Health and Disability Commissioner (2000) *Report of the Health and Disability Commissioner for the year ended 30 June 2000* AJHR E.17

Privacy Commissioner (1994) *Health Information Privacy Code 1994 with introduction, commentary and appendices 1994/1/1/* Privacy Commissioner

Privacy Commissioner (2000) *Health Information Privacy Code 1994 incorporating amendments and including revised commentary* Privacy Commissioner

bioethics commentary

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This review of the year in Bioethics is intended to appraise readers of prominent health care decisions, national reports and policies, and other significant matters in New Zealand and occasionally overseas which have informed the development of Bioethics.

Royal Commission on Genetic Modification

A Royal Commission on Genetic Modification was constituted in May 2000. Under the chairmanship of the former Chief Justice of New Zealand, Sir Thomas Eichelbaum, it is to:

> receive representations upon, inquire into, investigate, and report upon the following matters:
>
> 1. the strategic options available to enable New Zealand to address, now and in the future, genetic modification, genetically modified organisms, and products; and
>
> 2. any changes considered desirable to the current legislative, regulatory, policy, or institutional arrangements for addressing, in New Zealand, genetic modification, genetically modified organisms, and products[.]

The Commission commenced public hearings on 16 October 2000 and is due to report by 1 June 2001. Much information, including the full terms of reference and transcripts of submissions, is available on the Commission's website: www.gmcommission.govt.nz.

Prior to the commencement of the Commission's work the Independent Biotechnology Advisory Council of the Ministry of Research Science and Technology (IBAC) issued its report on the national consultation on genetic modification which took place over the first twelve months of its existence. This report contained an account of the ethical perspectives of the New Zealand population as nearly as they could be identified through the consultation process. Most of the opinions expressed to the Council could be summarised under two ethical values: i) respect for the liberties of citizens and ii) consideration of harms and benefits.

However identifying the ethical values which informed the debate did little to arbitrate between the polarised views which were passionately expressed. For example, with respect to liberty some organic farming groups claimed that the release of GM crops in New Zealand would encroach on their freedom to cultivate organic GM free crops because of the possibility of cross pollination and horizontal transfer from the GM crops grown by neighbours. On the other hand other agricultural interests claimed that a ban on GM crops would impair their ability to exploit advances in crop production and put them at a disadvantage in international markets.

The harms and benefits discussion was similarly polarised. Opposing groups claimed respectively that all GM foods were cancer causing and that all GM foods had been shown to be safe. It became clear that there was a distinct lack of solid evidence for either claim. Similarly both sides appealed to nature to substantiate their view of what protection of the environment and protection of individual human beings amounted to. There was an interesting mix of absolute and utilitarian cultural judgements about why ownership of indigenous species should be protected from interests external to New Zealand. The Report entitled *Biotechnology in New Zealand — Consultation Report* can be found on the IBAC website www.ibac.org.nz.

It will be interesting to note whether any new substantive issues emerge in the Report of the Royal Commission later in the year.

New Zealand Public Health and Disability Act 2000.

The new Health and Disability Act 2000 has something to say about ethics. It contains *inter alia* provision for setting

up a National Ethics Committee. Section 7 of the Act provides the Minister of Health with a discretion, but not a duty, to appoint a committee 'to advise the Minister on ethical issues of national significance in relation to such matters as the Minister specifies by notice to the committee'. There had previously been such an advisory committee to the Minister but this committee was disabanded after it had withered on the vine for a number of years because no money was provided for meetings and no advice was sought from it. The terms of reference of the new National Committee are somewhat ambiguous and they will be subject to a discussion paper and consultation in the next few months.

Section 16(1) of the new Act provides that:

> The Minister must, by written notice, appoint a national advisory committee on the ethics governing health and disability support services for the purpose of obtaining advice on ethical issues of national significance in respect of any health and disability matters (including research and health services).

Section 16 (2) provides that:

> The national advisory committee appointed under subsection (1) must determine nationally consistent ethical standards across the health sector and provide scrutiny for national health research and health services.

The relationship between this committee and the Health Research Council Ethics Committee, which currently has responsibility for the accreditation of Ethics Committees in New Zealand is unclear.

Perhaps of greater interest will be the relationship between this Committee and Regional Ethics Committees. The clause '...provide scrutiny for national health research and health services' could be read to mean that the National Committee will take an overarching control of the quality of ethical review of health research in New Zealand — by ownership and development of the National Standard for example — or that it will be expected to scrutinise protocols for national studies with a view to providing ethical approval for the studies to proceed. This latter role was never part of the terms of reference of the predecessor of the new National Committee and the adoption of this interpretation would raise important issues surrounding the independence and qualifications of the committee to carry out its work. With respect to the first issue such a role would appear to be in tension with the WHO guideline that such review should be: 'independen[t] from political, institutional, professional, and market influences' *[WHO, (2000); para.2].*

Given that the new committee will be a Ministerial Committee advising the Minister of Health processing the Ministry's own research through it would impugn the independence of the Committee. Presumably the Minister would also be free to reject its advice. These would be undesirable consequences for the process of ethical review in New Zealand and contrary to the spirit of the Cartwright Report which led to the current system of review. The second issue would be the ability of a central committee to represent the views and interests of a variety of population groups of which regional committees, currently responsible for such review, would be expected to be more cognisant.

National Standard for Ethics Committees

The first National Standard for Ethics Committees was published in 1988 and the current Standard dates from 1996. Given the requirement in section 16(1) of the New Zealand Public Health and Disability Act 2000 that the Minister of Health appoint a committee 'for the purpose of obtaining advice on ethical issues of national significance in respect of any health and disability matters (including research and health services)', this committee will be responsible for approving the final version of the next revision of the National Standard.

The working party on the restructuring of the Standard has been making very slow progress throughout the year. The process has now run for more than eighteen months and the prospect of further delays whilst the new National Ethics Committee is set up is disappointing. It is almost certain that it will contain a more detailed section on the ethical review of innovative treatment. This year has seen a great deal of progress in taking this aspect of ethical review in New Zealand seriously. Since the Cartwright Report led to the new system of ethical review this has been part of the brief of the review committees. However little of this work has in

fact been achieved by the committees. The experience of the Otago Committee in processing the CG Clip innovation has been of great assistance in formulating proper procedures for such review. Details of the innovation, the conceptual and practical problems it involves and the procedures developed are to be found in Gillett, (2000), and Evans (forthcoming).

The current National Standard has other limitations, including its provisions relating to health research with children. The ethical guidelines recently published in this journal (Peart and Holdaway, 2000) should provide a helpful basis for the revision of this aspect of ethical review of research.

Issues in Maori Health Research

The Health Research Council is responsible for accrediting Regional Ethics Committees through its Ethics Committee. The Council has been working hard to encourage greater responsiveness to Maori in its policies and practices. This has been extended to the accreditation of Ethics Committees process. Ethics Committees will now be asked to audit their responsiveness to Maori concerns and the responsiveness of the researchers who apply to the Committees for ethical approval by answering structured questions on the matter in their Annual Reports. Amongst other questions will be the questions: What reasons have been given by researchers for excluding Maori participants from trials and studies? What processes have the Committee set up to facilitate proper consultation with Maori in the development of research protocols? The questions will figure in the instructions to Committee Administrators which are about to be issued. The enterprise is a means of giving some precise meaning to the idea of respect for the Treaty of Waitangi in the process of ethical review.

Assisted Human Reproduction

The Select Committee procedure on the two outstanding Bills on Assisted Human Reproduction is due to be completed in June of this year. The delays in processing this legislation have caused the general issues to be overtaken by the explosion of interest in stem cell research and the British government's legalisation of the use of human embryos for research in this field in 2000. The delays might turn out to be fortuitous in that the UK Parliament was fortunate to have already enacted the Human Embryology and Fertilisation Act (1990) which covered both assisted reproduction matters and human embryo research. Though stem cell research as we now know it was almost unheard of at the time the provision of a regulatory body which could keep its ear to the ground for changes in public opinion and the needs of science was permitted to establish regulations through Parliament for research on human embryos. It was a relatively simple procedure for the legislators to extend the purposes for which such research could be carried out. This was achieved by a free vote in both the House of Commons and the House of Lords, each with large majorities. Other countries are not so well placed to permit stem cell research having enacted controls over human embryo research in their Assisted Reproduction legislation which often amount to a complete ban. It is now a difficult and drawn out process to change such laws, even if that is the wish of the people.

The delays in enacting legislation to control assisted reproduction in New Zealand offer the opportunity to take account of the call for such research. IBAC determined in 2000 to convene a national consultation on the subject as part of its urgent business for the first half of this year in an effort to gauge public feeling on the matter in time to inform the legislative process. In case there is not time to complete that consultation before the Select Committee reports to the House on the Assisted Reproduction Bills the Council has already briefed the Minister of Research Science and Technology of the complications which have arisen in this connection elsewhere.

The consultation booklet entitled *Stem Cell Research* will soon be available on the IBAC website www.ibac.org.nz.

References

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