9

Current Australian regulatory framework — non-legislative

INTRODUCTION

9.1 The previous chapter outlined the legislative framework governing the regulation of human cloning and research involving the use of embryos in Australia. This chapter completes the overview of Australia's regulation of these matters by outlining the non-legislative mechanisms that regulate human cloning and related research in Australia. The Committee will present its conclusions on the current regulation of human cloning in Australia at the end of the chapter.

NON-LEGISLATIVE REGULATION OF CLONING AND RESEARCH INVOLVING THE USE OF EMBRYOS

Overview

9.2 In NSW, Queensland, Tasmania, the ACT and the Northern Territory, where there is no legislation specifically regulating human cloning or embryo research, regulation is undertaken by non-legislative means. This primarily involves compliance with National Health and Medical Research Council (NHMRC) guidelines, the Reproductive Technology Accreditation Committee (RTAC) Code of Practice and the approval of

research by institutional ethics committees (IECs) in reliance on NHMRC guidelines.

National Health and Medical Research Council (NHMRC)

Overview

9.3 The NHMRC[1] requires all institutions or organisations that receive NHMRC funding for research to establish an IEC[2] and to subject all research involving humans, whether funded by the NHMRC or not, to ethical review by that IEC using the *National Statement on Ethical Conduct in Research Involving Humans* as the standard for that review.[3]

9.4 The NHMRC has issued a significant number of Guidelines covering a wide range of issues. The following discussion will focus on the two sets of Guidelines most relevant to this inquiry—the *National Statement on Ethical Conduct in Research Involving Humans* (the *National Statement*) (1999) and the *Ethical Guidelines on Assisted Reproductive Technology* (1996) (the *Ethical Guidelines*).[4]

9.5 The infringement of a provision(s) of NHMRC Guidelines does not constitute an offence. Sanctions for the breach of any guidelines involve the loss of access to research funds from the NHMRC or publication of the names of the infringers in Parliament.[5]

9.6 Associate Professor Loane Skene summarised the effect of the NHMRC Guidelines system as follows:

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1 The functions of the NHMRC are set out in the *National Health and Medical Research Council Act 1992*, section 7. They are primarily to inquire into, issue guidelines on and advise the community on matters related to health and health related research. The NHMRC carries out its functions through a network of committees such as AHEC – see generally Part 5 of the Act. AHEC is established under section 35 of the Act. Requirements as to its membership are provided in section 36 of the Act. Guidelines developed by AHEC must be laid before each House of Parliament (section 35(4)). AHEC also monitors and advises on IECs

2 NHMRC, *National Statement on Ethical Conduct in Research Involving Humans*, p.3. NHMRC refers to these bodies as Human Research Ethics Committees (HRECs). However the term 'institutional ethics committees'(IECs) has been the term most commonly used during the inquiry and for the sake of consistency that term is used here

3 NHMRC, *National Statement on Ethical Conduct in Research Involving Humans*, p.3

4 Other guidelines issued by the NHMRC that may be relevant in various contexts include: Supplementary Note 5 to the National Statement, 'The human fetus and the use of human fetal tissue', (1983); *Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies* (1999)*; Guidelines under Section 95 of the Privacy Act 1988* (Cth) (March 2000)

5 AHEC report, Chapter 4, paragraph 4.14. The *National Statement* states that observance of the procedures set out in the *National Statement* is mandatory for continuing eligibility for NHMRC research funds, pp.2-3. See also AHEC, *Submissions*, p.S811

> The NHMRC Guidelines apply throughout Australia. They are not, of course, law because they are as they are described—guidelines. This does not mean that they do not have legal effect. With regard to guidelines they are a statement of accepted practice… the guidelines can be enforced by the withdrawal of funding, if it is a project funded by the NHMRC; by peer pressure, which may prevent the publication of research that is undertaken that does not follow the guidelines; and the NHMRC has power to name somebody who offends against the guidelines in federal parliament… there are inducements to compliance. … However, they are not directly enforceable, so somebody who fails to comply with the NHMRC Guidelines cannot, on that account alone, be prosecuted or sued.[6]

9.7 Associate Professor Skene's summary of the effect of the NHMRC Guidelines system is applicable to both the *National Statement* and the *Ethical Guidelines* discussed further below.

9.8 NHMRC Guidelines are developed by people with considerable expertise and knowledge, but the public has little understanding of the process or the capacity to participate in it. The growth and spread of cloning research and the substantial involvement of the private sector in it[7] renders it very difficult for a body such as the NHMRC or AHEC to monitor this area of risk. The leverage of the NHMRC is very much tied to its capacity to grant or withhold funding and hence its real capacity to influence the private sector must be problematic as AHEC itself acknowledged.[8] In such an environment sanctions such as the loss of research funding may have minimal influence.[9]

Ethical Guidelines on Assisted Reproductive Technology (1996)

9.9 The NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996) (the *Ethical Guidelines*) were cited in the AHEC report and its recommendations address the provision of assisted reproductive technology services and research involving the use of embryos.[10]

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6 Associate Professor Loane Skene, *Transcript*, p.44

7 See the evidence of Dr John Smeaton, *Transcript*, pp.149-168 and Mr Robert Klupacs, *Transcript*, p.169

8 AHEC report, Chapter 4, paragraph 4.34

9 This may not be the case in other areas of research where the system of NHMRC Guidelines may still be entirely appropriate

10 It is noted in the *Ethical Guidelines* that they do not address issues of eligibility, surrogacy, consent for posthumous use, genetic diagnosis and selection or gene therapy - p.v. They state that in those states where there is specific legislation this must be observed. Where both State

9.10 Guideline 6 of the *Ethical Guidelines* deals with research on embryos. It notes that research involving early human embryos raises profound moral and ethical concerns and states that there are differences of opinion amongst Australians regarding the moral status of the human embryo that cannot be resolved.[11]

9.11 In those States and Territories without relevant legislation, Guideline 6 states that research on human embryos may only take place according to the *Ethical Guidelines*. The *Ethical Guidelines* differentiate between 'therapeutic' and 'non-therapeutic' research involving embryos. Professor Saunders, the Chairman of the NHMRC, stated:

> …the use of the word "therapeutic" in the context of these guidelines means therapeutic as it relates to the embryo itself… doing something to the embryo with the intention of having a therapeutic outcome for the embryo…[12]

So Guideline 6.2 states:

> Embryo experimentation should normally be limited to therapeutic procedures which leave the embryo, or embryos, with an expectation of implantation and development.

9.12 Professor Saunders described 'non-therapeutic' research as

> …research or interventions, …on the embryo which are not directed at the embryo's well being but the well being for some other technology…It is not to say that non-therapeutic research cannot have other therapeutic applications in adults or babies or whatever. It is just that, in the context of these guidelines, there is a need to distinguish between doing something on the embryo for the sake of the embryo—which in these guidelines is considered therapeutic—versus the other.[13]

9.13 Such non-therapeutic research is to be approved by an IEC only in exceptional circumstances. In relation to 'non-therapeutic' research involving embryos Guideline 6.4 states:

> Non-therapeutic research which involves the destruction of the embryo, or which may otherwise not leave it in an implantable

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law and the *Ethical Guidelines* apply the State law prevails (Guideline 1.1). The *Ethical Guidelines* also contain consent provisions and provisions concerning the storage of gametes and embryos and record keeping

11 Guideline 6 is reproduced in full at Appendix F of this report

12 Professor Nicholas Saunders, *Transcript*, p.196

13 Professor Nicholas Saunders, *Transcript*, p.196

> condition, should only be approved by an IEC in exceptional circumstances. Approval requires:
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> - a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed research;
> - that the research involves a restricted number of embryos; and
> - the gamete providers, and their spouses or partners, to have consented to the specific form of research …[14]

Professor Saunders indicated that if permission were to be given by an IEC for such non-therapeutic research it would be considered and granted on a case-by-case basis.[15]

9.14 The *Ethical Guidelines* were formulated before development of the somatic cell nuclear transfer cloning technique and do not refer to artificially created embryos. The *Ethical Guidelines* refer to research involving embryos created in the course of assisted reproductive technology. In relation to the production of embryos surplus to assisted reproductive technology requirements (discussed in Chapter 7 as a possible source of embryos for research involving cloning technologies), Guideline 6 states that clinics should seek to avoid the likelihood of production of embryos in excess of the needs of the couple.

9.15 Guideline 11 of the *Ethical Guidelines* includes among a list of practices that are 'ethically unacceptable and should be prohibited'—developing embryos for purposes other than for their use in an approved assisted reproductive technology treatment program, culturing an embryo *in vitro* for more than 14 days, placing an embryo in a body cavity other than in the human female reproductive tract, commercial trading in gametes or embryos, paying donors of gametes or embryos beyond reasonable expenses and:

> …experimentation with the intent to produce two or more genetically identical individuals, including development of human embryonal stem cell lines with the aim of producing a clone of individuals.

9.16 So the intentional creation of embryos for research is prohibited.[16]

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14 This particular guideline was criticised in some quarters. Mr / Ms Hartwig wondered what constituted 'exceptional circumstances' and stated that every circumstance could be claimed to be exceptional, *Submissions,* p.S24. See also Queensland Right to Life, *Submissions,* p.S264

15 Professor Nicholas Saunders, *Transcript,* pp.197-198

16 Dr Robert Loblay submitted that when this was drafted the possibility of cloning intact human individuals by somatic cell nuclear transfer was not anticipated. However, the intent of this Guideline was to proscribe the use of cloning techniques for reproductive purposes. In the light of recent developments, a more explicit rewording of this Guideline may be appropriate, *Submissions,* p.S678. Professor Julian Savulescu submitted that Guideline 11.3 has the effect of

The National Statement on Ethical Conduct in Research Involving Humans (the National Statement)

9.17 The *National Statement on Ethical Conduct in Research Involving Humans* (1999) (the *National Statement*)[17] affects the general design of research projects and the approval process for research.[18]

9.18 The National Statement does not define 'research involving humans'. Rather it focuses on trying to define what needs to be considered and approved by an IEC.[19] Evidence received by the Committee in respect of IECs is at paragraphs 9.24-9.36 below.

9.19 It is the responsibility of each institution and organisation to develop criteria to classify which of its activities are reviewable by its IEC and which are not.[20] Thus there may be variations in the classification of activity between and among institutions and organisations.[21] Research concerning human cloning and its related technologies would fall within the *National Statement*.

9.20 The *National Statement* covers a wide range of matters including research involving the use of human tissue samples (discussed in Chapter 8) and human genetic research.[22] In the case of research involving assisted reproductive technologies and embryo experimentation, the *National Statement* refers to the legislation in Victoria, South Australia and Western Australia and the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*.[23]

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banning ES cell research but it is understood in practice to refer to ES cell research for the purpose of cloning a human being, *Submissions*, p.S650

17 This replaces the guidelines entitled NHMRC *Statement on Human Experimentation and Supplementary Notes* except for Note 5 which has not yet been revised. These earlier guidelines were referred to in the AHEC report, Chapter 4, paragraph 4.17

18 The *National Statement* has been endorsed by the Australian Vice-Chancellors Committee, the Australian Research Council, the Australian Academy of the Humanities, the Australian Academy of Science and the Academy of the Social Sciences of Australia. It has been supported by the Academy of the Technological Sciences and Engineering. AHEC submitted that compliance with the *National Statement* is mandatory for all research funded by the Australian Research Council and the NHMRC as well as all research undertaken in Australian universities. Members of the four learned academies, AHEC submitted, are bound to apply the guidelines contained in the *National Statement* to their work. AHEC, *Submissions*, p.S811

19 NHMRC, *National Statement*, p.7

20 This should be decided according to whether the activity involves human participation or definable human involvement and has a purpose of establishing facts, principles or knowledge or obtaining or confirming knowledge. The features of human involvement will be the focus in deciding whether it is subject to IEC review. NHMRC, *National Statement*, pp.7 and 8

21 NHMRC, *National Statement*, p.8. See also AHEC, *Submissions*, p.S811

22 NHMRC, *National Statement* See pp.43-45 and pp.46-50 respectively

23 NHMRC, *National Statement* p.34

The Reproductive Technology Accreditation Committee (RTAC)— Code Of Practice

9.21 Self-regulation is also a feature of the regulation of assisted reproductive technology and hence of embryo research. The Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (a professional body) administers this self-regulation. The RTAC has issued a *Code of Practice for Units using Assisted Reproductive Technology* (Code of Practice) with the RTAC setting professional and laboratory standards for clinical practice. The Code of Practice encourages all centres practising assisted reproductive technology to have an active research program.[24]

9.22 For its part the RTAC Code of Practice[25] lists the following activities as unacceptable:

- keeping or using an embryo after the appearance of the primitive streak or after 14 days, whichever is the earlier;
- placing an embryo in a non-human animal;
- replacing the nucleus of a cell of an embryo with a nucleus taken from the cell of another person, another embryo or fetus;
- cloning human embryos in attempts to produce babies; and
- mixing gametes or embryos of different parental origin to confuse the biological parentage of the conceptus.[26]

9.23 The interaction of these various sets of guidelines is complex. Accreditation by the RTAC is not mandated but to become accredited a provider of assisted reproductive technology must comply with the Code of Practice which in turn requires compliance with NHMRC guidelines.[27] Dr Loblay submitted that:

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24 Accreditation is not mandated – NSW Government Discussion Paper, *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies,* paragraph 2.3. Guideline 2.1 of the *Ethical Guidelines* states that whether or not it is required by State law, reproductive medicine units must obtain accreditation by the RTAC. Such accreditation must include consideration of a number of matters including compliance with NHMRC guidelines, the RTAC Code of Practice and maintenance of proper professional standards

25 The RTAC Code of Practice deals with a range of matters including staff and resources, provision of information to patients, consent requirements, laboratory standards, treatment methods, record keeping, ethics and research, quality control and accreditation periods (normally three years)

26 This list does not include the creation of embryos for research purposes. This is different to the NHMRC *Ethical Guidelines*. The RTAC Code of Practice also provides that the NHMRC *Ethical Guidelines* must be adhered to and all aspects of the research program monitored by the IEC of the hospital or institution concerned

27 The South Australian Reproductive Technology (Code of Ethical Research Practice) Regulations also cross refer to the RTAC Code of Practice - see for example section 14

> … self-regulation is inappropriate in the field of [assisted reproductive technology]. Whilst it is entirely proper—necessary even—for the [Fertility Society of Australia] to be represented on any…accrediting body, such a body should be completely independent of the professional association to which those being accredited belong… A combination of the profit motive and the intense competition between …[clinics] operating in the private sector adds to the moral hazard.[28]

Institutional Ethics Committees

9.24 The discussion above indicates that institutional ethics committees (IECs) established within institutions or organisations to assess research proposals according to ethical criteria are central to the regulation of a large number of activities from general research involving humans to clinical trials. Most particularly, they are important to the regulation of research involving human cloning, the utilisation of embryos in research or the use of human tissue. This is especially the case in those States and Territories without legislation governing human cloning or embryo research.

9.25 The *National Statement* includes guidelines concerning IECs. These guidelines outline the composition of an IEC, appointment of members, procedures, use of advocates and interpreters, recording of decisions, monitoring of approved research, suspension or discontinuation of research and provision of compliance reports to the NHMRC.[29] IECs are expected to be constituted and to operate in accordance with the *National Statement*.[30]

9.26 This reliance on IECs as well as their structure and operation was the subject of comment and criticism during the course of the inquiry.

9.27 The Queensland Bioethics Centre noted the significant role of IECs and claimed that all scientific research falling outside Commonwealth funding would also fall outside the scope of the IEC process.[31] The *National*

28 Dr Robert Loblay, *Submissions,* p.S680

29 NHMRC, *National Statement,* pp.15-22

30 An independent review of the role and functioning of institutional ethics committees was initiated by the then Commonwealth Minister for Human Services and Health, the Hon. Dr Carmen Lawrence, in August 1994. The Review Committee was chaired by Professor Chalmers, then Chair of AHEC, and reported in March 1996 – Report to the Minister for Health and Family Services**,** *Report of the Review of the Role and Functioning of Institutional Ethics Committees*, Commonwealth of Australia, March 1996

31 Queensland Bioethics Centre, *Submissions,* p.S707. See also Catholic Archdiocese of Melbourne, *Submissions*, pp.S522-523

Statement has been endorsed by all the leading academies and hence would exercise strong persuasive power but the system would have only persuasive value as far as private sector research is concerned. This limitation was accepted to some extent by Dr P. Geoffrey Matthews, the Chairman of the Human Research and Ethics Committee of the Monash Medical Centre, who commented that there:

> …certainly is a limitation from the funding point of view that all projects do not have to come through these institutional ethics committees.[32]

9.28 The Queensland Bioethics Centre also criticised the lack of public accountability in the process and the 'in house' nature of the committees. It went on:

> To leave oversight of this important area to such committees would do little to inspire confidence in the community that justice was being done, whatever the good intentions of individual committee members.[33]

9.29 Dr Nicholas Tonti-Filippini questioned the adequacy of these committees given that they exercise such significant power[34] and commented that 'the more important they become, the more important it is that they be properly structured'.[35] He described IECs as a:

> … non-accountable, non-representative, largely in-house system of review whose processes and conclusions are not accessible to the community and not subject to scrutiny.[36]

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32 Dr Matthews, *Transcript*, p.56

33 Queensland Bioethics Centre, *Submissions*, p.S707 and Mr Raymond Campbell, Queensland Bioethics Centre, *Transcript*, p.98

34 Dr Nicholas Tonti-Filippini, *Transcript*, p.47

35 Dr Nicholas Tonti-Filippini, *Transcript*, p.55. The Consumers Health Forum expressed a particular concern about the composition of IECs, claiming that there is no means of ensuring lay people can effectively represent the interests of any group which will be affected by research proposals being considered let alone the broader community. The Forum cited concerns that consumer representatives wield much less influence than other members of IECs and are susceptible to direct and indirect co-option. It commented that this is likely to be a particular problem where the researchers involved are considered world experts and their influence is very strong, *Submissions*, p.S795

36 Dr Nicholas Tonti-Filippini, *Submissions*, p.S588. See also the Catholic Archdiocese of Melbourne, *Submissions*, pp.S522-523 and Youth Concerned with Cloning, *Submissions*, p.S548. The Privacy Commissioner, in an information paper entitled *The Privacy Implications of Genetic Testing* (1996), noted that in granting approval for NHMRC Privacy Guidelines he had expressed reservations about the structure of the guidelines system in that it produces a legally binding outcome from what are voluntary citizens' committees (p.50). He also argued that it was a matter for debate whether the most effective available institutional structure is one that leaves monitoring of scientists in relation to genetic information with their peers in

9.30 Dr Tonti-Filippini suggested that establishing IECs on a more impartial basis with a majority of members from outside the institution may assist in resolving some problems but at present IECs could not be regarded, in his view, as sufficient for regulatory purposes.[37]

9.31 Dr Robert Loblay, Chairman of the Ethics Review Committee of the Central Sydney Area Health Service, submitted that the relationship between IECs and reproductive medicine units should be clearly defined to ensure that ethical scrutiny is conducted at arms' length by an independent IEC and that such independence is particularly important in the private sector.[38] In Dr Loblay's view IECs should be required to review *all* clinical and research practices conducted in a reproductive medicine unit but an 'IEC can only review what is put before it'.[39] Under present guidelines, reproductive medicine units:

> … have the discretion to define "innovative practices" as they see fit, and thereby to evade ethical scrutiny when it suits them.[40]

9.32 Dr Loblay noted in this context that many clinical practices introduced within IVF, where there were variations from previous practices, were never submitted to an IEC before 1996. The NHMRC *Ethical Guidelines* now require that innovative clinical practice undergoes ethical scrutiny[41] but some practitioners have had difficulty adjusting to this cultural change and it was still open to the interpretation of a practitioner whether to submit a new procedure or activity for ethical review.[42]

9.33 Dr Loblay argued that there were no suitable sanctions for failure to submit proposals for ethical review and stated: [43] 'In order for us to do this kind of regulation effectively there need to be those kind of sanctions in place'.[44]

9.34 Conflicts of interest were more likely where the institutional (and therefore the IEC) focus was more narrow such as, for example, in a private reproductive medicine unit where the focus of the IEC is solely on

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the same institution working voluntarily and part-time. Subtle and organisational pressures and conflicting priorities might arise in such a situation, in his view, pp.49-50

37 Dr Nicholas Tonti-Filippini, *Transcript*, p.47

38 Dr Robert Loblay, *Submissions*, p.S679

39 Dr Robert Loblay, *Submissions*, p.S680 and *Transcript*, p.127

40 Dr Robert Loblay, *Submissions*, p.S680

41 See Guideline 2 of the *Ethical Guidelines*

42 Dr Robert Loblay, *Transcript*, p.127

43 Dr Robert Loblay, *Submissions*, p.S680 and *Transcript*, pp.127-128

44 Dr Robert Loblay, *Transcript*, p.128. Dr Loblay suggested the most appropriate sanction would be withdrawal of accreditation, *Submissions*, p.S680

the unit's work, Dr Loblay suggested. He suggested also that there may be less risk of such narrow focus in a larger institution and saw some advantages in area-based rather than institution-based ethics committees. He noted the difficulty in finding a balance between reviewing research in the context where it is occurring and reflecting broader community views.[45]

9.35 Dr Matthews could see the advantages of IECs in this contextual review of research in the form of direct supervision, on-site inspections and ensuring that research proposals are well considered and well expressed.[46] He did note, however, that IECs are 'relatively unfamiliar with the specific processes' related to human cloning and its attendant research and stated that genetic research:

> …contain[s] many new implications for human ethics…. Such developments, covering such a broad range of change, are largely beyond the scope and resources of any single institution.[47]

9.36 Professor Thomson, the Deputy Chair of AHEC, accepted that there are inadequacies in the transparency and accountability of IECs. He also stated that there:

> …is presently some extensive work on the notion of compliance and better methodology in seeing that the processes of [IECs] do conform and that there is some way of assuring that quality happens.[48]

CONCLUSIONS

9.37 Great social sensitivity concerning the use of embryos and embryonic tissue in research was reflected in the discussion in Chapter 7. This sensitivity has led to special regimes being put in place to regulate the use of embryos and embryonic tissue, as discussed in Chapter 8 and this chapter.

9.38 Professor Chalmers thought that 'we as a community would like to arrange our treatment of the embryo in ways which advance the dignity and respect for that embryo'.[49] He asked:

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45 Dr Robert Loblay, *Transcript*, p.126

46 Dr P. Geoffrey Matthews, *Submissions*, p.S701

47 Dr P. Geoffrey Matthews, *Submissions*, pp.S701-702

48 Associate Professor Colin Thomson, *Transcript*, p.199

49 Professor Donald Chalmers, *Transcript*, p.43

> … do we say no to every form of research or do we say there may be limited, exceptional circumstances that would allow us to move from the position of absolute protection of the embryo?[50]

9.39 The Committee concluded at the end of Chapter 7 that some balance needs to be struck between the special status of the human embryo and protection for that status on the one hand and facilitating research that may be of great benefit to society on the other. In many ways the current regulatory framework reflects that balance although differences exist between legislative provisions and non-legislative guidelines.

9.40 Dr Loblay summarised the disadvantages of non-legislative guidelines: they have no legal authority, compliance is voluntary, they cannot be enforced by the courts and there are no legal sanctions. The advantages, he considered, were flexibility in specific circumstances, responsiveness to rapidly changing technology, accurate reflection of community and professional values and expectations and indirect enforcement.[51]

9.41 The Committee acknowledges the advantages listed by Dr Loblay but considers they are outweighed by the disadvantages.

9.42 Regulation of assisted reproductive technology, embryo experimentation and now human cloning continues to become more complicated. In addition to legislation in three States there is a system of self-regulation coupled with non-legislative national guidelines administered by institutional ethics committees. The system is confused, inconsistent and ad hoc. It is hard for the public to understand and it lacks openness and transparency. Dr Tobin, a member of AHEC, acknowledged that the range of ethical views in the community about the status of the human embryo is represented on AHEC and to some extent these views cannot be reconciled.[52] The NHMRC *Ethical Guidelines on Assisted Reproductive Technology* and the AHEC report both represent the compromise positions arrived at by AHEC on these matters. Hence there is not a consistent ethical view underpinning either of these documents.[53] They represent a balance of ethical views.

9.43 The Committee agrees with the thrust of the criticisms that were made of institutional ethics committees. Each IEC is an individual body established within a particular research institution and will deal with each research application it receives on an individual basis. Therefore it may be

50 Professor Donald Chalmers, *Transcript*, p.43. Professor Chalmers thought that the latter was the position reflected in paragraph 6.4 of the NHMRC *Ethical Guidelines*

51 Dr Robert Loblay, *Submissions*, p.S678

52 Dr Bernadette Tobin, *Transcript*, p.194

53 Dr Bernadette Tobin, *Transcript*, p.206

anticipated that the outcome of IEC consideration of research applications may vary between IECs. There may be differences, possibly significant, in both the nature of research that is approved or rejected and / or in the conditions an IEC may attach to its approval**.** The two key elements governing the kind and degree of applicable regulation in these areas of research appear to be the jurisdiction in which the activity occurs and the source of funding for that activity.

9.44 The difficulties posed by this complicated system of regulation are highlighted by the differences in the definition of 'cloning' in various jurisdictions. These different definitions prohibit different conduct in different parts of the country. The resulting confusion is increased by other differences in the definition of such basic terms as 'embryo'.

9.45 Such fundamental inconsistencies do not assist researchers, businesses, investors or citizens who must try to navigate their way through this confusing and intricate array of regulatory instruments. It is also unfair that such different regulation applies to citizens living in different states. There appears to the Committee to be no obvious basis for maintaining such a variety of regulation.

9.46 Thus the Committee views the current regulatory environment in this area as deeply unsatisfactory. It appears to be out of date and ill equipped to cope with the challenges of current demands and a changing environment.

9.47 The current framework of non-legislative guidelines and IECs are the product of an era when the majority of research funding was provided by government and most research occurred within tertiary institutions that were publicly funded. For many areas of research that may still be the situation and the current framework entirely suitable to the needs of those involved.

9.48 However, in the area of human cloning and cloning related research including human embryo research, this environment has changed significantly. There is a heavy involvement of significant private sector funding in this research. Universities are under commercial pressure also. The result is a greater necessity for speed, efficiency, clarity and consistency in decision making.

9.49 In addition, this changing environment must reduce the capacity for IECs, composed largely of voluntary members and relying on non-legislative NHMRC guidelines, to be able to operate effectively in such an environment. If the current framework (outside those states with existing legislation) continues it is likely to lead to the evolution of a system increasingly similar to that in the United States (see Chapter 10). There the public sector is regulated and the private sector, where much of the

research is undertaken, is subject to limited regulation**.** One of the greatest inadequacies of the current regulatory framework in the United States is its differing application to the public and private sectors. The Committee considers that consistent regulation must be applied to both publicly and privately funded research.

9.50 The current regulatory framework cannot be allowed to continue. The questions raised by human cloning and research involving the use of embryos are complex social and ethical questions and should not be left to individual ethics committees to decide. Nor should the answer to such fundamental questions depend on geography or source of funding. It is vital to ensure public knowledge of, and confidence in, the regulatory processes in place. Consistency and transparency are necessary and in Chapter 12 the Committee will outline a regulatory framework that it believes will best facilitate this outcome.