

9 UNREGISTERED HEALTH PRACTITIONERS – NEW SOUTH WALES RESPONSE

9.1 Background

In Australia, individuals do not have to be registered as health practitioners in order to provide health services to members of the public. Many who offer alternative treatments practise in a safe and ethical manner, which includes obtaining informed consent from their patients. It has been established by this Inquiry that Noel Campbell is not one of them.

Essentially, community concerns about unregistered health practitioners are that they may not be suitably qualified and may be practising in an incompetent or unethical manner. The services offered by such practitioners have included cancer treatments, which often claim to cure or treat the illness by unconventional means and are offered at significant expense to vulnerable patients.

In response to such concerns, New South Wales has been the first Australian jurisdiction to enact legislation targeted specifically at unregistered health practitioners. In November 2006, the *Health Legislation Amendment (Unregistered Health Practitioners) Act 2006* was passed by the New South Wales Parliament. The Act made amendments to the *Public Health Act 1991*, the *Health Care Complaints Act 1993* and each of the health registration Acts.

Given that Noel Campbell and several other staff members of the Hope Clinic are not registered as health practitioners in Victoria but nonetheless have been providing health services at the clinic, the Inquiry considered the New South Wales unregistered health practitioner legislation with a view to ascertaining whether similar legislation should be enacted in this state.

9.2 New South Wales unregistered health practitioner legislation

9.2.1 Amendments to the Public Health Act 1991

9.2.1.1 Code of Conduct

A key feature of amendments made to the *Public Health Act 1991* is that the regulations under the Act may prescribe a code of conduct for unregistered health practitioners. A draft code of conduct, setting out the minimum practice and ethical standards with which unregistered health practitioners are required to comply, was released by the New South Wales Minister for Health for comment in January 2008.

According to the impact assessment statement to the draft code, the reference to an 'unregistered health practitioner' is to any person who provides a health service and who is not registered under a health professional registration Act in New South Wales.¹⁸¹ The term also refers to a registered health practitioner who provides health care treatment that is unrelated to the area of their registration.¹⁸² If this definition were to be applied to the Hope Clinic, the Inquiry notes the following current staff would be considered unregistered health practitioners pursuant to the draft code: Noel Campbell (who trained as a dentist but is not registered to practise dentistry in Victoria, and who conducts the initial consultation with patients and their families and administers treatments to patients); Ms Krishna (who has qualifications in acupuncture and administers non-invasive treatments to patients); Ms Blank (who is described as a 'medically trained

¹⁸¹ New South Wales Department of Health, *Unregistered Health Practitioners Code of Conduct - Impact Assessment Statement*, Sydney, NSW Department of Health, 2008, p 5. The online version of this document is located at <http://www.health.nsw.gov.au/pubs/2008/pdf/Unreg_practise_impct.pdf>.

¹⁸² Note 178, pp 5-6.

nurse', on the basis she is an overseas-trained doctor, but who is not registered as a medical practitioner or a nurse in Victoria); and Ms Corke (who has qualifications in homeopathy and transpersonal counselling, and whose role at the clinic is classified as 'naturopath').

The specific provisions of the draft code, as outlined in the impact assessment statement, are as follows:

- 'Practitioners must practise in a safe and ethical manner' (Item 1);

According to the impact assessment statement, this item emphasises the notion that practitioners are to practise in a manner that does not harm their patients and that accords with standards of behaviour regarded as acceptable by other practitioners and the broader community.

The Inquiry notes several guiding principles have been included in Item 1. The ones of direct relevance to the practices of the Hope Clinic are:

'Practitioners must not provide health care of a type that is outside the scope of their training and experience.' According to the impact assessment statement, this principle requires practitioners to recognise the limits of their competence. The Inquiry makes the following observations in relation to current staff at the Hope Clinic: Noel Campbell is involved in providing integrated cancer treatments to patients yet his only formal training has been in dentistry; Ms Krishna administers non-invasive integrated cancer treatments to patients (namely, photodynamic therapy, ozone therapy, electrotherapy and mild hyperthermia therapy) yet she only has qualifications in acupuncture and the only training she has received on the use of the equipment has been from Noel Campbell (in his capacity as 'clinical research scientist') and Dr Ballard; Ms Corke, who has a diploma in transpersonal counselling but is not registered with any board or organisation in Australia, is not appropriately qualified to provide counselling services at the clinic because of the extreme vulnerability of the patients.

'Practitioners must prescribe only the treatment or appliances that serve the needs of the client.' According to the impact assessment statement, this principle is designed to ensure that unregistered health practitioners will place the interests and health care needs of their patients first and ahead of their own financial interests. The Inquiry makes the following observations in relation to Noel Campbell: the evidence is that all patients who attended initial consultations at the Hope Clinic conducted by Noel Campbell were offered treatment; the efficacy of the therapies provided at the clinic is unproven yet the fees charged for treatment are significant; Noel Campbell is the sole director of the company which operates the clinic.

'Practitioners must ensure that appropriate first aid is available to deal with any misadventure during a client consultation. Practitioners must obtain appropriate emergency assistance (eg from the Ambulance Service) in the event of serious misadventure.' According to the impact assessment statement, this principle requires practitioners to recognise that there may be situations where patients suffer misadventure at their hands or in their practices and to ensure that appropriate arrangements are in place to deal with that misadventure. The Inquiry makes the following observations in relation to Noel Campbell:

- The evidence of complainant F is that on one occasion at the clinic, her friend (the patient) had a reaction to the intravenous vitamin C treatment, after which she could barely speak, yet all Noel Campbell did was keep her at the clinic 'sitting on a chair with a rug over her' for a few hours so he could see what effect the treatment had on her; he then drove her to the complainant's

house later that evening. The complainant was concerned that a patient was allowed to remain in such a state at the clinic without any medical supervision.

- o The evidence of complainant I is that following the administration of intravenous ozone therapy to her son by Noel Campbell, the change in her son was immediate. She states 'he was flushed, his whole body was leaning over to one side, he could not talk and he complained of no feeling down the right side of the body'. When she commented about her son's response, she was assured the symptoms would pass and was advised to take him home. Yet his condition continued to worsen. He was displaying all the signs of having had a stroke. It was the complainant who eventually took him to the Epworth hospital.

The Inquiry makes some additional observations in relation to Noel Campbell's professionalism, as outlined in various complaints: complainants A, C and H cite interruptions (by staff members and/or telephone calls) in the course of the initial consultation conducted by Noel Campbell with patients; complainant F, who was concerned about the terrible effects the 'brutal' treatments at the clinic were having on her friend, states she was not taken seriously by Noel Campbell and that his attitude was cavalier.

- 'Practitioners who have been diagnosed with an infectious medical condition must ensure that they practise in a manner that does not put clients at risk' (Item 2);
- Practitioners must not hold themselves out as qualified, able or willing to cure cancer and other terminal illnesses (Item 3);

According to the impact assessment statement, many complaints about alternative health practitioners to the Health Care Complaints Commission, the Department of Fair Trading and, to a lesser extent, the Australian Consumer and Competition Commission relate to the advertising of products or treatments that are claimed to cure cancer and other terminal illnesses. While existing legislation (namely, fair trading legislation and provisions in the Public Health Act dealing with false, misleading or deceptive advertising) is able to address individual instances of this type of advertising, the processes involved in finalising such matters are often drawn out and, in many respects, provide little, if any, ongoing protection for consumers. Incorporating this provision in the code of conduct gives practitioners clear guidance that advertising cures for cancer and other terminal illnesses is unacceptable and will allow the Health Care Complaints Commission to take effective action to prevent a practitioner from continuing to do so.

The guiding principle included with this item is as follows: *'Practitioners may make claims as to their ability and willingness to treat and alleviate the symptoms of these diseases where the practitioner can substantiate those claims to the satisfaction of the Health Care Complaints Commission, however claims to cure these diseases must not be made.'* According to the impact assessment statement, this guiding principle acknowledges that practitioners may legitimately make claims as to their ability to treat or alleviate the symptoms of cancer and other terminal illnesses, however any such claims must be able to be substantiated. The Inquiry makes the following observation in relation to the Hope Clinic's integrated cancer treatment program: Noel Campbell claims the program does not refer to 'cures' but seeks to increase the survival time of patients or improve their quality of life, yet the efficacy of the therapies provided at the clinic is unproven. Experts to the Inquiry are essentially of the view that the therapies offer no benefit to cancer patients.

- 'Practitioners who engage in skin penetration activities, as defined in section 51(3) of the Public Health Act 1991, must comply with all relevant requirements of the Public Health (Skin Penetration) Regulation 2000' (Item 4);

- Practitioners must not attempt to dissuade clients from seeking or continuing with treatment by a registered medical practitioner (Item 5);
- Practitioners must not practise under the influence of alcohol or other drugs (Item 6);
- A practitioner must not practise whilst suffering from a physical or mental impairment, disability, condition or disorder that detrimentally affects, or is likely to detrimentally affect, his or her ability to practice and which places clients at risk of harm (Item 7);
- Practitioners must not financially exploit their clients (Item 8);
- Practitioners must not diagnose or treat an illness or condition without an adequate clinical basis (Item 9);

According to the impact assessment statement, this item requires practitioners to base their treatments on clinical grounds and the health needs of the patient.

The guiding principle included with this item is as follows: *'Services and treatments provided by practitioners must be designed to maintain or improve the client's health or wellbeing and must not be provided for the sole purpose of financial gain.'* According to the impact assessment statement, the diagnosis of illness and prescription of treatments must be done with the patients' interests in mind rather than the financial interests of the practitioner. The Inquiry repeats the observations it made in relation to the second guiding principle in item 1 about Noel Campbell (namely, that the evidence is that all patients who attended initial consultations at the Hope Clinic conducted by Noel Campbell were offered treatment; the efficacy of the therapies provided at the clinic is unproven yet the fees charged for treatment are significant; Noel Campbell is the sole director of the company which operates the clinic). The Inquiry reiterates the opinion of the experts to the Inquiry that the therapies provided at the clinic offer no benefit to cancer patients.

- Practitioners must not engage in any form of misinformation or misrepresentation in regard to the products or services they provide or as to their qualifications, training and professional affiliations (Item 10);

According to the impact assessment statement, this item is designed to ensure that practitioners do not mislead or misinform their patients about their services or the products they supply or about their education, qualifications and professional memberships.

The guiding principles included with this item are as follows:

'Practitioners must provide factual information about their services and products, qualifications, training and professional affiliations.' According to the impact assessment statement, many patients, in determining whether to obtain health care services, request information about training, qualifications and other matters from prospective practitioners. Practitioners should provide that factual information.

- The Inquiry makes the following observations in relation to Noel Campbell's qualifications, training and professional affiliations: he uses the title 'Professor' yet fails to make clear to patients and their families that this is an honorary title and his only formal training has been in dentistry; he claims an affiliation with Dr Holt (who developed 'Holt microwave therapy'), yet this is denied by Dr Holt's staff; he claims to have been a 'Post Graduate Research Fellow' at the Victorian Anti-Cancer Council for four years in the 1970s when in fact it was only the proposal for the research project in question that was put to the

Anti-Cancer Council by the University of Melbourne, which had ultimate responsibility for the project.

- o The Inquiry makes the following observations in relation to the spirulina extract supplied by the clinic: there is evidence a patient was charged \$1,200.00 for thirty 'spirulina extract' tablets when a bottle of forty spirulina tablets could be purchased for \$20.00 from a health food store; Noel Campbell attributes the significant cost of the clinic's tablets to the process used by the clinic to extract chlorophyll from the spirulina, yet patients are expected to accept this at face value; no information (such as evidence of independent testing) is provided to validate his claim.

'Practitioners must not make claims, either directly or in advertising or promotional material, about the efficacy of treatment where those claims cannot be substantiated.' According to the impact assessment statement, this guiding principle is in keeping with the requirement to only provide factual information. The Inquiry repeats the observation made in relation to the guiding principle in Item 3 about the Hope Clinic's integrated cancer treatment program (namely, that Noel Campbell claims the program does not refer to 'cures' but seeks to increase the survival time of patients or improve their quality of life). In relation to Ms Krishna, there is evidence she told a patient that ozone treatment via cupping 'kills cancer' and that the vitamin C treatment 'scoops the cancer cells out' of the patient's body; as previously stated, these are statements she denies having made but the Inquiry accepts the evidence of the complainant. The Inquiry reiterates the opinion of the experts to the Inquiry, particularly the opinion of Professor Kefford, who states that none of the treatments offered by the clinic, to the best of his knowledge, have any level of accepted medical or scientific evidence relating to efficacy in the treatment of disseminated cancer of any type.

- Practitioners must not engage in any form of sexual or improper personal relationship with a client (Item 11);
- Practitioners must comply with privacy law in relation to their clients' personal information (Item 12);
- Practitioners must maintain accurate, legible and contemporaneous clinical records of each client consultation (Item 13);

According to the impact assessment statement, the health care record is the basic vehicle for communication among members of the health care team. The primary purposes of the patient record are to provide access to relevant information about the patient's care, history, test results and the like; to ensure continuity of care as responsibility for the patient is transferred between carers; and as an audit tool to monitor quality of care. Accurate, legible and contemporaneous records are also an extremely valuable tool for a practitioner to use in addressing patient concerns about their treatment or in defending themselves against allegations of negligence.

The guiding principle included with this item is as follows: *'Client records must be properly maintained with adequate information of a professional standard.'* According to the impact assessment statement, the patient record should fully document the patient's course of care and provide all relevant information necessary to ensure the safe and effective delivery of health care. It should include: the identity of the practitioner who made the record, and the patient it relates to; complete, legible notes of treatment and care given, any medications recommended or provided, tests ordered and test results; accurate statements of fact, or statements of clinical judgment or inquiry, made contemporaneously with the patient consultation; relevant dates, and the content of consultations, discussions and advice or information given to the patient; no material rendered unreadable or erasures; diagnoses, details of any

treatment plan or ongoing course of care; details of any allergies, adverse events, and relevant patient history of any of these, copies or other record of consents to treatment given by the patient; sufficient information in a form that enables other practitioners to deliver health care safely and promptly.

- The Inquiry makes the following observation in relation to the taking of notes by Noel Campbell during the initial consultation with patients: there is evidence from complainant C that he did not write anything down during the consultation.
 - The Inquiry makes the following observations in relation to the patient file of complainant I's son (a copy of which was provided to the Inquiry in late November 2007): it contains two sets of interview notes, made on computer, which are undated; the record of treatment administered appears to be incomplete – the spreadsheet only covers treatment administered from 5 March to 8 March 2007; there is no record of the patient's return to the clinic in late March 2007 when intravenous ozone therapy was proposed and administered.
- Practitioners must ensure appropriate indemnity insurance arrangements are in place in relation to their practices (Item 14).

As at late May 2008, the draft code of conduct is in the process of being finalised by the New South Wales Department of Health for approval by the Minister for Health.

9.2.1.2 Health practitioners who are de-registered or subject to prohibition orders

Amendments made to the *Public Health Act 1991* include provisions relating to de-registered health practitioners as well as those subject to prohibition orders as follows:

- It is an offence for a person to provide a health service in contravention of a 'prohibition order' (which essentially prohibits, or places conditions on, the future provision of health services by the person);
- Health practitioners who are de-registered or subject to prohibition orders are required to notify their patients and employers of their de-registration or prohibition order before providing a health service;
- Advertisements relating to the provision of health services by health practitioners who are de-registered or subject to prohibition orders must specify this.

9.2.2 Amendments to the Health Care Complaints Act 1993

The New South Wales Health Care Complaints Commission has the power, pursuant to the *Health Care Complaints Act 1993*, to investigate complaints against unregistered health practitioners. Previously, however, in the event such a complaint was substantiated, the action the Commission could take was limited to making adverse comments to the unregistered practitioner about the care provided or referring the matter to the Director of Public Prosecutions (if a criminal offence had been committed). Amendments made to the *Health Care Complaints Act 1993* have broadened the Commission's power to take action. Once the code of conduct for unregistered health practitioners is prescribed in regulations under the *Public Health Act 1991*, the Commission will be able to investigate a complaint that an unregistered practitioner has breached the code of conduct. If the Commission finds that such a breach has occurred and is of the opinion that the practitioner poses a substantial risk to the health of members of the public, the Commission has the power to issue an order prohibiting the person from providing health services for a period of time and/or issue a statement of warning to the public about the person and his or her services. Such action can also be

taken (following an investigation) against an unregistered practitioner who has, *inter alia*, been convicted of an offence under the *Fair Trading Act 1987* (NSW) or the *Trade Practices Act 1974* (Cth) relating to the provision of health services.

Additional amendments made to the *Health Care Complaints Act 1993* include the following:

- If, following an investigation, the Commission is of the view that a particular treatment or health service poses a risk to public health or safety, the Commission has the power to issue a statement of warning to the public about the treatment or service;
- The Commission is required to make the following information publicly available: the names of all practitioners who have been de-registered; tribunal decisions in respect of complaints that have been proved or admitted in whole or in part, unless the relevant tribunal has ordered otherwise; and decisions of certain health registration bodies, unless the registration body has ordered otherwise.

9.2.3 Amendments to the health registration Acts

Amendments made to each of the New South Wales health registration Acts essentially permit the respective tribunal or health registration body to make a 'prohibition order' when cancelling or suspending a person's registration, if the person poses a substantial risk to the health of members of the public. Each of those bodies is also required to make the following information publicly available: the names of all practitioners who have been de-registered; and tribunal decisions, where the complaint has been proved or admitted in whole or in part, unless the relevant tribunal has ordered otherwise.

Recommendation:

- 14. The Minister gives consideration to the New South Wales approach to unregistered health practitioners to determine if 'negative licensing' or some variation of it is warranted in Victoria.**

10 RESPONSES OF NOEL CAMPBELL AND DR BALLARD TO THE DRAFT INQUIRY REPORT

10.1 Background

Noel Campbell and Dr Ballard were legally represented by the same firm of solicitors. The Inquiry forwarded a partial draft of the Inquiry Report (chapters 2 to 7 of this Report) to these solicitors in mid-April 2008 for comment within six weeks. The final two chapters of the draft Inquiry Report (chapters 8 and 9 of this Report) were forwarded to the solicitors in early June 2008 for comment within two weeks; an extension to this was sought by the solicitors and the Inquiry granted an extension until 30 June 2008.

Both Noel Campbell and Dr Ballard were given a full opportunity to view the draft Inquiry Report and respond to this Inquiry in accordance with the rules of natural justice.

10.2 Responses of Noel Campbell and Dr Ballard

10.2.1 Noel Campbell

The Inquiry received a response dated 28 May 2008 from Noel Campbell to the partial draft of the Inquiry Report, and a response dated 30 June 2008 to the final two chapters of the draft report. Both these responses are attached to this Report as Attachment 1.

Accompanying each response from Noel Campbell were large amounts of material in a bound folder. These consisted mainly of various articles and other information which he states supports the efficacy of the treatments he provides. It was not practicable for such bulky material to be included in this Report. The material will be held on file at the Office of the Health Services Commissioner. Noel Campbell has the option of including the material on his website if he chooses to do so.

10.2.1.1 Inquiry's response to Noel Campbell's 28 May 2008 response

In his response to this Report, Noel Campbell requests he be referred to as Noel Campbell because: 'By using the title Mr. instead of Dr or Professor this Report implies that Noel Campbell has no qualifications and discounts the ten years of study at The University of Melbourne.' The Report therefore uses 'Noel Campbell' but does not agree with his assertion that the Inquiry believes he has no qualifications or he has not studied. The Inquiry accepts he has dentistry qualifications and a long term interest in, and involvement with, complementary health services. Noel Campbell is not a registered medical practitioner as many people would assume, especially in the context of someone who provides health services and who has used the term 'Professor' to describe himself.

'3.3 The first paragraph says we only offer complementary therapies'

Noel Campbell points out that complementary therapies offered by him should be referred to as 'integrated' as referrals are made to Dr John Sullivan, Oncologist. The Inquiry does not accept that a referral to a medical specialist changes the fact that complementary therapies are provided by the Hope Clinic, nor is this the central issue.

'3.4.1.1 Appendix 1: Photo Dynamic Therapy'

The Inquiry accepts there is some evidence-base for the use of photo dynamic therapy but not in the way it was provided at the Hope Clinic.

'Ozone Therapy'

Noel Campbell refers to some articles on the use of ozone treatments. These have been noted. The main findings of this Inquiry are that ozone treatment appears to have caused suffering in one patient and that the requirements of the Therapeutic Goods Administration on reporting may not have been complied with. The next section of Noel Campbell's response details therapies which may be useful but which are not evidence-based.

'3.7.1.1 Appendix 9: Grant in aid from the Victorian Anti-Cancer Council'

Noel Campbell refers to an article in *The Age* newspaper from 1970 which said he received some funding from the Victorian Anti-Cancer Council. The Victorian Cancer Council has objected to Noel Campbell's claimed affiliation with it and the Inquiry accepts this.

'Appendix 10: Appointment at Swinburne University'

The Inquiry accepts that Noel Campbell was appointed to the Graduate School of Integrated Medicine at Swinburne University but he gives no information on why this appointment ceased.

'Supreme Court'

Noel Campbell claims his appeal was not 'wholly unsuccessful'. The Inquiry stands by its account on page 28 of this Report.

'Title of Professor'

The Inquiry considers the use of the title 'Professor' is likely to mislead patients into believing Noel Campbell has the relevant qualifications from a university to call himself Professor.

With regard to funding by the University of Swinburne, the Inquiry does not dispute that it may have been funded by the Chancellor rather than the University itself.

'3.8 Affiliations Claimed'

Information accepted by the Inquiry is that Dr John Holt does not accept Noel Campbell's claimed affiliations despite the material Noel Campbell has provided to the Inquiry.

A declaration from Dr Ballard that Noel Campbell spent a few hours one morning with Dr Holt in his practice is insufficient to rebut this.

'3.8.2 Dr John Sullivan'

The Inquiry has accepted Dr Sullivan's comments, which are published on pages 34 and 35 of this Report.

'4. Perspectives of individuals whose interests are, or have been, affected by the services provided'

In relation to complainant A, the Inquiry has noted Noel Campbell's rejection of the complainant's account of Noel Campbell's descriptions of the treatments provided. The Inquiry accepts that the complainant was recounting her recall of what he told her.

In relation to complainant B, the Inquiry does not dispute that complainant B may have paid \$8,055 for treatment. The evidence to the Inquiry was that the treatment was for a six-week period. Noel Campbell's response is that it would be more likely that the \$8,055 was for treatment for a three-week period. If so, this does not assist his case.

In relation to complainant C, Noel Campbell's response is noted but adds little to assist his case.

In relation to complainant F, the Inquiry has accepted the findings of the NHRMRC Report and does not dispute what Noel Campbell has written on page 8 of his response at '4.3.6'. The Inquiry has weighed up credibility where there are differences between Noel Campbell and complainant F's evidence and has accepted those of complainant F.

In relation to complainant G, the comments made by Noel Campbell have been taken into account but have not altered the conclusions reached.

In relation to complainant H, the previous comments concerning alleged affiliations with Dr Holt claimed are pertinent.

In relation to complainant I, after weighing up credibility between Noel Campbell and complainant I, the Inquiry has accepted the evidence of complainant I.

'6. History of involvement of interstate and federal regulatory authorities'

In relation to the Therapeutic Goods Administration, the Inquiry has noted Noel Campbell's response and has recommended the Minister refer the matter to the TGA to decide whether further investigation by it is necessary.

'7. Offences under Victorian Legislation'

The Inquiry heard evidence presented to it from both sides and decided which was the most credible. It has decided to accept complainant G's evidence. This section of Noel Campbell's response also refers to claims of affiliation with Dr Holt which has been dealt with already. The Inquiry does not accept the contacts described by Noel Campbell entitle him to claim affiliations with Dr Holt in the way that he has done.

'7.6.2 Australian Competition and Consumer Commission v NuEra Health Pty Ltd'

The Inquiry has accepted the definition of evidence-based medicine on page 102 of this Report.

The Inquiry has considered the remainder of Noel Campbell's response and neither accepts nor rejects it as it is largely irrelevant.

10.2.1.2 Inquiry's response to Noel Campbell's 30 June 2008 response

'Response by Noel Campbell to Chapters 9 & 10 of the Draft Report'

Noel Campbell has stated that the material he provided to the Inquiry has been given little weight. The Inquiry gave Noel Campbell ample time to provide material and has taken the information provided by him into account.

Noel Campbell attached a large folder containing information and indicated he has no objection to it becoming a reference folder as part of the Report. As previously stated, it was not practicable for the Inquiry to include such a large amount of material in this Report. The material will be held on file at the Office of the Health Services

Commissioner and if Noel Campbell wishes to put any material on his website, he is free to do so.

Noel Campbell notes that complainants are de-identified and does not dispute there are good reasons for this, but states he cannot specifically refute certain aspects of their perceptions. The Inquiry has taken this into account and is satisfied Noel Campbell was given ample material in the draft Report to comply with requirements of administrative fairness.

The Inquiry notes Noel Campbell's comments that: 'If there has been an irregularity from an administrative point of view I take responsibility for any such irregularity.' The Inquiry accepts this, however notes that registered medical practitioners are responsible for their own standards of care.

Noel Campbell takes issue with some of the statements made by experts to the Inquiry, however their evidence has been accepted. With regard to the request to have a person from ACNEM contacted, the Inquiry has declined to do this as it is time for this long running Inquiry to be brought to an end. Noel Campbell again objects to the Inquiry's statement that his formal training is in dentistry without regard to experience over the years. The Inquiry does accept that his formal training was in dentistry and accepts that he has worked for many years providing complementary therapies. The Inquiry's findings relate to issues such as failure to obtain fully informed consent and to ethical issues.

10.2.2 Dr Ballard

The Inquiry received a response dated 30 May 2008 from Dr Ballard to the partial draft of the Inquiry Report, and an undated response to the final two chapters of the draft report on 14 July 2008. Both these responses are attached to this Report as Attachment 2. In relation to Dr Ballard's second response, identifying information about complainant I and her son (on pages 17, 18 and 22 as well as in the index on the final page) has been removed.

Dr Ballard's second response was accompanied by a large amount of material in a bound folder. It was not practicable for such bulky material to be included in this Report. The material will be held on file at the Office of the Health Services Commissioner.

10.2.2.1 Inquiry's response to Dr Ballard's 30 May 2008 response

In the letter of 30 May 2008, Dr Ballard's primary concern relates to complainant I. He states it is of considerable concern to him that he may have caused unnecessary distress to a patient and family. He also indicated he would, if it would be of assistance to the family, write or meet with them to apologise for any distress he may have caused. The Inquiry accepts Dr Ballard's good intentions in this regard and should the family wish to participate in any mediation at the Office of the Health Services Commissioner, this could be arranged.

With regard to the possible failure to notify the TGA of the use of the ozone treatment, Dr Ballard has accepted the possibility the Category A form may not have been sent. He also notes he takes responsibility for any error in good practice in this regard. The Inquiry does not dispute this. Dr Ballard goes on to note treatments used and states that the guidelines of the Hope Clinic promote ethical and safe practice. The Inquiry notes there were unethical and undignified practices.

10.2.2.2 Inquiry's response to Dr Ballard's undated response received 14 July 2008

Dr Ballard's second response requests that the letter of 30 May 2008 from his solicitor be taken into account. This has been done. He notes he ceased consulting with the Hope

Clinic in October 2007 and that he has no control over the Hope Clinic websites. The Inquiry accepts this.

Dr Ballard notes he supported the ideals the Hope Clinic was founded on. As for Dr Ballard's comments he has never made any claims to cure cancer, the Inquiry has no evidence one way or the other. He also notes he has relied on credible scientific data supporting the therapies the clinic has used. The Inquiry has accepted and applied the definition of evidence-based medicine on page 102 of this Report and the advice of experts that many of the treatments provided by the clinic are ineffective or unproven, or do not have any level of accepted medical or scientific evidence relating to efficacy.

The information further provided by Dr Ballard on duties of physicians in general may be helpful to the Medical Practitioners Board of Victoria should the Minister decide to accept the recommendation concerning Dr Ballard by referring him to the Board. Dr Ballard notes he undertook to improve the administrative processes at the Hope Clinic from late 2005 as these 'had not been maintained to my requirements during my absence'. The Inquiry does not dispute this.

On page 13 of his response, Dr Ballard objects to comments challenging his ethical practices and requested further information provided to him be taken into account. The Inquiry accepts the information contained in paragraph numbered 1.

The information in paragraph 2 is not disputed. Similarly, the comments in paragraph 3 have been taken into account and are not disputed. The Inquiry was required to weigh up whether complainant I's information or that of Dr Ballard was the most credible and decided to accept complainant I's account.

Dr Ballard refers in paragraph 4(b) of having ongoing difficulties in having the Hope Clinic's staff follow his instructions about carrying out an informed consent process. The Inquiry notes medical practitioners are responsible for their own standards of practice. The Inquiry does not dispute that Dr Ballard may only have been at the Clinic for short periods each week. The Inquiry does not dispute that complainant I initially wrote a letter expressing satisfaction with the clinic's treatments and processes. However she later was not satisfied, given the poor outcome her son experienced.

In paragraph 4(c), Dr Ballard refutes statements from complainant I that he did not inform her or her son about possible risks associated with intravenous ozone therapy. Dr Ballard supplied a copy of an email in his response to the draft Report which was not available to the Inquiry previously. Dr Ballard concedes in the email that he neglected to make a note in the file of the patient at the time and requested the email be placed on the file. The email includes the following statement: 'IV ozone therapy. I have explained the possible risk of fatal air embolism to [son's name deleted] and his parents – they accept this and have agreed to try the treatment. Please give them the IV Ozone consent form (attached).' The Inquiry does not accept this email is evidence that the family was given the opportunity to give fully informed consent. Informed consent is a process in which the relevant information and the risks associated with it must be conveyed to the patient. The Inquiry has found this was not done by Dr Ballard. The Inquiry has accepted the evidence of the complainant.

In paragraph 5, Dr Ballard disagrees with the suggestion he does 'not consider a proper informed consent process to be considered significant in seriously ill patients'. The Inquiry has made this suggestion based on the evidence of the complainants and considers it would be an appropriate issue for consideration by the Medical Practitioners Board of Victoria.

In paragraph 6, Dr Ballard notes that [on 26 June 2008] he requested by letter via his solicitor that the Inquiry approach ACNEM to seek further expert advice. The Inquiry has

decided not to do this at this late stage as the time taken to complete this Inquiry has already been very lengthy.

In paragraph 7, Dr Ballard disputed a comment by the Inquiry that he had been involved in developing the 'technologies' used at the Hope Clinic. This work, he said, had been done by Noel Campbell and others. The Inquiry accepts this and has amended its Report accordingly.

With regard to the second paragraph of paragraph 9, Dr Ballard notes Noel Campbell runs the clinic and ultimately makes all decisions as to what occurs there. Medical practitioners are responsible for their own standards of practice and are answerable to the Medical Practitioners Board of Victoria in this regard. In response to paragraph 10, the Inquiry notes that it has used the definition of evidence-based medicine on page 102 of this Report. The Inquiry has considered Dr Ballard's request to change statements in the report that treatments are not evidence-based and has rejected this.