by licensees concerning licensed activities, usually as a condition of licences.[254] Certain information from these records, together with any other information the regulatory agency requires, must be provided to the agency.[255] In the United Kingdom, Victoria and Western Australia the HFEA, ITA and Commission of Health respectively are required to maintain a central register of information.[256]

Inspection Powers and Enforcement

In each jurisdiction, authorised persons[257] have the power to enter and inspect licensed premises at all reasonable times.[258] Except in Victoria, authorised persons are also entitled to enter and inspect non-licensed

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254 UK Act ss. 12(d), 13(2), 14(1)(d) and 15(2); SA Act s.13(3)(d) (only in respect of assisted conception procedures, not embryo research); WA Act s.33(2)(f). In Victoria the maintenance of detailed records is a statutory requirement, rather than being imposed as a licence condition: see Victorian Act s.62.

255 UK Act s.12(g), WA Act s.33(22)(h), Victorian Act ss. 64 and 107. There is no statutory requirement in South Australia that information be provided to the SA Council, although regulations may be made to this effect: s.20(2).

256 Victorian Act s.68, UK Act s.31, WA Act s.45.

257 "Authorised persons" are generally employees or officers of the respective regulatory agencies: UK Act ss. 12, 39 and 40, SA Act s.3, Victorian Act s.155,WA Act s.3.

258 UK Act s.12(b), SA Act s.17. In Victoria authorised persons have power to inspect premises "at any time during ordinary working hours on any business day": s.156(2). In WA, the power to enter must be exercised "at all reasonable times and at reasonable intervals" unless there are "good grounds or a reasonable belief for doing otherwise": s.54(6).

premises at which procedures falling within the scope of the legislation are being carried out.[259] Authorised persons may have several of the following powers: to take possession of records,[260] and gametes, zygotes or embryos;[261] to inspect premises and equipment and records on the premises;[262] to require the production of records;[263] to take "such steps as appear to be necessary" to preserve or to prevent interference with things on the premises;[264] and to question any person on the premises.[265] It is an offence, punishable by a fine, to obstruct or hinder an authorised person in the exercise of these powers.[266]

Warrants can be obtained to enter and search any premises and seize items if there are reasonable grounds for suspecting that an offence against the legislation has been committed on the premises.[267] In Britain and Western Australia, warrants allow members or employees of the regulatory agency as well as police officers to enter the premises.[268] In Victoria, only police officers can apply for a warrant to enter, search and seize,[269] although the ITA can apply for a warrant in relation to an alleged breach of orders it issues.[270] A member of the police force and "any assistants" can execute the warrant.[271]

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259 UK Act s.40, SA Act s.17, WA Act s.54.
260 UK Act s.39(1)(a), Vic Act s.156(2), SA Act s.17(1)(a), WA Act s.54(2)(d).
261 UK Act s.39(3), WA Act s.54(1), Victorian Act s.162(7).
262 SA Act s.17(1)(a),(b),(e), Victorian Act s.156(2), WA Act s.54(1),(2)(a), UK Act s.12(b).
263 SA Act s.17(1)(d), Victorian Act s.156(2), WA Act s.54(1)(b), UK Act s.39(1).
264 WA Act s.54(3)(b), UK Act s.39(1)(b).
265 SA Act s.17(1)(c), WA Act s.54(1)(b)(ii).
266 SA Act s.17(2), WA Act s.54(7), Victorian Act s.157, UK Act s.41(6)(b).
267 UK Act s.40, WA Act s.55, Victorian Act s.162.
268 UK Act s.40(2), WA Act s.55.
269 Victorian Act s.162
270 Victorian Act s.162(2). The ITA has power to make orders, approved by the Minister, relating to various matters if it cancels or suspends a licence. Failure to comply with an order attracts a penalty and orders are published in the Government Gazette: Victorian Act s.116.
271 Victorian Act s.162(3).

Proceedings for offences in the United Kingdom may not be commenced without the consent of the Director of Public Prosecutions.[272] The same requirement does not appear in any of the Australian legislation, although it does appear in the Canadian Bill.[273]

Broad inspection powers are clearly necessary for the effective operation of the regulatory scheme, so that investigations can be carried out and evidence can be obtained to support decisions by the regulatory agency in relation to licences and the prosecution of offences. This observation causes one to question the effectiveness of the proposed Canadian legislation as it currently stands. Enforcement of this legislation, which, as discussed below,[274] prohibits several unacceptable practices by way of criminal sanctions, will be problematic in the absence of a regulatory authority with broad inspection powers. Until legislation is introduced establishing a regulatory scheme, investigation of alleged offences will be left to the police force, which arguably has higher priorities than the investigation of infertility clinics and research institutions for alleged offences under the legislation. In addition, the provision that the consent of the Attorney-General is required for prosecution of offences under the legislation leaves the way open for the Attorney-General to have a policy of non-prosecution which would further undermine the effectiveness of the legislation.[275]

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272 UK Act s.42.

273 Canadian Bill cl.11.

274 See pp.70-71 below.

275 A precedent for this in Canada can be found in the policy of non-prosecution that the Attorney-General has in relation to the withdrawal of life sustaining treatment which strictly contravenes s.217 of the Criminal Code of Canada RSC 1985 c.C-46. See further Law Reform Commission of Canada *Euthanasia, Assisting Suicide and Cessation of Treatment* Working Paper 28 (Ottawa: The Commission, 1982) at 17.

F. Research

Broadly speaking, all of the legislation distinguishes between research and therapy. For the most part, research projects are subject to greater scrutiny than assisted conception procedures, which are assumed to be acceptable and standard treatment procedures. In South Australia, research projects must be approved by the 11 member Council, while licences for assisted conception procedures are granted by the South Australian Health Commission.[276] In the United Kingdom, individual research projects must be licensed,[277] whereas a licence for assisted conception procedures may apply generally to treatment services at a particular clinic. In Victoria, applications for research approvals are considered by the 14 member SRACI, while applications for assisted conception procedures are considered by the ITA only. As noted above, the SRACI has a much broader membership, representing a wider range of interests than the ITA.[278]

The position in Western Australia appears to be slightly different. Specific research proposals may not need to be approved if the research is of a kind that is generally approved in the code of practice under the legislation.[279] Otherwise, the licensing procedure for research is the same as for assisted conception procedures. In South Australia and Victoria, decisions involving research licences are not reviewable by the courts,[280] and consequently, the SA Council, and ITA and SRACI have sole decision-making authority in relation to the acceptability of research projects.

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276 SA Act ss. 13(1) and 14(1).
277 UK Act Schedule 2 para. 4(2)(b).
278 See pp.52-54 above.
279 WA Act s.20(2).
280 SA Act s.16(4); Victorian Act s.150. The reviewability of decisions is considered in more detail in Part V.

None of the legislation in the Australian jurisdictions expressly allows the creation of embryos for research purposes.[281] Research involving human embryos is probably the most controversial area of RGTs because of the moral absolutes involved. The Australian legislation and Canadian bill all set down specific limits in which human embryo research may take place, which presuppose different views as to the status of the embryo.[282] Furthermore, legitimate research purposes appear to be limited to the acquisition of knowledge concerning the cause, treatment and prevention of infertility, including, by implication, improving clinical IVF and other assisted conception procedures. In addition, the means by which these research purposes are achieved must not violate prohibitions contained in the legislation. In South Australia, research falling within the scope of the legislation is limited to research involving human reproductive material.

To this extent these pieces of legislation may be characterised as prescriptive, and impose a certain moral standpoint that is not necessarily agreed to by all in the community. Acceptable research is research that falls within the boundaries set by the legislation, and these boundaries limit the discretion of the regulatory agency to make decisions about the appropriateness of research projects in the area of RGTs.

The British legislation takes a different approach. It adopts the broadest and most permissive stance in relation to embryo research. The legislation lists a range of purposes for which research may be

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281 As noted at pp.33-35 above, the creation of embryos for purposes other than implantation is prohibited in the Victorian Act s.49(1) and WA Act s.17(b). The creation of embryos for research purposes is also prohibited in the Canadian Bill cl.4(1)(k). In South Australia neither the legislation nor the codes of practice expressly prohibit nor allow the creation of embryos for research purposes.

282 See discussion at pp.33-35 above.

performed, and allows the creation of embryos for these purposes, subject to the approval of the licensing committee.[283] These purposes are promoting advances in the treatment of infertility; increasing knowledge about the causes of congenital disease and miscarriages; developing more effective techniques of contraception; and developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.[284] It does not follow however that all research projects, however destructive of or detrimental to the embryo, will necessarily be permitted. Rather, the legislation shifts the decision-making process from the legislature to the HFEA. The legislation thus facilitates debate and discussion within a forum that is equipped to deal with the issues as they arise, rather than resolving conflicts through the imposition of inflexible statutory rules. In not prohibiting certain practices such as "destructive" research on human embryos no the creation of embryos for research, it leaves the licensing committee with a broad discretion to evaluate the acceptability of the means by which research aims are achieved.

In all jurisdictions except Western Australia, research licences apply only to research using extracorporeal embryos,[285] but not to research involving human subjects. Thus, any research or experiments involving embryos *in utero* or women or men undergoing assisted conception procedures either fall within the scope of assisted conception procedures, as defined in the legislation,[286] or fall entirely outside the scope of the regulatory scheme. Except in Western

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283 UK Act Schedule 2 para 3(2).

284 The Act allows additional purposes to be specified in the regulations: UK Act Schedule 2 para 3(2). As at 1 January 1996, no purposes had been specified: *Halsbury's Statutes of England* (London: Butterworths, 1995).

285 In South Australia, research approval must also be obtained for research involving gametes as well: see SA Act s.3 and 14.

286 See *supra* at notes 167, 172, 177 and 183.

Australia research involving human subjects will be dealt with under existing ethical regimes for the evaluation of research projects, or if changes in procedure can be characterised as "innovative therapy",[287] will remain unregulated. Yet the inquiries agreed that this situation was insufficient to deal with the social, ethical and legal issues involved in the conduct of RGTs.

If the aim is to provide a comprehensive approach to the regulation of RGTs, this is a significant omission. The failure to include research on human subjects means that RGT research involving men and women is not subject to the same scrutiny or regulation as research involving human embryos. This is regrettable in legislation that purports to provide a comprehensive scheme for the regulation of conduct in this area, particularly in light of the less than optimal success rate of many assisted conception procedures.[288] The narrow scope of research under the legislation reflects the assumption that IVF and related procedures are standard and acceptable clinical practice. This implies that these procedures are safe and effective treatments for infertility or the avoidance of genetic abnormality. Yet IVF procedures have never been the subject of a well-designed, multicentre, randomised clinical trial to evaluate their effectiveness.[289] Consequently, comprehensive statistics on the outcome and effectiveness of these procedures are lacking.[290]

The assumption is also reflected in the legislation to the extent that assisted conception procedures are not subject to the same scrutiny as research projects involving human embryos. IVF and related procedures do however have experimental components and

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287 See further discussion at pp.82 & 87 below.
288 See *supra* at note 65.
289 Stanley & Webb in *supra* note 65 at 67. See also Shanner *supra* note 62 at 870.
290 See Royal Commission Report *supra* note 3 at 518.

applications, such as use in post-menopausal women.[291] In addition, it is undisputed that women face significant physical and psychological risks when undergoing IVF procedures. These observations, together with the relatively low success rate[292] challenge the notion that IVF is indeed a safe and effective procedure. As many feminists have pointed out,[293] given societal pressure on women to have children, women are at risk of being exploited in the conduct of RGTs. Social pressures also raises the question as to whether women's consent to these procedures is truly free and informed. Where procedures have a significant experimental component and/or the benefits do not clearly outweigh the risks, it is at least arguable that the performance of these procedures ought to be subject to additional scrutiny.[294]

Failure to include research on human subjects may lead to a fragmented approach to the regulation of the conduct of RGTs. Research involving women (and men) ought to be given the same scrutiny as research involving embryos under the legislation. Failure to do this suggests that the embryo is the only subject of IVF research, and obscures or even denies the necessary role that women in particular play in this research.[295] It is an example of the law being insensitive to the concerns of women, and a failure to recognise that women, as well as embryos, are at risk of exploitation in biomedical research in the field of RGTs. Only the Western Australian legislation appears to recognise this by including all research in the area of RGTs within its scope. It stands alone in requiring research involving "any

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291 *ibid* at 499; Australia, National Health and Medical Research Council *Statement on Human Experimentation and Supplementary Notes* [hereinafter NHMRC *Statement*], *Supplementary Note 4 In Vitro Fertilisation and Embryo Transfer* 1982.

292 See *supra* note 65.

293 See discussion in Part II at pp.36-37 above.

294 See further discussion at pp.86-87 below.

295 See Gaze B & Dawson K "Distinguishing Medical Practice and Research: The Special Case of IVF" (1989) 3 Bioethics 301 at 316-317.

person who is a participant in" assisted conception procedures, as well as research involving gametes and embryos, to be approved by the WA Council.[296]

G. *Prohibited Practices*

The legislatures in Canada, the United Kingdom, Victoria, and Western Australia have taken a prohibitive approach (though to differing degrees) to practices that are considered inappropriate or unacceptable in the field of RGTs. Prohibitions in the legislation generally stem from the recommendations of the inquiries that preceded the legislation. Prohibited practices (other than failure to comply with licences or carrying out activities without a licence)[297] are essentially those that challenge fundamental ideas about the individual and collective identity of humankind, such as cloning,[298] the production of animal-human hybrids, and certain genetic manipulation techniques.[299]

The criminalisation of RGTs has been criticised in detail elsewhere.[300] However, some points are worth noting. The prohibitive approach has been challenged on the basis that it is contrary to traditional criminal jurisprudence. The most common rationale for the implementation of criminal sanctions is the protection of society from harm.[301] Many of the criminally prohibited practices are not currently feasible.

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296 WA Act s.20. Research involving gametes must also be approved: *ibid*.

297 See pp.48-49 above .

298 As used in the legislation, cloning refers to the production from one person of another genetically identical person: see WA Act s.3, Victorian Act s.3. Cloning also refers to the process of replicating and using recombinant DNA molecules in biological cells (Baker R & Clough W "The Technological Uses and Methodology of Recombinant DNA" (1978) 51 Southern California LR 1009 at 1016), which was the type of cloning that prompted the "recombinant DNA controversy" in the 1970s. See further Fogelman V "Regulating Science: An Evaluation of the Regulation of Biotechnology Research" (1987) 17 Environmental Law 183.

299 Various other practices are prohibited and attract criminal sanctions but differ from jurisdiction to jurisdiction: see WA Act, s.7; Victorian Act ss. 39-50; UK Act ss. 3 and 41. The SA legislation stands out in not prohibiting any of these practices.

300 Dickens *supra* note 162; Healy *supra* note 139.

301 Healy *ibid* at 922.

Consequently, any alleged harm caused by these practices is necessarily speculative. It is thus not clear that the prohibited activities are so serious a threat that they should attract criminal sanctions. As Dickens has pointed out, a case can be made that certain of these practices may be beneficial and justifiable in certain circumstances, or may become beneficial or justifiable in the future.[302] An approach that prohibits these activities outright is inflexible, and denies this possibility. Furthermore, legislation adopting a prohibitive approach is not easily adaptable to scientific developments or changing social values.

The problems of a prohibitive approach may be illustrated by the recombinant DNA controversy in the 1970s. Although not strictly analogous, it provides some useful incites into some of the problems of regulating science through prohibitions.[303] The controversy arose as a result of concern of scientists involved in recombinant DNA experiments about the potential hazards to human health that could arise from the production of genetically manipulated bacteria. The main concern was how to balance the need for regulation with the freedom of scientific inquiry[304] when the hazards that were sought to be prevented were "unknown or ill-defined".[305] Although discussion took place at the level of the general public,[306] the issue was resolved

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302 Dickens *supra* note 162 at 11.

303 For a history of the controversy see further Swazey J, Sorenson J & Wong C "Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy" (1978) 51 Southern California LR 1019.

304 Gold J "Short Reviews of Selected Books and Articles" (1980) 6 Am J Law & Med 53 at 54 (Review of various materials about the recombinant DNA controversy).

305 Korwek E & Cruz P "Federal regulation of environmental releases of genetically manipulated microorganisms" (1985) 11 Rutgers Computer and Technology LJ 301 at 381-2.

306 Much of the writing of the issue at the time considered, among other things, the need for the public to be involved in the formation of public policy in the area: see for example Swasey, Sorenson & Wong *supra* note 303 at 1077 and articles contained in the symposium in Volume 51 Southern Californian Law Review. Who should be involved in public policy formation in science and technology is considered further below in Part V.

mainly within the scientific community. Self-regulation by the scientific community through the adoption of ethical guidelines promulgated by the National Institutes for Health in the United States was the favoured model.[307]

Subsequently scientists came to believe that recombinant DNA biotechnology was not as hazardous as originally thought.[308] As a result, since the late 1970s the guidelines have been periodically relaxed.[309] However, the concerns that prompted the debate continue to have a strong hold on the minds of the public, so that the scientific community now finds it difficult to convince the public of the safety of their research.[310]

The likelihood of a similar situation occurring in respect of RGTs is potentially great in those jurisdictions in which morally questionable conduct is prohibited in legislation and attracts criminal sanctions. Criminalisation reinforces the notion that the harms that will allegedly result from these practices are inevitable, a proposition that is speculative at best in the context of many of these practices. After the prohibitions have been in place for several years, it may be difficult to convince both legislatures and the public of the safety of procedures, even if there is strong scientific evidence to this effect. Prohibitions in legislation will be procedurally difficult to change, requiring legislative amendment and Parliamentary and community debate. Legislation that seeks to regulate conduct before enough is known about the consequences of that conduct may therefore be premature.

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307 Attempts to have the United States Congress pass legislation on the issue failed: see Jasonoff S *Science at the Bar Law, Science and Technology in America* (Cambridge, Massachusetts: Harvard University Press, 1995) at 143.

308 *ibid* at 142; Fogelman *supra* note 298 at 191.

309 Jasonoff *supra* note 307 at 142.

310 Fogelman *supra* note 298 at 191

It may be equally difficult to change the minds of individuals in relation to practices that are allowed to continue, but which are later shown to be of questionable morality. As noted above,[311] IVF procedures are assumed to be safe and effective, despite the absence of clear evidence to this effect. The response of many sectors of the community to the calls of radical feminists to outlaw these and related procedures altogether, demonstrate the difficulty of changing people's perceptions about conduct that has in many cases reached a certain level of acceptability by default.

Criminalisation should not be implemented if there is a less coercive form of effective control.[312] A regulatory approach, supported by administrative sanctions such as the revocation of a licence, or indirect prohibitions to ensure compliance with the regulatory scheme,[313] is a less draconian form of effective control.[314] A regulatory approach is also more flexible and more able to take scientific developments and changing social values into account. A regulatory approach has been adopted in South Australia. The South Australian legislation does not prohibit any particular uses of RGTs, leaving these matters to be dealt with by the regulatory body in the code of practice.

When considered in this light, it is debatable whether the argument for criminalisation can be sustained. Nevertheless, in Canada at least, a prohibitive approach is necessary for constitutional and political reasons. Bill C-47 has been proposed by the Canadian government under the criminal law power in the Canadian constitution.[315] Since

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311 See p.69 above.
312 Healy *supra* note 139 at 923.
313 *ibid* at 921; Dickens *supra* note 162 at 12.
314 Dickens *ibid* and Healy *ibid* both favour a regulatory approach to RGTs.
315 *Constitution Act 1982* being Schedule B to the *Canada Act 1982* (UK), 1982, c.11, s.91(27).

matters of health and the family are within the legislative jurisdiction of the provinces and territories, use of the criminal law power, and hence the enactment of prohibitions, is the only means, in the absence of cooperation by the provinces and territories, by which the federal Canadian government could enact legislation that applies uniformly throughout Canada. In the current political climate which views increased federal power with suspicion, cooperation of the provinces and territories is highly unlikely. When viewed in this light, the legislation evidences a grab for power by the Canadian federal government against provinces that are becoming increasingly disillusioned by federalism.

H. Characterisation of the Legislation

Each piece of legislation evidences various approaches to different matters, which makes characterisation difficult and to some extent artificial. Nevertheless for the purposes of the discussion that follows, the legislation is characterised according to its approach to two issues. First, the approach it takes to morally questionable practices is characterised as either prohibitive or regulatory. Secondly, the approach the legislation takes to the formation of public policy and standards of practice is characterised as either prescriptive or facilitative.[316]

The prohibitive/regulatory distinction is self-evident. Legislation taking a prohibitive approach uses the most draconian of legislative sanctions, criminalisation, in an attempt to prevent individuals from carrying out morally questionable conduct. By contrast, legislation

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316 Montgomery *supra* note 42 at 526.

adopting a regulatory approach relies on less coercive administrative sanctions to prevent morally questionable conduct.

Prescriptive legislation adopts certain substantive moral positions supported by sanctions to ensure compliance with the norms of conduct outlined therein. Legislation adopting a facilitative approach avoids substantive moral positions, and instead provides a framework within which public policy is made by a regulatory body established under the legislation rather than being imposed by the law.

Unacceptable practices

As noted above, the Victorian, Western Australian and United Kingdom statutes prohibit several morally questionable practices with criminal sanctions. Accordingly, this legislation may be categorised as taking a prohibitive approach to unacceptable practices. By contrast, the South Australian legislation prohibits few activities, preferring to take a regulatory approach. Unacceptable practices are prohibited in the code of practice. Failure to comply with the code attracts regulatory sanctions such as the revocation of a licence, rather than the criminal sanctions of a fine and/or imprisonment.

Public Policy Formation

The Victorian legislation can be characterised as prescriptive, the legislation laying down rules on substantive and procedural matters and leaves limited scope for these matters to be determined by the ITA or SRACI. The South Australian, United Kingdom and Western Australian statutes take a more facilitative approach to public policy formation, with the SA Council, HFEA and WA Council respectively playing a significant role in the formation of standards of practice of RGTs. In Western Australia, this approach is compromised by the

prohibitions contained in the legislation. Except in Western Australia then, the legislature plays a limited role in setting standards of conduct, shifting the locus of decision-making to the regulatory agency.

IV LEGISLATING SCIENCE

A. Introduction

In the previous Part, the legislative schemes for the regulation of research and clinical practice in RGTs in the United Kingdom, South Australia, Western Australia and Victoria were described. The regulatory agencies established under the legislation have a significant role in directing scientists and clinicians as to the norms and standards of conduct of RGTs. The legitimacy and effectiveness of these norms, whether determined by the regulatory agency or imposed by the legislation, depend on their ability to apply to the situations at hand.

However, the legal regulation of science is problematic because science and law operate on fundamentally different bases. Science is constantly progressing and changing in the continual quest for knowledge, or, in the medical context, the quest for a safer and more effective treatment. Law, on the other hand, seeks to provide a normative framework within which legitimate social activities can take place. Law seeks certainty, while science proceeds on the basis of uncertainty; the law is static, while science is constantly on the move.

The differences between law and science present a particular challenge for legislative regulation. Legislation is forward-looking, aiming to regulate future conduct. Yet in the scientific context, it is often difficult, if not impossible, to predict precisely what that conduct will be.

In this Part, the challenges to a legislative approach to the regulation of RGTs stemming from the differences between law and science are

examined, and the statutes in each jurisdiction evaluated for their adequacy in dealing with these differences. In the first section the distinction made in the legislation between research and clinical practice is analysed in light of the way in which science and medicine progress to illustrate some of differences between science and law. In the second section, the statutes are examined for the extent to which mechanisms are provided whereby the regulatory agencies can keep apprised of scientific developments and can incorporate these developments into the decision-making process in an attempt to regulate future conduct and to deal with the differences between science and law.

B. Research and Clinical Practice

As noted in Part III, the legislation distinguishes between research and clinical practice, such that research projects are for the most part subject to greater scrutiny than assisted conception procedures.[317] The distinction in the legislation between research and clinical practice is made for policy reasons. But as is demonstrated in the following discussion, although necessary, this distinction is arbitrary and difficult to maintain both in theory and in practice.

The distinction between "research" and "clinical practice" has been a concern of ethicists and others since the Second World War. The revelation of the atrocities that occurred during the Nazi regime in particular,[318] led to the promulgation of international codes of research

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317 See pp.65-66 above .

318 Experiments carried out during the Nazi regime in concentration camps are the most infamous of the twentieth century's abuses in medical research. There are several others such as the Tuskegee syphilis experiments in the United States, and the New Zealand cervical cancer affair in the late 1960s: see further Jones J *Bad Blood The Tuskegee Syphilis Experiments* (New York: Free Press, 1981) and New Zealand, Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer

ethics to the end of ensuring that "medical research should never again be tainted by such callous disregard for the rights of the individual".[319]

There are two important requirements of ethical research. First, because the proposed procedure or treatment has not yet been shown to be safe and effective, the respective risks and benefits of a proposal must be weighed. Risks must be minimised, but may be justified on the basis of the potential advantages of the research.[320]

Secondly, as a result of historical abuses, there is a minimum ethical requirement of obtaining the research subject's free and informed consent to involvement in a research project.[321] As it applies in research ethics, the doctrine of informed consent is in part a recognition of the potential conflict of interest that may arise in the context of research. While in clinical practice the medical practitioner has a duty to act in the best interests of the patient, in research the investigator (who may also be the subject's treating medical practitioner) may "see the development of new knowledge as an end that takes precedence over the well-being of the subject."[322]

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at National Women's Hospital and into Related Matters *Report* (Auckland: Government Printing Office, 1988) respectively.

319 Mason J & McCall Smith R *Law and Medical Ethics* 4th ed. (London: Butterworths, 1994) at 349.

320 *ibid* at 351; World Medical Association, *Declaration of Helsinki* 1964 as amended at the 29th World Medical Assembly Tokyo Japan October 1975 Principle 5; NHMRC *Statement supra* note 291 Principle 3 ; Canada, Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada *Code of Conduct for Research Involving Humans* (Draft document, March 1996) (Ottawa; Minister of Supply and Services, 1996) [hereinafter MRC *Code of Conduct*] at 2-11 - 2-12.

321 Australia, NHMRC *Statement supra* note 291 Principle 8; MRC *Code of Conduct supra* note 320 at 2-8 - 2-11.

322 Levine R "Boundaries between Research Involving Human Subjects and Accepted and Routine Professional Practices" in Bogomolny R, ed, *Human Experimentation* (Dallas: SMU Press, 1976) 3-20 at 4.

While a medical practitioner's duty to obtain a patient's informed consent is a prerequisite to the performance of clinical procedures,[323] there may a more stringent duty in relation to research.[324] In the legal context, in *Halushka v University of Saskatchewan*[325] the Saskatchewan Court of Appeal stated:

> the duty upon those engaged in medical research to those who offer themselves as subject for experimentation is at least as great as, *if not greater than*, the duty owed by the ordinary physician to his [sic] patient. ... There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may be in ordinary medical practice".[326] [emphasis added]

Despite the passing of almost fifty years since the doctrine of informed consent for research was first codified internationally,[327] the issue is still debated.[328] This is particularly the case for so-called "vulnerable" populations. The capacity of individuals within this category to

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323 Informed consent is an ethical and legal prerequisite in Canada. In relation to the legal prerequisite see *Reibl v Hughes* [1980] 2 SCR 880, (1980) 114 DLR (3d) 1; but see in Australia *Rogers v Whitaker* (1992) 109 ALR 625 in which the High Court of Australia articulated the principle in terms of the duty to warn and held that a medical practitioner has a duty to warn a patient of the material risks of a procedure, but expressly rejected the use of the term "informed consent" in this context: *ibid* at 633. Nevertheless, informed consent is an ethical requirement in Australia in relation to research: see NHMRC *Statement supra* note 291 Principle 8. The British authority on "informed consent" or, more accurately, the duty of warn is *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 All ER 643.

324 Gaze & Dawson *supra* note 295 at 303.

325 (1966) 53 DLR (2d) 436.

326 *ibid* at 443-4. But see Levine R "The Boundaries Between Biomedical or Behavioral Research and the Accepted and Routine Practice of Medicine" in The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research *The Belmont Report Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington DC: US Government Printing Office, 1978) [hereinafter *Belmont Report*] Appendix Volume 1, 1-1 - 1-44 at 1-2 who says that negligence for lack of full disclosure has been found (at least in the United States) in cases involving practice and not research and thus queries whether anything turns on the distinction at law. Nevertheless, my intuition is that in the reality of clinical practice, the notion of informed consent is somewhat illusory, with most patients doing what their doctors recommend to them. More stringent requirements in relation to research, where in many cases the benefit to the patient (as opposed to the wider community) may not be obvious, may accordingly be justified.

327 The first codification was in the Nuremberg Code in 1947 which arose from the Nuremberg Trials following the second World War. The principles contained in the Nuremberg Code were adopted by the World Medical Association in the Declaration of Helsinki in 1964: Mason & McCall Smith *supra* note 319 at 350.

328 For a brief discussion of some of the controversies, see *ibid* at 359-362.

consent is questioned, either because of incompetence arising for example from a mental disability or disorder, or because the circumstances are such as to raise the question as to whether consent is truly "free" and uncoerced, as in the case of prisoners or students.[329] People falling into this category are considered to be at greater risk of exploitation in research projects. Depending on one's moral viewpoint, human embryos may fall into the category of vulnerable research subjects.[330] While embryos are obviously unable to give consent, consent may be given by their "parents" (or the people on whose behalf they are held).[331]

A procedural consequence of the distinction between research and practice is the requirement that research be subject to greater scrutiny than the procedures involved in clinical practice. Thus, rather than being simply a matter of the clinical judgment of the practitioner/investigator, a research ethics board or institutional ethics committee is called upon to evaluate a research proposal to ensure that the ethical requirements are met.[332] The same scrutiny is generally not

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329 See for example discussion in MRC *Code of Conduct supra* note 320 at 12-10.

330 See generally Dworkin G "Law and Medical Experimentation; Of Embryos, Children and Others with Limited Legal Capacity." (1987) 13 Monash University LR 189-208. This would not be an issue if one's view of the moral status of the embryo is that it is equivalent to other tissue or as property. In that case, only consent of the "donor/s" would be required. There would be no question of protecting the embryo from potential abuse.

331 This situation may be considered analogous to the case of parental consent for research involving children. The legislation may be interpreted as reflecting such a position in its consent requirements for embryo research, although this is only one way of interpreting the legislation. An alternative interpretation is that consent requirements are analogous to those for research involving human tissue which call for the consent of the tissue donor. However, given the special status generally considered to attach to human embryos as discussed above in Part II, the interpretation of consent provisions as reflecting the notion that the embryo is a vulnerable research subject is to be preferred.

332 The requirement in the British and Australian legislation that research proposals be specifically approved by the regulatory agency in each jurisdiction can be considered a legal codification of this requirement. In addition to addressing the issue of consent and evaluating the respective risks and benefits of the proposal, research proposals must fulfil the general requirement of scientific merit: see MRC *Code of Conduct supra* note 320 at 2-4 - 2-7; NHMRC Statement *supra* note 291 Principles 1 & 4. For a more detailed examination of the requirement of scientific merit, see Freedman B

applied to interventions characterised as clinical practice which are assumed to be safe and effective. The morality of conduct of these interventions is left to be decided within the confines of the private doctor-patient relationship, and intervention by a third party is generally not considered necessary or justifiable. Third party scrutiny of clinical practice would not only be administratively burdensome, but is contrary to the characterisation of medicine as a profession.[333]

Distinguishing between research and clinical practice is difficult, both in practice and in theory. In practice, medical science does not proceed by way of discrete discoveries. Rather, progress occurs largely through incremental developments and variations in clinical practice as a consequence of observation and experience.[334] Much progress occurs as a result of "innovative therapy", that is, "the performance of a new or non-standard intervention as all or part of therapeutic activities and not as part of a formal research project."[335] Clinical practice is rarely fixed, but is continually developed and improved on the basis of new knowledge.

"Scientific Value and Validity as Ethical Requirements for Research: A Proposed Explication" *IRB* 1987; Nov/Dec: 7-10.

333 Two of the fundamental characteristics of a profession are that norms of practice are generally determined and enforced by the profession itself (self-regulation) and the professional practitioner is relatively free of lay control and evaluation: Clarke J *Health, Illness and Medicine in Canada* (Toronto: McClelland & Stewart, 1990) at 199.

334 An example of this progression comes from the Australian experience with the use of human pituitary gonadotropins as a treatment for infertility. Throughout the duration of the federal government-sponsored program, the optimal use of pituitary hormones was being worked out as a result of on-going clinical observation in patients who were treated with the hormones. See further Australia, Inquiry into the Use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease *Report* (Canberra: AGPS, 1994) at 719-722.

335 Dworkin *supra* note 330 at 192. The Draft Guidelines of the Australian National Health and Medical Research Council state that innovations in clinical practice in the field of RGTs, when applied to more than one individual are to be considered research: Australia, National Health and Medical Research Council *Draft Guidelines on Assisted Reproductive Technology* (April 1996) at 4, adopting the characterisation of the United Kingdom Medical Research Council in its report *Responsibility in Investigations on Human Participants and Material and on Personal Information* (1992).

This is certainly true of RGTs. Scientists and clinicians recognise that the practices and procedures involved in RGTs are far from optimal.[336] Despite IVF having been practiced since the late 1970s, its success rate remains modest.[337] Many genetic technologies are at relatively early stages of development, and have not attained the status of accepted or standard clinical practice. Scientists are only just beginning to understand the complexities of fertilisation and early embryonic development, and to apply this knowledge in clinical practice. Much work therefore needs to be done to improve the clinical procedures involved in the conduct of RGTs.

The continuing progress and development of RGTs typifies the challenge for legislation in this area. Are treatment variations innovative therapy and therefore within the scope of clinical practice, or do they constitute research with its attendant ethical and procedural implications? A more specific example: do changes in the cultural media in which embryos created *in vitro* develop prior to transfer to a woman's uterus constitute research or clinical practice?[338]

The legislation itself does not provide much guidance. In Canada, South Australia and the United Kingdom, the word "research" is undefined. In Victoria, the definition is so broad ("an experimental procedure or a clinical trial"[339]) as to be of little assistance. The common law in Canada, the United Kingdom and Australia is similarly

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336 Dawson K & Trouson A "Future Prospects" in Trouson A & Gardner D, eds, Handbook *of In Vitro Fertilization* (Boca Raton: CRC Press, 1993) 303-311 at 304;

337 See references at *supra* note 65.

338 Gaze & Dawson *supra* note 295 at 308. The cultural media in which embryos develop is not yet optimal, and hence is one of the aspects of IVF that is still being investigated: see Gardiner D and Lane M "Embryo Culture Systems" in Trouson & Gardiner *supra* note 336 at 85-114.

339 Victorian Act s.3. In addition, the definition specifically refers to parthenogenesis (cell division in an oocyte (female gamete) which only involves the chromosomes of an oocyte, with no contribution from male gametes).

of limited help, the difference between "research" and "clinical practice" not having been considered to any significant extent by the courts in any of these jurisdictions.[340]

Although the term "research" is not specifically defined in the United Kingdom legislation, the Act implies an approach which distinguishes research from practice on the basis of intent.[341] Research falling within the scope of the legislation is distinguished from treatment procedures on the basis of its purposes.[342] Similarly, in South Australia and Victoria, as noted in Part III, research falling within the regulatory jurisdiction of the agencies in each state appears to be limited to research for the purpose of investigating the causes, prevention and treatment of infertility generally. To this extent, a test for research based on purposes or intent is also implied in the South Australian and Victorian legislation.

In the Western Australian legislation, "research" is defined according to its primary purpose. Thus, "research" means:

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340 A search of various legal words and phrases dictionaries (James J, ed, *Stroud's Judicial Dictionary of Words and Phrases* 5th ed. (London: Sweet & Maxwell, 1986) and Canada's *Words and Phrases Judicially Defined in Canadian Courts and Tribunals* (Toronto: Carswell, 1993)) reveals a surprising lack of judicial consideration of the meaning of the terms "research", "clinical practice" or "experimentation". The meaning of the term "experimentation" has been considered in the context of legislation in two states in the United States: see *Margaret S v Edwards* 794 F 2d 994 (US CA 5th Circ 1986), and *Lifchez v Hartigan* 735 F Supp 1361 (US DC Illinios 1990). In both cases, in the absence of a definition of "experimentation", the legislation was struck down as constitutionally vague contrary to the 14th amendment to the American Bill of Rights.

341 An approach based on the intent of the research was adopted by the United States National Commission for the Protection of Human Subjects of Biomedical Research (the Belmont Commission). See *Belmont Report supra* note 326 at 2-4. Other bases for the distinction are design or the use of novel techniques or agents or that the research is described in a formal protocol: Freedman B et al "Demarcating Research and Treatment : A Systematic Approach for the Analysis of the Ethics of Clinical Research" *Clinical Research* 1992; 40: 653-660 at 653.

342 UK Act Schedule 2. A licence may not authorise the creation of embryos both for the purposes of research and for the provision of treatment purposes: Schedule 2 para 4(2)(a). Legitimate research purposes are described in Part III at pp.67 above.

> systematic investigations carried out for the primary purpose of adding to general knowledge, but includes the carrying out of an experiment, and "project of research" shall be construed accordingly.[343]

Interventions the primary purpose of which is to provide therapeutic benefit to a patient, would not appear to fall within the definition of research. Accordingly, interventions of this nature would be beyond the purview of the WA Council.

A test based on purposes and intention relies heavily on the view of the investigator as to the aim of the particular intervention. A definition of research based on primary or dominant purpose may be particularly problematic, since it calls for an arbitrary decision on research which may have several, equivalent purposes. Interventions can have as their aim the advancement of knowledge, while at the same time seeking to benefit the patient. If the implication of an intention test is that any intervention which does not have as its primary purpose advancing general knowledge is therefore clinical practice, then it is relatively easy to characterise an intervention as one or the other.[344]

Recognising the problems of a test based on primary purposes, some have suggested a test which characterises an intervention with any "investigational motive" as research.[345] While the primary purposes test may be considered under-inclusive of many interventions in the category of research, this sort of test may be over-inclusive, since to some extent all interventions assist in the advancement of knowledge.

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343 WA Act s.3. This definition is similar, although slightly narrower than the definition of research proposed by the Council for International Organisations of Medical Sciences: "The term 'research' refers to a class of activities designed to develop or contribute to generalizable knowledge. Generalizable knowledge consist of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference." extracted in MRC *Code of Conduct supra* note 320 at 1-4.

344 Gaze & Dawson *supra* note 295 came to a similar conclusion: at 305.

An alternative test, based on a risk/benefit evaluation has been suggested.[346] According to this test, research is characterised by a higher degree of risk and medical uncertainty, while practice involves procedures that are well understood and reasonably safe.[347] If we are truly concerned about the ethics of research and potential abuses, then it is at least arguable that a broader test for research than one based on primary purpose, or intention is required. Characterisation of research on the basis of a risk/benefit evaluation and an assessment of whether the particular intervention has been shown to be relatively safe and effective may lead to interventions being subject to greater scrutiny by non-experts.

A test based on a risk/benefit assessment may lead to a re-evaluation of current opinion about the characterisation of IVF and related procedures. As noted above,[348] these procedures are considered to be standard and acceptable clinical practice. This notion is supported in the legislation by the distinction between research and practice, and (except in Western Australia) the omission of research on human subjects from the jurisdiction of the regulatory agencies. Yet IVF procedures have never been shown to be safe and effective.[349] Such evaluation is made more difficult by the lack of uniformity in the measurement and reporting of success rates.[350]

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345 Dickens B "What is a medical experiment?" *CMAJ* 1975; 113: 635-639 at 636.

346 Schuchardt E "Walking a Thin Line: Distinguishing Between Research and Medical Practice During Operation Desert Storm" (1992) 26 Columbia J of Law and Social Problems 77 at 95.

347 *ibid*. See also McLaren A "Human Embryo Research: Past Present and Future" in Royal Commission on New Reproductive Technologies *Background and Current Practice of Fetal Tissues and Embryo Research in Canada* Research Studies Volume 15 (Ottawa: The Commission, 1993) at 249-275 at 258.

348 See p.69 above.

349 *supra* note 289 and text accompanying.

350 See *supra* note 65.

Despite the lack of guidance in the law and the ethical literature on the distinction between research and practice, it is a distinction that is necessary, primarily because of the greater potential for abuse in the research setting. In the particular context of RGTs, notwithstanding arguments in favour of considering IVF and related procedures as within the realms of research, it would be an administrative nightmare to require regulatory agencies to scrutinise individual treatment regimes. However, failure of the legislation to provide a workable and adequate definition of research challenges its effectiveness as a means of regulating the conduct of clinicians and scientists in RGTs.

Ultimately it is up to the clinicians and scientists to decide how to characterise interventions that they wish to perform. The characterisation of an intervention as research means that several procedural requirements must be complied with. A well-designed research proposal, consent forms, and the like must be produced and submitted to the regulatory agency for approval. Consequently the temptation may be to characterise an experimental intervention as "innovative therapy" and therefore as practice, rather than as research.

However, because of the technical nature of the issues involved, there is little alternative to keeping these questions within the scope of the technical expertise of clinicians. To this extent, the medical profession retains a significant amount of control over what matters will come to be considered by non-experts, either as members of the institutional ethics committees, or in the specific context of RGTs and the legislation, of the regulatory agencies. Yet, physician-regulated conduct is the very situation that has been considered inadequate as a regulatory mechanism in the context of RGTs. The hope is that the sanctions for

carrying out activities contrary to the Act are a sufficient deterrent to unethical practices.[351]

The reality of clinical practice is that safe and effective assisted conception procedures are in constant evolution. The purported distinction between research and practice fails to recognise this evolutionary process, except perhaps at the ends of the spectrum of medical interventions. The grey area of innovative therapy is problematic and illustrates the tension between an institution that traditionally operates on the basis of drawing lines, and an institution in which lines often can never be drawn.

Barring a fundamental change in the way we view either science or law, this tension is unlikely ever to be resolved. But it can be minimised by enacting a legislative regulatory scheme that is flexible enough to allow scientific progress to continue (within moral boundaries) within the jurisdiction, and to permit the incorporation of new developments into the legislative scheme.

C. Scientific Developments

As noted in several points throughout this thesis and elsewhere,[352] a significant amount of research is still needed to improve clinical IVF and associated procedures, and to understand the processes involved in conception and early embryonic development. Much of this research involves the human embryo. Other important research involving the human embryo concerns the use of embryonic tissue, particularly neural tissue, in the treatment of neurological disorders.[353]

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351 These sanctions are outlined and discussed at p.70ff above.
352 See for example McLaren *supra* note 347 at 266-267, 269, and Trouson & Gardiner *supra* note 336 generally.
353 McLaren *ibid* at 259.

This research may have important implications for medical treatment of a wide range of conditions in the future.

The main challenge for legislation in the area of RGTs, and indeed in the context of science and technology generally, is balancing "the attraction of advancing knowledge through research, and the need to constrain that advance when it threatens other values as important as the value of knowledge."[354] However, traditionally, the law has been slow to respond to new technologies, and/or has tended to be reactive rather than proactive. As Justice Windeyer of the High Court of Australia noted more than two decades ago, the relationship between law and medicine has been one of "law, marching with medicine, but in the rear and limping a little".[355] How to be proactive in a field where it is difficult to predict precisely what conduct will cause sufficient harm to justify limitations being placed on that conduct is a problem that calls into question the effectiveness of legislation in an area such as RGTs in which the science is constantly moving ahead.

On the one hand, reactive legislation that is too strict in its limitations may have the effect of stifling the advancement of knowledge within the jurisdiction in which the limitations are imposed. This could have an adverse effect on the relevant field, either by stifling its development or by encouraging talented scientists to undertake their work in more permissive jurisdictions. On the other hand, legislation that is too lax will be ineffective in protecting important values that come into conflict with scientific progress. Failing to regulate science may lead to society "being taken where scientists' and technologists'

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354 Gorovitz S "Engineering Human Reproduction: A Challenge to Public Policy" (1985) 10 J Med Phil 267 at 273.

355 *Mount Isa Mines v Pusey* (1970) 125 CLR 383 at 395 (HC) per Windeyer J.

imagination leads"[356] without due regard for the potential consequences.

The Victorian experience with the *Infertility (Medical Procedures) Act 1984* is illustrative of some of the problems of premature legislation. Shortly after the proclamation of the Act which preceded the current legislation in Victoria, researchers at Monash University submitted a research proposal to the SRACI. The proposal concerned the microinjection of a single sperm into the egg, which was proposed as a means of overcoming infertility problems due to difficulties of sperm with decreased motility penetrating the egg. Testing the safety of this innovation involved examining embryos for genetic and chromosomal abnormalities, which required the destruction of the embryos concerned. The SRACI could not approve the research because it would clearly contravene the legislation, which prohibited the creation of embryos specifically for research purposes and the fertilisation of eggs removed from the body of a woman for purposes other than implantation.[357] The researchers subsequently amended their proposal, so that the reliability of the procedure could be assessed by looking at the success of the sperm entering the egg prior to syngamy.[358] If syngamy were considered the point at which fertilisation was completed and an "embryo" was formed, then the research would be permissible.

In the absence of a legislative definition of "embryo", interpretation problems arose concerning when fertilisation actually took place. Was it when the sperm entered the egg, or at some later point, such as

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356 Morgan D & Neilsen L "Prisoners of Progress Hostages to Fortune" (1993) 21 J of Law, Med & Ethics 30 at 39.

357 *Infertility (Medical Procedures) Act supra* note 13 s.6(5).

358 For the definition of syngamy see *supra* note 118.

syngamy? It was unclear from the legislation whether the research proposal should be permitted or prohibited.

The SRACI was evenly divided on the issue of legality of the proposal but a majority agreed that the legislation required amendment to clarify the situation.[359] Accordingly, on the SRACI's recommendation the legislation was amended to permit the approval of research proposals such as the one submitted.[360] In the meantime, a moratorium on all embryo research was established,[361] and some scientists dissatisfied with the situation left the country.[362] Several other interpretation problems ultimately lead to the enactment of the current Victorian legislation. The Victorian experience illustrates some of the problems that may arise if legislation is enacted prematurely[363] and/or without due consideration of the effects of the language and definitions, or lack thereof in the legislation.

Lack of clarity in definitions may have an adverse effect on scientific developments in the jurisdiction. In South Australia, Western Australia and Victoria, the terms "destructive" or "detrimental" research and "therapeutic research" are used to delineate acceptable and unacceptable conduct[364] The terms "destructive", "detrimental" and "therapeutic" are not defined in any of the legislation. An Australian survey of scientists and clinicians involved in the clinical

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359 Buckle S, Dawson K & Singer P "The Syngamy Debate: When *Precisely* Does a Human Life Begin?" (1989) 17 Law, Med & Health Care 174 at 176. This implies that opinions were based on different interpretations of the legislation, rather than on moral grounds.

360 Thus, the legislation now permitted research involving development proceeding beyond the passage of sperm through the egg membrane, but stopping before syngamy.

361 Gunning & English *supra* note 21 at 145.

362 Kirby M "Bioethics '89: Can Democracy Cope?" (1990) 18 Law, Med & Health Care 5 at 9.

363 Gunning & English *supra* note 21 at 36.

364 SA Act s.14(2)(b) ("detrimental"), WA Act s.14(2)(a), (b) ("therapeutic", "detrimental") and Victorian Act s.24 ("destructive").

practice of IVF or human embryo research demonstrated uncertainty in the meaning of the terms and a need to clarify them.[365] Respondents to the survey noted that it was difficult to classify research as either therapeutic or destructive, and therefore the distinction was impractical.[366] Another respondent noted the possibility of misuse of the terminology:

> I fear that the distinction leads some groups to claim therapeutic potential, which is barely existent, for their experiments.[367]

One of the difficulties with the distinction between therapeutic and detrimental research is that it may require the researcher to preempt the research that he or she wants to carry out. This problem was recognised by the dissenting members of the Australia Senate Committee who noted that "the definition depends either on the actual outcome ie description after the event, or intention prior to the event."[368] One respondent to the survey noted above noted the impracticality of the distinction in this respect:

> ... It is not possible to distinguish between a viable and non-viable human pre-implantation embryo in most instances. Hence logically, we cannot assess whether our experiments are "therapeutic" or "destructive" in terms of the embryo's potential to continue to a viable birth.
>
> A therapeutic experiment on a single embryo can turn out to be destructive unintentionally.[369]

As one commentator stated in the context of the recombinant DNA debate in the 1970s "the information we arguably need to improve the

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365 See NBCC Report *supra* note 90 at 101, 102-3.
366 *ibid* at 102, 115.
367 *ibid* at 101.
368 Senate Select Committee *supra* note 105 at 85.
369 NBCC Report *supra* note 90 at 102.

moral status of experiments can be acquired only by the very experiments deemed immoral for lack of that information",[370] an observation that highlights the problems faced when attempting to regulate the advancement of scientific knowledge.[371]

Like the distinction between research and clinical practice discussed above, the distinction between detrimental and therapeutic research is difficult to make. Yet the absence of definitions in the legislation leads to uncertainty as whether certain practices are legal or illegal. The result of this uncertainty may lead to researchers moving to more permissive jurisdictions to avoid the possibility of their research being considered illegal. This in turn could have an adverse effect on the reputation of clinicians that remain and the services they provide. In federal countries such as Canada and Australia, this could result in fragmented and inconsistent policies throughout the country, and in the context of RGTs, could encourage "procreative tourism".

The difficulties confronted by legislatures in defining key terms are more acute when there is no clear medical or scientific consensus on what is meant by those terms, and where scientific developments alter scientists' understanding of concepts and processes which in turn alters the definition of terms used. These difficulties further illustrate the problems with regulating science and the differences between science and law. Scientific developments can quickly make legal definitions redundant, and turn established legal concepts upside down. The advent of ventilators, for example, which maintain

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370 Shapiro M "Introduction to the Issue: Some Dilemmas of Biotechnological Research" (1978) 51 Southern California LR 987 at 991.

371 In a recent examination of the current and likely future practice of embryo research for the Canadian Royal Commission on New Reproductive Technologies, it was noted that "[a]lthough therapeutic research is allowed in those countries that ban non-therapeutic research, no therapeutic research projects in progress are known to the author." McLaren *supra* note 347 at 265.

breathing and heart activity notwithstanding brain death, necessitated a fundamental change in the legal definition of death. Accordingly, in several jurisdictions, legislation has been enacted to supplement the common law definition of death, based on cessation of cardiopulmonary function, with a definition based on cessation of brain stem activity.[372]

D. Incorporating Scientific Developments

Many of the problems arising from the differences between science and law may be minimised by ensuring that the regulatory agencies keep apprised of current developments and that the legislation is flexible enough to permit the incorporation of these developments into the legislative scheme.

The principle that "[g]ood law and good ethics are grounded in good data"[373] cannot be overstated. Scientific developments may change our viewpoints of the morality of certain practices, or even obviate the need for morally controversial practices. For example, Somerville notes that once techniques for freezing of ova have been sufficiently developed to be used clinically, it will not longer be necessary to freeze embryos. This then will make unnecessary much of the discussion that has taken place to date concerning the moral status of the embryo and the morality and legality of human embryo research.[374]

Being up-to- date with current scientific developments is important for ensuring that decisions are made which reflect the current state of

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372 See for example in South Australia the *Death (Definition) Act 1983* (SA) No.12 of 1983.

373 Kirby *supra* note 362 at 5

374 Somerville M "Weaving 'Birth' Technology into the 'Value and Policy Web' of Medicine, Ethics and Law: Should Policies on 'Conception' be Consistent?" (1989) 13 Nova Law Review 515 at 533.

knowledge. Each of the regulatory agencies established under the legislation has an obligation to keep up-to-date with current developments in the field of RGTs. This obligation is not expressly stated in the legislation, but is implied by the functions of the regulatory agencies. All regulatory agencies are required to report annually to the respective health ministers on the activities under their supervision, and on RGTs generally.[375] In the United Kingdom, Western Australia and South Australia, an understanding of scientific principles is essential for the determination of ethical guidelines which comprise the codes of practice. In Victoria, the SRACI and ITA both have among their functions to advise the Minister for Health of scientific developments.

Information may be gathered in several ways. Information on activities within the jurisdiction will be obtained by regulatory agencies from licensees. Conditions on licences requiring licensees to furnish information enables the relevant agency to keep track of research projects that it has approved, and assisted conception procedures that it has licensed.[376] In addition, the agencies have the power to request additional information from licensees as they see fit.[377] This, together with broad powers of inspection, allows the regulatory agencies to obtain significant amounts of information from licensees.[378]

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375 SA Act s.12(1)(b); UK Act s.7; Victorian Act s.137; and WA Act s.14.

376 UK Act s.12. Section 20(2) of the SA Act allows regulations to be made requiring licensees to furnish periodic returns of information to the Council. Licenses must contain a condition requiring the licensee to keep specified records in relation to artificial fertilisation procedures (s.13(3)(d)), but not research, although the Council may impose such a condition in respect of research.

377 See *supra* note 255 and text accompanying.

378 See pp.61-65 above.

The importance of a uniform approach to the issues in the context of RGTs has been noted,[379] and obtaining information from other jurisdictions is important to achieving this aim. Among other things, it may give the regulatory agency a feeling for the extent of "procreative tourism" that may be occurring due to a lack of a uniform approach. Information on activities outside the jurisdiction can be obtained from agencies carrying out similar functions. In this respect, the WA and SA Councils are expressly required to collaborate with similar agencies elsewhere.[380]

A strict reading of the legislation may confine the types of scientific developments of which the agencies are required to keep apprised. For example, in South Australia, the term "reproductive technology", which essentially determines the scope of the Council's functions and supervisory jurisdiction, is defined in the Act as "the branch of medical science concerned with artificial fertilisation". As outlined in Part II,[381] reproductive technology is not confined to artificial fertilisation procedures, but may include genetic technologies, and non-reproductive uses of reproductive technologies. The definition contained in the legislation would appear to exclude, for example, certain developments in the field of reproductive genetics unassociated with artificial fertilisation, such as prenatal diagnosis, and is therefore narrow and may be unduly restrictive. Similarly, in Western Australia, "reproductive technology" is defined by reference to artificial fertilisation procedures, and the comments concerning the SA legislation therefore apply with respect to the Western Australian

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379 Royal Commission Report *supra* note 3 at 16-18; Family Law Council *supra* note 141 at 32.

380 WA Act s.14(1)(h); SA Act s.10(1)(g).

381 See pp.11-12 above.

legislation as well.[382] In Victoria, as in South Australia, the obligations of the ITA and SRACI to advise the Minister extend only to developments in the treatment of infertility. A literal reading of the legislation thus suggests that neither body has a duty to monitor developments in RGTs unrelated to the treatment of infertility. In practice, though, it is likely that the agencies would not restrict themselves to developments only in artificial fertilisation procedures and infertility.

In contrast to the Australian legislation, a wide range of activities, particularly research activities, fall within the supervisory jurisdiction of the HFEA in the United Kingdom. The HFEA's obligations in respect of review and advice to the Secretary of State for Health may therefore be extensive. Further, in order to properly evaluate the merits of research proposals, the HFEA will need to be up to date with developments in all activities encompassed within the term "reproductive technologies" as defined in Part II.

The obligation to keep apprised of scientific developments in the field may extend further than the definitions in the legislation might imply as a result of the principles of administrative law. All decisions of the regulatory agencies (except decisions concerning research licences in South Australia and Victoria)[383] are open to judicial review. Decisions by the regulatory body will only be legitimate and will withstand judicial review if they are based on accurate and up-to-date scientific knowledge. This, in combination with the obligation implied by the functions of the respective regulatory bodies, means that the scope of

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382 WA Act s.3.

383 The non-reviewability of research decisions in these jurisdictions is discussed further in Part V.

relevant information of which the regulatory agencies need to keep apprised is probably wider than is apparent on the face of the legislation.

Incorporating scientific developments into the decision-making process will be a matter for the regulatory agency itself. However, the extent to which developments can be incorporated in practice will be limited by the approach taken in the legislation. Legislation that takes a prescriptive/prohibitive approach, in which norms of conduct are laid down in the legislation and unacceptable conduct is supported by criminal sanctions, as typified by the Victorian legislation, may have little capacity to incorporate future developments which result in those practices being shown to be beneficial, without amending the legislation. Indeed, as outlined above,[384] the need to amend the legislation to take into account a new development faced by the Victorian legislature in relation to its previous legislation.

By contrast, the United Kingdom legislation leaves the way open for the incorporation of new developments into the legislative scheme. The Act allows additional activities requiring a licence, additional research purposes, and longer or shorter storage periods for gametes and embryos to be specified in regulations to the Act.[385] While somewhat annoying in the sense that all the relevant information is not contained within one document, this approach nevertheless provides greater flexibility for the incorporation of new knowledge without requiring legislative amendment.

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384 See pp.90-91 above.
385 UK Act Schedule 2 paras 2(1)(g) and 3(2), s.14(5).

As noted above, there are two main approaches to the regulation of RGTs evidenced in the legislation. The prescriptive/prohibitive legislation enacted in Victoria, Western Australia and proposed in Canada typifies the traditional approach whereby the law seeks to constrain the advancement of knowledge where it conflicts with other values by setting limits on permissible conduct. Impermissible conduct is prohibited with criminal sanctions, thus tipping the balance against individual autonomy in favour of protecting fundamental values which may come into conflict with the aims of science.

A regulatory approach which does not impose criminal sanctions and in which standards of conduct are established by the regulatory agency for example in a code of practice, and not by the legislature is more flexible. Such an approach is more able to adjust to scientific developments and changing social values than an approach that lays down inflexible rules and, in the opinion of the author, is to be preferred.

V WHO SHOULD DECIDE RGT POLICY ?

A. Introduction

In this Part, the focus shifts from scientific matters to broader issues concerning community participation in the formation of public policy about the future conduct of RGTs. As indicated by the discussion in Part II, there are a wide range of positions with respect to the morality of RGTs. Despite the many governmental and nongovernmental reports and position papers that have been produced, there is no general consensus about the morality of the conduct of RGTs, nor about what constitutes the central moral controversy surrounding research and clinical practice in the field.

In this Part, the issue of who decides public policy in RGTs in a secular pluralist society is considered. Theoretical concerns of moral pluralism and the moral authority of decisions are examined. The legislation in the United Kingdom, Victoria, South Australia and Western Australia is then evaluated for its attempts to deal with issues of moral pluralism and legitimate decision-making in a secular pluralist society.

B. The Secular Pluralist State

Moral Pluralism

The decline of the Christian state means that there is no overarching morality based in religious beliefs which can be imposed by the state on its citizens to guide them when ethical dilemmas arise.[386] Nor does there seem to be a common secular moral vision that can guide

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386 See Engelhardt *Foundations supra* note 61 at 3-5.

behaviour.[387] Rather, there are many different versions of "the good life", and in a liberal secular state, individuals should be permitted to pursue their view of the moral life as they see fit without interference from the state. Many commentators have noted the moral pluralism that characterises modern Western society.[388] This is certainly true of the morality of practices using reproductive and genetic technology. Although Part II did not purport to be a thorough analysis of the substantive morality of various practices in the field of RGTs, it at least in part illustrated the moral pluralism that exists in our society in this context.

Liberal pluralism implies a limited role for the state in moral matters. Yet the controversy surrounding RGTs calls for public policy to guide the conduct of those involved in the field. But if there is no "canonical concrete moral vision",[389] how can public policy have the moral authority needed to bind participants involved in RGTs?

Moreno is of the view that moral authority comes from societal consensus.[390] Consensus, which is more than simply agreement or compromise, is not only an outcome but also refers to the process by which that outcome is achieved. A particular policy will have moral authority where it represents a consensus reached by a process that reflects society's deeply held values, such as respect for personal autonomy and willingness to consider alternative points of view.[391]

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387 See *ibid* at 8, 40-65. This proposition is not self-evident, nor uncontroversial. Nevertheless, the political philosophy of liberal pluralism is assumed in this thesis.

388 Macintyre A *After Virtue* (Notre Dame: University of Notre Dame Press, 1981) at 1-5; Komesaroff P "Introduction: postmodern medical ethics?" in Komesaroff *supra* note 127 1-19 at 10, 11-12; Englehardt *Foundations supra* note 61 at 3-8.

389 Englehardt *ibid* at x.

390 Moreno J *Deciding Together: Bioethics and Moral Consensus* (New York: Oxford University Press, 1995) at 5.

391 *ibid* at 62-63.

Despite claims of "an emerging consensus",[392] true consensus in the field of RGTs is virtually impossible to attain.[393] Any "consensus" in reality either reflects a compromise or the majority view. Engelhardt is of the view that moral authority of public policy derives from consent or "permission" of the individuals concerned.[394] This broader position in which public policy is based on something less than consensus is more realistic and appropriate in the context of RGTs. In order to avoid moral majoritarianism though, public policy will need to be formed by a process that allows the legitimate interests of minorities to be taken into account. Only then will it have the authority to bind all members of the community.

The Role of Law

In light of this background, what role should the law play in a secular pluralist state? The relationship between law and morality continues to be the subject of much debate.[395] Two spheres of morality are distinguished: the public and the private. Consistent with the tenets of liberalism, the law, as a state institution, has a limited role to play in matters of private morality. However, once an individual's conduct takes on the character of public morality by impacting on the conduct of others, the law may intervene where necessary to protect the public interest. The various inquiries held on the issues raised by RGTs concluded that RGTs have implications beyond the private sphere of the doctor-patient relationship. Legislative intervention was therefore

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392 See generally Knoppers & Sloss *supra* note 21 and Knoppers & Le Bris *supra* note 21.

393 See for example Engelhardt H "Consensus: How Much Can We Hope For?" in Bayertz *supra* note 17, 19-40 at 20, 25.

394 *ibid* at 33; Engelhardt *Foundations supra* note 61 at 83.

395 McTeer M "Law in Matters of Morality" (1995) 40 McGill L J 893 at 896.

justified because existing regulation was considered ineffective to protect the interests of the public.

As noted in Part I, these observations are adopted as assumptions in this thesis,[396] and accordingly are not considered in detail here. The more interesting and relevant question for the purposes of this study and what has provided the basis for the analysis throughout is what sort of legislative regulatory approach should be implemented to protect the interests of society.

The approach adopted in the legislation impacts upon public policy formation by the regulatory agency. Two approaches have be identified in the statutes under consideration in this thesis: prescriptive and facilitative.[397] Legislation taking a substantive approach assumes the "rightness" of certain substantive moral viewpoints. Public policy made within that legislative framework must therefore be consistent with and is limited by the moral positions taken therein. To this extent the legislature imposes a certain morality on its citizens which may not be shared by all.

By contrast facilitative legislation provides a neutral framework in which public policy decisions can be made. A facilitative approach to regulation is more consistent with the doctrine of liberal neutrality which asserts that the state should be neutral and not impose any particular moral viewpoint on its citizens.

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396 See p.4 above.
397 See p.74 above.

The Role of the Community[398]

As noted above, in a secular pluralist society which seeks to avoid moral majoritarianism, public policy will only be legitimate if a wide range of views and interests are taken into account in the decision-making process. Only then will public policy have moral authority and be binding on the community.

Traditionally scientific and medical policy has been made by the scientists and clinicians themselves. Decisions concerning the conduct of science and medicine were seen to be technical and therefore within the realm of the expert. However there is an increasing awareness amongst experts and non-experts alike that technical expertise is not moral expertise. The acceptability of RGTs based on the goals of medicine or freedom of choice may take on new meaning when considered from an alternative perspective such as a religious or feminist perspective. Furthermore, scientists and clinicians have differing perceptions of the risks and harms that may arise from a certain intervention.[399] Psychological studies have shown that experts tend to be more optimistic about benefits and less concerned about risks, while non-experts preferred to avoid present or future harms than to take risks in the hope of benefits.[400] The input of community opinion may assist experts to view RGTs from perspectives they may not have otherwise considered.

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398 Many of the issues discussed in this section have arisen in the context of environmental law and policy. For a brief discussion see Bates G *Environmental Law in Australia* 3rd ed (Sydney: Butterworths, 1992) at 120-121. It would be interesting to compare the way in which environmental law has dealt with the issues of science and public participation with the way in which the law has dealt with these issues in the context of RGTs, but such an analysis is beyond the scope of this thesis.

399 Sieber J "Ethical Considerations in Planning and Conducting Research on Human Subjects" *Academic Medicine* 1993; 68(Supp 9): S9-S13 at S13.

Failure to taken into account the community's views in biomedical decision-making may result in public policy being weighted towards scientific and medical interests, and a subsequent loss of public confidence in the regulatory agency from which that policy emanates. By contrast, decisions may be afforded greater support by the community if the community has contributed to them.[401] Indeed public support for government action is important for "harmonious social relations and the absence of strife."[402] Better decisions will be made, since the activities of scientists and clinicians will be subject to a more comprehensive analysis of the risks, benefits and alternatives than is the case with peer review.[403] The need for a broader range of interests than medical and scientific ones was explained by the Warnock Committee:

> If the public is to have confidence in that this is an independent body, which is not to be unduly influenced by sectional interests, its membership must be wide-ranging and in particular the lay interests should be well represented.[404]

Participation by the community will thus help to maintain the legitimacy of the regulatory agency, and to ensure that the agency is not co-opted to medical and scientific interests.

Some commentators hold that where the community bears the consequences, whether beneficial or harmful, of a technology, it has a moral right to participate in decisions surrounding the use of that

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400 Dutton D "The Impact of Public Participation in Biomedical Policy: Evidence from Four Case Studies" in Petersen J, ed, *Citizen Participation in Science Policy* (Amherst: University of Massachusetts Press, 1984) 147-181 at 156.

401 Daniels K & Taylor K "Formulating Selection Policies for Assisted Reproduction" (1993) 37 Social Science and Medicine 1473 at 1479.

402 Kuhse H "New Reproductive Technologies: Ethical Conflict and the Problem of Consensus" in Bayertz *supra* note 17, 75-96 at 77.

403 Dutton *supra* note 400 at 171.

404 Warnock Report *supra* note 25 at 76.

technology.[405] This moral right is grounded in an analogy with the doctrine of informed consent within the doctor-patient relationship.[406] Thus society has a right to function as a self-governing body, and consequently has a right to be informed of the physical, psychological and social implications of social enterprises, such as science and medicine.[407]

Another justification for the role of the community is grounded in political theory. Consistently with the classical theory of participatory democracy, the citizen's right to participate in decision-making is important for the legitimacy of decisions in a democratic society.[408] The theory of participatory democracy can be contrasted with representative democracy. According to this theory, the role of citizens is confined to selecting and rejecting leaders who will represent their interests.[409] Political and moral authority is vested in the state because of the mandate of the citizens and derives from the consent of the citizens in electing members of Parliament and agreeing to government conventions.[410] Representative democracy thus envisages a restricted role for citizens in public policy formation.

The notion of representative democracy is problematic in a pluralist society. Representative democracy favours majority rule, the consequences of which may be "the successful tyranny of a preponderant majority over an oppressed minority",[411] and it may be difficult to overcome this problem because of practical difficulties in

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405 Holman H & Dutton D "A Case for Public Participation in Science Policy Formation and Practice" (1978) 51 Southern Californian Law Review 1505 at 1505.
406 See Lappé M & Martin P "The Place of the Public in the Conduct of Science" (1978) 51 Southern Californian Law Review 1535.
407 *ibid*.
408 Dutton supra note 400 at 170.
409 *ibid*.
410 Engelhardt *Foundations supra* note 61 at 169-171.
411 Engelhardt *supra* note 393 in Bayertz *supra* note 17 at 20.

getting representatives of minority groups elected into Parliament. In any event, the issues raised by morally controversial practices such as those involving RGTs are sufficiently complex as to raise doubts about their amenability to resolution in the political forum.[412] Indeed, on controversial issues, members of Parliament tend either to tow the party line, thus favouring political expediency over true representation, or have such strongly held personal opinions about moral issues that their personal viewpoint holds sway, rather than the views of their constituents.[413] The theory of representative democracy is thus inadequate when controversial moral issues are at stake. Accordingly, the ideals of liberal pluralism and liberal neutrality may not be attained. Instead, the state may impose a moral viewpoint on its citizens which is not supported by significant sections of the community, and thus does not have true moral authority.

The participatory democracy theory seeks to overcome these difficulties by envisaging a greater role for the public in policy formation. In participatory democracy, moral authority derives from general societal agreement and not just the agreement of Parliament. The doctrine of participatory democracy is therefore more appropriate in a secular pluralist society. It recognises that Parliament is not necessarily representative of the views of the community, and advocates direct citizen involvement in public policy formation.

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412 Charlesworth M *Life, Death, Genes and Ethics* (Crows Nest: ABC Books, 1989) at 97.

413 A case in point is the current debate in Australia concerning euthanasia legislation. The *Euthanasia Laws Bill 1996* (Cth), a private members bill introduced in September 1996 into the House of Representatives of Australian parliament, seeks to overturn the validly enacted Northern Territory *Rights of the Terminally Ill Act 1995* (NT) No. 12 of 1995 which legalises physician-assisted suicide. The former was passed in the House of Representatives on 9 December 1996 by a clear majority of 88 votes to 35 (with 25 abstentions) despite an alleged majority of the community being in favour of euthanasia legislation: see Ceresa M "We cannot fight MP's vote: Stone" *The Australian* (11 December 1996) 2. The Bill is currently before a Senate Committee and must be passed by the Senate to become law.

Community participation may be also be justified on the basis that "he who pays the piper calls the tune" where the technology concerned is publicly funded.[414]

Despite the importance of community participation, there are significant barriers to effective public involvement in biomedical decision-making. If there is a greater representation of scientific interests in the decision-making process, or the framework in which decisions are made assumes a certain moral viewpoint, public participation may be symbolic rather than actual, with the result that decisions may merely legitimise the status quo.

Secondly, depending on the mechanisms for public participation, the public may have only limited opportunities to become involved. The costs and administrative aspects of producing consultation documents or carrying out opinion polls and the like may be prohibitive, particularly if the relevant agency's budget is allocated as a part of the overall health care budget, which in Canada, Australia and the United Kingdom is facing cutbacks and restrictions.

Thirdly, meaningful public participation may be compromised by a lack of information. To have effective public involvement, the public must be adequately informed[415] with accurate, comprehensible information concerning all aspects of the relevant issue. Failure to fully understand the scientific aspects of RGTs in particular can lead to wildly speculative claims about future harms that may arise. Legitimate concerns of the community may then be dismissed because of their inaccurate scientific foundations and emotional tone.

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414 Dutton *supra* note 400 at 169; Holman & Dutton *supra* note 404 at 1505 and Abram J & Wolf S "Public Involvement in Medical Ethics: A Model for Government Action" *NEJM* 1984; 310(10): 627-642 at 628.

Finally, where the means of public participation is committee representation, representing all relevant interests of the community will be difficult. The trade-off for extensive community representation on a committee may be a decreased efficiency in decision-making. However, there are other mechanisms by which community opinion on morally controversial issues may be gauged. These include referenda,[416] consultation by the agency with the public, cooperative projects involving experts and citizens, public hearings and debate on important issues, advisory committees containing community representatives,[417] and public opinion polls and surveys.

Whatever the means, it is crucial to gauge the opinion of the community on morally controversial issues.[418] It is particularly important to try to determine the views of "ordinary people", which may differ from the various interest groups, such as churches, feminist groups and the like who purport to represent the religious or philosophical opinions of certain groups of ordinary people in the community. [419]

C. Policy Formation under the Statutes

The discussion so far demonstrates that in order to obtain meaningful public policy with moral authority under the legislation the following is required. First, a role for the public should be recognised in the legislation. Secondly, a wide range of interests and viewpoints ought

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415 Kirby *supra* note 362 at 5; Kuhse *supra* note 402 in Bayertz *supra* note 17 at 92.

416 Citizen-initiated referenda are common in states in the United States such as Oregon. One of the most famous of these in recent years is the citizen-initiated referendum on physician-assisted suicide. For discussion of this referendum see Campbell C "When Medicine Lost its Moral Conscience: Oregon Measure 16" *Biolaw* 1995; II: S1-S16.

417 I use the term "community representatives" in the broadest sense to refer to ordinary people as opposed to representatives of certain interest groups.

418 Charlesworth *supra* note 412 at 102.

419 *ibid*.

to be taken into account through multidisciplinary membership of the agency making the policy, and through consultation with an informed community. Thirdly, the formation of public policy should not be constrained by substantive positions on moral issues imposed by the legislation. Fourthly, the actual decision-making process ought to maximise consideration of disparate interests and viewpoints, and finally, the regulatory scheme should be sufficiently flexible to incorporate changing social and moral values.

A Role for the Public

There are essentially two means by which the public can have a role in the formation of public policy under the legislation. The first, discussed further below, is through consultation with the public. Secondly, the public can be represented on the regulatory agency which makes the policy.

The statutes in the United Kingdom and the three Australian states envisage a role for the public in the formation of public policy, though to varying degrees. On its face, the United Kingdom legislation sees a restricted role for the public, taking what has been described as a "technocratic elite" approach to decision-making.[420] According to this approach, policy is best made by specialists who have the knowledge to understand technical issues. As outlined in Part III, the United Kingdom legislation contains specific requirements in relation to scientific and medical representation, but no such requirements in relation to community representation.

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420 Miall C "The Regulation of Reproduction: The Relevance of Public Opinion for Legislative Policy Formation" (1993) 7 International J of Law and the Family 18 at 33.

It is in the discretion of the Secretary of State for Health as to the interests that non-scientific members of the HFEA represent. A Secretary of State committed to the notion of community participation and mindful of the need to take a wide range of social and ethical issues into account should ensure that a wide range of interests are represented. However, there is no legislative guarantee that this will be done, although the provision disqualifying those members representing scientific interests from appointment as the chair or deputy chair recognises the persuasive power of the chair and represents one way of decreasing the possibility of persuasion by "sectional interests".[421]

The United Kingdom legislation gives the HFEA a large discretion with respect to decision-making, allowing it to determine its own procedure.[422] There is scope for the HFEA therefore to make up for the relative lack of community representation in its membership by consulting with the public as a means of determining community views on controversial matters as it sees fit. Indeed the HFEA currently operates in this manner, producing discussion and consultation papers on controversial issues in respect of which the public may make submissions.[423] However, again, there is no legislative guarantee that this approach will always be taken and consequently there is a real potential for the HFEA to favour scientific interests. A strong scientific presence in the HFEA may also lead to the dismissal of non-expert submissions as emotional and speculative.

The Australian legislation is quite different from the United Kingdom legislation, evidencing a pluralist rather than technical elite approach

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421 See extract from Warnock Report at pp.105 above.
422 UK Act Schedule 1 para 9(1).
423 Gunning & English *supra* note 21 at 141.

to public policy formation. In contrast to the elitist approach, a pluralist approach assumes that interested individuals and not just experts will be involved in decision-making.[424] As noted in Part III, the South Australian, Victorian and Western Australia statutes each contain a list of backgrounds and disciplines from which members of the respective agencies should be drawn. Although the presence of each interest is not mandatory under the legislation, the Ministers appointing members are obliged to ensure as far as practicable that as many of the listed interests are represented as possible. Such an approach is certainly an improvement on the United Kingdom approach, since there is some legislative guarantee that community interests are represented when policy decisions are made.

The need for wide ranging membership of the agency applies also to the need for a range of expert membership of the agency. The discussion so far has tended to assume that experts equal scientific experts, and has contrasted technical scientific representation with the somewhat amorphous notion of "community representation". As recognised by the Australian legislation, experts for example in the fields of law, philosophy, theology, social work and psychology are a welcome and necessary addition to panels involved in forming public policy on RGTs. It should be noted at this point that moral expertise does not reside in one person or the representative of one particular interest. It is arguably not sufficient to have one representative of a particular religion as the "moral expert", since he or she only represents one view of morality. The rise of the secular state has lead to a recognition that mainstream religions are not the arbiters of morality in society. There are many other belief systems that have

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424 Miall *supra* note 420 at 33.

different perspectives and opinions on what constitutes "the moral life". As many groups, including religious groups, as possible should be represented on, or where this is not possible, at least consulted by the regulatory agency.

Barriers to Effective Participation

While broad community representation and consultation are required for public policy to be legitimate in a secular pluralist society, such representation and consultation may be compromised in three ways. First, where the main role for the public is through representation on the regulatory agency, participation may be compromised by the difficulty of representing all relevant interests.

Not all interests can be represented on a statutory body with only a small number of members. With the wide range of positions and interests that exist within our modern pluralistic society, it may be difficult to determine which interests ought to be represented. The Western Australian legislation is somewhat unrealistic in its requirement that the Minister for Health must endeavour to ensure that "no one person is the sole representative of disparate interests."[425] On a Council comprising ten members, only three of whom are not nominated by professional bodies, this requirement is virtually impossible to comply with given the diversity of opinion that exists on the morality of RGTs.

Although all interests may not be represented, it does not however follow that these interests cannot be taken into account at all. The Western Australian legislation provides a mechanism whereby

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425 WA Act s.9(2)(c).

interests other than those represented on the Council may be taken into account. Thus, the WA Council is required to consult with "bodies representing persons having relevant expertise or sections of the public having appropriate interests" before compiling the code of practice.[426] The WA Council thus has a duty under the legislation to consult with bodies representing the public.[427] The sections of the public with which the Council is required to consult are not listed in the legislation, but it is reasonable to assume that they would include women's groups, child welfare agencies, persons who have used reproductive technologies, children born of reproductive technologies and the like. The consultation mechanism is not laid out in the legislation, and therefore it is up to the Council to decide the best way of consulting with the public on these matters. The Western Australian legislation is unique in this respect. No such commitment exists in any of the other jurisdictions under consideration here, though the HFEA in the United Kingdom has a practice of consulting the public on important and controversial issues.

One way in which interested parties can take part in public decision-making is seen in the model for public participation provided in the Australian *National Health and Medical Research Council Act 1992*. (Cth).[428] The National Health and Medical Research Council ("NHMRC") has a statutory duty of public consultation[429] and the

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426 WA Act s.14(1)(c).

427 Failure to consult where there is a statutory duty to do so may be grounds for judicial review of the code of practice. The Australian Federal Court recently held that the National Health and Medical Research Council, which has a statutory duty of public consultation, had failed to comply with its duty in failing to "give positive consideration" to the contents of a submission "as a fundamental element in its decision-making" notwithstanding that in the end it may give it no weight: see *Tobacco Institute of Australia Ltd v National Health and Medical Research Council* (20 December 1996) ACT G40 of 1996 [unreported] (FC).

428 No.225 of 1992 [hereinafter NHMRC Act].

429 NHMRC Act s.3(2).

legislation provides detailed steps of the procedure involved.[430] Thus, once it intends to produce guidelines or make recommendations, it must publish a notice informing the public of its intention and inviting submissions. It must then prepare a draft or outline having regard to any submissions and invite futher public comment, or publish a notice that it no longer intends to produce the guidelines or make the recommendations. A similar model is found in environmental legislation in most Australian states. Development proposals are subject to "environmental impact assessment" the aim of which is to ensure that environmental considerations receive equal weight in the decision-making process with social and economic factors.[431] A draft environmental impact statement which contains this assessment is made available for public comment, and submissions by the public are to be taken into account in the decision-making process by the relevant decision-maker. Case law on the procedures involved has emphasised the need for environmental impact statements to be written in language that is understandable to the general public, and "should contain material that would alert lay persons and specialists to [environmental] problems inherent in the carrying out of the activity".[432] A similar mechanism could be implemented in respect of particularly controversial research in the field of reproductive technologies. Such a mechanism may permit a broader range views to be obtained and hence a broader range of interests to be taken into account.

Meaningful participation may also be compromised by a lack of relevant information. The need for the community to be adequately

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430 NHMRC Act s.12.
431 Bates *supra* note 398 at 93.
432 *Prineas v Forestry Commission* (1984) 49 LGRA 402 (NSW Land and Environment Court) at 417.

informed so that it can make a meaningful contribution was noted above. Where public participation is to be encouraged, ensuring that the public is informed is essential. Although probably most important in the context of scientific information, since science is at the foundation of public policy in RGTs, informing the public also extends to other technical and expert knowledge such as law and philosophy.

In Western Australia and South Australia, the regulatory agencies have among their functions to encourage informed public debate of the issues surrounding reproductive technology. The South Australian Reproductive Technology Council must "promote (by the dissemination of information and other ways) informed public debate on the ethical and social issues that arise from reproductive technology."[433] Similarly, the Western Australian Reproductive Technology Council has among its functions "to promote informed public debate, and to consult with bodies representing the public or sections of the public on the ethical, social, economic and public health issues that arise from reproductive technology."[434] It is only in Western Australia and South Australia that there is a legislative commitment to informed public debate. In the other jurisdictions, lack of adequate information may be a significant barrier to meaningful participation by interested parties.

The difficulty will be in communicating technical knowledge so that it is understood by non-experts. The legislation provides no guidance on how this communication can be effectively carried out, although this lack of guidance is probably appropriate, for effective communication depends on both the information and the personalities involved. This

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433 SA Act s.10(1)(f).

434 WA Act s.14(1)(g). Failure to consult the public may give rise to judicial review of the Council's decisions: see further *supra* note 427.

places a large burden on scientific members of the regulatory agencies to present objective information to non-expert and inexperienced members, and to the public. This must take place from a purely technical position though, since it is not up to the scientific experts alone to decide on the morality of practices. Scientific expertise does not equate with moral expertise.

Finally, public participation may also be compromised where the legislation assumes certain moral standpoints. For example in Western Australia, the fairly conservative stance taken in relation to human embryo research challenges the effectiveness of the large role envisaged for the community, and thus begs the question whether public consultation is largely symbolic. Those on the Council who are in favour of embryo research, for example, will have their voices silenced by the legislative framework itself. The important moral issue of the extent to which human embryo research should be permitted has already been decided by the legislature. The same can be said of the prohibitions contained in the Victorian legislation.

In the jurisdictions in which the legislation takes a prescriptive approach to regulation, public policy must be consistent with the substantive moral judgments made in the legislation. Such substantive judgments limit the discretion of the regulatory agency in decision-making, and effectively deny those who disagree with these judgments an opportunity to have their voices heard and their interests taken into account. This is the major deficiency of the Victorian legislation, which leaves little scope for the SRACI to make policy regarding the conduct of RGTs, and even less scope for the ITA to do so. To the extent that these bodies have any function in making policies for the conduct of RGTs, this function must be exercised within the morally

charged framework of the legislation, or alternatively the legislation must be amended.

These problems may be avoided by adopting a facilitative approach in the legislation, as has been done in the United Kingdom. Rather than imposing substantive moral judgments, the facilitative approach shifts the decision-making process from the legislature to the regulatory agency. Legislation which adopts a facilitative approach and envisages a large role for the public either through multidisciplinary membership of the policy-making agency or a legislative commitment to community consultation is more consistent with the doctrines of liberal neutrality and participatory democracy than the substantive approach. In the specific case of the United Kingdom legislation, the facilitative approach is compromised by the bias towards scientific interests, and to a lesser extent the few prohibitions in the legislation. Nevertheless, it is to be preferred to the approach taken in the Victorian legislation.

The Decision-Making Process

An important aspect of the decision-making process is the evaluation of relevant information for its relevance and impact on current projects. This extends beyond scientific information, which was considered in Part IV, to other relevant information such as legal and philosophical information. Expert representatives, whether scientific, legal or philosophical, should play essentially an educative role. Decisions should be made as a group and should not be monopolised by one perspective. The issue of communicating relevant information goes the other way as well, with community representatives educating the experts, particularly the scientists, about their concerns.

The procedure by which decisions are made, and the extent to which disparate interests are taken into account within the discretion of the regulatory agency are matters within the discretion of the agency in each jurisdiction. The HFEA in the United Kingdom has a wide discretion to determine its procedure as it thinks fit.[435] There is no indication in the legislation whether decisions should be made unanimously or by majority. In the Australian jurisdictions, decisions are made by majority vote, with the chair or deputy chair having a casting vote.[436]

The problem with majority voting procedures is that they do not always respect the interests of minorities.[437] Absent a specific requirement in the legislation that minority interests be considered, there is a real risk that representation of these interests will be merely symbolic. Despite the wide range of interests that are potentially represented, any public policy made by the agencies will represent a majority opinion.[438] However, because of the controversial issues involved and wide range of interests represented, the alternative of requiring unanimity in decisions may not work in practice. Operating on a unanimity basis may frustrate effective and efficient decision-making, particularly when, as noted above, it is unlikely that unanimity or consensus will be reached on issues surrounding the conduct of RGTs. In an area in which substantive agreement is difficult if not impossible, ensuring that a consistent procedure is followed in

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435 UK Act Schedule 1 para 9.

436 SA Act s.8(4); Victorian Act s.129(3) (ITA), s.148 (SRACI); WA Act Schedule para 7. In Western Australia the legislation specifically states that decisions are to be made by majority vote.

437 Moreno *supra* note 390 at xiv.

438 In Victoria and Western Australia these problems may be only theoretical, since many of the controversial moral issues have been predetermined by the legislation itself.

decision-making is important.[439] The regulatory agency should implement a procedure which maximises consideration of a wide range of interests, including minority views.

Whatever procedure is adopted, and however much public participation is encouraged, it is beyond doubt that the outcome of the process will not be accepted by all of the community. If an interested party is dissatisfied with a decision of the regulatory agency, the decision may be subject to judicial review. However, in Victoria, the United Kingdom and South Australia, the avenues for review are limited.

In the United Kingdom, licensing decisions of the HFEA are only reviewable on a point of law.[440] The option of a hearing *de novo* on the facts is therefore not available. Similarly, in Victoria and South Australia, decisions relating to the approval of research proposals are unreviewable in the courts.[441] The jurisdiction of the courts to review such decisions is specifically ousted in the legislation.

Standing to challenge decisions whether by way of *de novo* review or on a question of law extends only to applicants for licences or licensees who have been given notice of a decision.[442] These restrictions on standing reflect a notion that is to some extent at odds with the idea that the issues surrounding the conduct of RGTs are not private matters, but may impact upon the wider interests of the public. In other areas of administrative law, interest groups have been given

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439 Somerville *supra* note 374 at 533.
440 UK Act s.21.
441 SA Act s.16(4); Victorian Act s.150.
442 WA Act s.42; UK Act s.21; Victorian Act s.149 ("a person aggrieved"). The SA Act does not contain specific provisions with respect to standing, but according to the common law, persons aggrieved by licensing decisions of the SA Health Commission would be able to challenge those decisions.

standing to challenge the decisions of government agencies affecting the public interest where the interest group is a suitable body to represent the public, and has a "special interest" in the subject matter of the action" which is something more than a mere emotional concern.[443]

The absence of the possibility of testing the legitimacy of decisions, whether due to restricted rules of standing or because the jurisdiction of the courts has been ousted, reflects the notion that the courtroom is a less than adequate milieu in which to discuss the wider implications of the issues arising out of the conduct of RGTs. It also reflects the confidence that the legislature has in decision-making by the agency, and suggests that judges lack the expertise to rule on moral issues.

Such a position is to be preferred. Moral viewpoints are inherently value-laden and personal. In a pluralist society, the decision of one person, a judge, on a moral (as opposed to a legal) issue has no moral authority in and of itself, and as such cannot be morally binding on the rest of the community.[444] This argument presupposes a separation between law and morality, and denies any moral authority a judicial decision may have by virtue of it representing "the law" with which citizens have a moral obligation to comply. However, leaving aside the question of the relationship between law and morality which is ambivalent at best, in a secular pluralist society, the decisions of one person cannot have binding moral authority without a clear mandate from the rest of the community. While judges do have a mandate from

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443 See for example *Australian Conservation Foundation v Minister of Resources* (1980) 146 CLR 493 (HC); *Ogle v Strickland* (1987) 71 ALR 41 (FC).

444 I am referring here to first instance decisions. Appeal decisions will of course be heard by more than one judge, but the same considerations will strictly not arise since appeals will proceed on errors of law, rather than errors of fact, although I recognise that appeal decisions will frequently involve questions of policy in the interpretation of the law, and to this extent moral matters may be at issue.

the community, it extends to deciding questions of law and not questions of morality.

While decisions of a multidisciplinary agency may not strictly have absolute moral authority (to the extent that they are not agreed to or accepted by all citizens), they are arguably more representative of the community than the decision of a judge. Allowing decisions of a multidisciplinary agency on moral issues to be replaced by a decision of one person may undermine rather than legitimate the public policy that emanates from the agency.

Taking Into Account Changing Social and Moral Values

The importance of flexibility in the regulatory scheme in the context of changing scientific knowledge was considered in Part IV. Flexibility in the regulatory scheme is also important for changing social values.

As with scientific developments, the prohibitive approach to RGTs is restrictive and clearly less able to incorporate changing opinions about the morality of certain practices. The regulatory approach such as that taken in South Australia in which little conduct is prohibited in the legislation, but the norms of conduct are contained within a code of practice is preferable. A code of practice is more easily amended than legislation to take changing opinions into account.

In summary a pluralistic approach to decision-making within a neutral framework is to be preferred. It is more consistent with theoretical concerns, and will maximise the role of the community in matters that may have a significant impact on society as a whole.

VI CONCLUSION

At the heart of issues surrounding the regulation of RGTs, as with the regulation of biomedicine generally, is the interrelationship between science, morality and law, and the role the law should play in mediating the conflict between science and morality. The conflict between science and morality in the area of RGTs was noted in Part II through consideration of several of the moral and social issues surrounding the conduct of RGTs. The ability to pursue knowledge, both for its own sake and for future clinical application, without restriction, would be the ultimate existence for many scientists. But the means by which knowledge is obtained is important, for the value of knowledge obtained by morally dubious practices is questionable. Furthermore (the legitimacy of slippery slope arguments notwithstanding),[445] it is arguable that the continuation of practices contrary to accepted views of good behaviour may lead to the moral and/or physical destruction of the human race.

The conflict between science and morality is age-old. In the seventeenth century Galileo was accused of being a heretic by the Catholic Church in promoting the notion that the earth revolved around the sun contrary to the Church's teachings at the time, and which resulted in Galileo being brought before the Inquisition. In those times the church and the law were closely allied, and the role of the law was to uphold morality as taught by the church. With the separation of church and state and the rise of moral pluralism in modern Western society, the role of law in mediating the conflict between science and morality is complex. This complexity is

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445 For a critique of slippery slope arguments see for example van der Burg W "The Slippery-Slope Argument" (1992) 3 J Clinical Ethics 256.

heightened by the separate relationships between law and science and law and morality.

These relationships were considered in Parts IV and V respectively. Law and science are reluctant partners because they proceed on different bases: law seeks certainty while science thrives on uncertainty; law draws lines and distinctions where scientifically none can be drawn. The relationship between law and morality continues to be the subject of much debate, and the role of law in a liberal pluralist society where there is a separation between church and state is controversial.

Within this context, this thesis began by asking what sort of statutory scheme could be implemented to regulate the conduct of RGTs and to produce meaningful public policy in the area. The statutory schemes described have been characterised here and elsewhere[446] in several ways. Distinctions have been drawn between a prohibitive approach and a regulatory approach; between a prescriptive approach and facilitative approach; and between a technical elite approach and a pluralist approach. The difficulty of characterising the models as reflecting one or other of these approaches arises from the presence of features of several of these approaches within one statute, and the dependence of a characterisation on the particular feature of the legislation sought to be characterised. For example, the elite/pluralist distinction applies in relation to the approach taken to community participation in public policy formation, while the prohibitive/regulatory distinction applies to the approach taken to the regulation of conduct falling within the scope of the legislation.

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446 See for example Jabbari D "The role of law in reproductive medicine: a new approach" (1990) 16 J Med Ethics 35; Morgan & Nielsen *supra* note 356.

Despite these difficulties, it is useful to characterise the legislation in order to draw some conclusions about the optimal legislative model to implement in circumstances of rapid scientific change and diverse moral opinion.

In Part III, the legislation was characterised as regulatory or prohibitive according to the approach taken to the regulation of morally questionable conduct. In light of the subsequent discussion in Parts IV and V concerning the regulation of science and the regulation of morality, in this context a regulatory approach is to be preferred to a prohibitive approach. A regulatory approach is more able to deal with the tension between law and science. Such an approach is more flexible and more able to take into account scientific developments and changing moral opinion. It will be more difficult to change the legislation and the collective mindset of the community to take into account such changes where a prohibitive approach is adopted. A prohibitive approach typifies the static nature of the law in its inflexibility.

Administrative sanctions such as the cancellation of licences are effective and less draconian measures than criminal prohibitions for unacceptable practices. Criminal prohibitions may be overly restrictive and may have an adverse effect on the progress of science in the jurisdiction in which they are imposed. This may in turn lead to the loss of eminent clinicians and scientists to more permissive jurisdictions, and in the context of RGTs, to procreative tourism.

The approaches adopted in the legislation to public policy formation were examined in Part III in the context of the statutory schemes, and in Part V in the context of the relationship between law and morality. In Part III, the legislation was described as facilitative or prescriptive.

In Part V the characterisation of the legislation was based on the extent of community participation in decision-making and public policy formation. A technical elite approach was contrasted with a pluralist approach.

Legislation adopting a prescriptive approach assumes the "rightness" of certain moral viewpoints which are reflected in the rules laid down therein. Such an approach effectively discounts the legitimacy of any other moral opinion, and to this extent is inconsistent with moral pluralism and liberal neutrality.

However, the pluralist criticism of the prescriptive approach should not be taken too far, since to do so could result in regulation that is laissez-faire. Thus, it could be argued that in a liberal pluralist society the lack of consensus on moral issues mitigates against substantive state intervention, but in favour of formal regulation which leaves the conduct of morally controversial practices to the consciences of the individuals involved.[447] Such formal regulation would be essentially symbolic, and may have little real impact upon morally questionable practices.

A middle ground between laissez-faire and prescriptive regulation needs to be achieved. This middle ground can be achieved by the facilitative approach wherein decision-making and public policy formation is shifted from the legislature to the regulatory agency, and where public policy is supported by regulatory sanctions rather than criminal prohibitions. Combined with a pluralist approach to community participation, such an approach would maximise the opportunity for the views of the community to be gauged and taken

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447 See Jabbari *ibid* at 35.

into account in the decision-making process. Decisions emanating from the statutory body would then be more acceptable to the community and less open to the criticism that scientific and medical interests are favoured. The morality of an individual case may be determined on the merits of the case, and within the boundaries of public policy that has been determined by a process committed to participatory democracy, rather than being predetermined by the legislature.

Some would be critical of this *ad hoc* approach to science policy. But it is difficult to have anything but an *ad hoc* approach because it is virtually impossible to predict with certainty what knowledge will be obtained in the future, and the impact this will have on current practices. This is particularly the case for research proposals, since each individual application will need to be considered on its own merits. To a lesser extent the same applies to clinical practice, since clinical practice, particularly in the context of new technologies such as RGTs, is not fixed but may also change with new knowledge. Consequently, policy on clinical practice may also require change to take new developments into account. It should not be assumed that an established procedure lacks experimental components, and therefore falls outside wide-ranging moral scrutiny.

A facilitative approach would focus on procedural aspects of decision-making rather than substantive ones. The legislation should be non-directive and should facilitate decision-making and oversight by an agency that contains community representatives, and has a commitment to obtaining and taking into consideration all relevant interests. Policy should be determined by a consistent procedure that takes into account scientific developments, and diversity of moral

opinion. Public policy that comes from the agency will then have the "stamp of democratic legitimacy",[448] and will have moral authority to bind the community.

The comments so far apply to the legislative regulation of science and morality in general. In the more specific context of RGTs, the analysis in this thesis may be useful for the Canadian government in relation to the regulatory component of its RGT legislation which is yet to be precisely formulated.[449]

Several observations can be made, which are to an extent repetitive. First, a wide range of interests and backgrounds should be represented on the regulatory agency. An elitist approach to decision-making should be avoided. The agency should maximise community participation through encouraging informed public debate and consulting the public on controversial issues. Thus, even if the decision represents a majority consensus, minority interests have at least been canvassed and considered in the policy formation process. However, the need for technical expertise cannot be overstated, for a sound understanding of the science is essential for the formation of public policy in biomedicine.

All research in the area of RGTs should be subject to the scrutiny of the agency, not just embryo research. Otherwise research on different aspects of RGTs may be subject to inconsistent policies. A fragmented approach to public policy should be avoided.

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448 Stephen Sir N "Judicial Independence - A Fragile Bastion" (1981) 13 MULR 334 at 342.

449 As noted above at p.2, a general outline of the regulatory component is contained within the Canadian Health Minister's discussion paper: see generally Government of Canada *supra* note 2.

The prohibitive approach should be replaced by a regulatory approach. This is probably unrealistic in the political and constitutional context in Canada. In the absence of cooperation of all the provinces and territories (which in the present political climate is unlikely to be realised in the near future), use of the criminal law power is really the only means by which the federal government can have national jurisdiction to legislate on RGTs. If Canada is going to maintain the prohibitive approach, the legislation should give maximal discretion to the regulatory agency to determine norms of conduct within the legislative framework. An approach similar to that in South Australia wherein the norms of conduct are to be determined by the regulatory agency and contained within a code of practice is to be preferred to the Victorian approach in which norms of conduct are outlined in the legislation.

If it is assumed, as is the case in this thesis, that a legislative approach is the most appropriate in the context of RGTs, then the deficiencies of such an approach should be avoided as far as possible. Throughout this thesis, these deficiencies have been alluded to. In order to avoid them, legislation needs to be as flexible as possible without sacrificing clarity, so that science can progress in a morally acceptable matter, and so that scientific developments can be incorporated into the public policy formation process. In this way, the law will fulfil a role as mediator between the scientists and the community, rather than being a heavy-handed interventionist laying down inflexible rules and draconian measures in the search for an ordered society.

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IMAGE EVALUATION
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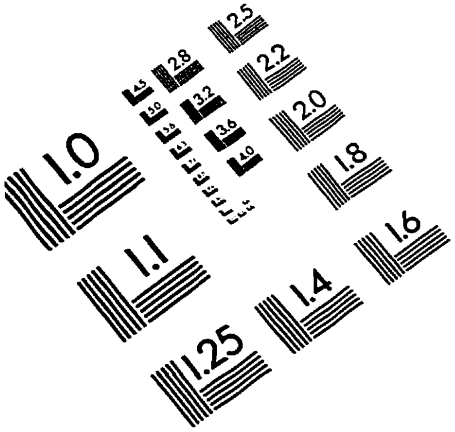

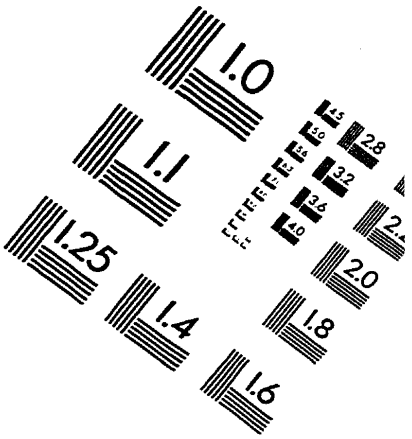

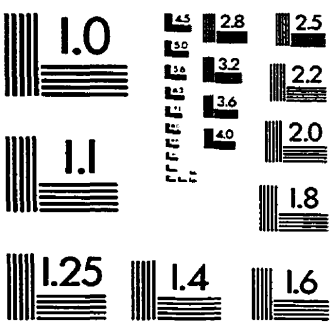

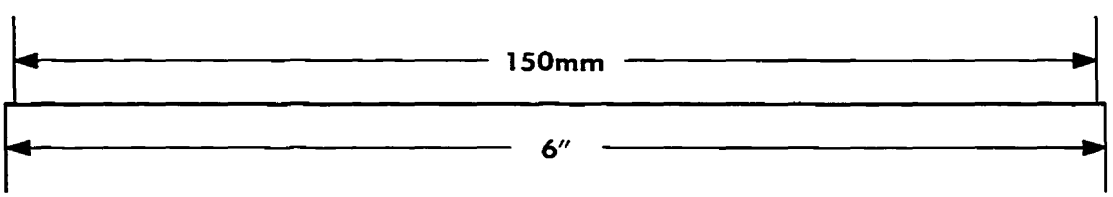

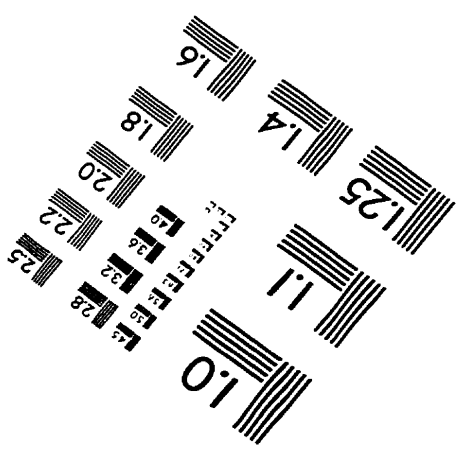

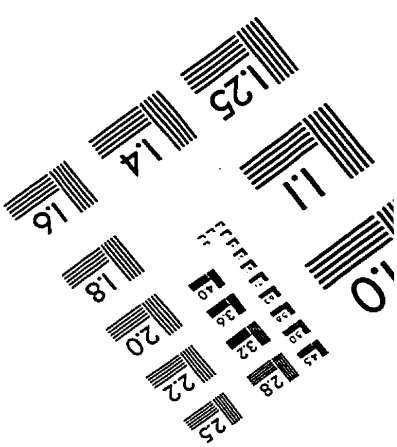

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