Submission to the House of Representatives Standing Committee on Legal & Constitutional Affairs

Inquiry into the Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings

by the Research Department of the Australian Catholic Bishops Conference

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Executive Summary

- 1. Human dignity must be accorded to all members of the human family, from the creation of the first cell (through which stage all of us have travelled), until natural death.
- 2. Human dignity must be the principal touchstone against which policy and law are measured.
- 3. Human life, of whatever age, and especially the most vulnerable (*e.g.* those with a voice still to be recognised completely in law conceptus, embryos and foetuses) must be protected from exploitation. No member of the human family may be exploited, for economic or other gain, so as to become a field for harvesting embryonic stem cells or embryonic germ cells.
- 4. Human life, of whatever age, and especially the most vulnerable (*e.g.* those with a voice still to be recognised completely in law conceptus, embryos and foetuses) must be protected from being produced in order to be sacrificed for the purpose of gaining "scientific information" or otherwise sacrificed `for the benefit of others.'
- 5. Law, and the public policy which it purports to reflect, has an educative dimension, a protective dimension, and a regulative dimension, all of which are for the common good of the community. The legislative regulation of artificial reproductive technology must attend to all such dimensions.
- 6. Medical and scientific research is to be encouraged and supported but not at all costs. The cost is too high if eugenic philosophies and practices infiltrate such research. That is to say, the elimination of imperfect genes *via* the destruction of the possessor of those genes (*i.e.* abortion), is never acceptable; *a fortiori* if a conceptus is produced specifically for experimentation or as part of a group which is deemed "surplus" for implantation purposes.
- 7. There is a significant body of opinion (scientific and ethical) which holds that "...cloning would be a poor method indeed for improving on the human species. If widely adopted, it would have a devastating impact on the diversity of the human gene pool."
- 8. Cloning, using embryonic stem ("ES") cells and embryonic germ ("EG") cells, is inherently parasitic. Embryonic stem cells, embryonic germ cells and embryoid bodies should be treated and accorded the respect, and the proper protection, due a conceptus, foetus or embryo.
- 9. The distinction between "reproductive cloning" and "therapeutic cloning" is spurious and should be discarded. The cloning of reproductive cells should be prohibited throughout all jurisdictions in Australia, as should any and

all practices related thereto, such as the importation of ES and EG cells and embryos.

- 10. Cloning technology to produce specific non-reproductive cells and tissues (*e.g.* skin, muscle) for the clinical treatment of patients should be supported.
- 1. Introduction
- 1.1_ It is incontestible that cloning is one of the most distinctive and critical current issues in biotechnology to confront public policy, medicine, law, ethics and theology. Raised by it directly "lie the deepest matters of our humanity."¹ A number of these "deep matters" are considered in the National Health and Medical Research Council's ("NHMRC") advice and report² to the Commonwealth Minister for Health and Aged Care dated 16 December 1998 ("the Advice"), and in two publications from the Australian Academy of Science ("the Academy"), *On Human Cloning: A Position Statement* (4 February, 1999) and *Therapeutic Cloning for Tissue Repair Report from a Forum held on 16 September 1999* (November 1999).
- 1.2_ The focus of this submission is primarily on the ethical and regulatory aspects raised by the Advice and touched on, in not altogether satisfactory ways³, in the papers published by the Academy. It proceeds in four parts.

¹ The description belongs to Leon Kass in a seminal article, "Practicing Ethics: Where's the Action?" (January/February 1990) 20 *Hastings Center Report* 5-12 at p.12.

² National Health and Medical Research Council - Australian Health Ethics Committee, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*, 16 December 1998.

³ For example, although slightly modified in its later paper, the Academy's *Position Statement* of February 1999 said (p.5): "For Australia to participate fully and capture benefits from recent progress in cloning research, it is necessary to revise the 1996 NHMRC Ethical Guidelines on Assisted Reproductive Technology and repeal restrictive legislation in some States." While the Academy's *Report from a Forum* of

First, a brief critique is given of some prominent philosophies employed in the debate on cloning and bioethics generally. Secondly, an equally brief critique is provided of the NHMRC Advice. Thirdly, attention is given to anthropological considerations; that is, questions relating to human dignity. Finally, attention is turned to regulatory considerations (that is, issues relating to ethics, the role and rule of law, public policy and such matters).

November 1999 does not press for repeal of current legislation on ART and says now that it supports the NHMRC's call, supported also by others, for "regulation, within a uniform, national legislative framework [which] can provide the accountability in research that the public demands," the driving, but doubtless not sole, force of economic return seems to remain.

1.3_ All of the following remarks are predicated on the view that (a) human dignity must be accorded to all human life and must be the touchstone for every consideration in relation to the regulation of artificial reproductive technology ("ART"), including cloning, and (b) that uniform statutory prohibition or regulation throughout Australia of ART, of which cloning is a rarefied part, is essential and is to be preferred to unenforceable guidelines and still less, to self-regulation and accreditation. In this regard, it is crucially important to repeat that cloning is intimately connected with all other aspects of ART, such as genetic screening and IVF.⁴

II Bioethics: Philosophies & Methods - A Critique⁵

2.1 Because bioethics is the formal discipline within which issues, such as cloning, are customarily discussed, it is apposite to consider briefly some of the more common theories which are employed either to justify practices which are dubious (at least) or to obfuscate truths about practices which should not be permitted under any circumstances.⁶ Gilbert Meilaender, formerly Professor of Religion at Oberlin College, now Professor of Theological Ethics at Valparaiso University, Indiana, begins his detailed critique thus:

Bioethicists have begun to reflect upon the history of their discipline. Whether that is a sign of maturity or unease may be debated, but it is a fact. Albert Jonsen dates "the birth of bioethics" from the year 1962, when Shana Alexander's article describing the Seattle dialysis selection committee appeared in *Life* magazine. Elsewhere Jonsen describes 1965-75 as the "formative decade" for bioethics in this country. David Rothman ... dates its beginning with the 1966 publication of Henry Beecher's article exposing abuses in human experimentation. Less concerned than Jonsen to focus on bioethics alone, Rothman attends more to the great changes in American medicine that were taking place - changes in which bioethics played an important role. For him the

⁶ The Bard, among others, was acutely aware of the proclivities of the human heart. Thus,

"... but man, proud man,

Dressed in a little brief authority,

Most ignorant of what he's most assured -

His glassy essence - like an angry ape

Plays such fantastic tricks before high heaven

As makes the angels weep."

Measure for Measure, II.ii.117.

⁴ *E.g.* "Cloning provides a quite specific instance of the interaction between genetic and reproductive technologies, and the difficulty they provide for the traditional concepts and understandings of human rights law." D. Bell, "Human Cloning and International Human Rights Law," (1999) 21 *The Sydney Law Review* 202-230 at p.203.

⁵ This section relies heavily on the learned studies of Gilbert Meilaender, *Body, Soul, and Bioethics*, (Notre Dame & London: University of Notre Dame Press, 1995) and Michael Banner, *Christian Ethics and Contemporary Moral Problems*, (Cambridge: Cambridge University Press, 1999).

"critical period of change" was 1966 to 1976, beginning with Beecher's article and ending with the Quinlan decision by the New Jersey Supreme Court. During this decade physicians increasingly became "strangers" to their patients, and, simultaneously, a new set of strangers - bioethicists - established their role as authority figures near the bedside.⁷

2.2 This passage identifies critical issues which remain with us: rapid change in biomedical science, changes in doctor-patient relationships, both of which, in turn, affect dramatically our understandings of personhood, family, reproduction, autonomy, community and related matters. And bioethicists, the new doyens, and arbiters, of all that the new "advances" in biotechnology herald, are now ensconced as a fixed feature of the biomedical landscape. These matters will be dealt with in due course. But first, a basic question must be addressed.

⁷ *Body, Soul, and Bioethics, op. cit.* p.1. Internal references omitted.

- 2.3 Why are the questions of "philosophy" and "method" relevant to the current discussion? Precisely because the philosophy and method employed to present "the message[s]" of ART and cloning, are the vehicles used to promote or to justify⁸, on the one hand, or, on the other, to urge the prohibition or restriction of ⁹, certain practices. Hence, some appreciation of the philosophical vehicles used in the debate, and those driving them, are critical.
- 2.4. Meilaender proceeds by asking whether the professions, especially medicine, have anything left to profess in the light of much bioethical debate given that bioethics, more often than not, and especially in the growing absence of moral and philosophical absolutes, "...have by and large behaved as if they could (and should) do no more than give pious blessings to the inevitable."¹⁰ A very good, and very recent example of this kind of yielding to presumed inevitability, where assertions are often presented as established facts, is the recommendations of the US National Bioethics Advisory Commission's ("NBAC") concerning "embryonic stem cells" and

¹⁰ L. Kass, "Practicing Ethics: Where's the Action?" op. cit. p.8.

⁸ *Cf.* the general remarks of Loane Skene in her address to the Fertility Society of Australia in December 1997, and summarised in her brief remarks to the Australian Academy of Science in September 1999, published as "Why Legislate on Assisted Reproduction?" in *Controversies in Health Law* (I. Freckleton & K. Petersen, eds.) (Sydney: The Federation Press, 1999) 266 - 274.

⁹ *Cf.* the general remarks of John Finnis in his Seegers Lecture, "Public Reason, Abortion, and Cloning," (1998) 32 *Valparaiso University Law Review* 361.

"embryonic germ cells." Alarmingly, but unsurprisingly, the NBAC concludes:

Recent developments in human stem cell research have raised hopes that new therapies will become available that will serve to relieve human suffering. These developments also have served to remind society of the deep moral concerns that are related to research involving human embryos and cadaveric fetal tissue. Serious ethical discussion will (and should) continue on these issues. However, in light of public testimony, expert advice, and published writings, we have found substantial agreement among individuals with diverse perspectives that although the human embryo and fetus deserve respect as forms of human life, the scientific and clinical benefits of stem cell research should not be foregone. We were persuaded that carrying out human stem cell research under federal sponsorship is important, but only if it is conducted in an ethically responsible manner. And after extensive deliberation, the Commission believes that acceptable public policy can be forged, in part, on widely shared views.¹¹

2.5 Similar statements are found in documents produced by organisations in Australia. For example, the Australian Academy of Science's *Position Statement* says:

Cloning techniques may one day revolutionise medical treatment of damaged tissues and organs, should it become possible to use human adult cells as the starting material for growth of new tissues.

... In the United Kingdom, government advisors have recognised that legislation introduced in 1990 to ensure ethical practices in research in IVF and embryology has been overtaken by advances in cloning techniques. In December, 1998, the UK Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority recommended that licences might be issued for research involving human embryos for development of therapeutic treatments for diseased or damaged tissue or organs.

 \dots The Academy's Steering Group has studied the U.K. advice and its basis and believes it has many features worth adapting to the Australian research environment. $^{\rm 12}$

This, and other such comments, indicate that principles, public policy, and the law, ought be shaped according to the dictates of the state of the science, without (apparently) any other considerations being relevant.

¹¹ "Ethical issues in human stem cell research," National Bioethcis Advisory Commission, text as printed in (December 1999) 153 *Bulletin of Medical Ethics* 8-10 at p.10. It is hard to know whether the Commission has taken out insurance against unauthorised or unacknowledged use of scripts from Sir Humphry Appleby and the "team" from *Yes Minister*.

 ¹² On Human Cloning: A Position Statement, Australian Academy of Science, 4 February, 1999,
pp.4 & 13. See also the Academy's later publication, *Therapeutic Cloning for Tissue Repair*, 1999, *passim*.

- 2.6 The NBAC concludes, with the time-honoured disclaimer, "*At this time*, the Commission believes that federal funding for the use and derivation of ES and EG cells should be limited to two sources of such material: cadaveric fetal tissue and embryos remaining after infertility treatments."¹³ (*emphasis added*) Having given the `green light' to the use of foetal tissue from the sources noted, it is hardly conceivable that at another (later) time such an approval would be reversed by the Commission. More will be said shortly in relation to the utilitarian "philosophy" which undergirds decisions like those articulated by the NBAC.
- 2.7 Meilaender notes how essential it is that the medical profession maintain a certain critical distance from the larger society. Without that distance, among other things, professions simply posit inconsistent or illogical positions and conduct practices on the basis of [uninformed or ill-informed] public opinion much like those cited from the NBAC above.

¹³ "Ethical issues in human stem cell research," *op. cit.*, p.8.

2.8 In contrast, the Hippocratic tradition pictured medicine as a profession with its own internal goals and norms, providing "the necessary and sufficient ingredients for a coherent medical ethic from within the culture of medicine itself."¹⁴ Within this view, the norms of medicine are generated from within the practice itself; they are not the application to medicine of more universal norms - while not being excluded from them. Meilaender continues:

To think of medicine's goals and norms as internal to its practice is not a rejection of moral theory; it is the adoption of an Aristotelian understanding of morality. On this view, appropriate behaviour is not determined by the reflective application of moral rules, as if we determined what we ought to do by specifying more precisely the application of universal rules to particular cases. Instead, appropriate behaviour is learned as one gradually learns a way of life - the habits of conduct that constitute its grammar and syntax.

 \dots [However,] the history of the past quarter century of bioethics is in large measure a story of movement away from such a view. 15

2.9 Daniel Callahan observes that this shift from an Aristotelian, or virtuebased profession, such as medicine, to one where external measures gauged according to the fluctuating moral standards of the wider community become increasingly prevalent, explains, in large measure, why autonomy has assumed such a prominent place in bioethical decision-making.¹⁶ This is because, in the absence of consistent specific norms or principles which are largely internal to the medical profession, and their replacement by

¹⁴ D. Callahan, "Morality and Contemporary Culture: The President's Commission and Beyond," (1984) 6 Cardozo Law Review 348.

¹⁵ Body, Soul, and Bioethics, op. cit. pp.4 & 5. Cf. E.D. Pellegrino & D.C. Thomasma, *The Virtues in Medical Practice*, (New York: Oxford University Press, 1993).

¹⁶ "Morality and Contemporary Culture..." op. cit. 348.

more general and amorphous principles imbibed from the wider community, the only thing which, in a sense, binds any system together is autonomy.¹⁷

2.10 In the absence of a consistent virtue-based ethical system, what has taken its place? Four basic, representative versions of bioethical philosophies can be noted: a communitarian ethic, "principlism", casuistry and consequentialism. A brief overview of their basic features, relevance and prevalence in current discourse, follows.

¹⁷ The same is true of medical law. For example, autonomy features as a prominent, if not the predominant, "virtue" in Kennedy and Grubb's *Principles of Medical Law* (Oxford: Oxford University Press, 1998). Indeed, it is the only "principle" enunciated.

2.11 Ezekiel Emanuel is an oncologist and bioethicist at Harvard Medical School. In his book, The Ends of Human Life: Medical Ethics in a Liberal *Polity*¹⁸, Emanuel proposes a communitarian medical ethic in which some moral norms, internal to medicine, exist but which are held to be unable to solve all of medicine's moral problems. Thus, it becomes, in his view, necessary to supplement deficient moral norms with political theories; ethics, in this view, becomes a branch of politics. Emanuel states this bluntly: "Medical ethics is a sub-field of political philosophy."¹⁹ Meilaender suggests that there must be, according to this view, an integration of medical ethics and universal morality within a community (or communities) in which there is agreement not just on a few general principles but on the meaning of the good life. But, continued commitment to our liberal political tradition must inevitably, Emanuel argues, lead to frustrating deadlocks over the problems in bioethics. His solution: a *consensus* worked out in public discussion and debate. In seeking a consensus (usually a hybrid form which aspires to the lowest common denominator), we do not seek to impose any one view, but rather we seek only to persuade. Meilaender observes wryly:

¹⁹ *ibid.* p.23.

¹⁸ The Ends of Human Life: Medical Ethics in a Liberal Polity, (Cambridge & London: Cambridge University Press, 1991).

Understanding that what persuades us may not always persuade others ... we agree to let that "form of ritual combat" that is voting be determinative (at least for now).²⁰

And further,

...lacking substantive agreement there remains only the search for ways to honour everyone's autonomy. $^{21}\,$

²¹ *ibid.* p.29.

²⁰ Body, Soul, and Bioethics, op. cit. p.10.

2.12 The second type of ethical theory is "principlism", the term coined by critics²² of Beauchamp and Childress's four principles of biomedical ethics.²³ Although it has recently been diagnosed as a patient who is ill²⁴, nonetheless, the ethical philosophy of these two scholars remains very influential. It is referred to briefly in the NHMRC Advice, but not by name.²⁵ Beauchamp and Childress describe a process by which particular moral judgements are *justified* by appeal to moral rules, which are in turn *justified* by more general principles, which themselves are *justified* by an ethical theory. Most curiously, however, they admit that the four basic principles which they have developed are "binding but not absolutely binding."²⁶ They acknowledge that when particular judgments are needed about cases, we can only "weigh" their respective claims - a procedure for which the theory gives no guidance.²⁷ This can, at best, be a form only of

²⁴ E.R. DuBose, R.P. Hamel, L.J. O'Connor, (eds.) *A Matter of Principles? Ferment in US Bioethics*, (Valley Forge, PA: Trinity Press International, 1994).

²⁵ See par.3.2 of the Advice in which "the four principles" are described as `broad duties.'

²⁶ This text is taken from the Third Edition of *Principles of Biomedical Ethics*, (New York & Oxford: Oxford University Press, 1989) p.51. In the latest edition (see note 23, above), Beauchamp and Childress, while maintaining their insistence that their principles are intended, primarily, as a means of justifying conduct, appear to re-cast their language ever so slightly. Nonetheless, the Fourth Edition is replete with statements of which the following are typical examples:

Throughout this book we view the norms to be balanced - principles, rules, rights and the like - as *prima facie*, and not as absolute, as rules of thumb, or as hierarchically (lexically or serially) ordered. However, some specified norms are virtually absolute, and therefore usually escape the need to balance. (p.32)

... in light of the enormous range of possibilities for contingent conflicts among rules, absolute rules are best construed as ideals rather than finished products. (p.33)

... we treat principles as both prima facie binding and subject to revision. (p.105)

²⁷ Beauchamp and Childress are clearly sensitive to criticisms such as these. In the Fourth Edition of *Principles of Biomedical Ethics*, they go to some lengths to try to answer some of their critics - but not successfully. For example, they say:

As a response to criticisms that the model of balancing is too intuitive and open-ended, we can list a few minimal conditions that reduce [but not eliminate] the amount of intuition involved. These conditions add content to the requirement of giving good reasons for actions and norms. The following conditions must be met to justify infringing one prima facie norm in order to adhere to

²² K. Danner Clouser & B. Gert, "A Critique of Principlism," (1990) 15 *The Journal of Medicine and Philosophy* 232.

²³ Principles of Biomedical Ethics, (Fourth Edition) (New York & Oxford: Oxford University Press, 1994). A thorough-going critique of the "four principles" is provided by John Finnis and Anthony Fisher OP, "Theology and the Four Principles: A Roman Catholic View I," in *Principles of Health Care Ethics*, (ed. R. Gillon) (Chichester: John Wiley & Sons, 1994) 31-44. Other essays in the same volume also provide strenuous critiques of the "four principles" albeit from different perspectives.

intuition. This is a theory fashioned largely with public policy in mind "driven by the search for consensus in a pluralistic society."²⁸

2.13 The most philosophically developed alternative to the "applied ethics" approach of Beauchamp and Childress is casuistry.²⁹ Stated simply, the casuist does not begin moral reflection at the level of theory, nor does he or she reason deductively. Rather, the casuist begins from cases about whose resolution most of us are relatively confident, cases that are "too clear and simple, too nearly paradigmatic to be in any way problematic or open to doubt."³⁰ The object of the casuist is simply to find an opinion that could be reasonably entertained. In this respect, casuistry becomes a panacea to palliate difficulties which arise, and are otherwise unable to be confronted, in dealing with complexity and moral ambiguity. But, in proceeding thus, "[w]e need refer to no underlying principle or theory; we simply need to offer good reasons."³¹ In Toulmin's words:

... the philosopher's task is not to find an underlying principle that binds all obligations and claims together; rather, it is to develop a sufficiently varied

another (however, these conditions, being norms themselves, are also prima facie, not absolute).... (p.34)

See further, "A Reply to Some Criticisms", pp.106-108.

²⁸ Body, Soul, and Bioethics, op. cit. p.18.

²⁹ See here Albert Jonsen and Stephen Toulmin, *The Abuse of Casuistry: A History of Moral Reasoning*, (Berkeley, LA, London: University of California Press, 1988).

³⁰ *ibid.* p.7.

³¹ Body, Soul, and Bioethics, op. cit. p.22.

taxonomy of cases, circumstances, and considerations, allowing for (and doing justice to) the differences between them. $^{\rm 32}$

³² The Place of Reason in Ethics, (Chicago and London: University of Chicago Press, 1986) p.xix.

2.14 Put another way, the object of the modern casuist is to engage in a "conversation" in which reasons are offered, hoping that others will find them to be good reasons. According to this view, the function of ethics becomes the achievement of social harmony in which there is a hope that a conversation between people of good intentions, that is, good-hearted people, "will not need any principles to protect them against the evils of the human heart."³³ In a number of respects, the ethical writings of the geneticist, Robert Williamson of the Murdoch Institute, might be so characterised - but not so some of his collaborators.³⁴ Of course, the modern casuist can equally be a consequentialist - considered next.

³³ Body, Soul, and Bioethics, op. cit. p.25.

³⁴ On Williamson, see for example, "What's `new' about `genetics'?" and "Human reproductive cloning is unethical because it undermines autonomy: commentary on Savulescu," both in *Journal of Medical Ethics* 25 (1999) 75-76 & 96-97 respectively. Perhaps Professor Williamson's most prominent collaborator - not least because of his advocacy of abortion as a remedy for the conception of a child unwanted because of his or her sex - is Julian Savulescu; see his "Should we clone human beings? Cloning as a source for transplantation," *Journal of Medical Ethics* 25 (1999) 87-95. Savulescu is a forthright consequentialist/ utilitarian almost in the same league as Michael Tooley. Tooley, of course, is prominently known, like Peter Singer, Jeff McMahan and others, who advocate, *inter alia*, that human life worthy of protection are only those sections of the human family who have certain attributes such as nominated psychological capacities, self-awareness and such matters; all others are expendable. See further below on Tooley *et al.*

2.15 The final approach to consider, and very briefly, is that of consequentialism, the most fervid form of which is utilitarianism. Michael Banner, in describing consequentialism as the simple maximising of benefits and the minimising of harms, and the attempt to ensure good outcomes in circumstances of empirical uncertainty, warns vehemently against this "controversial moral theory" especially in its unchallenged use as the, apparently, preferred vehicle of evaluation of new biomedical technologies.³⁵ It seems very much to be the preferred philosophy of the Australian Academy of Science, among others. Tellingly, as the Chair of the Committee which produced the Banner Report³⁶, he observes:

... though they may not use this language, many people have intrinsic objections to the use of the emerging technologies. They may well be concerned about the effect of these technologies on animal welfare, genetic diversity, the environment, the pattern of farming and rural life, etc., but their concerns would not be exhausted by a consideration of these matters. For as well as worrying about the effects of the new technology, *they feel distinct unease about its very use.*³⁷ (Emphasis added)

³⁶ The Report of the Committee to Consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals (London: 1995).

³⁷ *Christian Ethics and Contemporary Moral Problems, op. cit.* p.216, quoting from the Banner Report, par.3.3.

³⁵ Christian Ethics and Contemporary Moral Problems, op. cit. Ch. 6, "On not begging the questions about biotechnology," 204-224.

If this concern is articulated in the application of the `new technologies' to farming and such matters, could, or should, we be any less concerned in relation to its unfettered application to human life? The answer must be a resounding "no." And this must be so in a particular way because the shift is from professions, like medicine and science, traditionally at the service of life to those sections of our communities which are more interested in its manipulation.³⁸

2.16 An important, further, example, in addition to that of the NBAC, but from the other side of the Atlantic, of the `maximising benefit and minimising harm approach' is the recently published study by the British Medical Association, *Human Genetics: Choice and Responsibility.*³⁹ It is replete with references to it. One example must suffice, thus: "The BMA's published view is that health professionals who provide any form of assisted reproduction have particular duties to ensure that the resulting child is not foreseeably disadvantaged."⁴⁰ Appropriately, it treats cloning as part of the world of ART.⁴¹

⁴⁰ *ibid.* p.17.

⁴¹ *ibid.* par.11.6. See also the following statement from the Human Genome Organisation ("HUGO") Ethics Committee on cloning, par.2.4:

... Certain research not included under 2.2 ["Basic Research"] and 2.3 ["Therapeutic cloning"] but of indisputable and widespread benefit to humanity may require the creation of embryos as usually understood, without any opportunity for early embryonic development in utero, in order to grow stem cells. This might be considered, in societies whose laws permit this course, in the rare circumstances where the study of a particular disease or its potential cure can only be facilitated by studying embryonic stem cells in cell culture.

No criteria is given as to how one might judge when "certain research" is "of indisputable and widespread benefit to humanity." Perhaps the HUGO Committee has in mind statements like those of Julian Savulescu, thus:

The most publicly justifiable application of human cloning, if there is one at all, is to provide selfcompatible cells or tissues for medical use, especially transplantation. Some have argued that this raises no new ethical issues above those raised by any form of embryo experimentation. I argue that this research is less morally problematic than other embryo research. Indeed, it is not merely morally permissible but morally required that we employ cloning to produce embryos or fetuses for the sake of providing cells, tissues or even organs for therapy, followed by abortion of the embryo or fetus.

"Should we clone human beings? Cloning as a source of tissue for transplantation," (1999) 25 *Journal of Medical Ethics* 87-95 at p.87. Michael Tooley argues in identical terms in "The moral status of the cloning of humans," (1999) 18 *Monash Bioethics Review* 27. "Baby farming" takes on a whole new meaning indeed!

³⁸ Similar concerns in relation to cloning and human life are articulated in the seminal article by Leon Kass, "The Wisdom of Repugnance." *The New Republic* (2 June 1997).

³⁹ (Oxford: Oxford University Press, 1998). For a discussion of the defects of consequentialism and utilitarianism, see generally Anne Maclean, *The Elimination of Morality: Reflections on Utilitarianism and Bioethics*, (London: Routledge, 1993).

Meilaender notes in this regard the similarity, however politically incorrect to do so, between such propositions and those advanced by the Nazi doctors. Quoting from Robert Lifton's seminal *The Nazi Doctors: Medical Killing and the Psychology of Genocide* (New York: Basic Books, 1986) pp.286 *ff*, he (Lifton) notes that "In the absence of ethical restraint, one could arrange exactly the kind of surgical experience one sought, on exactly the appropriate kinds of `cases' at exactly the time one wanted. If one felt Hippocratic twinges of conscience, one could usually reassure oneself that, since all of these people were condemned to death in any case, one was not really harming them." Meilaender observes:

Let us note that justification: Because, by virtue of decisions others had made, the victims had no future life prospects, they could not really be harmed if subjected to experiments that would never have been carried out on other people. Structurally, it is the justification offered by some on the National Commission for the Protection of Human Subjects for contemplating what would ordinarily be considered research involving more than minimal risk on fetus-to-be-aborted. Structurally, it is similar to the Human Embryo Research Panel's willingness to permit experiments involving greater risk of harm to embryos not intended for transfer.

Body, Soul, and Bioethics, op. cit., pp.103-104. Structurally, the argument so propounded by the Nazis is identical to that of the NBAC quoted earlier, that of Savulescu and also of Professor Trounson, and not dissimilar to the Australian Academy of Science. Allow Meilaender again to comment:

To read Lifton's account is, for the most part, to read of good and ordinary people in the grip of an ideology, who suppose themselves to be engaged in the purely scientific (and philosophically neutral) practice of medicine. And something like this, Lifton suggests, is an almost universal human possibility. Therefore, ... it is always fair, appropriate, and important to ask what kind of bioethics can best protect us against the possibilities for evil that may lie within us. I do not think we ought to place much confidence in a bioethics that, thinking itself free of religious or philosophical contamination, goes in search of public policy.

ibid. p.105.

III NHMRC Advice - A Critique⁴²

- 3.1 Properly, the NHMRC advice notes those three jurisdictions in Australia (Vic, SA, WA) which have legislation to regulate ART. It notes, too, various Guidelines which purport to do the same without enforcement, of course. Appropriately, the Advice to the Minister also refers to the nine (9) pieces of legislation relating to the status of children.
- 3.2 The NHMRC Advice deals summarily with the position at common law concerning public policy considerations in the enforcement of certain kinds of contracts. Surprisingly, there is no discussion of surrogacy either as to the link between cloning, ART and surrogacy, or those jurisdictions which have legislated against surrogacy altruistic or otherwise. Perhaps the Advice proceeded on the basis that anyone who wished to know more about these matters would consult some or all of the Reports listed in footnote 60 of the Advice. It is regrettable that it did not deal with the subject directly.

 $^{^{42}}$ As noted in the Introduction to this submission, this critique is limited largely to the legal and ethical sections of the Advice.

- 3.3 The Advice also does not deal with questions of patenting and the regulation which that discipline of the law provides. Given that issues relating to patenting have been raised in academic, and judicial, circles overseas for some time⁴³, as well as in Australia⁴⁴, it is remarkable that there is no mention of patenting in the Advice to the Minister.
- 3.4 There seems to be a significant trend among the scientific community to regard the manufacturing of `life products' as more closely akin to matters of property than to life. Thus, in a discussion of the deliberations of the ethics advisory board ("EAB") of prominent genetics corporation, Geron (which bought Ian Wilmut of "Dolly" fame and his laboratory), Lori Knowles notes the oscillation between, on the one hand, the classification of "embryonic tissue" as "potential progeny" (as in "life" and "person"), and on the other, the Geron EAB statement that "...donors should be advised as to whether they have property rights in stem cells derived from their embryos" which suggests a more property-oriented view.⁴⁵ The NHMRC Advice, regrettably, seems not to address, or address directly, this production manufacture commodification commercialisation of life paradigm. To be fair, the ethics section of the Advice raises these questions although somewhat ambivalently.⁴⁶

⁴⁴ See Anaesthetic Supplies Pty Ltd v Rescare (1994) 50 FCR 1; Patricia Loughlin, "The patenting of medical treatment," (1995) 162 *Medical Journal of Australia* 376; Michael Blakeney, "Bioprospecting and the Protection of Traditional Knowledge of Indigenous Peoples: An Australian Perspective," [1997] 6 *European Intellectual Property Review* 298; Charles Lawson, "Patenting Genes and Gene Sequences in Australia," (1998) 5 *Journal of Law and Medicine* 364; *id.* "Patenting Genetic Materials: Old Rules May Be Restricting the Exploitation of a New Technology," (1999) 6 *Journal of Law and Medicine* 373.

⁴⁵ Lori Knowles, "Property, Progeny, and Patents," (1999) 29 Hastings Center Report 38-40 at p.39.

⁴³ See, for example, Alain Pottage, "The Inscription of Life in Law: Genes, Patents, and Biopolitics," (1998) 61 *Modern Law Review* 740; Richard Ford, "The Morality of Biotech Patents: Differing Legal Obligations in Europe?" [1997] 6 *European Intellectual Property Review* 315; Lionel Bentley & Brad Sherman, "The Ethics of Patenting: Towards a Transgenic Patent System," (1995) 3 *Medical Law Review* 275; Sigrid Sterckx, "Some Ethically Problematic Aspects of the Proposal for a Directive on the Legal Protection of Biotechnological Inventions," [1998] *EIPR* 123; John Doll, "The Patenting of DNA," (1 May, 1998) 280 *Science* 689; *Biogen Inc v Medeva PLC* (1996) 36 IPR 438 (HL); A. Varma & D. Abraham, "DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market," (1996) 9 *Harvard Journal of Law & Technology*53-85. And recently, see Lori Knowles, "Property, Progeny, and Patents," (1999) 29 *Hastings Center Report* 38-40 & G. Vogel, "Company Gets Rights to Cloned Human Embryos," (28 January 2000) 287 *Science* 559; P. Ducor, *Patenting the Recombinant Products of Biotechnology and Other Molecules*, (London: Kluwer Law International, 1998); E.R. Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials*, (Washington, DC: Georgetown University Press, 1996); B. Knoppers (ed.) *Human DNA: Law and Policy: International and Comparative Perspectives*, (The Hague: Kluwer Law International, 1997).

⁴⁶ See pars.3.27, 3.28, 3.30 & 3.32. One of the strongest statements against cloning is, fortunately, quoted by the Advice (par.3.28). The statement is one of many found in Leon Kass's important article, "The Wisdom of Repugnance," *The New Republic* (2 June 1997), "... [a]sexual reproduction confounds all normal understanding of father, mother, sibling, grandparents, etc. and all moral relations tied thereto." The ambivalence of the Advice is that it provides a range of opposing views on issues raised by cloning without

staking too many claims as to what should or should not prevail from an ethical perspective. Indeed, the ethical section of the Advice says as much, thus: "In this chapter, an attempt has been made to sketch some of the main considerations which should enter into reflection on the ethics of cloning." (par.3.33) It concludes, in hardly stentorian tones, "Overall, it has been suggested that the more convincing, weighty and cogent arguments support constraints on the use of cloning techniques which involve human embryos." No constraints are articulated.

3.5 These lacunae highlight another aspect of the Advice. The terms of reference given to AHEC/NHMRC were "cloning specific". However, similar exercises overseas have helpfully discussed cloning in the context of the wider field of ART; the NHMRC advice, at least in its discussion of law, did not. For example, the British Medical Association discusses cloning in its much more fulsome study, *Human Genetics: Choice and Responsibility*. So, too, does controversial US attorney, Martine Rothblatt, in her *Unzipped Genes: Taking Charge of Baby-Making in the New Millennium*.⁴⁷ Under the heading of "personal eugenics: my perfect baby", Rothblatt's discussion of "self-selected demographics" proceeds under the following headings - "adoption, mate selection, sperm differentiation, sperm banking, egg banking, selective fertilization, selective abortion, selective infanticide, [and] cloning."

⁴⁷ (Philadelphia: Temple University Press, 1997).

3.5 The most glaring gaps, however, in the legal section of the Advice concern (a) the absence of discussion of common law questions relating to the duty to provide information (e.g. to "donors" of biological material, and/or their next of kin) and other issues relating to professional negligence⁴⁸, (b) the question of "parental rights"⁴⁹, and (c) the schizophrenic state of the law concerning, on the one hand, the status of the unborn child and, on the other, the law on abortion.⁵⁰ The BMA, Rothblatt, and others do not duck these issues, however unsatisfactory their approach or conclusions may be. Moreover, these omissions in the advice are astonishing in the light of Slicer J's significant decision concerning the inheritance entitlements of frozen embryos in *In re the Estate of the Late K*⁵¹ and recent decisions of the

Astonishingly, the Academy of Science's *Position Paper* on cloning refers to the Allars-CJD Report and claims that the former practice of extracting human growth hormone and gonadotrophins from pituitaries of human cadavers was abandoned "following scientific advances that enabled production of unlimited quantities of pure hormones of genetically engineering bacteria." Doubtless it slipped the Academy's Steering Group's attention that the CJD Report notes that many of the practices of extracting hGH and HPG were unethical, some were illegal, most were performed in highly unsanitary surroundings, most of the recipients were not advised (or advised poorly) of any dangers inherent in the use of the materials extracted and used in the treatment of these women, and that the women recipients had grounds to make substantial damages claims against those responsible for their treatment - assuming they lived to do so. Perhaps the Academy could read the three pages of recommendations of the Report, or even consider just this paragraph from it:

It is a dangerous situation if no attempt is made to draw the lines between ordinary exercise of clinical judgment, research, experiment and clinical trial, even if those lines be blurred lines. The absence of lines is most dangerous when new advances in medicine are being explored through new procedures, a particular problem in the field of reproductive technology, as is illustrated by the treatment regimes operating under the AHPHP [Australian Human Pituitary Hormone Program] and the Egg Project.

Report of Inquiry Into the Use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease, (June, 1994) p.722

⁴⁹ Cf. questions posed by decisions such as *Marion's Case* (1992) 175 CLR 218 concerning what "power" parents have in relation to authorising "medical treatment" on their "children" and what "power" courts have in this regard. Other questions under the *Family Law Act* (1975) arise in this connection, as well as the power of the Commonwealth to legislate in matters relating to "parental rights". See s.51 (xxii) of the *Constitution*.

⁵⁰ See the submission of the Australian Catholic Health Care Association and the Australian Catholic Bishops Conference to the High Court in the appeal of *CES v Superclinics Australia Pty Ltd* (1995) 38 NSWLR 47; W. Neville, "Abortion Before the High Court - What Next? Caveat Interventus: A Note on *Superclinics Australia Pty Ltd v CES*" (1998) 20 *Adelaide Law Review* 183-192.

⁵¹ (1996) 5 Tas R 365. See also Leanne Bunney, "The Status of Frozen Embryos," (1995) 9 *Australian Journal of Family Law* 121 and David Clark, "en ventre sa frigidaire: Zygotes as children," (1996) 21 *Alternative Law Journal* 165.

⁴⁸ Thus, there is no discussion about the High Court decision of *Rogers v Whitaker* (1992) 175 CLR 479. See generally Loane Skene, *Law and Medical Practice: Rights, Duties, Claims and Defences* (Sydney: Butterworths, 1998) Chap.6. Moreover, the *CJD Inquiry* of Professor Margaret Allars (see below) referred, *inter alia*, specifically to issues relating to the provision of information and the giving of consent.

House of Lords⁵² and the Canadian Supreme Court⁵³ concerning the status of the unborn child.

IV Related Considerations -Anthropological, Theological & Legal

4.1 **Introduction**: In the course of her introduction to a recent collection of papers concerning reproductive technology and human rights, Gale Professor of Law in the Faculty of Medicine at McGill University, Montreal, Margaret Somerville, referred to two separate statements from international documents. First, the *Universal Declaration of Human Rights* ("everyone has the right ... to share in scientific advancement and its benefits"); secondly, the 1990 report on "Human Rights Aspects of Transactions in Body Parts and Human Fetuses," prepared for UNESCO ("It is likely that the potential for anxiety and suffering in relation to the new biomedical technologies ... [including] severe emotional conflict (with human rights implications) is just beginning").⁵⁴ Her remarks, particularly in relation to anxiety and suffering, are salient.

4.2 Anthropological & Theological Considerations:

⁵² Attorney-General's Reference (No.3 of 1994) [1998] AC 245.

⁵³ Winnipeg Child and Family Services (Northwest Area) v DFG [1997] 3 SCR 925.

⁵⁴ K.E. Mahoney & P. Mahoney (eds.), *Human Rights in the Twenty-First Century: A Global Challenge*, (Dordrecht: Martinus Nijhoff Publishers, 1993) Section V (d) "Reproduction, Technologies and Human Rights" 871-874.

Anthropology, in the present context, is understood as a foundational discipline, and context, for a discussion of questions relating to the dignity of the human person. `The inherent and inviolable dignity of the human person', a phrase found regularly in international instruments and used in international⁵⁵ and domestic⁵⁶ legal discourse, refers to the anthropological locus of ethical, theological and legal reflection, especially concerning basic considerations of human rights, such as the foundational right to life, the general principle of non-discrimination, and such matters. In the context of genetic engineering in general and cloning in particular, human dignity assumes special importance because, in the course, or in the name, of "medical progress", what it means to be human is often reduced, wrongly, to possessing certain attributes or capabilities, and/or the genetic composition of a person.⁵⁷

 56 See, for example, Brennan J in *Marion's Case* (1992) 175 CLR 218 at pp.263-288. See also the judgment of Brennan J in $P \, v \, P$ (1994) 181 CLR 583 at pp.608-626.

⁵⁷ See, for example, Henk Jochemsen, "Reducing People to Genetics" and V. Elving Anderson, "Resisting Reductionism by Restoring the Context," both in *Genetic Ethics: Do the Ends Justify the Genes?* (eds. J. Kilner, R. Pentz, F. Young) (Grand Rapids, MI: Eerdmans, 1997) at 75-83 and 84-92 respectively.

⁵⁵ See, for example, O. Schachter, "Human Dignity as a Normative Concept," (1983) *American Journal of Jurisprudence* 848-54.

More generally, see also, *inter alia, Man-Made Man: Ethical and Legal Issues in Genetics*, (eds. P. Doherty and A. Sutton) (Dublin: Open Air/Four Courts Press, 1997); G. Annas & M. Grodin (eds.), *The Nazi Doctors and the Nuremburg Code: Human Rights in Human Experimentation*, (New York: Oxford University Press, 1992); G. Annas & S. Elias (eds.), *Gene Mapping: Using Law and Ethics as Guides*, (New York: Oxford University Press, 1992).

Important anthropological and related metaphysical questions generally are considered in the following representative studies: Arthur Dyck, *Rethinking Rights & Responsibilities: The Moral Bonds of Community*, (Cleveland: The Pilgrim Press, 1994); Robert George (ed.) *Natural Law Theory: Contemporary Essays*, (Oxford: Clarendon Press, 1994); Iris Murdoch, *Metaphysics as a Guide to Morals*, (New York: The Penguin Press, 1993); Charles Taylor, *Sources of the Self: The Making of the Modern Identity*, (Cambridge, MA: Harvard University Press, 1989).

For a specifically Christian discussion of anthropology, see *The Catechism of the Catholic Church* (1994) pars.1700-1715 ("The Dignity of the Human Person") & pars.2292-2296 ("Respect for the person and

4.3 The Judeo-Christian tradition holds as true that all human life comes from the one Creator, is dignified by virtue of its divine origin, and has a divine destiny to spend eternity with God. As the Second Vatican Council put it:

scientific research"); Benedict Ashley, *Theologies of the Body: Humanist and Christian*, (Braintree, MA: The Pope John Centre, 1985); B. Ashley & K. O'Rourke, *Health Care Ethics: A Theological Analysis* (4th Edition) (Washington DC: Georgetown University Press, 1997) Chapter 1.

The dignity of the human person rests above all on the fact that all men and women are called to communion with God. This invitation to converse with God is addressed to each person as they come into being. For if human beings exist, it is because God has created each person through love, and through love continues to hold each person in existence. Men and women cannot live fully according to truth unless they freely acknowledge that love and entrust themselves to their creator.⁵⁸

4.4 A practical consequence of this view of reality is expressed well by Michael Banner, of Kings College, London:

... our own and nature as such, confronts us not as a raw material on which we must impose our purposes or which must submit to our projects if it is to have form or meaning, but that it is, in contrast, a nature which, in virtue of its being created, [already] possesses form and meaning.⁵⁹

4.5 Two recent contributions are instructive in teasing out what flows from Banner's remarks and the Christian tradition generally. In his paper, Christopher Newell, from the University of Tasmania, questions what constitutes "difference" and "imperfection" in our modern era, suggesting that the eradication of imperfection is illusory. He contends, rightly, that it tells us more about society's voracious appetite for only the most perfect and its distancing from, if not discarding of, anything and anyone who is considered imperfect. Newell goes so far as to suggest that the fundamental problems stem from societal notions of `perfection' and the inability of

⁵⁹ Christian Ethics and Contemporary Moral Problems, op. cit p.223.

⁵⁸ See *The Pastoral Constitution on the Church in the Modern World (Gaudium et Spes)*, par.19; *Catechism of the Catholic Church* (1994) pars.27-30, 1700-1748 & 1929-1930, and *The Gospel of Life (Evangelium Vitae)* (1995), pars.1-4. See also "Can human cloning be `therapeutic'?" Document of the Centre for Bioethics of the Catholic University of the Sacred Heart, Milan, *L'Osservatore Romano* (17 February, 1999) pp.6-7 and generally, *Human Genome, Human Person and the Society of the Future*, Proceedings of Fourth Assembly of the Pontifical Academy for Life (Vatican City, 23-25 February, 1998) (eds. J.DD.V. Correa & E. Sgreccia) (Città del Vaticano: Libreria Editrice Vaticana, 1999).

society to cope with persons who have any disability. Thus, it is no surprise to find, in his view, that much of ART constitutes "technologies of oppression and control" which seek to eradicate any kind of imperfection.⁶⁰ Given his own disabilities, Newell speaks with some authority.

⁶⁰ "Critical Reflections on Disability, Difference and the New Genetics," in *Goodbye Normal Gene: Confronting the Genetic Revolution*, (eds. G. O'Sullivan, E. Sharman, S. Short) (Annandale: Pluto Press, 1999) 58-71.

4.6 British commentator, Bryan Appleyard, draws on his personal experience of his niece Fiona who "survived" more than 30 years with muscular dystrophy. In the light of many misdiagnoses, and a plethora of mis-placed judgments about what would be `best for Fiona ' (*e.g.* that she would be better off dead, etc), he notes sagely the prevailing concept of "the self" is "consumerist" and that "a free market in moral choice is a dangerous illusion" especially when "the dominant force of our age is the medical-industrial complex that is now selling eugenics as a privatised industry."⁶¹ He continues:

.... The self can be improved, altered or aborted when it is found to be deficient. It is not a moral absolute, it is merely a chance product of its genes. Such a view represents such a fundamental change in our interpretation of the human world that, once it is fully accepted, nothing will remain unchanged. We shall have become shrunken, more spiritually impoverished entities, but, perhaps luckily, we shall be too stupid to be aware of the fact. Fiona spent her life in a condition of sickness which few of us experience or could imagine. ... Yet I know that long before she was, strictly speaking, Fiona - when she was a foetus - the science of genetics could have detected her disease and she could have been aborted. I always wanted Fiona to live. But would I then have wanted her to die? Or is that an illegitimate use of the word "her"?

The question then becomes: When she was a foetus, what was she? If, before there is a self, there is no person, then it would not have been Fiona that would have been lost in an abortion. But, on the other hand, what would it have been? It could not have been nothing. It must somehow have been part of the realm of the human concern. It is too easy and too convenient to say Fiona was what she became. In some sense what she became was present in that foetus. And, just as important, what she became was the product of a history and a culture that has been founded on the conception of the moral absolute of the individual, on the sacredness of human life. If we consumerise human life, then there will be no more Fionas, not just because they will be aborted but also because the culture will have lost the spiritual resources to nurture such a human, such a very human being.⁶²

62 ibid. pp.167-168.

⁶¹ "Would We Let It Live?" in *Goodbye Normal Gene: Confronting the Genetic Revolution, op. cit* pp.157-168. See also the comments of Mary Jane Owen, executive director of the National Catholic Office for Persons with Disabilities, given in a formal briefing to US Senators, and others, in relation to the NIH draft guidelines on stem cells research, "Recomputing the Quality-of-Life Equations," (17 February, 2000) 29 *Origins* 572-573.

- 4.7 The basic point of Newell and Appleyard is the need for extreme caution in assessing the usually untested claims of ART, including cloning, and that one sure criterion against which ART can be evaluated is the respect given to the most vulnerable members of the human family. The converse proposition is that by having basic, sound criteria against which to assess new technologies (and laws which are designed to regulate them), a measure of public accountability for medical researchers can come into play. Given the astronomical sums of money involved in the new technologies⁶³, and the less than perfect track record of institutions to comply with even basic standards of accountability⁶⁴, this would be no small advance!
- 4.8 Pope John Paul II has put the matter, in the context of threats to nascent human life, in the following terms: "Some people try to justify abortion by claiming that the result of conception, at least up to a certain number of days, cannot be considered a personal human life. ... what is at stake is so important that, from the standpoint of moral obligation, the mere probability that a human person is involved would suffice to justify an absolutely clear prohibition of any intervention aimed at killing a human embryo."⁶⁵
- 4.9 Consistent with the magisterial teaching of Pope John Paul II in *Evangelium Vitae*, and with their own *Ethical and Religious Directives for Catholic Health Care Services*, in evidence to the National Bioethics Advisory Commission, on behalf of the Catholic Bishops of the United States, the Associate Director for Policy Development of the US Bishop' Secretariat for Pro-Life Activities, Mr Richard Doerflinger noted, initially quoting US congressional policy:

"Fetal tissue from an abortion may only be harvested after the embryo or fetus is dead, and the needs of research are not permitted to influence the abortion decision or the timing or method of an abortion" (42 USC §289g-1).

⁶⁵ Evangelium Vitae, par.60.

⁶³ See the comments of Don Chalmers, "The Role of Various Players in the Ethics of Human Genetics," in *Goodbye Normal Gene: Confronting the Genetic Revolution, op. cit* pp.75-82, especially his discussion of "commercialisation" at pp.80-81 *cf.* L. Skene, "DNA to Dollars: The Commercialisation of DNA Research - Ethical, Legal and Policy Issues," (1999) 6 *Journal of Law and Medicine* 233-240.

⁶⁴ Among other sources, see the helpful outline of a number of failures of prestigious medical centres in the US, among them Rush-Presbyterian-St Luke's Medical Centre, Chicago, City University of New York, Mount Sinai School of Medicine (NY), and Duke University Medical Centre, to comply with the formal regulation of government-funded research in relation to `human experimentation', noted in "Research ethics across the pond," (1999) 153 *Bulletin of Medical Ethics* 3-7. Closer to home, one could profitably consult the 1994 *CJD Report* of Professor Margaret Allars, noted above, footnote 48.

By contrast, harvesting of embryonic stem cells would not be done after the embryo is killed; it is precisely what kills the embryo. Embryos would be destroyed by a method whose only reason for existence is the goal of obtaining usable stem cells for research.⁶⁶

4.10 The National Catholic Bioethics Centre of the United States has published recently three important articles in its bulletin, *Ethics & Medics*, on stem cell research and the destruction of embryos therefor. The remarks of this Centre also include comments on the Draft National Institutes of Health "Guidelines for Research Involving Human Pluripotent Stem Cells" as well as recording the scientific progress on adult stem cells. After observing the lamentable view, held in some scientific circles, that "it is possible to destroy human embryos in an ethical manner because the benefits to be obtained by that destruction outweigh any inherent value that belongs to the human embryos", the Centre notes further:

⁶⁶ "Destructive Stem-Cell Research on Human Embryos," (29 April 1999) 28 Origins, 769 at p.772.

Adult stem cells now appear to have a similar (and perhaps even identical capacity) to become cells of other types. And because they can be taken from the patient, the problem of immune rejection does not affect them. ...The scientific community apparently understands that this represents a very promising new development.⁶⁷

Then follows a quote from the Editor-in-Chief of the journal *Science*, Floyd Bloom, saying that stem cells from adults "are much more accessible" than embryonic stem cells and that, given the moral problems associated with the destruction of human embryos, "the more utility [there is] to be gleaned from adult stem cells, the less these concerns about embryonic stem cells will matter."⁶⁸

4.11 Most recently, commenting on the National Institutes of Health ("NIH") Draft Guidelines concerning the harvesting of ES cells for research, the General Secretary of the United States Catholic Conference, Monsignor Dennis Schnurr, said that "...the government must still make its own moral decision to respect life - it cannot single out certain lives as disposable or as uniquely fit for harmful research simply because someone else plans to destroy those lives." He notes that "in radical discontinuity with [Congressional] tradition, the policy of the new NIH guidelines is that human embryos outside the womb may be exploited and killed as nothing more than "tissue." In short, live human embryos are dismissed as mere "tissue" to be destroyed for useful cells."⁶⁹

⁶⁷ (March 2000) 25 *Ethics & Medics* 1 & 3.

⁶⁸ (December 17, 1999) *Science* 2238 at p.2267. It should be noted, too, that the position of the Victorian Department of Human Services, in relation to the interpretation and application of the *Infertility Treatment Act* 1995, is that that legislation "bans destructive embryo research. [And that] [t]otipotent stem cells are considered equivalent to embryos, whether they arise from fertilisation of nuclear transfer or any other means." Letter from Professor John Catford, Director, Public Health and Development, to N. Tonti-Filippini, 14 October 1999.

⁶⁹ "Harvesting Embryonic Stem Cells for Research: Response to NIH Draft Guidelines," (17 February, 2000) 29 *Origins* 566-571.

4.12 In the light of the magisterial teaching in *Evangelium Vitae*, the *Ethical and Religious Directives for Catholic Health Care Services* approved by the National Conference of Catholic Bishops of the United States, the statement of Mons. Schnurr on behalf of the US Catholic Conference in relation to the NIH Draft Guidelines and the harvesting of ES cells for research, the evidence given to the NBAC on behalf of the Catholic Bishops of the US, and in view of the principles of co-operation documented in those same *Directives*, the appropriate judgment concerning the use of human ES cells is that it is unethical to create and/or to dismember human embryos in order to derive ES cells from them⁷⁰ and that prudentially, ES cells should be treated with the respect due an embryo. *A fortiori* is this judgment apposite in the light of scientific evidence indicating that adult stem cells are more readily accessible and, from an immuno-suppressive perspective, medically superior to ES cells.

4.13 Legal & Historical Considerations:

All significant international instruments, beginning with the *Universal Declaration of Human Rights* in 1948, through to the UNESCO *Universal Declaration on the Human Genome and Human Rights* in 1997 refer, in some form, to the `inherent and inviolable dignity of the human person.'⁷¹ If those instruments are to have any practical effect, they should protect the most vulnerable members of the human family, and be instruments which foster the education of all in relation to what violates, and what enhances, human dignity.

4.14 The *Universal Declaration of Human Rights* 1948 provides that the foundations of international law are human dignity and equality, and that "human rights should be protected by the rule of law." In this regard, it is

⁷⁰ Par.39 of the *Ethical and Religious Directives for Catholic Health Care Services*, approved by the National Conference of Catholic Bishops of the United States, states:

Those techniques of assisted conception that respect the unitive and procreative meanings of sexual intercourse and *do not involve the destruction of human embryos or their deliberate generation in such numbers that it is clearly envisaged that all cannot implant and some are simply being used to maximise the chances of others implanting*, may be used as therapies for infertility. (Emphasis added.)

⁷¹ See also the Council of Europe's Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine (1996) and the same Council's Additional Protocol on the Prohibition of Cloning Human Beings (1998). Article 2 of the former document says: "The interests and welfare of the human being shall prevail over the sole interest of society or science;" Article 11 says: "Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited." For a discussion of the Church's treatment of human dignity, see the references in footnote 56.

essential that the rule, and role, of law, and its foundations, be appreciated anew. For example, throughout history, principles considered foundational to civilised societies have been articulated. An early example of them is the *Institutes of Justinian*. They were first promulgated on 21st November, 533 AD and begin with a brief discourse on "justice and law", saying:

Justice is the constant and perpetual desire to give each man his due right. ...These are the precepts of the law: to live justly, not to injure another and to render each his own. (Bk I.I)

Similar principles have been part of the jurisprudential and philosophical traditions from Aristotle, through to Thomas Aquinas, Thomas More, and others.⁷² Such principles, and laws founded thereon, have had, as their principal goal, the common good of the individual, and of the general community.

4.15 More recently, Pope John Paul II has set out the relationship between civil law and moral law, thus:

... Certainly *the purpose of civil law* is different and more limited in scope than that of the moral law. ... [It] is that of ensuring the common good of people through the recognition and defense of their fundamental rights, and the promotion of peace and of public morality. The real purpose of civil law is to guarantee an ordered social existence in true justice.... Precisely for this reason, civil law must ensure that all members of society enjoy respect for certain fundamental rights which innately belong to the person, rights which every positive law must acknowledge and guarantee.

He continues:

First and fundamental among these [rights] is the inviolable right to life of every innocent human being. While public authority can sometimes choose not to put a stop to something which - were it prohibited - would cause more serious

⁷² For Aristotle, see *Nicomachean Ethics*, Bk.V, and his *Politics*, Bks.III & VII; for Aquinas, on law and political theory, see *Summa Theologiae* IaIIae, qq.90-97, and on justice generally, IiaIIae, qq.57-62; for Thomas More, see generally G.B. Wegemer, *Thomas More on Statesmanship*, (Washington DC: The Catholic University of America Press, 1996).

harm, it can never presume to legitimise as a right of individuals - even if they are the majority of the members of society - an offense against other persons caused by the disregard of so fundamental a right as the right to life.⁷³

Human embryos are part of the human family. They ought not be exploited in any way. Civil law must ensure that all members of the human family, including embryos (however conceived), are protected.

⁷³ Evangelium Vitae par.71. Generally, *"Evangelium Vitae" and Law*, Acta Symposii Internationalis in Civitate Vaticana Celebrati 23-25 Maii 1996, (Roma: Libreria Editrice Vaticana, 1997); *Medicine and Law: For or Against Life?* (Pontifical Academy for Life) (Roma: Libreria Editrice Vaticana, 1999); and see M. Rhonheimer, "Fundamental Rights, Moral Law, and the Legal Defense of Life in a Constitutional Democracy: A Constitutionalist Approach to the Encyclical *Evangelium Vitae*," (1998) 43 *The American Journal of Jurisprudence* 135.

- 4.16 **Lessons from History:** Because cloning is part of a drive toward genetic perfection, and because genetic screening (to check one's genetic purity or sex) and genetic privacy (to protect the individual from prying eyes seeking genetic information) go hand in glove with cloning, some consideration should be given to this part of the landscape. Many of the most important concerns in this regard are raised in a collection of papers edited by eminent authors, George Annas and Sherman Elias.⁷⁴ The papers prepared by Judith Swazey and Robert Proctor in particular warrant careful reading.⁷⁵ For example, both authors caution against the use of genetic screening to raise a biological under-class who are excluded, by virtue of their genetic pre-disposition to particular medical conditions, from (a) certain kinds of medical treatment on the grounds of cost, (b) employment opportunities because of a projected limited working life, or (c) insurance cover on the basis of being a "bad risk."⁷⁶
- 4.17 Annas and Elias, and many others, warn against the [usually unintended] rise of a biological underclass (noted above), and the discrimination against persons on the basis that they are a burden (primarily, but not exclusively, financial) on society.⁷⁷ Such discriminatory treatment is born of a drive toward genetic perfection and a concomitant intolerance of imperfection. No less is it born of a biological determinism and mechanistic reductionism toward the human person in which a person's worth and dignity is presented, indeed assessed, as being dependent upon his or her genetic and biological composition. Historically, reductionism or biological determinism has provided a fertile environment for the rise of eugenically-based social and political agendas.⁷⁸

⁷⁵ Respectively, "Those Who Forget Their History: Lessons from the Recent Past for the Human Genome Quest" and "Genomics and Eugenics: How Fair Is the Comparison?", *ibid.* 45-56 & 57-93.

⁷⁶ Cf. M. Fotheringham, "Insurers and Genetic Testing: an Uncertain Future," (1999) 11 Insurance Law Journal 1-25.

⁷⁷ Generally see the Report of the Senate Legal and Constitutional Legislation Committee, *Provisions of the Genetic Privacy and Non-discrimination Bill 1998* (March 1999).

⁷⁴ Gene Mapping: Using Law and Ethics as Guides, (New York: Oxford University Press, 1992). See also their equally important work, *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation*, (New York: Oxford University Press, 1992), especially the articles by Jay Katz, "The Consent Principle of the Nuremberg Code: Its Significance Then and Now," Ruth Macklin, "Universality of the Nuremberg Code," and Arthur Caplan, "The Doctors' Trial and Analogies to the Holocaust in Contemporary Bioethical Debate," pp.227-239, 240-257 & 258-275 respectively.

⁷⁸ The literature on this and related issues is immense. The following is a representative sample of significant studies (not all of which one would necessarily endorse): M. Burleigh, *Death and Deliverance:* 'Euthanasia' in Germany 1900-1945 (Cambridge: Cambridge University Press, 1994), id. Ethics and extermination: Reflections on Nazi Genocide, (Cambridge: Cambridge University Press, 1997); R. Hubbard & E. Wald, Exploding the Gene Myth: How Genetic Information is Produced and Manipulated by Scientists, Physicians, Employers, Insurance Companies, Educators, and Law Enforcers, (Boston: Beacon Press, 1993); B.M. Knoppers, C.M. Laberge, M. Hirtle (eds.), Human DNA: Law and Policy, (The Hague: Kluwer Law International, 1997); P. Doherty & A.

Sutton (eds.), Man-Made Man: Ethical and Legal Issues in Genetics, (Dublin: Four Courts Press, 1997); R. Rowland, Living Laboratories: Women and Reproductive Technologies, (Bloomington: Indiana University Press, 1992); R. Chadwick (ed.), Ethics, Reproduction and Genetic Control, (London: Routledge, 1992); T. Iglesias, IVF and Justice: Moral, Social and Legal Issues related to Human in vitro Fertilisation, (London: The Linacre Centre for Health Care Ethics, 1990); P. Spallone, Beyond Conception: The New Politics of Reproduction, (London: Macmillan Education, 1989); D. Mathieu, Preventing Prenatal Harm: Should the State Intervene? (Second Edition) (Washington, DC: Georgetown University Press, 1996); N. Fujiki & D.R.J. Macer (eds.), Intractable Neurological Disorders, Human Genome Research & Society, (Christchurch: Eubios Ethics Institute, 1994); E. Agius & S. Busuttil (eds.), Germ-Line Intervention and our Responsibilities to Future Generations, (Dordrecht: Kluwer Academic Publishers, 1998); A. Sutton, Prenatal Diagnosis: Confronting the Ethical Issues, (London: The Linacre Centre, 1990). For a very recent populist, provocative argument concerning "personal eugenic choices" in which, inter alia, "personal [as opposed to governmental] eugenic choices" are encouraged, and unwanted pregnancies are treated simply as a disease, see Martine Rothblatt's Unzipped Genes: Taking Charge of Baby-Making in the New Millennium, (Philadelphia: Temple University Press, 1997). At a broader, theoretical level, but consistent with Rothblatt's 'world view', see M.J. Eriksson, Reproductive Freedom: In the Context of International human Rights and Humanitarian Law, (The Hague: Martinus Nijhoff Publishers, 2000).

- 4.18 The logical expression of the prevailing utilitarian philosophy of leading practitioners in genetic engineering is that only those members of the human family who are `practically perfect in every way' (to borrow from the lexicon of Mary Poppins and her description of herself) are worthy of life. Converse propositions are promoted as true also, namely, that anyone with any disability is better off dead, and that parents are entitled, indeed they have a moral and financial responsibility to society, to ensure that any imperfect members of the human family are screened (namely, embryos), even for late onset conditions, so that the less than perfect may be eliminated. And, to complete the picture, better to clone a perfect individual than to give birth to a less than perfect individual, or even to replace a deceased member of the family.⁷⁹
- 4.19 All of the above needs to be seen in the context of the consistent teaching of the Church (espoused also by many fellow travellers) about the dignity of procreation and its central place in marriage. In the particular context of cloning, to quote but two examples:

⁷⁹ See for example the work of John Robertson, *Children of Choice: Freedom and the New Reproductive Technologies*, (Princeton: Princeton University Press, 1994); *id*, "Liberty, Identity, and Human Cloning," (1998) 76 *Texas Law Review* 1371-1455; Lawrence Wu, "Family Planning Through Human Cloning: Is There a Fundamental Right?" (1998) 98 *Columbia Law Review* 1461. Gilbert Meilaender provides a detailed critique of the ethically impoverished, "quality-control" Robertson proposal in *Body, Soul, and Bioethics, op. cit.,* Ch.3 "How Bioethics Lost the Body: Producing Children." See also Jean Bethke Elshtain, "To Clone or Not to Clone," and Eric A. Posner & Richard A. Posner, "The Demand for Human Cloning," both in *Clones and Clones: Facts and Fantasies about Human Cloning*, (eds. M.C. Nussbaum & C. Sunstein) (New York: W.W. Norton & Co., 1998) 181-189 & 233-261 respectively.

... this practice [of cloning] distorts the human meaning of procreation, which is no longer considered or practised for reproductive reasons but programmed for medical and experimental (and therefore commercial) purposes.

This project [of cloning] is encouraged by the progressive depersonalisation of the generative act (introduced by the practice of extracorporeal fertilisation) which becomes a technological process making the human being an object to be used by anyone who can reproduce him in the laboratory.

In human cloning for therapeutic or commercial purposes, the role of the "parent" is distorted, reduced to that of a donor of biological material for producing a child/twin intended to be used as a source of spare organs and tissues.⁸⁰

And this from the Pontifical Academy for Life:

In this vision [of cloning] we find the logic of industrial production: market research must be explored and promoted, experimentation refined, ever newer models produced.

Women are radically exploited and reduced to a few of their biological functions (providing ova and womb) and research looks to the possibility of constructing artificial wombs, the last step to fabricating human beings in the laboratory.

In the cloning process the basic relationships of the human person are perverted: filiation, consanguinity, kinship, parenthood.

A prohibition of cloning which would be limited to preventing the birth of a cloned child, but which would still permit the cloning of an embryo-foetus, would involve experimentation on embryos and foetuses and would require their suppression before birth - a cruel, exploitative way of treating human beings.⁸¹

5. Conclusion

5.1 A rather direct editorial appeared in a recent issue of the *Bulletin of Medical Ethics.* Its points seem well made and equally applicable to law, as to ethics. In part, it said:

> "Knowledge of physical science will not console me for ignorance of morality in time of affliction, but ignorance of morality will always console me for ignorance

⁸⁰ "Can human cloning be `therapeutic'?" Document of the Centre for Bioethics of the Catholic University of the Sacred Heart, Milan, *L'Osservatore Romano* (17 February, 1999) 6-7 at p.6. See also the detailed submission of the Linacre Centre for Health Care Ethics to the [UK] Human Fertility and Embryology Authority's consultation document "Cloning Issues in Reproduction, Science and Medicine," (1998).

⁸¹ "Reflections on human cloning," Pontifical Academy for Life, *L'Osservatore Romano* (9 July 1997) 10-11 at p.10.

of physical science." So wrote Pascal in a note found after his death and published in *Pensées*.

Today, Pascal's belief has been turned on its head by many in the health professions. Ignorance of ethics is still acceptable in a way that ignorance of the latest best clinical practice would not be. Clinical researchers often complain that it takes about a decade for important research findings to be incorporated into routine clinical practice. This is swift compared to the time it takes for researchers and others to acknowledge, let alone act on, developed consensus on ethical issues.

... Sometimes the problem appears more to be accelerated memory deficit than ignorance - witness the rapid change of mind of various scientific leaders over the issue of cloning. Whatever the precise diagnosis, however, it is surely time that the [UK] General Medical Council took prevention seriously. It may be doing more to catch misbehaving doctors, but self-regulation will only be seen to be serious if there is proper education in ethics, law, and communication skills for medical students....⁸²

5.2 A no less blunt article appeared in a recent issue of the *New England Journal of Medicine*. Professor Eisenberg's comments appear to refute at least some of the media claims for cloning curing everything from baldness to bigotry. The child psychiatrist and professor of social medicine and health policy at Harvard University says:

> In sum, cloning would be a poor method indeed for improving on the human species. If widely adopted, it would have a devastating impact on the diversity of the human gene pool.

... Proposals for human cloning as a method for `improving' the species are biologic nonsense. To elevate the question to the level of an ethical issue is sheer casuistry. The problem lies not in the ethics of cloning a human but in the metaphysical cloud that surrounds this hypothetical cloned creature. Pseudobiology trivialises ethics and distracts our attention from real moral issues: the ways in which the genetic potential of humans born into impoverished environments today is stunted and thwarted. To improve our species, no biologic sleight of hand is needed. Had we the moral commitment to

⁸² (February, 1999) 145 Bulletin of Medical Ethics, 1.

provide every child with what we desire for our own, what a flowering of humankind there would be. $^{83}\,$

⁸³ (1999) 340 NEJM 471-5.

- 5.3 A passing word about terminology. If, as is the case, the British Medical Association says publicly that genetics, from which cloning is not excluded, is "currently largely non-therapeutic"84, and the Academy of Science, among others, says that a distinction ought be made between `reproductive" and `therapeutic' cloning, the latter being permissible because it `could be therapeutic', but without acknowledging that it would be fatal for the embryo from whom ES cells are harvested, surely the use of the word `therapeutic' is no more than a ruse to make palatable the destruction of embryos whose cells will be used in experiments which may, sometime in the future, bear fruit for others. In any event, the two statements cannot both be correct. One, at least, must be something of a distortion. Indeed, as the Linacre Centre said in its submission to the Human Fertilisation and Embryology Authority and the Human Genetics advisory Commission, "[t]he ethical issues raised by the cloning of human embryos for the purpose of research should not be obscured by misdescribing such cloning as `nonreproductive'. For current purposes, neither should obfuscation occur by misdescribing such cloning as "therapeutic."
- 5.4 Finally, it is useful to juxtapose two passages. The first is from Ulrich Beck, writing in the mid-1980s. In his book *Risk Society*, Beck says:

The fear of the `advances' in genetic technology is widespread today. Hearings are held. Churches protest. Even scientists faithful to progress cannot shake off their uneasiness. All of this takes place, however, like an obituary for decisions taken long ago. Or rather, no decision has ever occurred. The question of `whether' was never waiting at the door. No committee ever let it in. It has always been on the way. The age of human genetics, the reality of which people are debating today, actually started long ago. One can say `no' to progress, but that does not change its course at all. Progress is a blank check to be honoured beyond consent and legitimation.⁸⁵

The second is by Professor Waller who notes the 1981 remarks of former High Court Justice, and Governor-General, Sir Ninian Stephen. Thus,

The passage of a measure through the legislature confers a unique stamp of democratic legitimacy, valuable in a country possessing democratic traditions. Moreover, the legislative process is exposed to, and provides a safety valve for, those community pressures which, if not released in this way, build up to levels dangerous to the system itself. An elected legislature as the identified and visible maker of laws can be seen to be responsive to legitimate pressures and to the strongly held views of the community.⁸⁶

⁸⁴ Human Genetics: Choice and Responsibility, op. cit., p.8.

⁸⁵ Quoted by the editors, Professors Brownsword, Cornish & Llewelyn, in their introduction to the special edition of the *Modern Law Review* entitled "Human Genetics and the Law: Regulating a Revolution." (1998) 61 *Mod LR* 593 at 597.

⁸⁶ "Regulating Birth technology," (1998) 7 Res Publica 18-24 at p.20.

These comments are apposite to the current discussion concerning the regulation of ART in general and cloning in particular. An informed legislative response in accordance with the executive summary of this submission is surely preferable to writing "obituaries for decisions taken long ago" especially in relation to issues dealing with "the deepest matters of our humanity."