

# Current Developments in New Zealand Health Law

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The legal framework governing health care in New Zealand is similar in many respects to that in Canada and other common law jurisdictions. There are however, some important differences, which are of interest from both an academic and a practical perspective. In addition, New Zealand health law is in the midst of an especially dynamic period, with legislative reforms recently undertaken or on the horizon in a number of areas. This paper will briefly describe a few of the more significant current developments, aiming to highlight features that are unique to New Zealand or otherwise of particular interest.

## **1. Context: The New Zealand health care system and legal system**

The health care system in New Zealand is composed of a comprehensive public system much like Canada's, but unlike in Canada a parallel system of private insurance and private clinics and hospitals exists alongside the public system. The public system is administered by 21 District Health Boards (DHBs), reporting to and receiving funding from the Ministry of Health. The DHBs are generally responsible for planning and providing services for the population of a specific area, though the Ministry retains a degree of direct involvement in some areas including mental health and public health.<sup>1</sup>

There are a few significant differences between the New Zealand and Canadian legal systems that are relevant to health care. First, unlike Canada and neighbouring Australia, New Zealand is a unitary jurisdiction with no provinces or territories, so there is no division of powers and national legislation regulates health care throughout the country. A

further difference is the lack of a written constitution or a constitutional charter of rights. The *New Zealand Bill of Rights Act 1990*<sup>2</sup> includes many of the same rights as the *Canadian Charter of Rights and Freedoms*, but has only the status of ordinary legislation and gives way to an inconsistent provision in another statute.<sup>3</sup> As well as the rights to life and liberty, the Bill of Rights includes explicit rights "not to be subjected to medical or scientific experimentation without ... consent" and "to refuse to undergo any medical treatment."<sup>4</sup>

Apart from these differences in general public law, the most striking – and probably the best known – feature of the New Zealand legal system that is relevant to health law is the existence of a no-fault compensation system for personal injuries due to accident. A brief discussion of this scheme as it applies to "medical misadventure" will be discussed in the next section. Before turning to that topic, one important institution should be mentioned: the Health and Disability Commissioner (HDC). The HDC was created in response to the report of the Cartwright Inquiry,<sup>5</sup> a committee of inquiry established in 1987 following public outcry about a research study undertaken at the National Women's Hospital in Auckland. From 1966 to the mid-1980s, women at the hospital were subjected to repeated cervical smear tests and biopsies without being offered adequate treatment, in order to test a theory that carcinoma in situ was not a precursor of invasive cervical cancer, as was (and still is) the prevailing view. The great majority of women were not informed that they were participating in a research study, and it appeared that obvious symptoms of invasive cancer were overlooked or downplayed. Following protests by members of the medical community and the public, a committee of inquiry was established, led by Justice Silvia Cartwright.<sup>6</sup>



Among the recommendations of the inquiry was the need to appoint a Health Commissioner to receive and investigate complaints and raise health professionals' awareness of patients' rights, and the need to develop a statement of patients' rights. In 1994, the office of the HDC was established,<sup>7</sup> and the Code of Health and Disability Services Consumers' Rights (the Code) was enacted as a regulation in 1996.<sup>8</sup> This Code includes the right to be treated with respect; to freedom from discrimination, coercion, harassment and exploitation; to dignity and independence; to services of an appropriate standard; to effective communication; to be fully informed; to make an informed choice and give informed consent; to support; and to complain about a health or disability service provider.<sup>9</sup> These rights incorporate the essential common law principles of medical negligence, consent, and informed consent as well as other basic rights. In the event of a complaint, the onus is on providers to show that they took "reasonable actions in the circumstances" to give effect to these rights.<sup>10</sup> Any person may complain to the HDC of an alleged breach of the Code,<sup>11</sup> and the Commissioner may commence an investigation either in response to a complaint or on his own initiative.<sup>12</sup> Complaints may also be referred to the HDC from health professional bodies, in which case proceedings by those bodies will be suspended pending the Commissioner's investigation.<sup>13</sup> If a breach of the Code is found, the Commissioner may make recommendations to the provider; report his opinion to the health professional body, Minister, or other appropriate person; make a complaint to a health professional body (or assist the individual in making a complaint); or refer the matter to the Director of Proceedings.<sup>14</sup> The Director of Proceedings may then provide assistance or representation to a complainant in disciplinary proceedings, or institute proceedings before the Human Rights Review Tribunal or disciplinary proceedings.<sup>15</sup> If the matter goes to the Human Rights Review Tribunal, the Tribunal has the power to declare a breach of Code and order any appropriate relief.<sup>16</sup> The HDC framework therefore combines some of the advantages of the ombudsman model – providing relatively simple, accessible, flexible, and speedy procedures for the resolution of complaints – with more extensive powers, where appropriate, to provide an important independent accountability mechanism for health care in New Zealand.

## 2. The ACC framework and "medical misadventure"

Originally established by the *Accident Compensation Act 1972*, the accident compensation scheme has been revised several times and is now governed by the *Injury Prevention, Rehabilitation, and Compensation Act 2001*.<sup>17</sup> The scheme is administered by the Accident Compensation Corporation

(ACC; formerly Accident Compensation Commission) and is funded by premiums paid by employers and employees as well as a variety of other sources including some direct payment from government. It provides no-fault insurance for personal injury caused by accidents (including, but not exclusively, motor vehicle accidents), occupational conditions and diseases, and "medical misadventure."<sup>18</sup> A claimant who is covered by the Act may be eligible to receive rehabilitation (including medical treatment) as well as weekly or lump sum compensation.<sup>19</sup> The Act bars court proceedings for damages arising directly or indirectly from personal injury that is covered by the scheme,<sup>20</sup> so it is not possible to sue for damages in addition to or instead of claiming under the Act. The exception to this is claims for exemplary damages,<sup>21</sup> but the courts have insisted that exemplary damages will only be awarded in exceptional cases, are not intended to be compensatory, and are not to be used to remedy any perceived inadequacy of ACC entitlements.<sup>22</sup>

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Personal injury caused by "medical misadventure" is among those covered under the Act, and includes personal injury suffered by someone seeking or receiving treatment by or at the direction of a registered health professional.<sup>23</sup> Abnormal reactions and complications, as well as injuries suffered in the context of a clinical trial, are included only if certain conditions are met.<sup>24</sup> Cover extends to a third party such as a spouse or child who is infected as a result of infection caused by medical misadventure.<sup>25</sup> In all cases, only personal injury *caused by* medical misadventure is covered, so causation must be established. It is up to the claimant to prove causation; the fact that medical misadventure *might have* contributed to the injury is not sufficient to establish a claim.<sup>26</sup>



Medical misadventure may consist of either “medical mishap” or “medical error.”<sup>27</sup> Medical mishap refers to a severe, rare adverse consequence of treatment that was properly given.<sup>28</sup> Medical error, by contrast, is essentially medical negligence: “the failure of a registered health professional to observe a standard of care and skill reasonably to be expected in the circumstances.”<sup>29</sup> It can include a similar failure by an organisation where “the error cannot readily be attributed to a particular registered health professional.”<sup>30</sup> The statute specifies that medical error can arise in the course of diagnosis, giving treatment, deciding about treatment, or obtaining consent to treatment.<sup>31</sup> Failure to obtain adequate informed consent for a procedure can therefore fall within the scope of medical error under the Act.<sup>32</sup> As with a common law negligence action, the fact that the desired results were not achieved or that in retrospect it seems a different decision might have produced better results will not be sufficient to establish medical error; furthermore, a delay or failure attributable to a resource allocation decision does not in itself amount to medical error.<sup>33</sup>

Though the ACC scheme otherwise operates as a “no-fault” scheme, its coverage for injuries caused by medical error is clearly fault-based insofar as it requires evidence of negligence. Concern about this anomaly is one of the reasons behind a current review of medical misadventure within the ACC scheme. The need to establish fault for this category of cover is seen as creating a number of problems for health professionals, patients, and the ACC, including perpetuating a “blaming culture” which in turn inhibits improving patient safety, delays in cover decisions, and the significant cost of investigating medical error claims.<sup>34</sup> In essence, having a negligence-based standard for medical error embedded within the ACC scheme means that this part of the scheme fails to avoid many of the problems with private litigation that the no-fault system was intended to avoid. In addition, some consider the provisions on medical mishap to be problematic in that the requirements of rarity and severity are confusing and arbitrary.<sup>35</sup>

A public consultation process held in 2003 strongly supported the need for reform.<sup>36</sup> Three options were put forward for consideration, all of which would remove requirement of the attribution of fault for medical error.<sup>37</sup> The first option would modify the existing definitions of medical mishap and medical error, replacing the rarity criterion for medical mishap with an “individualised risk assessment” and requiring only some (unattributed) fault factors for medical error.<sup>38</sup> It seems unlikely that this option would adequately resolve the problems identified with the current definitions.

The second and third options would replace the existing provisions with a single category of “preventable” (option two) or “unintended” (option three) injuries in the treatment process.<sup>39</sup> Although they would likely expand the pool of potentially eligible claimants somewhat, all of these options are still intended to provide some way of distinguishing between, on the one hand, unintended adverse outcomes, and on the other hand, the underlying illness or condition, or treatment outcomes that are intended but might otherwise fall within the definition of “personal injury by accident” under the Act (e.g. the “injury” caused by an invasive procedure such as surgery).<sup>40</sup> The third option, “unintended injury in the treatment process”, was preferred in the consultation process,<sup>41</sup> and a subsequent document from ACC responds with two further options mixing concepts of preventability, adverse consequences, unintended injury and seriousness.<sup>42</sup> The task of defining the category of injuries that should be covered in a way that is practical, fair, conceptually coherent, and yet not unduly complex, is a challenging one. This discussion will clearly be of interest to any jurisdiction contemplating a similar compensation scheme, as well as, more generally, to those concerned with the law’s response to adverse events.

### **3. Health Practitioners Competence Assurance Act 2003**

As in other jurisdictions, an important part of the accountability framework for health professionals is the operation of professional bodies with statutory authority over the registration, competence, and discipline of practitioners. Until very recently, this statutory authority was provided by eleven discipline-specific statutes, but in late 2003 the *Health Practitioners Competence Assurance Act 2003*<sup>43</sup> (HPCAA) was enacted to bring the regulation of health professionals under a single legislative framework. The HPCAA will come into force in stages over one year from the date of royal assent (18 September 2003), replacing all or part of the pre-existing health professions statutes.<sup>44</sup> This reform was intended to increase consistency, transparency, and efficiency, and to update the legislative framework.<sup>45</sup>

Although the legislation currently applies to existing health professions that were regulated by previous statutes, it also leaves open the possibility for new regulated professions to be recognised and regulated under this Act. Where health services of a particular kind pose a risk of harm to the public or where it is otherwise in the public interest that they be regulated, and where there is general agreement on the qual-



ifications, standards, and competencies required to provide those services, they may be designated as a health profession to be regulated under the Act by a newly appointed authority or an existing authority.<sup>46</sup> Separate “authorities” for each profession, continued from the bodies in existence under the earlier statutes or created under the new statute,<sup>47</sup> will be responsible for registration, practising certificates, and oversight of competence and fitness to practise. However, there will be a single Health Practitioners Disciplinary Tribunal to deal with disciplinary matters involving members of any of the regulated professions. Complaints about conduct will be considered first by the HDC (as described above), then, if appropriate, by the professional conduct committee of the relevant authority. If further action is warranted, charges will be brought by the Director of Proceedings (of the HDC office) or the professional conduct committee before the Tribunal. If the Tribunal finds professional misconduct or other grounds,<sup>48</sup> it can order that the practitioner’s registration be cancelled or suspended, that conditions be imposed on his or her practice, that the practitioner be censured, or that the practitioner pay a fine or costs and expenses.<sup>49</sup>

There are several notable features of this legislation, some of which have been quite controversial. The development of the legislation and responses to it have highlighted perceived tensions between “the demands of public safety” and a desire for increased regulation and accountability on one hand and professional autonomy and self-regulation on the other.<sup>50</sup> Health professions groups such as the New Zealand Medical Association (NZMA) were (and remain) concerned that the new legislation undermines professional self-regulation.<sup>51</sup> For example, the legislation provides for members of the authorities to be appointed by the Minister of Health (rather than being elected by members of the profession),<sup>52</sup> and these authorities will then have powers over registration and oversight as well as setting standards of “clinical competence, cultural competence, and ethical conduct.”<sup>53</sup> Pressure from professional groups resulted in some changes at the Committee stage, such as increases in the professional membership (at the expense of lay membership) of the Health Practitioners Disciplinary Tribunal and the authorities.<sup>54</sup> Nevertheless, according to the NZMA, several aspects of the legislation reflect increased “political and bureaucratic control” of health professions and diminish

self-regulation.<sup>55</sup> Consequently, the legislation was opposed by the NZMA and the Association of Salaried Medical Specialists (ASMS); significantly, “this is the first time both the NZMA and the ASMS have withdrawn their support from the principal legislation governing medical practice.”<sup>56</sup>

Another contentious aspect of the HPCAA is the use made of the concept of “scopes of practice.” These will define “the services a practitioner is competent to offer, and the parameters within which those services can be offered.”<sup>57</sup> Each authority will be responsible for defining one or more scopes of practice for its profession and the qualifications required for each.<sup>58</sup> It is contemplated that scopes of practice of various professions may overlap and any dispute over scopes of practice, if it cannot be resolved, will be determined as directed

by the Minister.<sup>59</sup> Health practitioners registered with a particular authority will be authorised to practice within one or more scopes of practice, which will be endorsed, if appropriate with amendments or conditions, on the practitioners’ annual practising certificates; practitioners are then prohibited from practising outside their scope(s) of practice.<sup>60</sup> Scopes of practice are intended to be broad,<sup>61</sup> but there are concerns that they will in effect be narrow and restrictive.<sup>62</sup> These concerns are exacerbated by the fact that although scopes of practice had been defined within the pre-existing professional bodies, they have never before been codified in legislation, and legislated scopes of practice are a relatively new and untested concept that has not been the subject of a great deal of study or discussion.<sup>63</sup>

The legislation is currently being implemented and is scheduled for review in three years.<sup>64</sup> It will be important to monitor and assess the functioning of the legislative framework and the impact of new provisions such as the scopes of practice, in order to determine whether the vocal criticisms of the legislation by the NZMA and others are justified.

#### **4. Joint trans-Tasman Therapeutic Products Agency**

While the framework for the regulation of health professions is undergoing these changes, a new regime for regulating therapeutic products is also on the horizon. On 10

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December 2003, Australia and New Zealand signed a treaty providing for the creation of a joint agency to regulate therapeutic products.<sup>65</sup> The agency, which is expected to be in operation by 2005, will replace the existing Australian Therapeutic Goods Administration and New Zealand Medicines and Medical Devices Safety Authority (Medsafe), and administer a joint regulatory scheme.<sup>66</sup> There is already a significant amount of regulatory cooperation between the two countries, which has developed within the framework of the Agreement on Closer Economic Relations (CER),<sup>67</sup> including the Trans Tasman Mutual Recognition Arrangement (TTRA), which allows goods from either country to be traded in the other without regulatory impediments – a scheme from which therapeutic products are currently exempt.<sup>68</sup> As well as effectively extending mutual recognition to therapeutic products, the joint scheme contemplated under the treaty represents an unprecedented degree of regulatory integration – between Australia and New Zealand, or indeed, it is believed, between any two countries in the world.<sup>69</sup> For this reason and on account of a number of other features of the proposed scheme, this development is significant.

Development of a joint scheme was initiated several years ago, as part of the general movement toward greater integration and harmonisation but also as a result of specific concerns about the ability of New Zealand to sustain an effective independent regulatory scheme, particularly as therapeutic products become more complex, given the shortage of local technical expertise.<sup>70</sup> The treaty envisages the establishment of a joint scheme for regulation, standard-setting, post-market monitoring, and enforcement, to be administered in both countries by a single joint agency (“the Agency”).<sup>71</sup> Approvals granted by the Agency will normally have effect in both countries.<sup>72</sup> A Ministerial Council and a Board, both with representation from each country, will be responsible for oversight and governance of the Agency, respectively.<sup>73</sup> The Agency will be established as a corporate body under Australian legislation, and will be given the rights, powers, and privileges required to administer the scheme in both countries by their respective implementing legislation.<sup>74</sup> What this means is that an Australian

corporate entity will be given the authority, by New Zealand legislation, to set *and enforce* standards within New Zealand. This represents a step beyond, for example, the current scheme for food standards, in which standards are set by a joint agency (Food Standards Australia New Zealand) but then these standards (the Australia New Zealand Food Standards Code) are incorporated into New Zealand legislation and enforced by New Zealand authorities.<sup>75</sup> How this unprecedented scheme for therapeutic products will work in practice will not be fully understood until the implementing legislation is drafted.

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In its report on the proposed scheme, the Health Committee had advised caution with respect to regulatory integration and preferred a mutual recognition model (similar to the food standards scheme).<sup>76</sup> It expressed particular concerns about the inclusion of complementary health products in the joint scheme, and this has emerged as its most controversial aspect.<sup>77</sup> The scheme pro-

vided for in the treaty applies to all therapeutic products unless specifically excluded, and therapeutic products are broadly defined to include anything “presented or for any other reason, likely to be taken to be for therapeutic use.”<sup>78</sup> Complementary health products would clearly seem to fall within this scope unless they are specifically excluded.<sup>79</sup> The controversy surrounding this feature of the scheme stems from the fact that the existing approach to complementary health products in New Zealand is best described as a “permissive, laissez faire system” which in practice amounts to deregulation,<sup>80</sup> as opposed to the more rigorous Australian regime. The new joint scheme appears essentially to adopt the Australian approach of integrating the regulation of complementary products into a single scheme with other therapeutic products. The different approaches reflect distinct views on the regulation of complementary medicine, but the immediate practical concern is the impact of the proposed change on the New Zealand complementary health products industry.<sup>81</sup>

Although the issue of regulating complementary medicines under this scheme has been the primary focus of press attention, there are other important questions about its implications. One of these is the treatment of therapeutic products



advertising under the joint scheme. Regulation of advertising falls within the joint scheme and the Agency's mandate, as part of setting and enforcing standards for "promotion of therapeutic products."<sup>82</sup> This is another area in which the two countries currently have different approaches, so harmonisation will mean change for one or both of them. New Zealand presently has a voluntary self-regulatory system for all advertisements making therapeutic claims, while Australia regulates advertisements in certain media and relies on self-regulation for other media and advertisements to health professionals.<sup>83</sup> Although the New Zealand scheme is generally thought to be effective, both have experienced some problems.<sup>84</sup> It is proposed under the new joint arrangements that advertising to health professional continue to be self-regulated by industry codes of practice, but that a regulatory scheme for direct-to-consumer advertising will be developed.<sup>85</sup> An Interim Advertising Council has been established to develop the new regime, including a draft advertising code for therapeutic products.<sup>86</sup> As the controversy continues surrounding therapeutic products advertising, particularly direct-to-consumer advertising, and the regulation of complementary health products, it will be worth following these developments.

## 5. Conclusion

The health law environment in New Zealand is in a particularly dynamic phase: in addition to the developments described above there are ongoing or forthcoming changes to public health legislation and screening programs,<sup>87</sup> regulation of human assisted reproduction technologies,<sup>88</sup> and compulsory care and rehabilitation for intellectually disabled offenders.<sup>89</sup> This evolving legal framework presents rich opportunities for comparative studies of health law. It is hoped that a further exchange of information and ideas will be useful in this complex and challenging area of the law.

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## Notes

1. The respective responsibilities of the Ministry, the DHBs, and other entities are set out in the *New Zealand Public Health and Disability Act 2000*, No. 91.

2. 1990 No.109.
3. *Ibid.*, s. 4.
4. *Ibid.*, ss. 10, 11.
5. *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* (Auckland: Government Printing Office, 1988). The information about the events and recommendations as stated here is summarised from this report.
6. As she then was (now Dame Silvia Cartwright, Governor-General of New Zealand).
7. *Health and Disability Commissioner Act 1994*, No. 88.
8. *Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996*, SR 1996/78.
9. *Ibid.*, s. 2 (Rights 1-8, 10). These rights apply equally when a consumer is participating or proposed to participate in teaching or research (*ibid.*, Right 9).
10. *Ibid.*, s. 3.
11. *Health and Disability Commissioner Act 1994*, *supra* note 7, s. 31.
12. *Ibid.*, s. 35(2). The Commissioner may decide to take no action on a complaint in some situations: s. 37.
13. *Ibid.*, ss. 33, 39.
14. *Ibid.*, s. 45. In addition, in the event of a significant breach or misconduct, the Commissioner "shall refer the matter to the appropriate person or authority" (s. 48).
15. *Ibid.*, s. 45(f).
16. *Ibid.*, s. 54. This may include an order restraining the defendant from certain conduct or compelling the defendant to perform any acts to redress loss or damage suffered (s. 54), or an award of damages (s. 57, excluding an award for personal injury other than punitive damages: s. 52(2)). Potential orders following disciplinary proceedings are outlined below at note 50.
17. 2001 No. 49 [IPRCA].
18. See *ibid.*, ss. 20-24 for details of injuries covered under the Act.
19. *Ibid.*, s. 69.
20. *Ibid.*, s. 317. Note that the bar on proceedings applies regardless of whether the potential claimant actually lodges a claim or whether he or she actually receives any entitlement under the Act: s. 317(7).
21. *Ibid.* s. 319. Claims by "secondary victims" such as family members or others affected by the injury, but who have not themselves suffered a covered injury, are also allowed: *Queenstown Lakes District Council*



- v. *Palmer* [1999] 1 NZLR 549 (CA); *van Soest v. Residual Health Management Unit* [2000] 1 NZLR 179 (CA).
22. See *A. v Bottrill*, [2003] 1 AC 449 (PC) at para. 64.
  23. IPRCA, *supra* note 17, s. 32(1)(a). A “registered health professional” is defined in s. 6.
  24. *Ibid.*, s. 32(2)-(5).
  25. *Ibid.*, s. 32(6).
  26. *Atkinson v Accident Rehabilitation Compensation and Insurance Corporation*, [2002] 1 NZLR 374 (CA). This case considered the wording of a previous statute; the need to prove causation is even clearer under the current wording.
  27. IPRCA, *supra* note 17, s. 32(1).
  28. *Ibid.*, s. 34(1). Subsections (2) and (3)-(5), respectively, define what is meant by severe and rare in these circumstances.
  29. *Ibid.*, s. 33(1).
  30. *Ibid.*, s. 33(2).
  31. *Ibid.*, s. 33(3).
  32. Strictly speaking, it would seem that only a failure to obtain informed consent (i.e. to disclose the information required prior to obtaining consent), which the common law would treat as negligence, should be covered here and not a failure to obtain a valid consent (i.e. voluntary, competent, and specific consent), which the common law would treat as battery; in practice, however, both types of situation seem to be dealt with under this provision. See e.g. Caroline Henckels, “Consent Error Claims” (ACC Medical Misadventure Report, November 2002), online: ACC <<http://www.acc.co.nz/for-providers/resources/medical-misadventure-unit-reports/informed-consent.pdf>> (date accessed: 15 January 2004).
  33. IPRCA, *supra* note 17, s. 33(4).
  34. Accident Compensation Corporation, “Review of ACC Medical Misadventure: Consultation Document” (2003), online: ACC <<http://www.acc.co.nz/for-providers/news-for-providers/consultation-bk.pdf>> (date accessed: 15 January 2004) at 11. The impact on health professionals is compounded by the fact that the ACC is required (by s. 284 of the Act) to report medical error to the relevant professional body and to the Health and Disability Commissioner: *ibid.*
  35. *Ibid.*
  36. Accident Compensation Corporation and the Department of Labour, “Summary of ACC Medical Misadventure Consultation” (2003), online: ACC <<http://www.acc.co.nz/for-providers/news-for-providers/final-report-medical-mis-consultation.doc>> (date accessed: 15 January 2004) at 6.
  37. Accident Compensation Corporation, “Review of ACC Medical Misadventure: Consultation Document”, *supra* note 34 at 13.
  38. *Ibid.* at 16.
  39. *Ibid.* at 18-21.
  40. *Ibid.* at 13.
  41. Accident Compensation Corporation and the Department of Labour, *supra* note 36 at 6. 60% of those consulted chose option 3; option 2 was the second preferred option: *ibid.*
  42. Accident Compensation Corporation, “Review of ACC Medical Misadventure: Feedback Document” (11 November 2003), online: <<http://www.acc.co.nz/for-providers/news-for-providers/feedback?doc.pdf>> (date accessed: 15 January 2004). The first option in this new document uses preventability, adverse consequences, and seriousness; the second uses unintended injury and seriousness (*ibid.* at 7, 10). The seriousness criteria have been further developed to include both fixed levels of seriousness and a measure of “relative seriousness” as compared to the expected treatment outcome (*ibid.* at 6). Subsequently, on 16 March 2004, the Minister for ACC announced that legislation to amend the scheme will be introduced in mid-year, with medical misadventure being replaced by a category called “treatment injury”, apparently without a seriousness threshold: Hon. Ruth Dyson, Minister for ACC, Media Statement, “‘Treatment injury’ to replace ACC medical misadventure” (16 March 2004).
  43. 2003 No. 48 [HPCAA].
  44. *Ibid.*, s. 2.
  45. New Zealand Ministry of Health, *Health Professionals’ Competency Assurance Bill Discussion Paper* (Wellington: Ministry of Health, 2000) [*HPCA Discussion Paper*] at 3. Although the *Medical Practitioners Act 1995* was quite a recent enactment (and used as a model for the new bill), some of the other statutes dated back to the late 1940s or to the 60s or 70s.
  46. HPCAA, *supra* note 43, ss. 115-16.
  47. *Ibid.*, s. 114. Schedule 2 lists the bodies continued as authorities under the new legislation.
  48. *Ibid.*, s. 100. Grounds for discipline include professional misconduct because of an act or omission that amounts to negligence or malpractice or brings discredit to the profession, conviction of an offence reflecting adversely on fitness to practise, practising without a current certificate, performing a service



outside of his or her scope of practice (see the discussion of scopes of practice below), failure to observe conditions on his or her scope of practice, or breach of an order of the Tribunal.

49. *Ibid.*, s. 101(1).
50. Health Committee, *Health Practitioners Competence Assurance Bill, As reported from the Health Committee: Commentary* (16 May 2003) [*HPCAA Commentary*] at 2-3.
51. See e.g. New Zealand Medical Association, "Submission to the Health Select Committee on the Health Practitioners Competence Assurance Bill" (27 November 2002), online: <<http://www.nzma.org.nz/news/issues/issues.html>> (date accessed: 27 January 2004); New Zealand Nurses Association et al., "The Health Practitioners Competence Assurance Bill (HPCA)" (Joint submission) (no date), online: <<http://www.nzma.org.nz/news/issues/issues.html>> (date accessed: 27 January 2004); Tricia Briscoe, "The HPCA Act – back to the future" (2003) 116:1183 NZMJ 621.
52. HPCAA, *supra* note 43, s. 120. There is, however, provision for regulations to be made allowing one or more members to be elected: s. 120(4).
53. *Ibid.*, s. 118(i). For criticism of this provision and other examples, see New Zealand Medical Association, *supra* note 51 at 16 and 4-5, respectively.
54. Health Committee, *HPCAA Commentary*, *supra* note 50 at 5-6. Health professionals now comprise the majority of the Tribunal and the authorities.
55. New Zealand Medical Association, *supra* note 51 at 4-5; Briscoe, *supra* note 51 at 621.
56. Briscoe, *supra* note 51 at 621.
57. New Zealand Ministry of Health, *HPCA Discussion Paper*, *supra* note 45 at 10.
58. HPCAA, *supra* note 43, ss. 11, 12.
59. *Ibid.*, ss. 127-28.
60. *Ibid.*, ss. 21, 32, 29, 8(2). There is an exception for services performed in an emergency or as part of training, instruction, examination, assessment or competence review: s. 8(3).
61. New Zealand Ministry of Health, *HPCA Discussion Paper*, *supra* note 45 at 10; Health Committee, *HPCAA Commentary*, *supra* note 50 at 3.
62. Health Committee, *HPCAA Commentary*, *supra* note 50 at 3; Briscoe, *supra* note 51 at 621; New Zealand Nurses Association et al., *supra* note 51 at 4.
63. New Zealand Medical Association, *supra* note 51 at 5. According to this submission, "an Official Information request of the Ministry of Health in respect of discussion papers on the issue of scopes of practice revealed that no serious internal discussion or debate has taken place" (*ibid.*). See also Health Committee, *HPCAA Commentary*, *supra* note 50 at 3, 13. This commentary notes that the only place the concept of legislated scopes of practice has been trialled is in British Columbia (*ibid.* at 13).
64. HPCAA, *supra* note 43, s. 171.
65. *Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products*, 10 December 2003 [JTA Treaty].
66. Annette King & Trish Worth, Joint Media Statement, "Australia and New Zealand Sign Treaty to Regulate Medicines & Therapeutic Products" (10 December 2003).
67. *Australia New Zealand Closer Economic Relations Trade Agreement*, 28 March 1983.
68. Therapeutic Goods Administration (Australia) and Medsafe (New Zealand), *Proposal for a Trans Tasman Agency to Regulate Therapeutic Products: Discussion Paper* (June 2002), online: Trans-Tasman Therapeutic Products Agency Project <<http://www.jtaproject.com/Downloads/Key%20Documents/june02.pdf>> (date accessed: 28 January 2004) at xviii.
69. King & Worth, *supra* note 66; Health Committee, *Inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products: Report of the Health Committee* (9 December 2003) [*Trans-Tasman agency report*] at 41.
70. Therapeutic Goods Administration (Australia) and Medsafe (New Zealand), *Proposal*, *supra* note 68 at xviii, xxi.
71. JTA Treaty, *supra* note 67, articles 3, 5.
72. *Ibid.*, article 11(3). Differential effect or departure from the joint scheme are provided for in "exceptional circumstances" where certain conditions are satisfied: articles 11(4), 12.
73. *Ibid.*, articles 4, 6. The Ministerial Council will have the authority to make "Rules" (the equivalent of regulations) on a broad range of matters, which will have effect in each country under that country's implementing legislation after being published in its official Gazette (article 9).
74. *Ibid.*, article 5(4)-(5).
75. Food standards are issued under the *Food Act 1981*, No. 45; the New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002, which incorporate the joint standards, are one such standard. On the difference between the two schemes, see



- Health Committee, Trans-Tasman agency report, *supra* note 69 at 41.
76. Health Committee, *Trans-Tasman agency report*, *supra* note 69 at 41-43, 47-48. The treaty was signed only one day after this report was released, which in itself caused some controversy and raised questions about democratic process.
77. See e.g. Ruth Berry, "Parties band against Government" *The New Zealand Herald* (11 December 2003), online: The New Zealand Herald <<http://www.nzherald.co.nz/storyprint.cfm?storyID=3538835>> (date accessed: 11 December 2003).
78. JTA Treaty, *supra* note 65, article 2. Therapeutic use, which is the key part of this definition, is also broadly defined (*ibid.*) to include:
- (i) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in humans;
  - (ii) influencing, inhibiting or modifying a physiological process in humans;
  - (iii) testing the susceptibility of humans to a disease or ailment;
  - (iv) influencing, controlling or preventing conception in humans;
  - (v) testing for pregnancy in humans; or
79. There is provision for certain products to be excluded from the scheme by Rule or by Order: *ibid.*, articles 9(1)(p), 10(2).
80. Health Committee, *Trans-Tasman agency report*, *supra* note 69 at 41.
81. See e.g. Kevin Taylor, "Outrage over pills law" *The New Zealand Herald* (8 December 2003), online: The New Zealand Herald <<http://www.nzherald.co.nz/storyprint.cfm?storyID=3538181>> (date accessed: 11 December 2003); Health Committee, *Trans-Tasman agency report*, *supra* note 69 at 26&ff.
82. JTA Treaty, *supra* note 65, articles 3(1)(a) and 5(2)(a). Promotion is specifically defined to include advertising: *ibid.*, article 1.
83. Toogoolawa Consulting Pty Ltd, *Report of a Review of Advertising Therapeutic Products in Australia and New Zealand* (November 2002), online: Therapeutic Goods Administration (Australia) <<http://www.tga.health.gov.au/docs/pdf/advrev.pdf>> (date accessed: 27 January 2004) at 8-9.
84. *Ibid.*
85. Therapeutic Goods Administration (Australia) and Medsafe (New Zealand), *Proposal*, *supra* note 68 at 144-45. See Toogoolawa Consulting Pty Ltd., *supra* note 83 at 28ff for detailed recommendations on the proposed joint scheme for advertising.
86. Australia New Zealand Therapeutic Products Advertising Code (Draft, Version 7; December 2003), online: Therapeutic Goods Administration (Australia) <[http://www.tga.health.gov.au/tta/advttcode\\_v7.pdf](http://www.tga.health.gov.au/tta/advttcode_v7.pdf)> (date accessed: 27 January 2004).
87. See e.g. New Zealand Ministry of Health, *Public Health Legislation: Promoting public health, preventing ill health and managing communicable diseases: Discussion Paper* (Wellington: Ministry of Health, 2002); *Health (National Cervical Screening Programme) Amendment Bill*, No. 214-2. This Bill, which received second reading on 2 December 2003, responds to recommendations made by another inquiry concerning cervical cancer, this one investigating the underreporting of cervical cancer in the Gisborne region: A. P. Duffy, D. K. Barrett & M. A. Duggan, *Report of the Ministerial Inquiry into the Underreporting of Cervical Smear Abnormalities in the Gisborne Region* (2001), online: Cervical Screening Inquiry <<http://www.csi.org.nz/report/csireport.pdf>> (date accessed: 27 January 2004). One of the recommendations made was to give auditors greater access to personal health information in facilitate assessment of the screening programme (*ibid.* at 226, 232-37).
88. Supplementary Order Paper, 2003 No. 80 (proposing amendments to the Human Assisted Reproductive Technology Bill). For further information on these developments see New Zealand Ministry of Justice, "Government Proposals to Amend the Human Assisted Reproductive Technology Bill: Questions and Answers" (May 2003), online: Ministry of Justice <<http://www.justice.govt.nz/pubs/other/pamphlets/2003/hart/questions.html>> (date accessed: 27 January 2004).
89. *Intellectual Disability (Compulsory Care and Rehabilitation) Act 2003*, No. 116. This legislation received royal assent on 30 October 2003.

