new developments
Bioethics and Health Law in New Zealand

bioethics commentary

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This report concentrates on public and policy events in bioethics in Aotearoa New Zealand. 2001 has witnessed the publication of two major reports with substantial implications for New Zealand bioethics, and progress towards setting up a new National Ethics Committee. The reports were of The Royal Commission on Genetically Modified Organisms (Royal Commission, 2001) published in July, and of the Ministerial Inquiry Into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region (Duffy, 2001) published in April. Terms of reference for the National Ethics Committee came out in May (Ministry of Health, 2001a) and its membership was announced in the first few days of 2002.

Genetic Modification (GM)

The Royal Commission began its work in 2000 (Evans, 2001, p.6). Its report takes account of a wide range of considerations (from spiritual to economic) and their implications for an equally wide range of practical issues (research, crop and field uses, food, medicine, intellectual property, Treaty of Waitangi issues, and liability). It consulted widely with groups perceived to have special interests, Maori groups and individuals, and the general public.

The Commission's 'Major Conclusion' reflects an attempt to take the middle line between a total ban on all Genetic modification in NZ and complete unregulated freedom. The Commission believed that an 'all or nothing' approach was not fruitful, and that, at least in some cases, genetically modified organisms could live in the environment without affecting the GM-free status of other organisms. Moreover, they recognised a tendency among many who contributed to their deliberations to wish to pursue the possible medical advantages of genetic modification. The Commission sought to 'preserve opportunities' in exploring and developing both genetic modification and non-genetic options.

Accepting the Royal Commission's Major Conclusion, the Government introduced 'a two year constraint period on commercial release while allowing strictly controlled contained research on a case-by-case basis' during which time necessary amendments to the *Harmful Substances and New Organisms Act 1996* (HSNO Act) could be drafted (Ministry for the Environment, 2001b). Contained research includes both laboratory and field trials. Not surprisingly, fears continued to be voiced over the level of containment possible in the latter, and the hence the meaningfulness of a policy allowing for both GM and GM-free crops (Green Party of Aotearoa New Zealand, 2001). There is also opposition to certain forms of genetic modification (for example the transfer of human genetic material into cows) on principle.

The Commission also suggested that for the 'Century of Biotechnology' (as, perhaps somewhat prematurely, the 21st Century is already being dubbed) NZ required a mechanism for proper consideration of ethical, cultural and spiritual dimensions of particular proposals for Biotechnological advance and research. Accordingly, the government is to set up Toi te Taiao: the Bioethics Council. Toi te Taiao is rendered in the Report as 'the sphere of the spiritual and natural worlds'. The Council's main purpose is 'to advise, provide guidelines and promote dialogue on the cultural, ethical and spiritual issues associated with biotechnology' (Ministry for the Environment, 2001a). The establishment of the council with this brief, and a proposed amendment to the HSNO Act to allow ministerial call-in of applications on cultural, religious or ethical grounds may represent an increased role in future planning for

considerations of this kind (Ministry for the Environment, 2001a). The problem is to see what dialogue on, for example, cultural issues amounts to where the general drift is towards cautious acceptance and utilitisation of the technology yet much of the opposition to this drift can be characterised as cultural. Furthermore, subsequent comment has indicated a lack of satisfaction with characterising Maori opposition to Genetic Modification as 'cultural', as if it were somehow distinct in nature from positions which embrace GM (Jackson, 2001).

Despite these difficulties, the commission also recommended, and the government has accepted, the development of a biotechnology strategy aimed at ensuring that 'New Zealand kept abreast of developments in biotechnology, and that these were used to national advantage while preserving essential social, cultural and environmental issues' (Royal Commission, 2001, p.349; Ministry for the Environment, 2001a).

Cervical Screening

A question perceived to be ethically (and legally) central by the Gisborne Inquiry *Report* is what weight should be granted to privacy and related consent issues over against public health concerns (for a consideration of this question, see Davidson, Dawson and Moore, 2001). The Inquiry heard – and evidently shared – opinion that effective audit of the National Cervical Screening Programme (NCSP) had been unacceptably held up by Ethics Committees which had insisted on the consent of women for access to their identifiable data held by the Cancer Registry. The *Report* recognises that if consent were genuinely to be sought, then refusal would need to be a real possibility, and worries that enough women might refuse it to undermine any conclusions about the effectiveness of the programme.

On the other hand, the *Report* doubts that, if access without consent were to be allowed, women would leave the programme. The *Report* rejects the argument that since consent was a major concern to the Cartwright Inquiry, it should be the major concern here: it is argued the context is altogether different. Dr Green's activities, it is said, were clearly experimental; audit of the NCSP, in contrast, is a necessary part of the women's treatment. It is the *Report*'s view that the only ethical way forward would be to make a legal change, removing the requirement for consent. It would be unethical, they argue, to continue a programme the value of which was unknown, while enrolling women into it on the basis that it would help them.

In line with the *Report*'s consequent recommendation that the law be changed to allow access to women's records without the individual's consent, the government put out a discussion document *Improving the National Cervical Screening Programme* (Ministry of Health, 2001b) which explained the proposed changes to the law and the safeguards of privacy and confidentiality it gave. Some reservations about the proposed changes to the law were voiced (see Anderson, 2001; Paul, 2001). When the consultation period was over, the Government revealed that three quarters of the submissions had been against allowing auditors access to records without consent (Gisborne Cervical Screening Enquiry, 2001) and the proposed legislation was altered to reflect this.

National Ethics Committee

As reported last year (Skegg, 2001; Evans, 2001) a National Advisory Committee on Health and Disability Support Services Ethics ('National Ethics Committee'), responsible to the Minister of Health, has already been legislated for (*New Zealand Health and Disability Act 2000*, s.16). The Terms of Reference, spelling out and elaborating the role of the new committee, were issued in May. Here we will pick up on three issues raised by these: (1) Relations with the Health Research Council Ethics Committee (HRCEC); (2) Relations with Regional Ethics Committees (RECs); (3) role in review of protocols.

(1) The terms of reference appear to give the National Ethics Committee some responsibilities which also lie within the HRCEC remit, such as giving second opinions in cases where another committee and a researcher are at loggerheads, and monitoring and reviewing the operation of the RECs (Ministry of Health, 2001a, p.2). However, it does not state that the HRCEC is to relinquish any of its responsibilities.

(2) The Terms of Reference place upon the National Ethics Committee tasks recommended by the Gisborne Inquiry. These tasks relate *inter alia* to RECs, and include (i) review of the impact of the decisions of ethics committees on independently funded evaluation exercises and on medical research generally; (ii) development of guidelines on conducting observational studies and on weighing up harms and benefits of that kind of research; and (iii) consideration of the application of an appeal procedure to be recommended for use by ethics committees (Ministry of Health, 2001a, p.2). The idea of an appeal procedure awaits further elaboration. Currently, the HRCEC can give a second opinion, which takes

the form of advice to any Ethics Committee involved in a dispute with a researcher, but in the end the final decision rests with the involved committee (Health Research Council, 1997). The Terms of Reference for the National Ethics Committee also mention its role in giving second opinions. However, appeals, which – on a judicial model – would presumably be to some perceived 'higher' authority, would be quite a new departure, as well as opening up conceptual questions regarding what a higher *ethical* authority could come to.

(3) Under the heading 'The Role of the Committee' the Terms of Reference for the National Ethics Committee use the term 'provide scrutiny' for national health research and health services. Professor Evans (2001, p.7) raised a question about the meaning of these terms. Did they, he asked, imply scrutiny of research protocols? With respect to this, it should be recalled that the Gisborne Inquiry recommended that a National Committee should be available to review national studies (Duffy, 2001, 9.33, p.243, 11.22, p.259) but this role is not mentioned explicitly in the Terms of Reference. On this matter, however, as with the other two, the Terms of Reference for the new committee leave matters unclear for the present.

Also facing the members of the National Ethics Committee, is the task of determining 'nationally consistent ethical standards across the health and disability sector'. One imagines that the difficulty will be in finding any reasonably substantive standards which are both consistent and 'national'. As the government found when it consulted about the proposed changes to the law concerning access to women's records, though the change was a recommendation of the Gisborne Inquiry and perceived as necessary to enable effective evaluation of the NCSP, surprising results can emerge. The same problem may beset any attempt to set out substantive guidelines on the weights to be given to harms and benefits of observational studies. The twelve members of the committee who are to take on the National Ethics Committee's tasks, whatever they may be, were announced at the very beginning of 2002. The Chair is to be Dr Andrew Moore of Otago University (*The Dominion,* 2 January 2002).

Stem Cell Research, Cloning and Genetic Testing

Aside from debates about GM, discussions in genetics world wide were headlined by predictions of human clones (cf. Gibbs, 2001). Claims to have cloned a human being made later in the year proved to be slightly controversial – what had been produced was a small number of human cells, which according to reports did not develop beyond the 6 cell stage (USA Today, 2001). Nonetheless, when a loophole which would have allowed cloned embryos to be implanted in wombs and developed to term was identified in UK Law, the government there rushed through a bill to prevent it (BBC News, 2001). In New Zealand, ethical discussion on such topics was informed by the Independent Biotechnology Advisory Council (IBAC) which published *Cloning and Stem Cell Research Some Questions to Consider* (IBAC, 2001), and which is soon to publish a further booklet on genetic screening (Don Evans, private communication).

Under proposals of the Royal Commission, accepted by the government, IBAC will cease to exist, its functions largely being taken over by the Bioethics Council (Royal Commission, 2001, p.350; Ministry for the Environment, 2001a).

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law commentary

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The year 2001 witnessed the culmination of a number of high profile cases against and inquiries into the misdeeds of two doctors, Dr Michael Bottrill and Dr Graham Parry. These cases call into question the effectiveness of the existing processes by which health professionals may be monitored and called to account. Ms Helen Cull QC, appointed by the Government towards the end of 2000 to review the processes for dealing with adverse medical events, reported her findings and recommendations in March 2001. This note will discuss the various processes against Dr Bottrill and Dr Parry and will then consider the changes recommended in the Cull Report.

The Processes Against Dr Bottrill

In 1995 Dr Bottrill was found to have misread and misreported the results of four cervical smears taken from Mrs A between 1990 and 1994. By the time Dr Bottrill finally reported high grade lesions, Mrs A had developed invasive cervical cancer requiring radical treatment. Her complaint led to a number of processes. The Medical Practitioners Disciplinary Tribunal found Dr Bottrill guilty of conduct unbecoming a medical practitioner and fined him $400.[1] Mrs A received accident compensation, but her claim in the High Court for exemplary damages failed, initially because there was no evidence at the time of the trial that Dr Bottrill was fundamentally incompetent.[2] When an external review of 23,000 of his slides revealed a very high error rate, Mrs A applied to re-try her claim for exemplary damages, but she failed again, this time because Dr Bottrill was not aware that he was doing anything wrong.

The Court of Appeal held by a majority of 4:1 that awards of exemplary damages were intended to punish and would be awarded only when there was a consciousness of wrongdoing.[3] There had to be evidence of either intentional wrongdoing or conscious risk taking. While the Court accepted that Dr Bottrill was grossly incompetent in reading and reporting cervical smears between 1990 and 1996, there was no evidence that he knew that he was misreading Mrs A's slides, thereby putting her at risk of harm. Thomas J dissented. In his view exemplary damages could in rare cases also be awarded when the defendant was not consciously aware of wrongdoing, but his or her conduct was so outrageous and contumelious as to deserve condemnation. He thought that Dr Bottrill could have been such a case.

As is apparent, the judges are not agreed on the functions of exemplary damages and for this reason leave to appeal to the Privy Council has been granted. The basis upon which exemplary damages can be awarded is of particular importance in New Zealand with its statutory ban on personal injury claims for compensation and the paltry sums available under the accident compensation scheme.[4] The Privy Council hearing is scheduled to take place on 23 March 2002.

Concerns raised during and after Mrs A's trial in 1999 prompted the Health Funding Authority to investigate the reading of cervical smears by Dr Bottrill's laboratory. Some 23,000 slides from 12,000 women were re-read by a laboratory in Sydney, which found an alarmingly high error rate (Health Funding Authority, 2001). A Ministerial Inquiry was set up, chaired by Ailsa Duffy QC, to investigate the under-reporting

of cervical smear abnormalities in the Gisborne region. The Inquiry found that there had been an unacceptable level of under-reporting by Dr Bottrill's laboratory in the period 1990-1996 (Duffy, 2001). A number of causes specific to Dr Bottrill's practice were identified, such as his failure to monitor his own performance by peer review or otherwise, and his disinclination to institute effective quality control measures. However, the reason that his high error rate continued undetected was in large part because of systemic flaws in the National Cervical Screening Programme (Duffy, 2001, 1.3). The absence of compulsory quality assurance and performance standards for laboratories reading cervical cytology and the failure routinely to monitor and evaluate all parts of the Programme's performance made the Programme defective. Because of these deficiencies in the Programme, the Committee could not exclude the possibility that unacceptable underreporting had occurred elsewhere in New Zealand (Duffy, 2001, 1.7).

Some of the problems identified by the Inquiry have since been addressed. However, a major obstacle to independent monitoring and evaluation of the Cervical Screening Programme is the requirement in s74A(5) of the Health Act 1956 that no information on the Cervical Screening Register that could identify the women be disclosed without their consent (Duffy, 2001, 9.1; Davidson *et al.*, 2001).[5] The Inquiry recommended that independent evaluation teams be given access to that information without the women's consent. There was considerable public opposition to that recommendation and on 3 October 2001 Cabinet agreed not to adopt it.[6] Charlotte Paul criticised this decision in a letter to the editor of the *New Zealand Medical Journal*, expressing concern that 'cervical screening will now become the most difficult service to audit' (Paul, 2002). Given the impracticality of obtaining consent from a large number of women and the adverse effect this is likely to have on the validity of an audit, her prediction is undoubtedly correct.

The Processes Against Dr Graham Parry

Meanwhile, there was another medical scandal unfolding in Northland, once again in the area of women's health. Close to death and frustrated by the delays in processing her complaint to the Health and Disability Commissioner, Colleen Poutsma went to the media with her story. Her diagnosis of invasive cervical cancer had been delayed because Dr Graham Parry, an obstetrician and gynaecologist, failed to investigate her fully when she was first referred to him with significant gynaecological problems. While there was no evidence to suggest that an earlier diagnosis would have saved Mrs Poutsma's life, she lost the chance that earlier intervention might have changed her prognosis.

Again, several processes were initiated. The Health and Disability Commissioner promptly attended to Mrs Poutsma's complaint and referred the matter to the Director of Proceedings.[7] The Medical Practitioners Disciplinary Tribunal found him guilty of disgraceful conduct and struck him off the Register. It also fined him $15,000, the highest fine ever imposed.[8] There was a great deal of publicity surrounding this case, including three *20/20* television programmes, which suggested that many more complaints were forthcoming. However, on appeal against the Tribunal's decision, the District Court found that the 'public hue and cry' about Dr Parry's conduct was not supported by the facts.[9] While his conduct in respect of Mrs Poutsma was disgraceful overall, his neglect was not deliberate and related only to his gynaecological practice. Nor was there any evidence of multiple complaints. At the time of the Court hearing only one further charge was proceeding before the Medical Practitioners Disciplinary Tribunal. The Court reduced the fine to $5000 and permitted Dr Parry to practise under supervision in his sub-specialties of obstetrics and ultrasound. This decision was upheld by the High Court.[10]

These two cases in particular highlighted concerns about the effectiveness of the existing processes in identifying incompetence and handling medical complaints. At the time the Government was considering replacing the existing 11 health occupational regulation Acts with one overarching statute to be called the Health Professionals' Competency Assurance Bill. To ensure that this Bill included appropriate processes for dealing with adverse medical events, the Government appointed Helen Cull QC to conduct a review of the existing processes and recommend legislative, regulatory or procedural changes which would ensure that adverse medical outcomes were identified and appropriate, timely remedial action was taken (Cull, 2001, p.6).

Cull Report

Ms Cull reported in March 2001. She concluded that the current complaints system was confusing, cumbersome, difficult to access and costly, both financially and emotionally (Cull, 2001, p.15). It also failed to detect repeated patterns of

adverse medical outcomes (Cull, 2001, p.22). She identified the following principal problems (Cull, 2001, pp.15-6):

- There was no streamlined approach to complaint mechanisms, with up to 14 agencies separately investigating the same adverse medical event.
- The time delays in undertaking complaint investigations were frustrating and burdensome. Complaints to the Health and Disability Commissioner, for instance, took on average between 18 months and 2 years to resolve and some disciplinary proceedings took even longer.
- There was no agency interaction or co-ordination to enable the disclosure of relevant information.
- The complaint mechanism was difficult for patients to access because of lack of knowledge, the way the complaint was treated and the failure of agencies to refer patients to the appropriate complaint mechanism.
- There was no centralised data base to detect repeated poor practice, nor were practitioners reporting colleagues who were practising below an acceptable standard.
- There was no power to suspend a practitioner prior to a charge being laid and during a process of investigation, even if a potential public risk was identified.
- Access by patients to compensation, either through ACC or to cost recovery and damages through the Complaints Review Tribunal, was unsatisfactory; and
- delays in processing ACC entitlements for medical misadventure were not meeting patient needs at the relevant time. They could take 12 to 15 months.

To redress these problems, Ms Cull recommended three immediate solutions. Her first solution was to require various agencies to report practitioners whose practice was below acceptable standard to the Health and Disability Commissioner and professional bodies. This has in part been addressed through new reporting provisions in the Injury Prevention, Rehabilitation, and Compensation Act 2001 which come into force on 1 April 2002.[11] They require the Accident Compensation Corporation to report a 'medical error' and permit it to report a 'medical mishap' to the relevant professional body and to the Health and Disability Commissioner.[12] The Corporation is also obliged to report to the relevant professional body any concerns it has about a registered health professional's competence. So, in effect, the Corporation is expected to monitor the performance of health professionals through accident compensation claims.

The draft Health Professionals' Competency Assurance Bill will also require employers and colleagues to report health professionals who are performing below an acceptable standard to the appropriate registering authority. Conversely, if the registering authority is aware that a health professional is putting the public at risk of harm, it will be obliged to inform the employer, ACC, the Health and Disability Commissioner and any other relevant parties.[13]

Ms Cull recommended two further immediate solutions. One was to remove barriers to disclosure of relevant health information by and to agencies in the interest of public health and safety so as to aid early detection of repeated adverse medical outcomes and concerns about competency. She suggested that the Health and Disability Commissioner's Office become a repository for information about medical errors, medical mishaps and guilty findings from the Disciplinary Tribunal and that it regularly audit that material to identify concerns about competence. Her second solution was to give the registering authority a power to suspend practitioners temporarily or to impose conditions on their practice prior to laying a charge before the Disciplinary Tribunal if they posed a risk to public safety. An amendment to this effect was being considered for the Medical Practitioners Act 1995, but presumably will now be included in the Health Professionals' Competency Assurance Bill.[14]

These recommendations significantly extend existing powers of the various agencies and should aid timely detection of incompetence. However, excessive and unwarranted use, particularly of discretionary powers in reporting medical mishaps, could have a corrosive effect on the health profession. It could lead to defensive medical practice and aggravate existing perceptions that the system is unduly harsh and punitive (Paterson, 2002). Such a result would be detrimental to society as a whole. A sensible approach by the agencies is therefore crucial to the success of this new system and the long term future of medical practice in New Zealand.

The Cull Report also suggested, as a long term solution, a 'one stop shop' for all complaints against health professionals. This proposal has found favour with the current Government and in August 2001 Cabinet agreed to include it in the draft Health Professionals' Competency Assurance Bill.[15] If the Bill is adopted in conformity with the agreed proposals, all complaints will go to the Health and Disability Commissioner

in the first instance, who will be responsible for making preliminary enquiries and determining what action, if any, is appropriate. Section 36 of the Health and Disability Commissioner Act will have to be amended to provide greater flexibility in dealing with complaints and to enable immediate referral to the Director of Proceedings or a registering authority if urgent action is required.

Cabinet also agreed with Ms Cull's recommendation that the various existing disciplinary tribunals be replaced with one Health Practitioners Disciplinary Tribunal and that the same disciplinary processes apply to all health professionals. This reform will also be incorporated into the Health Professionals' Competency Assurance Bill. The Tribunal will be chaired by a barrister or solicitor of the High Court with three practitioners from the same profession as the practitioner under investigation and three non-health professionals. Ms Cull's recommendation that the Tribunal be chaired by a judge was rejected by Cabinet. There will be six disciplinary grounds for all health professionals: malpractice, professional misconduct, conviction of an offence against a health-related Act, conviction of a serious offence, practice outside the scope of permitted practice and breaching an order of the Health Practitioners Disciplinary Tribunal. It is proposed that the processes and penalties will be similar to the Medical Practitioners Act 1995 with some modifications. The Complaints Assessment Committee, for instance, will be given investigative powers and be renamed the Complaints Investigation Committee; and the maximum fine will be $30,000, rather than $20,000.

It is further proposed that the registering authorities will be empowered to review the competence of health professionals and be required to do so if they receive notification from bodies, such as ACC and the Health and Disability Commissioner's office, that there are reasonable grounds for concern.

The Health Professionals' Competency Assurance Bill has yet to be introduced into Parliament and changes may well be made. There is some opposition to the proposed reforms from health professional bodies. However, this Bill also provides significant improvements for health professionals over the existing processes. While the Cull Report was concerned primarily with consumer dissatisfaction, many of the problems identified are equally unsatisfactory for health professionals. Multiple investigations into the same adverse event and lengthy time delays are stressful and burdensome for consumers and health professionals alike. Moreover, they are detrimentally affecting the relationship between patients and health professionals. As the Health and Disability Commissioner recently acknowledged:

> In some cases the way in which current complaint mechanisms are working, and complaints, inquiries and disciplinary hearings are being reported in the media, is undermining the essential trust between patients and doctors (Paterson, 2002).

If the proposed streamlined approach is properly resourced and sensibly implemented, it may go some way to rebuilding patient confidence and restoring the essential trust between patients and health professionals.

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Notes

1. This case was decided in 1997 under the old Medical Practitioners Act 1968 when the maximum penalty was $1000.
2. High Court Auckland, CP 310/96, 28 March 1999, Young J.
3. [2001] 3 NZLR 622.
4. Injury Prevention, Rehabilitation, and Compensation Act 2001, ss317-319; and the Accident Insurance Act 1998, ss 319 & 396.
5. Ibid at 9.1.
6. Cabinet Minute: National Cervical Screening Programme: Law Changes to Support Audit, Monitoring and Evaluation, CAB Min (01)27/17.
7. Opinion 98 HDC 13810.
8. *Director of Proceedings v Parry*. Medical Practitioners Disciplinary Tribunal, Decision No 139/00/62D, 31 October 2000.
9. *Parry v Medical Practitioners Disciplinary Tribunal.* Auckland District Court, NP4412/00, 10 May 2001, Hubble D C J.
10. High Court Auckland, AP61-SW01, 15 October 2001. Paterson J.
11. Sections 284 and 285.
12. 'Medical error' means the failure of a registered health professional to observe a standard of care and skill reasonably to be expected in the circumstances: s 33 Injury Prevention, Rehabilitation, and Compensation Act 2001. 'Medical mishap' means an adverse consequence of treatment given properly by or at the direction of a registered health professional which is both rare and severe: s34.
13. Health Professionals' Competency Assurance Bill, CAB (01) M 15/1, para 4.10 and 26.
14. Ministry of Health, Health Professionals' Competency Assurance Bill – Discussion Paper (2000) p.16.
15. Memorandum to Cabinet Committee on Education and Health, Health Professionals' Competency Assurance Bill, EHC Min (01) 9/8.

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