

# REGULATION OF ASSISTED HUMAN REPRODUCTION: THE RECENT NEW ZEALAND MODEL IN COMPARISON WITH OTHER SYSTEMS

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*Ce n'est qu'après de nombreuses années de réflexions que le Parlement néo-zélandais a finalement voté le Human Assisted Reproductive Technology Act 2004.*

*Ce texte, qui s'apparente à bien des égards à la législation en vigueur dans ce domaine au Canada, fournit le cadre juridique qui dorénavant régleme les recherches en matière de bioéthique et plus particulièrement pour les techniques de reproductions humaines assistées.*

*Le système mis en place, qui selon l'auteur est un heureux compromis entre les différentes sensibilités morales actuellement en vigueur en Nouvelle Zélande, se caractérise par sa relative souplesse, laissant le soin à deux organismes de veiller à la mise en oeuvre pratique des dispositions légales. Le premier est plus particulièrement chargé des questions d'éthique alors que le second, purement consultatif, a pour mission de définir les lignes directrices qui sous-tendront les mesures mises en place au fur et à mesure de l'évolution de la société néo-zélandaise.*

*After a long gestation, New Zealand finally passed legislation in 2004 on assisted human reproduction. This article critically examines the principles on which the new Act is based and then explores a range of models for the regulation of assisted reproduction. The New Zealand approach, which is not unlike the new law in Canada, may be described as a middle way. It has a limited list of proscribed activities, but also establishes a flexible mechanism for new techniques to be considered as they come along. It is suggested that this is suitable for a small but increasingly secular and pluralist society.*

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## **I BACKGROUND**

The scientific and medical developments in human reproduction have been massive in the last two decades. They raise significant issues for individuals, families and communities. How they should be regulated – what should be the role of the law – has been a matter of great debate around the world with little overall consensus emerging. Determining the priorities in this area appears to be influenced by a wide range of factors – political, cultural, religious, ethical, scientific, professional, legal – with the result that responses range from laissez faire to highly controlled and restricted, with other models in between.

After many years' consideration, New Zealand passed legislation in this area in 2004, the Human Assisted Reproductive Technology Act. Like Canada which also legislated in 2004 and the earlier Human Fertilisation and Embryology Act 1990 in Britain, the New Zealand law establishes a framework of regulation that relies on appointed statutory bodies to manage assisted reproduction. However unlike those other jurisdictions, New Zealand has not introduced a specialised licensing system, but instead relies on a softer level of control. Two bodies are provided for in the New Zealand Act, one dealing with ethics applications and the other an "advisory" committee which in broad terms is a policy-making body. The former is effectively the continuation of a pre-existing ethics committee; the latter is completely new.

This article considers the New Zealand system but will not discuss in any detail other issues recently addressed by the New Zealand Parliament. These include access to donor information and rules relating to parentage where assisted technologies have been used. It will be suggested that the New Zealand regulatory approach is something of a middle way, but one that may be appropriate for a small nation which is becoming increasingly pluralist and, with the possible exception of indigenous spirituality, less religious.

## **II HISTORY OF THE LEGISLATION**

The New Zealand legislation has been long in gestation. In Britain, there was legislation six years after the landmark Warnock Report.<sup>1</sup> In New Zealand, the gap was ten years, a similar period to Canada's.<sup>2</sup> In 1994, the Ministerial Committee on Assisted Reproductive Technologies delivered its report *Navigating Our Future* to the Minister of Justice.<sup>3</sup> The Committee's brief was to find out

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1 Human Fertilisation and Embryology Act 1990, which was preceded by Department of Health and Social Security *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (1984, London, "the Warnock Report").

2 Assisted Human Reproduction Act 2004. See *Proceed with Care Final Report of the Royal Commission on New Reproductive Technologies* (1993, Canada Communications Group – Publishing, Ottawa).

3 *Assisted Human Reproduction Navigating Our Future Report of the Ministerial Committee on Assisted Reproductive Technologies* (1994, Department of Justice, Wellington). The author was one of the two members of the Committee, the other being Dr Paparangi Reid, a distinguished Maori health professional and researcher.

what was happening in New Zealand and present options on the ways ahead. The Committee's task was therefore partly fact-finding and it was not necessarily expected to produce the perfect blueprint. However, while the Committee explored a range of options, where appropriate it did advance what it saw as the preferred position. It thought for instance that a greater degree of central control was necessary, yet hopefully not being overly bureaucratic. It was also firm in the view, highly consistent with Maori perspectives, that donor anonymity was undesirable. It took a rather more agnostic approach to surrogacy.

Much of the Ministerial Committee's thinking is reflected in the legislation finally passed in 2004. However the path to the statute book was somewhat tortuous. It began with a Bill introduced into Parliament by Labour Opposition MP, Dianne Yates, the Human Assisted Reproductive Technology Bill 1996. This Bill, while including a number of the Ministerial Committee's suggestions, was rather more interventionist and would have set up a licensing structure for health providers and clinics. In 1998 the Minister of Justice finally introduced a Government Bill, the Assisted Human Reproduction Bill. This again was based in part on the work of the Ministerial Committee, including the collection of and access to donor information, but overall the 1998 Bill was far less prescriptive than the Yates' Bill. Thus, Parliament had two different Bills to consider, starting from rather different premises, one a little suspicious of assisted reproduction, the other preferring a more minimalist role for the State.

In 1999 there was a change of Government. The new centre-left administration was more sympathetic to Yates' approach but had many other urgent matters and the two Bills languished until the Parliamentary select committee again met with new impetus to push the legislation along. A "supplementary order paper" was introduced into Parliament containing a vast array of amendments to the Human Assisted Reproductive Technology Bill. In fact it is fairer to say that it was virtually a complete re-write of the Bill and as a result it was thought desirable to have a further round of public submissions. It took another year before the select committee finally reported back to Parliament, after which the legislation was on an inevitable path to enactment. It passed by 102 votes to 18.

Parliament decided to pass the Human Assisted Reproductive Technology Bill and drop the Assisted Human Reproduction Bill. The decision to do this may have been political: the Labour-led Government preferred the name its own MP had come up with, even though the final statute was more truly an amalgam of both Bills. In the author's opinion, the final name is clumsy compared to the alternative, which interestingly Canada has opted for. Further, the emphasis should be on "human reproduction" rather than "human assisted" as in "human assisted animal reproduction" (a major industry in a heavily agricultural country such as New Zealand), so that the title is technically a little inaccurate.

### **III THE PRINCIPLES IN BALANCING THE INTERESTS IN ASSISTED REPRODUCTION**

The area of assisted human reproduction is a controversial one. Some people will regard it as cutting edge science which should be pursued with minimal constraints in the interests of progress. Others regard it as raising acute questions that challenge the core of our value system. Some religious approaches would regard the technologies, even ones which have become standard, as usurping the role of God and interfering with the divinely ordered world. Green activists might see it as unduly interfering with the ways of nature and thus upsetting the natural equilibrium of the world. Feminists might see it as raising issues about control of women's fertility. Another group of people are those who have difficulties conceiving a much-wanted child. These "consumers" do not want obstacles placed in the way of fertility treatment but will nevertheless want to be sure that the process is safe and professional. The general public's view is likely to be a mixed one but may depend on the kind of society that they form. The Warnock report recognised the difficulties of reaching consensus:<sup>4</sup>

...it would be idle to pretend that there is not a wide diversity in moral feelings, whether they arise from religious, philosophical or humanist beliefs. What is common...is that people generally want *some principles or other* to govern the development and use of the new techniques.

A largely secular society like New Zealand is unlikely to take a staunch black and white stance on these issues but, with a history of prominent involvement of the State in the health sector, New Zealanders will expect the State to safeguard people's interests.

There are therefore a number of competing interests and interest groups who jockey to get their voices heard. In the New Zealand context, there were 79 submissions plus 25 "form submissions" on the Supplementary Order Paper to the Human Assisted Reproductive Technology Bill. Many called for stringent controls, including licensing. However, the legislation was eventually passed without any public outcry. The broad question remains as to how a system can be put in place that reconciles or at least gives due consideration to the variety of viewpoints, be they scientific, professional, cultural, ethnic, religious, academic, feminist, or personal. Underlying this is a preliminary question: what overall principles should guide decision-making in this area?

Section 4 of the New Zealand Act sets out seven principles and reads as follows:

All persons exercising powers or performing functions under this Act must be guided by each of the following principles that is relevant to the particular power or function:

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4 Department of Health and Social Security *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (1984, London, "the Warnock Report") 2 (italics in original).

- (a) the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure:
- (b) the human health, safety, and dignity of present and future generations should be preserved and promoted:
- (c) while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and well-being of women must be protected in the use of these procedures:
- (d) no assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given informed consent:
- (e) donor offspring should be made aware of their genetic origins and be able to access information about those origins:
- (f) the needs, values, and beliefs of Maori should be considered and treated with respect:
- (g) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

This has clear echoes of the Canadian principles<sup>5</sup> but is a rather different list from, for example, that found in the Victoria, Australia, legislation, the Infertility Treatment Act 1995 which has only four principles found in section 4:

- (a) the welfare and interests of any person born or to be born as a result of a treatment procedure are paramount;
- (b) human life should be preserved and protected;
- (c) the interests of the family should be considered;
- (d) infertile couples should be assisted in fulfilling their desire to have children.

Subsection (2) states that these principles are in descending order of importance, whereas the New Zealand and Canadian statutes impliedly treat all the principles as of equal importance.

Common to all three sets of principles is a reference to children born through assisted reproduction. The language however differs. Victoria uses the familiar word "paramount" while Canada has the phrase "must be given priority", which arguably will bear a very similar meaning. New Zealand watered down the terminology. Earlier versions of the legislation had language similar to Victoria but this was changed during the legislative process to "important consideration". The

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5 Section 2, Assisted Human Reproduction Act 2004 (Can).

ostensible reason for this was advice from officials in the Crown Law Office that the use of "paramount" might expose the government to "legal risk" because of the inability properly to balance all the risks and benefits of a proposal.<sup>6</sup> If health and well-being were paramount, it might be necessary, according to the advice, to reject new and existing procedures "that involve *any* health risk".

Paramourncy ought to trump other considerations or else that factor is not paramount, but how do we determine the offspring's interests at the pre-conception stage? New Zealand and Canada refer to children "born as a result of" or "through the application of" assisted reproduction. It follows that an unborn child or an embryo is not to be taken into account. At this point, the concern, it may be argued, is with safe procedures that will ensure the health and well-being of the child once born. What happens to the embryo qua embryo is not in issue, a conclusion that is consistent with provisions in the New Zealand Act which for example leave open the possibility of research on hybrid or cloned embryos. The Victorian formula is a little more problematic because it includes a person "to be born", which suggests that the interests of the unborn child are paramount. What is not clear is whether this could extend to an embryo, the consequences of which ought to lead to a very restrictive law about research and storing of embryos as is the situation in countries such as Germany.<sup>7</sup> The Victorian phrase might be read to mean a child in utero, thus with a definite chance of being born, as opposed to a stored embryo which may never be implanted. Enough has been said to indicate that paramourncy language can be problematic.

The New Zealand and Canadian Acts both refer to human health, safety and dignity, with Canada adding "rights". These are to be "preserved and protected" in New Zealand while in Canada the language is "protection and promotion". New Zealand relates this to "present and future generations" while Canada talks about "benefits... for individuals, for families and for society in general". The Victorian Act does not refer to these notions as such but its remaining three principles may be said to relate to dignity-type concerns. The value placed on human life is a fundamental part of human dignity; likewise the family is usually seen as part of the glue in the human condition, although there is also a need to recognise the diversity of family situations; and infertile couples as a special category of families can too easily be the meat in the sandwich rather than central figures in the assisted reproduction debate. It is interesting that the Victorian Act is explicit in recognising the place of families and infertile couples whereas New Zealand and Canada develop other dignity interests. Both use near identical phraseology to identify the position of women. One might well wonder why the position of women should be singled out when that of infertile couples and families is not.

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6 Cf Ministry of Justice memorandum to the Associate Minister of Justice, 4 May 2004.

7 Embryo Protection Act 1990.

Dignity interests are apparent in the references to informed consent in the New Zealand and Canadian legislation, something which is missing from the Victorian principles. The Canadian phraseology is preferable in that it refers positively to "free and informed consent" being promoted and applied whereas the New Zealand version is in the negative.

Likewise, a Canadian reference to non-discrimination is a reflection of human rights and dignity. The Canadian Act states that "persons who seek to undergo assisted reproductive procedures must not be discriminated against, including on the basis of their sexual orientation or marital status." Why does this not appear in the New Zealand set of principles?

In some jurisdictions, discrimination questions are highly controversial and reproductive services are restricted to married or unmarried heterosexual couples.<sup>8</sup> New Zealand's human rights legislation has long included marital status as a non-discrimination ground and since 1993 sexual orientation as well.<sup>9</sup> When the Ministerial Committee was deliberating, the question of whether same-sex couples and single people could access services was a live issue. While some clinics were somewhat reluctant to extend access fearing a moral backlash, the Committee accepted advice from the Human Rights Commission that discrimination on any of the grounds set out in the law was prohibited.<sup>10</sup> The Committee did not think it was appropriate to recommend a change in these laws to single out reproduction as an exception to the rules which otherwise applied generally. Indeed, to ensure safe and healthy procedures and to avoid back-street activity, it was thought important that people use recognised health professionals.

Despite some Australian authority to the contrary,<sup>11</sup> it is now generally acknowledged in New Zealand that assisted reproduction cannot be denied to people, for instance, because they are a lesbian couple. Given this, a reference to discrimination in the principles section might be thought to be redundant. On the other hand, a provision consistent with the discrimination laws ought to have been easy enough to insert. The Ministerial Committee had "justice" as one of its principles and it envisaged this, among other things, as incorporating human rights and international standards as

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8 Eg article 5 of the Italian Law 40/2004 "Norms on the matter of medically assisted procreation" refers to "couples made up of persons of different sex having reached the age of majority, married or living together, of potentially fertile age and both living".

9 Human Rights Act 1993, s 21, New Zealand Bill of Rights Act 1990, s 19.

10 *Assisted Human Reproduction Navigating Our Future Report of the Ministerial Committee on Assisted Reproductive Technologies* (1994, Department of Justice, Wellington) chapter 6. The Submission of the Human Rights Commission is found in Appendix F.

11 *JM & QFG and GK* [2000] 1 Qd R 373 (Queensland Court of Appeal; leave to appeal to the High Court of Australia denied 24 June 1999) drawing a distinction between medical and social infertility. See also on the question of access to reproductive technologies by single women Susan Millns "Reproducing inequalities: assisted conception and the challenge of legal pluralism" (2002) 24 *Journal of Social Welfare and Family Law* 19.

essential touchstones.<sup>12</sup> Again, this broader concept is valuable but perhaps unnecessary in legislation as compliance with those standards is in general necessary anyway.

The remaining principles show different emphases when comparing Canada and New Zealand. Canada has a provision that deals with the commercialisation of reproduction. This is ignored in New Zealand, although in the body of the Act trade in embryos and gametes is banned as is profit-making from surrogacy arrangements.<sup>13</sup>

New Zealand regards access to information as being a priority, whereas Canada is silent on this and indeed has chosen a much narrower route, broadly speaking allowing access to information only for health reasons or with the donor's consent. The Ministerial Committee came down firmly in favour of openness, a view that resonates with the country's history of open adoption since the 1970s and with the Maori value-system. The practice of clinics has in any event been to strongly encourage parties to follow a policy of openness, made easier because of rules which mean that the donor faces no liabilities such as child support or inheritance claims.<sup>14</sup> Part 3 of the Human Assisted Reproductive Technology Act 2004 sets in place a system that, when there has been donation of gametes or embryos, information must be kept both by clinics and by a central registrar, and it must be accessible to the child on reaching 18, as well as other parties.

Canada's final principle is about "human individuality and diversity" with an explicit reference to "the human genome". New Zealand's version talks about respecting "the different ethical, spiritual, and cultural perspectives in society". The Canadian formula is broader and sits well with the anti-discrimination principle. New Zealand's focuses more on pluralism in values and connects with the principle relating to the indigenous Maori people.

To sum up, the Canadian and New Zealand principles have much in common but diverge at one or two critical points. Perhaps the main point of difference relates to access to information, the other differences on analysis being more ones of emphasis. The Victorian principles represent a sharper contrast. They are much more Spartan and focus more on particular groups – children, families and infertile couples – and eschew wider concepts such as diversity and dignity.

#### ***IV MODELS FOR DETERMINING PRIORITIES***

##### ***A Options***

One might well ask why assisted reproduction is an area that should attract any special legal attention at all. Could it not simply be treated as part of the general law, for instance that which

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<sup>12</sup> *Assisted Human Reproduction Navigating Our Future Report of the Ministerial Committee on Assisted Reproductive Technologies* (1994, Department of Justice, Wellington) 30-32.

<sup>13</sup> Human Assisted Reproductive Technology Act 2004, ss 13 and 14.

<sup>14</sup> Status of Children Amendment Act 1987, now found in Part 2 of the Status of Children Act 1969, as amended in 2004.

governs health and safety and leave it at that? This was largely the position in New Zealand prior to the Human Assisted Reproductive Technology Act, with the exception of rules relating to the status of the donor child. "Why interfere with private choices?" as one commentator asks.<sup>15</sup>

On the other hand, is reproduction purely a scientific and medical matter? Is it just a matter of individual choice? History would suggest otherwise. It has exercised the minds of very many ethicists, theologians, policy-makers, lawyers and others. Conception does appear to be more than a medical process, and more than something like healing a broken leg. The question becomes not so much whether there should be special regulation in this area but what form that regulation should take. This question has been answered in a wide variety of different ways, reflecting the very different ideological stances taken in different jurisdictions. The answer may also depend on whether the country is a homogeneous one, perhaps with a strong religious tradition, or whether it is more pluralist and secular. New Zealand is moving in the latter direction. How are the priorities in this area to be determined? What are the main options?

#### *1 Highly restrictive*

At one end of the spectrum, the legal system can ban or heavily restrict the activities that can take place. This tends to be the policy in countries with a heavy Catholic influence, Italy being the latest and prime example. After a very free system, the Italian Parliament moved in quite the opposite direction, banning most activities other than IVF for heterosexual couples. Cryo-preservation, donation and most research are outlawed.<sup>16</sup>

There are some advantages in this approach. It is very clear: people know just where they stand. Also, if the country regards the embryo, including the pre-implantation pre-embryo, as a human being, then the system that has been put into place in Italy will safeguard human life and human rights. The system also addresses the "fear factor". Biomedical developments are lurching humankind into the unknown and the science is rapidly outflanking the law and the ethical debate. Are we unleashing a technological monster that will deprive humans of their essential humanity? By banning all but the most routine of procedures, we buy time.

However, there are also many disadvantages. First, the clarity of the law may be deceptive. What is clear at the time of enactment may be murky in a very short space, especially as science advances. The British Human Fertilisation and Embryology Act 1990 was thought to be a blueprint that would last the distance. Yet, several issues such as those to do with research but also treatment have had to be litigated with pragmatic judicial outcomes.<sup>17</sup> Latterly, the House of Commons

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15 Margaret Brazier "Regulating the Reproductive Business?" (1999) 7 Med Law Rev 166, 174.

16 For a critical commentary, see G Benagiano and L Gianaroli "The new Italian IVF legislation" (2004) 9 Reproductive BioMedicine Online 117.

17 See for example *R (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687 (creation of an embryo by cell nuclear replacement); *R (on the application of Quintavalle) v Human Fertilisation and Embryology*

science select committee has recommended radical changes to the legislation because it no longer serves all the needs of the various parties involved.<sup>18</sup> To put this point another way, a prescriptive approach is likely to leave gaps with no satisfactory mechanism for dealing with new developments.

Secondly, the clarity of one age may soon be replaced by a new set of values. Public opinion can change fast. People must have surely wondered about IVF itself when it first occurred but, with the exception of some groups such as the Roman Catholic Church, it is now widely accepted as routine. Thus, the "fear factor" may still be relevant but the content of people's fears may change far more rapidly than legislation. A highly restrictive law may be very difficult to unravel in reasonable time. Again, if a country has a disparate range of ethical positions, rules banning too many activities may simply not reflect community values and may therefore fall into disrepute.

Thirdly, the law may be avoided. This may happen internally by finding novel ways of getting round the letter of the law or by resorting to do-it-yourself methods (eg of donation) but it can also lead to reproductive tourism: people find another country with less restrictive laws where the procedure can take place or the research can be done. This can itself raise other ethical questions. It tends to favour the wealthy who can afford to travel and pay high fees. Furthermore, access to assisted reproduction is an issue itself and fairness may well depend on the extent of public funding, but this will not apply to reproductive tourism which the parties will have to finance themselves. On the research front, there is the dilemma for restrictive countries that they will almost certainly benefit in due course from discoveries from things like stem-cell research. How can they avoid being compromised?

In the end, the main disadvantage of a restrictive system is its inflexibility. However, many states may still wish to ban some activities. The question is how extensive the banning rules are.

## 2 *Laissez faire*

At the other end of the spectrum is a largely unregulated approach, leaving the market to determine priorities. Parts of the United States and New South Wales tend to fall into this category. New Zealand, which through the second half of the 80s and the 90s was affected by New Right ideology with its minimalist state and market focus, also fell into this category. It tended to take a back-seat and see what happened elsewhere.

The market approach has some benefits. One of the biggest points in favour is freedom of choice. People who wish to use assisted reproductive services can do so, without having to look

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*Authority* [2005] 2 FCR 135 (tissue typing; pre-implantation genetic diagnosis); *In re R (A Child) (IVF: Paternity of Child)* [2003] 2 WLR 1485 (donor sperm, treatment after separation of parties); and *Evans v Amicus Healthcare Ltd* [2004] 3 WLR 681 (use of frozen embryo after separation of parties).

18 House of Commons Science and Technology Committee "Human Reproductive Technologies and the Law" (24 March 2005) HC 7-I.

over their shoulder at what Parliament might be saying. Great reliance is placed on professional integrity. However, if a clinic were not up to standard, then the message would soon get round and consumers would go elsewhere. The health professions themselves would haul recalcitrant members into line. Fundamentally, support for this approach would ask why the State should be involved in the market?

However, the *laissez faire* approach leaves a number of factors out of the equation. What if something really does go wrong through a lack of regulation? Corrections might be made but in the meantime some individuals have suffered. Is that fair? How can people have confidence in the system if there is not proper public oversight? An unregulated system leaves the way open for the rogue. Considerable damage may be done before this door is bolted.

Further, it may be argued that reliance on the market essentially commercialises reproduction. Some would describe this as the commodification of human life. While money may control many aspects of our lives, arguably it should not be the controlling factor at the beginnings of life itself. The commodification proposition can be taken to extremes: people should still have to pay properly for services and the costs of assisted reproduction cannot be ignored. Just because a couple pay money, possibly quite a lot, for services does not mean that the resulting child is somehow tainted. Nevertheless there is a residual feeling that an unregulated market may exploit the individuals involved and be driven essentially by profit rather than the well-being of the parties. Professionals at their best will be driven by higher motives, but there is room in an unregulated market for players who do not share these ideals.

The *laissez faire* approach also leaves out of the equation the place of public debate and public concern. The road of individual freedom is a legitimate ideological position. However, many would see countervailing values at stake and would see these as requiring communal responses. The market by definition permits of only minimalist societal control, essentially only such control as will enable the market to function efficiently. In the end, this is unsatisfying in the context of assisted reproduction because it leaves the public as represented by the State unable to determine the priorities and principles in this area.

### 3 *Professional regulation*

A variation on the market model is one which emphasises the role of self-regulation by the health professions. This is not a pure market model as it implies a legislative framework that provides the umbrella under which the professions exist. One of the concerns of the New Zealand Ministerial Committee on Assisted Reproductive Technologies was that, while the small number of clinics providing fertility services maintained rigorous standards and were highly knowledgeable about the ethical developments in the area, some people could operate outside the regular patterns.<sup>19</sup>

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19 *Assisted Human Reproduction Navigating Our Future Report of the Ministerial Committee on Assisted Reproductive Technologies* (1994, Department of Justice, Wellington) 40.

While this activity was likely to be at the low end of technological intervention, for example donor insemination, nevertheless the gap was worrying. So, the State could aid professional self-regulation by ensuring that no one could practise assisted reproduction except under appropriate professional auspices.

Another way in which the State might assist the effectiveness of this model is through the existence of ethics committees. In New Zealand, ethics committees in the health sector were given a major boost as a result of the recommendation of the "Cartwright Report" which investigated questionable research on women with cervical cancer in the late 1980s.<sup>20</sup> A later addition to regional health committees was a government-appointed national committee dealing exclusively with assisted reproduction applications. Latterly known as the National Ethics Committee on Assisted Human Reproduction, this committee has dealt with novel treatments and research but it has also filled a policy vacuum and released guidelines on various topics, including pre-implantation diagnosis and the use of a dead person's gametes. One of the difficulties with the ethics committee prior to the 2004 legislation was that there was nothing in the law to say that the committee's approval had to be sought and that its decisions had to be complied with.

Thus, self-regulation can walk in tandem with the State in varying degrees. However, does the system delegate too much power to health professionals? Should the whole process of assisted reproduction be medicalised? Brazier says:<sup>21</sup>

The central role granted to professionals in British law relating to reproductive medicine is one of its key features. The law grants doctors powers to make social judgements with the inevitable result that the substance of any "right" of access to regulated fertility treatments is determined by clinics, by doctors, generally working with ethics committees. The disadvantages of such a system are patent.

So, we are left wondering whether this model truly allows for individual autonomy on the one hand, and proper public and political input into decision-making on the other.

#### *4 Prescription through licensing or similar state agencies*

This fourth model of regulation is closer to the first model than anything else but much may depend on the way in which the legislation is crafted. It assumes a degree of prescription and therefore does not trust *laissez faire*. However, it may also be a highly flexible system, allowing alternatively for prohibitions if there are warning signs about a particular development or for a green light if a development appears to be worthy.

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20 S R Cartwright *The Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters* (Ministry of Health, Wellington, 1988).

21 Margaret Brazier "Regulating the Reproductive Business?" (1999) 7 *Med Law Rev* 166, 178.

A classic example of this approach is the Human Fertilisation and Embryology Authority in Britain. This Authority carries a multitude of functions, one of the most important being to license the providers of reproductive services. It also has a policy-making function, along with a public education one.

Not dissimilar is the new Assisted Human Reproduction Agency of Canada.<sup>22</sup> This Agency has licensing functions with accompanying inspection and enforcement powers. It also gives the government advice, monitors developments, looks after health reporting information, and has consultation and education roles with respect to the public and the professions. The Agency's objectives are "(a) to protect and promote the health and safety, and the human dignity and human rights, of Canadians, and (b) to foster the application of ethical principles".<sup>23</sup> Despite the reference to ethical principles, there is no explicit ethical approval function given to the Agency. Doubtless this will come into play when the Agency grants a licence for a "controlled activity"<sup>24</sup> but the Agency will also be bound by any regulations, which may be made on a vast array of topics.<sup>25</sup>

The use of a State agency specially designed to handle assisted reproduction matters has a number of advantages. It has the capacity to adapt to changing circumstances and, unlike the legislature, can do so without being too laborious. It can bring together a range of people with different backgrounds but relevant expertise. It can engage in study and consultation in a way that the government and parliamentarians are rarely able to do. There is therefore a degree of control that does not rely on wide-ranging proscriptions but that will not at the same time cramp the use of novel treatments and frontier research.

However, there are also drawbacks. There may be a lack of transparency. Much of the work of these State bodies is done behind closed doors. When dealing with individuals' personal lives, privacy is vital but it may also mean that wider policy discussions are held outside the public domain. Where under the self-regulation approach there was the risk of capture of policy-making by health professions, we now find a parallel risk of capture by experts.

There is therefore a risk to the democratic process. Instead of the elected representatives determining policy, it has been delegated to the agency. Unelected personnel may make critical decisions into which the public may have only marginal input.<sup>26</sup> Much may depend on the way in

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22 Assisted Human Reproduction Act 2004, ss 21-39.

23 Assisted Human Reproduction Act 2004, s 22.

24 Assisted Human Reproduction Act 2004, ss 10-13.

25 Assisted Human Reproduction Act 2004, s 65.

26 Cf House of Commons Science and Technology Committee *Developments in Human Genetics and Embryology: Fourth Report of Session 2001-02* (HC791, The Stationery Office, 2002) which said that "democracy is not served by unelected quangos taking decisions on behalf of Parliament" (para 19).

which the body is established and the safeguards that are built into the governing legislation. Arguably the wide regulation-making power in Canada reserves to the politicians power over critical matters. There will thus be parliamentary scrutiny and accountability. The Canadian Act even requires a parliamentary review of the legislation three years after the Act comes into force.<sup>27</sup> This will ensure at least initial parliamentary oversight of the operation of the legislation.

There is also the possible problem of continuity. While in existence, specialist bodies can add to their experience and expertise. However, they are open to political whims and may have their personnel drastically altered by a differently flavoured government or the body could even be abolished. These risks are not ones faced by professional bodies.

### **B Summary**

To summarise this part of the paper, all the forms of regulation discussed have their plusses and minuses. Within the spectrum, there may be many other variations but what is apparent is that there is little international consensus. In weighing up the options, it may be useful to return to the report of the New Zealand Ministerial Committee. It believed that:<sup>28</sup>

...there must be a system in which the public can have confidence. ART ["assisted reproductive technologies"] is an area of peculiar public interest because of the questions it raises about the beginning of life, what it means to be human, and the mind-bending potentiality of technology. The public has an interest in ensuring that there is proper quality control, accountability, and debate of controversial issues, and that the interests of all parties – offspring, women, men, infertile couples, minority groups, professionals – are protected.

And again:<sup>29</sup>

...is there a legitimate public interest in the control of ART? Put another way, does the State have a particular obligation to regulate ART services? We believe that the answer to this is clearly yes. The State should certainly aim to promote fundamental values in a democratic society, such as privacy and procreative autonomy. But ART gives rise to very fundamental questions about what it is to be human, and how far we can travel down the path of intervening in natural human process raises deep metaphysical questions for most people. These are issues for the whole community, and not ones to be left to a section of the community. The State has an ancient and overriding obligation to protect the interests of children, and the promotion of human rights and justice is the task of the State. These are all poignantly affected by ART.

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27 Assisted Human Reproduction Act 2004, s 70.

28 *Assisted Human Reproduction Navigating Our Future Report of the Ministerial Committee on Assisted Reproductive Technologies* (1994, Department of Justice, Wellington) 35.

29 *Assisted Human Reproduction Navigating Our Future Report of the Ministerial Committee on Assisted Reproductive Technologies* (1994, Department of Justice, Wellington) 37-38.

We turn next to examine how well the new regime in New Zealand has balanced the various interests and values.

#### ***V THE TRIPARTITE NEW ZEALAND SYSTEM***

The regulatory system introduced in to New Zealand through the Human Assisted Reproductive Technology Act 2004 is a three-tiered one. At one tier, various activities are banned. Although the list is quite extensive, most of the items are far from mainstream and the list is a more liberal one than some jurisdictions would favour. At the second tier there is a new Advisory Committee. This Committee is charged with high-level policy advice but its functions go beyond this to the preparation of guidelines that have legal force. Just what the legal status of these guidelines is will be considered later. The third tier is the national ethics committee, now placed on a proper statutory basis and given clearer functions. Its role is primarily to assess applications for new treatments and research.

While this tripartite system contains elements of the "highly restrictive" model of regulation discussed above, its core is found in the symbiosis between the two committees. This structure takes New Zealand away from the market orientation that used to prevail but it has no licensing requirements<sup>30</sup> and in this sense is less interventionist than other jurisdictions. It is nevertheless a middle way, one which relies on a degree of prescription through State agencies.

What are the hallmarks of the New Zealand line? Given that many of the issues can be controversial and can have major political ramifications, does it appropriately allow for these wider concerns? Is there proper Parliamentary scrutiny? Who sets the policy-making agenda?

#### ***A Prohibitions***

The prohibitions in the New Zealand Act are found in several different places. Schedule 1 contains "prohibited actions", of which there are nine. The creation of cloned or hybrid embryos is banned but, importantly, only for reproductive purposes. Their creation for research purposes is something which is left for the Advisory Committee to consider.<sup>31</sup> The remaining matters contained in the Schedule involve the implantation into either a human being or an animal of hybrid or cloned embryos or embryos or gametes of the opposite species. These actions constitute an offence, punishable with up to 5 years' imprisonment or NZ\$200,000, as does the export or import of in vitro embryos, fetuses or (oddly) gametes formed in contravention of the Schedule.<sup>32</sup> Possession of a

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30 Providers of fertility services must meet safety standards and be certified as fertility services providers by the Director-General of Health under the Health and Disability Services (Safety) Act 2001. The definition of "health or disability services" in s 5 includes inter alia "fertility services". New Zealand clinics have also long obtained professional accreditation under RTAC, the Australian Reproductive Technologies Accreditation Committee.

31 Human Assisted Reproductive Technology Act 2004, s 37.

32 Human Assisted Reproductive Technology Act 2004, s 8.

gamete, embryo, foetus or being formed in contravention of the Schedule is also an offence but there is a "reasonable excuse" defence.

An embryo must not be allowed to develop after the 14<sup>th</sup> day, the day on which the primitive streak is understood to first appear in an embryo.<sup>33</sup> This time-frame is found elsewhere, for instance in Britain's Human Fertilisation and Embryology Act 1990.<sup>34</sup> There is a similar rule for hybrid embryos but the day is earlier if the primitive streak appears earlier. Embryos and gametes are not to be stored for more than ten years unless the ethics committee has approved an extension.<sup>35</sup> Sex selection is outlawed but again this is not unqualified: it does not apply if sex selection is for the prevention or treatment of a genetic disorder or disease.<sup>36</sup> Gametes may be obtained from a child under the age of 16 but only for storage purposes or for the creation of another child whom the gamete provider is likely to bring up.<sup>37</sup> Trade in embryos and gametes is banned, as is advertising in relation to any prohibited activities.<sup>38</sup>

Surrogacy is a controversial topic around the world. Until the 2004 Act there was no legislation on surrogacy but at one stage there was an effective ban on surrogacy through clinics because the ethics committee refused to approve IVF surrogacy, ie altruistic embryo transfer to a relative or friend with the intention that the genetic parents would bring up the child. This decision was criticised by the Ministerial Committee in its 1994 report<sup>39</sup> and eventually the ethics committee, now with changed membership, altered its policy. Given the green light for at least this form of surrogacy, it would have been a radical shift if Parliament had decided to reverse the position and ban surrogacy outright. Instead, it adopted a half-way house.

Section 14 of the 2004 Act declares negatively that a "surrogacy arrangement is not of itself illegal" but then states that it is not enforceable. Contrast the Canadian provision, which leaves the validity of surrogacy agreements to provincial law.<sup>40</sup> A "surrogacy arrangement" is one where "a woman agrees to become pregnant for the purpose of surrendering custody of a child born as a result of the pregnancy".<sup>41</sup> Contrary to the Canadian position,<sup>42</sup> this definition is not restricted to

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33 Human Assisted Reproductive Technology Act 2004, s 9.

34 Human Fertilisation and Embryology Act 1990 (UK), s 3(4).

35 Human Assisted Reproductive Technology Act 2004, s 10.

36 Human Assisted Reproductive Technology Act 2004, s 11.

37 Human Assisted Reproductive Technology Act 2004, s 12.

38 Human Assisted Reproductive Technology Act 2004, ss 13 and 15.

39 *Assisted Human Reproduction Navigating Our Future Report of the Ministerial Committee on Assisted Reproductive Technologies* (1994, Department of Justice, Wellington) 112-114.

40 Assisted Human Reproduction Act 2004 (Can), s 6(5).

41 Human Assisted Reproductive Technology Act 2004, s 5.

surrogacy using assisted means but will include arrangements that rely on natural intercourse and probably includes the Maori practice of "whangai" where there is an understanding that a child will be handed over to another member of the family.

This becomes rather more important when the remaining provisions are noted. No one, including the surrogate mother, commissioning couple and an intermediary arranging a surrogacy, may give or receive "valuable consideration". The Canadian Act does not use the word "valuable" and does not direct its ban against the surrogate mother but otherwise leaves the question of monetary payments there.<sup>43</sup> In contrast, the New Zealand section expressly stipulates that "any reasonable and necessary expenses" for professional services, including legal advice, are not caught by the ban on "valuable consideration".

The result of section 14 is that in New Zealand not-for-profit surrogacy is allowed. Whangai and do-it-yourself arrangements that do not involve cash transactions for profit are legal. Surrogacy through a regular clinic with the usual costs associated with the procedures is also legal. Anyone, including the surrogate mother, who steps outside these boundaries may have committed an offence.

### ***B Advisory Committee***

The new Advisory Committee has a number of the hallmarks of the Council that the Ministerial Committee had proposed in 1994. However, a body such as this was not originally in the government's plan. Later thinking gave the policy function to the National Advisory Committee on Health and Disability Support Services Ethics, which has a generic responsibility for advising on ethical issues.<sup>44</sup> The decision was eventually made in favour of a stand-alone specialist group, which would maintain the clear split between policy development and individual ethics approvals.

The Committee is appointed by the Minister of Health. This in itself is interesting as the 2004 Act is formally administered by the Ministry of Justice and historically the Minister of Justice has had a heavy hand in the development of policy on assisted human reproduction. For example, it was the Minister of Justice who appointed the Ministerial Committee originally in 1993. Perhaps there is a subtle shift in emphasis from human rights considerations to medical ones.

The Committee's functions are to issue guidelines and give advice to the ethics committee, to advise the Minister on procedures and research as well as the overall framework for handling assisted reproduction matters, to liaise with the ethics committee, to consult relevant people, to monitor procedures and developments in research, and to deal with any other matter that the Minister has assigned to it.<sup>45</sup> Sections 37 and 38 set out various specific topics that the Committee

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42 Assisted Human Reproduction Act 2004 (Can), s 3, definition of "surrogate mother".

43 Assisted Human Reproduction Act 2004 (Can), s 6(1)-(3).

44 Now found in s 16 of the New Zealand Public Health and Disability Act 2000.

45 Human Assisted Reproductive Technology Act 2004, s 35.

must report on to the Minister. These include some controversial topics such as cloning and hybrids, but also the use of gametes from foetuses and dead people, genetic modification and pre-implantation genetic diagnosis.

Possibly the most important aspect of the Committee's work is the production of "guidelines" on any assisted reproductive procedures or research.<sup>46</sup> The precise legal status of these guidelines is uncertain. They appear to be a low level form of delegated legislation but they are not the equivalent of statutory regulations. During the passage of the Bill, the Green Party unsuccessfully advocated that any such guidelines should only be issued as regulations but officials argued that, because of requirements for regulations such as Parliamentary drafting and Cabinet approval, this would make the system too slow and cumbersome.<sup>47</sup> The guidelines nevertheless have teeth: the ethics committee must act in accordance with the guidelines and, where there are no guidelines, it must refer the issue to the advisory committee.<sup>48</sup> Where an approved procedure or research project is not carried out in accordance with the ethical approval, which will embrace any conditions laid down in the guidelines, the ethics approval can be cancelled and the activity must cease.<sup>49</sup> Subject to a judicial review challenge, the guidelines in effect have the force of law – at least where it matters.

The Advisory Committee will obviously play a leading role in the formulation of policy. While the Act partly sets the agenda, as time passes and new issues arise the Committee itself will doubtless take initiatives. To what extent is the public to be involved in the process and to what extent is there accountability to Parliament?

"Transparency" appears to be one of the goals of the operation of the Committee. For example, the agenda and minutes of its meetings must be published on the internet. Where it proposes to provide advice on non-urgent matters of public interest or issue guidelines, it must first generate a discussion paper or an outline of its guidelines or advice and then allow interested parties and members of the public to make submissions.<sup>50</sup> Where giving advice, the Committee must also hold public meetings if a significant number of people wish to make oral submissions. These submissions must be taken into account and, given the nature of the topics, one can well imagine certain interest groups being active in advancing their opinions. It is also likely that the Committee will have a regular group of individuals and organisations who receive its papers automatically. Indeed, in

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46 Human Assisted Reproductive Technology Act 2004, s 36.

47 See for example "HART SOP Guidelines and Regulations" MLE 001 05 03 (24 May 2004) released under the Official Information Act 1982.

48 Human Assisted Reproductive Technology Act 2004, ss 19(2), 29 and 18(2).

49 Human Assisted Reproductive Technology Act 2004, ss 22 and 23.

50 Human Assisted Reproductive Technology Act 2004, ss 36(1) and 39(2).

addition to a general call for submissions, there is a positive obligation to consult appropriate individuals, groups, governments departments and agencies, as well as the Minister of Health.<sup>51</sup>

After issuing guidelines, the Committee must publish them widely, including on the internet and the Minister must present them to Parliament. Thus, although they are not regulations as such and therefore do not attract scrutiny from Parliament's Regulations Review Committee, they will be readily available for Parliamentarians to examine and debate. Under Parliamentary rules, Parliament's health select committee can choose to undertake an inquiry into any guidelines.<sup>52</sup> Furthermore appointments to the Committee, which must be widely representative and at least half of which are required to be laypersons, must be notified to Parliament as well as an annual report.

There is therefore some general Parliamentary oversight of the Committee's processes and decision-making. In addition to this, the government still retains wide regulation-making powers<sup>53</sup> and another safeguard is found in sections 24 to 26. This allows for a moratorium of up to two and a half years to be imposed on any particular activity, during which time no ethics applications are to be considered but the Advisory Committee must study the issues and report to the Minister, where appropriate with a set of recommendations.

### ***C Ethics Committee***

Under the 2004 Act the Minister of Health can designate any committee to be the ethics committee.<sup>54</sup> In practice, there will continue to be one committee, the principal function of which is to determine applications for "assisted reproductive procedures" and "human reproductive research".<sup>55</sup> "Human reproductive research" is defined as "research that uses or creates a human gamete, a human embryo, or a hybrid embryo" while an "assisted reproductive procedure" is one involving the creation of an embryo, the storage, manipulation and use of gametes and embryos, the use of embryo cells and the implantation of gametes and embryos.<sup>56</sup> Importantly, a procedure that needs approval does not include an "established procedure". Established procedures are ones that are declared to be such by the Governor-General by Order in Council, which can be done only after the Advisory Committee has given the Minister advice.<sup>57</sup> This system is designed to ensure that regular

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51 Human Assisted Reproductive Technology Act 2004, s 41.

52 Standing Orders of the House of Representatives (New Zealand), SO 189(2).

53 Human Assisted Reproductive Technology Act 2004, s 76.

54 Human Assisted Reproductive Technology Act 2004, s 27.

55 Human Assisted Reproductive Technology Act 2004, s 28.

56 Human Assisted Reproductive Technology Act 2004, s 5.

57 Human Assisted Reproductive Technology Act 2004, s 6.

donor insemination, IVF treatments and the like that have long been practised are not caught up in a bureaucratic approvals system.

Another important provision is one that makes it illegal to perform procedures or engage in research without ethics committee approval.<sup>58</sup> This is the first time that ethics committees' determinations have been given this kind of legal status in New Zealand. Coupled with the requirement that providers of fertility services (including established procedures) must be certified under the Health and Disability Services (Safety) Act 2001, it appears that any gap in the law allowing inappropriate people to conduct research or offer assisted reproductive treatment has been plugged.

#### ***D Summary***

The new tripartite structure just outlined is, it is suggested, a middle way in regulating assisted reproduction issues. Parliament has placed some activities on a prohibition list. In the light of rapid technological developments and given that there is no moral consensus on many fundamental questions, it has not sought to be overly prescriptive. Instead, it has left many other activities, known and unknown, for the new Advisory Committee to examine on a flexible issue-by-issue basis. Nevertheless, there remain important safeguards ensuring public consultation, along with Ministerial and Parliamentary scrutiny. Once the policy has been settled, the ethics committee then vets individual applications relating to particular treatment or research.

#### ***VI CONCLUSION***

Assisted human reproduction attracts a wide range of reactions. Some people see it as part of an exciting new dawn. Others see it as raising deep dark ethical and philosophical issues about the meaning of life and the human condition. This paper has looked at the principles found in three jurisdictions, including New Zealand, and then has assessed some of the major models for regulating assisted human reproduction. The New Zealand regime was enacted in 2004 and represents a moderately interventionist model, but arguably one that is adaptable enough to accommodate new science and to meet the political and ethical demands of a small but increasingly secular and pluralist society.

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58 Human Assisted Reproductive Technology Act 2004, s 16.