

new developments

Bioethics and Health Law in New Zealand

This is the first of a series of annual reviews of developments in Bioethics and Health Law in New Zealand to be published each February in the New Developments section. This review will consist of two articles from guest commentators reflecting on selected events, cases and debates of general interest and significance in the previous year.

law commentary

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In the year 2000 the most important change in New Zealand health law resulted from the enactment of the New Zealand Public Health and Disability Act 2000. The new Act repealed the Health and Disability Services Act 1993 and provided a new statutory basis for the provision of state-funded health and disability services in New Zealand. (A few of the sections came into force in mid December; the remainder on 1 January 2001 (s2).)

National Ethics Committee

This note will focus on the provisions in the Act that relate to a National Ethics Committee (as it will be referred to here, and quite possibly in practice). The role and composition of the National Ethics Committee is likely to become a matter of some interest if, as now seems likely, the committee is to be used as a means of reducing the influence of the Regional Ethics Committees. (The reasons why this is being planned lie outside the scope of this note, but much relevant information is to be found on the website of the Gisborne Cervical Screening Inquiry: <http://www.csi.org.nz/> accessed 17 February 2001.)

Section 16 of the Act is headed 'National advisory committee on health and disability support services ethics'. The section is made up of seven subsections, the last four of which deal only with duties to consult and to report, and the laying of information before Parliament. It is the first three that will be examined here.

Section 16(1) provides:

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).

This seems to give the committee an advisory rather than executive role, and would be consistent with its being described as the 'National advisory committee on health and disability support services ethics'.

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.

This contrasts with section 16(1) in several respects. One is that it contains no reference to disability support matters. Another is that it gives the committee more than an advisory role: the committee '*must* [emphasis added] determine nationally consistent ethical standards across the health sector and provide scrutiny for national health research and health services'. It would be difficult to exaggerate the difficulty and size of this task.

Other Committees

Section 16(3) does not deal expressly with the National Ethics Committee. Its role is to ensure that the Minister may use other committees, rather than the National Ethics Committee, to obtain advice about specific ethical issues. Section 16(3) reads as follows:

For the purpose of obtaining advice on specific ethical issues of national, regional, or public significance in respect of any health or disability matters, the Minister may, by written notice, appoint any 1 or more of the following committees:

- (a) 1 or more committees established under section 11:

(b) the ethics committee of the Health Research Council established under section 24 of the Health Research Council Act 1990—

to consider matters specified by the Minister and to report to the Minister or a person specified by the Minister.

Paragraph (a) permits the use of 'Ministerial committees' (as the heading to section 11 describes them), rather than the National Ethics Committee, as a source of advice on specific ethical issues.

Paragraph (b) permits recourse to the Health Research Council (HRC) Ethics Committee, a committee whose membership is not, for the most part, determined by the Minister (HRC Act 1990, s26). It is convenient to list here the statutory functions of the HRC Ethics Committee. Not surprisingly some of them relate specifically to the role of the Council. Section 25(1) of the HRC Act 1990 commences:

The functions of the Ethics Committee shall be—

(a) To consider and make recommendations to the Council on ethical issues in relation to health research, especially those emerging through the development of new areas of health research:

(b) To provide and review ethical guidelines for the Council:

(c) Subject to paragraph (d) of this subsection, to ensure that, in respect of each application submitted to the Council for a grant for the purposes of health research, an independent ethical assessment of the proposed health research is made either by the Ethics Committee itself or by a committee approved by the Ethics Committee:

(d) Where an application for a grant for the purposes of health research is submitted to the Council in respect of health research that is of national importance or great complexity, to itself make an independent ethical assessment of the proposed health research:

However, the HRC Ethics Committee is not limited to these tasks, as section 25(1) of the HRC Act goes on to provide that the functions of the committee extend to the following:

(e) To review, at the request of any person who has made an application for a grant for the purposes of health research, the independent ethical assessment made, in respect of the proposed health research, by a committee approved under paragraph (c) of this subsection:

(f) To give, in relation to ethics committees established by other bodies, advice on—

(i) The membership of those committees; and

(ii) The procedures to be adopted, and the standards to be observed, by those committees:

(g) To provide independent comment on ethical problems that may arise in any aspect of health research.

These functions overlap to some extent with those which are likely to be exercised by the National Ethics Committee.

National Ethics Committee and Review of Research Protocols

Section 16 of the new Act does not expressly state that the National Ethics Committee is to provide ethical review of national studies which the Ministry wishes to undertake or see undertaken, and it does not alter the duty imposed on the HRC Ethics Committee by section 25(1)(d) of the HRC Act 1990. However, it does provide a much clearer statutory basis for the review of national research protocols than the Regional Ethics Committees can be said to possess.

The Ministry of Health places great store on the Terms of Reference which are provided for committees. In the case of committees whose function is laid down by statute, the legal effect of these terms of reference is sometimes open to doubt. In law, these terms of reference cannot empower a committee to do more than a statute permits. In practice, however, they sometimes have this effect. This is borne out by the terms of reference of the former National Ethics Committee.¹ The statutory role of that committee was 'to

advise the Minister on ethical issues of national significance in relation to such matters as the Minister specifies by notice to the committee' (Health and Disability Services Act 1993, s7). However, the terms of reference went well beyond this, and were in practice acted upon.

In practice, the terms of reference of the new National Ethics Committee will be much more important than Parliament's delineation of its role and responsibilities. If they include ethical review of proposed national studies, it will be hard to argue that this is inconsistent with the statutory role of the committee.

Codes and Commissioners

The Health Information Privacy Code and the Code of Health and Disability Services Consumers' Rights ('Code of Rights') are both important aspects of New Zealand health law.

When the Health Information Privacy Code was first issued, the Privacy Commissioner provided an introduction to and commentary on it, which was published along with an appendix of extracts from relevant statutes (Privacy Commissioner, 1994). In 2000 this publication was updated and expanded, in part to incorporate subsequent amendments to the Code (including two in 2000) and to take account of other legislative changes. For this revised edition (Privacy Commissioner, 2000) the extensive explanatory commentary has also been rewritten. The new publication supersedes the earlier publication, and provides much helpful guidance. Once again the Commissioner, Mr Bruce Slane, has stressed that the introduction, commentary, notes and appendix are not themselves part of the Code.

In 2000 New Zealand's first Health and Disability Commissioner, Mrs Robyn Stent, was succeeded in office by Mr Ron Paterson (an exceptionally able lawyer with significant experience in the health sector and a longstanding interest in bioethics). The first Annual Report for which he was responsible (Health and Disability Commissioner, 2000) provided some indication of which of his predecessor's recommendations for reform (Health and Disability Commissioner, 1999) he planned to pursue. However, these recommendations may be overshadowed soon by those of Ms Helen Cull QC, who has been appointed by Government to review processes concerning adverse medical events.

A great deal of useful information relating to the Code of Rights, and the Health Information Privacy Code, is available on the respective Commissioner's internet sites: www.hdc.org.nz (accessed 17 February 2001) and www.privacy.org.nz/shealthf.html (accessed 17 February 2001). Their opinions and notes contain much of value, and will soon be supplemented on the web by more information about decisions of the Medical Practitioners Disciplinary Tribunal.

Note

1. The earlier National Advisory Committee on Health and Disability Services Ethics functioned from 1995 to 1997. Its terms of reference were as follows:

- To advise the Minister of Health on ethical issues relating to health and disability services and research;
- To promote and foster the development of Maori perspectives on ethical issues;
- To undertake periodic revision of the National Standard for Ethics Committees and develop national guidelines to assist with local ethics committees' operations;
- To have overall responsibility for the accreditation and monitoring of local ethics committees;
- To coordinate the networking of local ethics committees, including the coordination of meetings of the National Chairpersons of Ethics Committees, and the National Hui of Maori Members;
- To provide second opinions as requested for ethical approvals;
- To advise on any related matters as may from time to time be referred to the committee by the Minister of Health;
- To provide on request advice on ethical issues to purchasers, providers, professional groups, community groups, iwi and hapu.

Only two of these tasks were clearly related to statutory role of the Committee.

References

Health and Disability Commissioner (1999) *A Review of the Health and Disability Commissioner Act 1994 and Code of Rights for Consumers of Health and Disability Services: Report to Minister of Health October 1999* Health and Disability Commissioner.

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