

HPDT

1045/Med 19/442P

UNDER

The Health Practitioners Competence Assurance Act 2003 (“the HPCA Act”)

IN THE MATTER

of a disciplinary charge laid against a health practitioner under Part 4 of the Act.

BETWEEN

A PROFESSIONAL CONDUCT COMMITTEE appointed by the **MEDICAL COUNCIL**

Applicant

AND

DR MITCHELL DEAN FELLER
previously of Hawera, registered medical practitioner

Practitioner

HEARING held at Wellington on 22 and 23 July 2019

TRIBUNAL:

Mr D M Carden (Chair)

Dr G Sharpe, Dr J Kimber, Associate Professor D Read and

Ms L Carlyon (Members)

Miss D Gainey (Executive Officer)

APPEARANCES:

Ms K Feltham and Mr E Foxall for the Professional Conduct Committee

No appearance by or for the practitioner

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Introduction

- [1] The decision in this case concerns the clinical trial of a product named Te Kiri Gold (also TKG and TKG100) (TKG); and the supply or sale of the product by a medical practitioner. The medical practitioner involved was Mitchell Dean Feller then of Hawera (Dr Feller). The Charge was laid by a Professional Conduct Committee (PCC) of the Medical Council of New Zealand (MCNZ) under the Health Practitioners Competence Assurance Act 2003 (the HPCA Act). The Charge was amended by the PCC before the hearing, by deletion of a sub-particular concerning compliance with ethical guidelines. The full text of the amended Charge is set out in the Schedule to this decision.
- [2] Essentially it is alleged that between 19 July 2016 and 6 July 2017 Dr Feller developed and /or conducted a clinical study and/or a clinical trial, undertaken in circumstances where he had failed to seek or obtain the necessary approvals and failed to adequately follow or comply with relevant ethical guidelines for clinical research studies, namely the National Ethics Advisory Committee (NEAC) Guidelines.
- [3] During the same period, 19 July 2016 to 6 July 2017, Dr Feller is charged with supplying or assisting in the supply or otherwise encouraging the use of TKG in circumstances affecting his patients, including using his influence or position to encourage patients to participate, failing to obtain informed consent by not providing sufficient appropriate information, failing to disclose certain financial interests, using a patient group which included vulnerable or terminally ill patients, and/or acting in contravention of the Health Information Privacy Code 1994 (HPIC).
- [4] The Charge was heard by the Tribunal over two days. The PCC was represented by counsel. There was no appearance by or for the practitioner, Dr Feller. Evidence was produced which satisfies the Tribunal that Dr Feller has been fully and adequately informed of the Charge and of the time and place for hearing; and of compliance with an order made by the District Court for substituted service on Dr Feller. He made no appearance, did not submit any material in response to the Charge, and did not refer to any evidence.
- [5] Despite that, the onus is on the PCC to establish the Charge to the necessary standard and it proceeded accordingly. The PCC called evidence from:

- a) Mr David Peter Dunbar, the Registrar of the MCNZ who referred to Dr Feller's qualifications and background, the complaint process that had been followed in relation to the matters at issue, the investigation of the documents by the PCC appointed, and reference to certain MCNZ statements namely *Good Medical Practice* (December 2016), *Statement on Complementary and Alternative Medicine* (March 2011) and *Information, Choice of Treatment and Informed Consent* (March 2011). Mr Dunbar produced all relevant documents referred to in his evidence and verified these.
- b) Mr Robert John McHawk, Manager Ethics at the Ministry of Health, a registered nurse and nurse researcher who gave evidence about the Ministry's first awareness of Dr Feller's involvement with TKG, the regulatory framework, the NEAC and its establishment, the Ethical Guidelines produced by the NEAC, definitions of "*intervention study*" and "*observational study*", that detailed matters concerning the Health and Disability Ethics Committee (HDEC) are addressed in Standard Operating Procedures (SOPs), and a description of certain of the SOPs and their application to intervention studies and observational studies.
- c) Professor Mark Barry Hampton, a research Professor at the University of Otago who produced a report dated 12 April 2018 that he had written for the PCC concerning his investigation of Dr Feller with respect to the product TKG and his conclusions from that investigation.
- d) Professor John Robert McMillan, a Professor of Bioethics at the University of Otago who had reported on 13 February 2018 to the PCC in relation to the conduct of Dr Feller with comment on his clinical trial and whether that required ethics approval and on Dr Feller's use of his position and relationship as a doctor to recruit patients into the trial. He had been provided with submissions sent to the PCC by lawyers for Dr Feller dated 13 March 2018 and confirmed that those submissions did not alter the opinion he had expressed a month earlier. He produced his 13 February 2018 report and gave evidence confirming it and his opinions expressed in it.

- e) Ms Phyllis Margaret Huitema, the convenor of the PCC, who referred to the investigation of the matter by it and produced documents that had been received by the PCC in the course of its investigation. These included
- i) a copy of a presentation made by counsel for Dr Feller on 14 June 2017,
 - ii) an Information Sheet concerning hypochlorous acid
 - iii) information and documents concerning TKG and its on-line shop, customers, notice to customers from Dr Feller and testimonials,
 - iv) financial records of sales of TKG kept by PureCure Limited (PureCure),
 - v) correspondence and further submissions on behalf of Dr Feller to the PCC dated 13 March 2018 and 18 September 2018,
 - vi) various patient records and medical information (comprising significant volumes).

Ms Huitema referred to the expert opinions received from Professor Hampton and Professor McMillan and the determination made by the PCC to lay this Charge before the Tribunal.

Background

- [6] Based on information supplied to the MCNZ by Dr Feller himself, counsel for the PCC described the product TKG as “*a dilute solution of salt water that has gone through the process of electrolysis (anolyte water) thereby creating the active ingredient hypochlorous acid*”.
- [7] About 2014 a dairy farmer named Mr Vernon Coxhead was using the anolyte solution in the water supply on his dairy farm. This was part of a dairy farm trial that had been agreed between Mr Coxhead and others. There had been problems of water contamination in the dairy industry and all farms were requested to try to find a means of ensuring that their water supply was not contaminated.
- [8] Mr Coxhead researched the problem and found that anolyte water would be a suitable solution. Hypochlorous acid is the active ingredient in the anolyte water. It was said by lawyers for Dr Feller that the hypochlorous acid was manufactured and produced by Mr Coxhead at his farm and was a recognised disinfectant and method of killing micro-organisms in water.

- [9] The submission from those then lawyers claimed that it became apparent to Mr Coxhead that his family members, also living on the farm, were experiencing significant improvements to their general health. The submission also claimed that, when a friend who came to visit Mr Coxhead at the farm and who had skin cancer on his hand happened to apply it topically to his hand, the skin cancer cleared up within a very short period of time after the application. Others were told of this and tried the anolyte water which was supplied to them at no cost and it was claimed that the cancers of these people had gone into remission.
- [10] The submission said that Dr Feller became involved in the product after noting that some of his patients' cancers appeared to have gone into remission and he discovered that they had been drinking the same anolyte water that had been prepared by Mr Coxhead.
- [11] It was claimed in the submission that Dr Feller's curiosity was aroused and he formed a friendship with Mr Coxhead in about mid-2015. That friendship developed, it was said, along with the mutual interest in anolyte water and on 19 July 2016 Dr Feller and Mr Coxhead incorporated the company PureCure Limited.
- [12] Dr Feller and Mr Coxhead were then and have been since the two directors of the company and equal and only shareholders in it. The commercial activities of PureCure Limited included the manufacture and supply of TKG to participants in the trial to which the Charge refers.
- [13] Since 1 January 2017 TKG has been sold and sales information from financial records showed sales between December 2016 and 30 November 2017 of TKG by PureCure yielding approximately \$327,000.00.
- [14] From the Informed Consent Forms and medical information supplied to the PCC by or on behalf of Dr Feller it was apparent that approximately 500 patients of his were involved in Dr Feller's trial of TKG.

The Charge – general

- [15] In considering the individual particulars of the Charge it is necessary to consider:
- a) The nature and composition of TKG; and statements concerning it by Dr Feller.
 - b) Whether there was a clinical study or clinical trial involving TKG.

- c) The role of Dr Feller in any such study or trial.
- d) The applicable relevant accredited ethical guidelines.
- e) Whether there was a failure on Dr Feller's part to seek or obtain the necessary approval from the relevant accredited ethics committee, namely the HDEC.
- f) Dr Feller's role in the supply or assistance in supply or other encouragement in the use of TKG in the five sub-particulars of particular 8.
- g) Whether there was a breach of the applicable MCNZ statements and whether there has been on Dr Feller's part malpractice or negligence in relation to his scope of practice or acts or conduct which have brought or were likely to bring discredit to his profession.

The nature and composition of TKG and statements concerning it by Dr Feller

[16] The submissions for the PCC were that the evidence of Professor Hampton in relation to his analysis of a sample of TKG and his opinion on the results of that analysis included the following:

- a) TKG is constituted of hypochlorous acid/hypochlorite (0.04%, 370 ppm), formed as a result of electrolysis of dilute solutions of salt water.
- b) While produced by different processes, the same compounds are used in the sterilisation of swimming pools and drinking water, and are the active ingredients in household chlorine bleaches such as *Janola*.
- c) Hypochlorous acid is a strong oxidant, indiscriminately stripping electrons away from many different biological molecules including proteins, lipids and nucleic acids. It is a very reactive compound, and in biological systems it will only last seconds before it reacts with the nearest target molecule.
- d) Hypochlorous acid is toxic to all cells; there is no selectivity for bacteria or human cells.
- e) Dilute solutions of hypochlorous acid have been used as topical antiseptics to improve wound healing. In this situation hypochlorous acid will kill effectively pathogens on the surface of the skin. It is important that these are dilute solutions to prevent damage.

- f) Hypochlorous acid consumed orally will immediately react with cells lining the mouth and throat. It will not enter the circulation and as such it will not have access to cells in other parts of the body (e.g. tumours).
- g) Dilute solutions of hypochlorous acid are unlikely to cause acute injury, however the long-term effects of exposure have not been investigated.
- h) The ability of hypochlorous acid to kill cells and modify a range of biomolecules means that it warrants investigation as a potential carcinogen.

[17] The detail of Professor Hampton's evidence on the inaccuracies of Dr Feller's descriptions is discussed below in the context of absence of informed consent.

[18] The submission for the PCC based on Professor Hampton's opinion was that Dr Feller's attempts to describe the physical properties of hypochlorous acid in a range of sources are often factually incorrect. Dr Feller's claims in relation to the potential benefits of TKG on internal cancers were incorrect and often misleading. What patients taking TKG receive (and when taken with milk as instructed by Dr Feller's instructions), is "*... an expensive formulation of milk and salt water*".

Whether there was a clinical study or clinical trial involving TKG

[19] Documents sent by Dr Feller to the MCNZ included an "*Informed Consent Form*" which introduced the Description of the Study in these words:

"You are being invited to participate in a clinical trial being conducted by Pure Cure Limited to demonstrate and document the usefulness of TKG001, the Company's proprietary solution, in the treatment of terminal cancer.

This study is being conducted by Dr Mitch Feller (Curriculum Vitae (CV) available upon request. Dr Feller has over three decades of private practice experience, and has been the Principal Investigator or Sub-Investigator in over 220 clinical trials ... since 1998.

...

We believe the solution, TKG001, to be of significant potential value in helping individuals with cancer. A large body of published research indicates that this should be the case."

[20] The form then continues with significant description of the process and this is considered further below in the context of particular 8(b) of the Charge. This

form was part of a bundle of documents sent by Dr Feller to the MCNZ on 28 May 2017.

- [21] The bundle also included a Curriculum Vitae for Dr Feller which the Tribunal has noted in detail but specifically which included reference to “*Research*” participation by Dr Feller on numerous occasions as “*Principal Investigator*” or “*Sub-investigator*” between 1998 and 2016. In his evidence Professor McMillan addressed the express question of whether what was occurring was clinical research or a clinical trial. He referred to the first sentence of the Information Sheet transcribed above and the description on the Consent Form by Dr Feller of himself as “*Principal Investigator*”.
- [22] He also referred to an extract from the Te Kiri Gold website printed on or before 18 April 2017 which included:

“Dr Mitch Feller talks about the clinical trials of Te Kiri Gold he is working on with Vernon Coxhead. Read the whole story on stuff.co.nz (<https://www.stuff.co.nz/taranaki-daily-news/877188000/cancer-specialist-warns-magic-water-not-approved-by-medsafe>)”.

- [23] Professor McMillan also referred to the description on the Consent Form of PureCure Limited as “*the Sponsor*” which he said implied that this was a consent form for a clinical trial; and also that the title “*The Potential Utility of TKG001 in the induction of remission in metastatic cancer*” implied that the aim was to study the clinical utility of a novel medical intervention, which meant that this was a clinical trial.
- [24] Professor McMillan expressed the opinion that it was beyond reasonable doubt that Dr Feller believed he was conducting a clinical trial.
- [25] Reference was made by Professor McMillan to the World Health Organisation definition of a clinical trial as

“... any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes”;

and said that Dr Feller’s study fitted that definition. He did, however, say that matters were complicated in New Zealand by the use in ethical reviews of the terms “*intervention study*” and “*observational study*” with separate guidance for these categories of research from the NEAC publications.

- [26] Included in the material provided to The Tribunal were letters dated respectively 23 May 2017 and 13 March 2018 from the then lawyers for Dr Feller. In those letters it was argued that Dr Feller was involved in an observational study.
- [27] In his evidence, however, Professor McMillan said that it seemed “*very unlikely that Dr Feller was not conducting a clinical trial when that’s what he claimed he was doing.*” He did refer however to the question of whether the conduct could reasonably be considered to be an observational study and analysed the position. Quoting from the information sheet, Professor McMillan said that the trial lacked a clear and adequately specified study question and without that it could not have succeeded as a study. He accepted that one of Dr Feller’s aims was to observe and analyse information about the health of those with end stage cancer but he said that that was not his only aim.
- [28] The Information Sheet (which formed a part of the Informed Consent Form) instructed participants not to diverge from the treatment recommended by their oncologist. It could be argued, Professor McMillan said, that Dr Feller did not intend to alter the treatment the participants received, because TKG 001 was administered with the hope that it would provide therapeutic benefit (even if only in terms of a perceived improvement in quality of life). Dr Feller’s study had, however, changed the care that the participant was receiving because TKG had complemented the care offered by the participant’s oncologist.
- [29] Professor McMillan expressed the clear opinion that the information provided by Dr Feller was that he controlled and studied the administration of TKG to end stage cancer patients for the purpose of adding to knowledge of the health effects of this intervention and this made it an intervention study as defined by the NEAC Guidelines.

The role of Dr Feller in any such study or trial

- [30] The PCC submitted, and the Tribunal accepts, that Dr Feller was the leading investigator in the TKG trial, that is the principal/coordinating investigator. It referred to *Ethical Guidelines for Intervention Studies: Revised Edition July 2012* where paragraph 3.1 provides that investigators are responsible for identifying and satisfactorily addressing ethical issues in their studies; and that where there is more than one investigator, the coordinating investigator has

overall responsibility for the ethics of a study. There is an equivalent provision in the *Ethical Guidelines for Observational Studies*, although the Tribunal has found that this was an intervention study. There is similar provision in the Standard Operating Procedures (SOPs) for Health and Disability Ethics Committees where the coordinating investigator (formerly known as the “*principal investigator*”) has the primary responsibility for the design and conduct of the study in New Zealand, including compliance with all relevant legal and ethical standards.

[31] Dr Feller’s own description of himself (in his own documents and from his lawyers) includes reference to:

- a) his CV “*Chief Science Officer: PureCure Limited*”.
- b) The Informed Consent Form for the TKG trial “*Principal Investigator*”.
- c) Submissions to the MCNZ on 23 May 2017 “*Principal Investigator of the study and director of PureCure Limited*”, and “*Observer, investigator and record keeper*”.
- d) In 18 March 2018 submissions from his lawyers: “*Part of his duties as a director of [PureCure] was to oversee the efficacy of TKG*”. “... *as an employee of [PureCure] who is giving advice to the company about how to run the review of the efficacy of TKG using his special skills as a trained doctor...*”

[32] The Tribunal accepts the submissions for the PCC that Dr Feller’s role in the TKG trial was as lead investigator as earlier described by him and that his later submissions downplayed his role and responsibilities.

The applicable relevant accredited ethical guidelines

[33] Submissions for the PCC referred first to the NEAC established under section 16 of the New Zealand Public Health and Disability Act 2000 (the NZPHD Act). In discharging the duty imposed by section 16(2) of that Act to determine nationally consistent ethical standards across the health sector, the NEAC established two Guidelines. The first of these Guidelines was the *Ethical Guidelines for Intervention Studies* (Intervention Guidelines) and the second the *Ethical Guidelines for Observational Studies* (Observational Guidelines).

[34] Reference was made to the definitions of “*intervention study*” and “*observational study*” and to the requirement that all intervention studies required ethics committee review. This is expressly required by clause 3.2 of the Intervention Guidelines.

[35] Reference was also made to the HDECs established by section 11 of the NZPHD Act and the SOPs containing detailed matters concerning the HDEC review of intervention and observational studies. The SOPs set out criteria for when the lead investigator of a research study must obtain HDEC approval. Clause 29 of the SOPs reads:

29. “*Health and disability research requires HDEC review only if it involves one or more of the following:*

29.1 *human participants included in their capacity as:*

29.1.1 *consumers of health or disability support services, or*

29.1.2 *relatives or caregivers of consumers of health or disability support services, or*

29.1.3 *volunteers in clinical trials ...*”

[36] Whether a study requires HDEC review is comprehensively summarised in a flowchart to the SOPs produced to the Tribunal; and on the evidence given to the Tribunal it is satisfied that, following that flowchart, the study did require HDEC review.

[37] The PCC submitted, and the Tribunal accepts, that patients participating in the TKG trial were (by and large) terminally ill patients who were receiving, or were planning to receive, or had been receiving, health care procedures on account of their cancer diagnosis. They were also recruited in their capacity as consumers of health or disability support services in that they intended to take TKG as a health care procedure to treat their cancer.

[38] The Tribunal accepts that the process for their involvement was recruitment as that term is described in the NEAC Guidelines and the SOPs. It had earlier been submitted for Dr Feller that the patients were not recruited but rather that they approached him as the result of learning of the trial by word of mouth, but the Tribunal accepts the PCC submission that this is in itself a form of recruitment.

[39] Clause 6.4 of the Observational Guidelines, under the heading “*Recruitment of participants*” reads:

“If a patient (or her or his family or friends) approaches her or his health practitioner or an investigator about study participation, this situation needs to be managed using the same principles outlined in paragraph 6.3 above”.

[40] Professor McMillan in his evidence said:

“Research participants often hear about a study via informal means, as well as via advertisements. Once they are aware of a study and if they have an interest in it, then they might make contact with those running the study.... Recruitment to research is often via word of mouth and via social media platforms... Page two of the Information Sheet describes a word of mouth method of recruitment that is no different from how many participants are ordinarily recruited to clinical trials “.

[41] The Tribunal accepts the PCC submission accordingly that there were human participants as that term is understood in clause 29 of the SOPs who were recruited by Dr Feller for the trial of TKG; and that Dr Feller was obliged to obtain HDEC approval.

[42] The Tribunal has noted above Professor McMillan’s clear opinion that this was an intervention study; and it accepts that opinion. There is no evidence to the contrary and the opinion is clearly expressed.

[43] In the context of a submission made by Dr Feller and on his behalf referring to the World Medical Association’s Declaration of Helsinki, Professor McMillan said that that Association is not a certifying body. It follows from that that, where Dr Feller’s Information Sheet refers to “*his active certification*” with the Association, this would not be correct.

[44] Professor McMillan did say, however, that a doctor who is familiar with, and follows, the World Medical Association is alerted to the importance of national guidelines and following them. The Declaration of Helsinki, Professor McMillan said, acknowledges that the research conducted by doctors upon patients brings into play additional ethical considerations, especially when the patient population is a vulnerable group. Vulnerable research populations include, he said, children, those with mental illness, prisoners. and end stage cancer patients.

- [45] Professor McMillan also said that another reason why the Declaration is followed and has been influential is its emphasis upon the importance of ethical review.
- [46] Having concluded that this was an intervention study, Professor McMillan expressed the opinion, which the Tribunal accepts, that the NEAC Guidelines state that these need HDEC approval, that it is a study upon a vulnerable research population, and that it is required by the World Medical Association Declaration of Helsinki.
- [47] Professor McMillan concluded with the opinion that Dr Feller should have sought ethical approval prior to commencing this study.
- [48] The submissions for the PCC also included comment on issues arising should the Tribunal not have found that this was an intervention study. These do not need further consideration because the Tribunal has so found, but short comment is required.
- [49] Dr Feller had stated that the trial was a “*minimal-risk observational study*” and therefore exempt. The SOPs extract to which the Tribunal was referred described an observational study as requiring HDEC review only if there were more than minimal-risk, that is

“... if the potential participants could reasonably be expected to regard the probability and magnitude of possible harms resulting from their participation in the study to be greater than those encountered in those aspects of their everyday life that relate to the study”.

- [50] Express reference was made to the absence of informed consent to participate and to the vulnerability of participants as indicating an observational study which involved more than minimal risk. The PCC submitted, and the Tribunal accepts, that the trial could clearly not be described as a minimal-risk observational study because there was an absence of informed consent as noted below and a number of the participants were vulnerable. The vulnerability particularly arose in the case of patients who were suffering serious and often terminal cancer.
- [51] Even if this were not an intervention study (which the Tribunal does not find), it is not a minimal-risk observational study and therefore not exempt from requiring HDEC approval.

Whether there was a failure on Dr Feller’s part to seek or obtain the necessary approval from the relevant accredited ethics committee, namely the HDEC

[52] This is the express issue raised by particular 6 of the Charge. The matter is clearly covered by the evidence of Mr McHawk.

[53] Having canvassed the regulatory framework, Mr McHawk concluded:

“The Ministry [of Health] has consulted with the HDEC in relation to records held, and I confirm: Dr Feller (or PureCure) did not apply for HDEC approval; and Dr Feller (or PureCure) does not hold, and has never held, HDEC approval for any health and disability research”.

[54] At no time has Dr Feller or counsel on his behalf ever suggested he made any application or that he even contemplated doing so. His responses have been rather on whether he was obliged to do so and this is canvassed above.

Dr Feller’s role in the supply or assistance in supply or other encouragement in the use of TKG in the five sub-particulars of particular 8

[55] This issue is the substance of particular 8 and its sub-particulars; and is considered in further detail below.

Particulars 1 – 5: background factual matters

[56] The first five particulars in the Charge are found to be made out. The background is canvassed earlier in this decision and the Tribunal does not perceive that there is any factual dispute with the background from Dr Feller. The only question may be whether the active ingredient in TKG is hypochlorous acid. That is canvassed above and is accepted as factually correct by the Tribunal.

Particular 6: clinical study or trial without necessary approval

[57] This particular addresses the period between 19 July 2016 and 6 July 2017. The first date, 19 July 2016, was when the company PureCure was incorporated and the trial commenced and the latter date, 6 July 2017, is when the trial concluded

by Dr Feller having signed a voluntary undertaking with the MCNZ. That followed the receipt by the MCNZ of the letter expressing concerns from the Director of the Protection, Regulation and Assurance branch of the Ministry of Health and exchanges between the MCNZ and Dr Feller and his lawyer. The undertaking from Dr Feller dated 6 July 2017 included that he agreed not to participate in the research or clinical trial of TKG or related products. That effectively brought an end to the trial, if that had not already occurred.

[58] The particular alleges that Dr Feller developed and/or conducted a clinical study and/or clinical trial involving TKG. For the reasons mentioned above the Tribunal finds that Dr Feller was involved in the development and conducting of the clinical trial involving TKG.

[59] The particular then alleges a failure on Dr Feller's part to seek and/or obtain the necessary approval from the relevant accredited ethics committee/organisation namely the HDEC. It refers to circumstances as including that human participants were recruited in their capacity as consumers of health or disability support services and/or were recruited in their capacity as volunteers in clinical trials.

[60] The individual aspects of this particular are addressed above. There was a trial conducted of the TKG product. Although this was done in the name of PureCure Limited, Dr Feller was the principal investigator. Appropriate approval was required from the HDEC. Dr Feller failed to seek or obtain approval. The human participants in the trial were recruited in their capacity as consumers of health or disability support services. Furthermore, those human participants were recruited in their capacity as volunteers in clinical trials. That recruitment meant that the HDEC SOPs applied.

[61] What was being conducted by Dr Feller was an "*intervention study*" and this required ethics committee review in every case. The TKG trial was extensive, including some 500 or so participants recruited in their capacity as health or disability support service consumers or otherwise as volunteers in the trial.

[62] There was produced to the Tribunal the consent forms and medical information obtained by the PCC in respect of all, or at least most of, these participants.

[63] Dr Feller studied the intervention, being TKG, on the effect it had on the participants' metastatic, and often terminal, cancer. The decision has already referred to the establishment of the NEAC and its role, the differences between

intervention studies and observational studies, the establishment of the HDEC and the applicable SOPs. HDEC approval was required because of the recruitment of human participants and clause 29.1 of the SOPs applies.

- [64] The Tribunal relies on Professor McMillan's opinion that recruitment to research is often by word of mouth and social media platforms and accepts the submission that participants coming to Dr Feller in this way is no different from the way recruitment often works in a clinical trial.
- [65] As noted above the Tribunal accepts that this was an intervention study. Even if it were an observational study, it was not a minimal-risk observational study. Accordingly, being an intervention study, it did require HDEC approval but, even if it were an observational study, that would still have been required because of the fact that this was not a minimal-risk observational study.
- [66] Some, if not all, of the participants had not given informed consent as noted below. These patients were provided with inaccurate, inadequate or otherwise insufficient information so as to prevent them from providing true informed consent to the TKG trial.
- [67] Professor McMillan said that in his opinion the Information Sheet provided by Dr Feller to patients would not enable patients to understand the uncertainties and lack of evidence base for the treatment he was giving them. It fell short of the standard required by the MCNZ statement *Information, choice of treatment and informed consent*.
- [68] Informed consent is discussed further below in the context of particular 8(b), but it is relevant to the question of whether or not this was a minimal-risk observation study for the reasons provided in the SOPs referred to above. As noted above also, some, if not all, of the participants were vulnerable as described by the SOPs. Many, if not all, were suffering serious and often terminal cancer conditions and were vulnerable especially because this doctor was purporting to offer a treatment that may be of benefit to treating them.
- [69] The Tribunal finally notes that the NEAC Guidelines expressly provide that, in situations where an investigator is unsure whether ethics committee review of a particular study is required, that person should seek advice from an ethics committee which Dr Feller failed to do.
- [70] The Tribunal finds particular 6 made out as malpractice and negligence on Dr Feller's part and as conduct bringing discredit to his profession separately

warranting disciplinary sanction. The participants were recruited both in their capacity as consumers of health or disability support services and as volunteers in clinical trials.

Particular 7 - failure to follow or comply with relevant ethical guidelines

- [71] The Charge as laid was amended by deleting reference to certain guidelines and now limiting the allegation to the NEAC Guidelines. Essentially, the allegation is that Dr Feller, in undertaking the trial, failed to follow or comply with the NEAC Guidelines, being the relevant guidelines for clinical research studies.
- [72] Compliance with the NEAC Guidelines is required whether or not HDEC review and approval is required for a trial. This is expressly provided for in paragraph 1.9 of the Ethical Guidelines for Intervention Studies and paragraph 1.8 of the Ethical Guidelines for Observational Studies.
- [73] Accordingly, whether or not Dr Feller failed to obtain HDEC approval prior to commencement of the TKG trial, he was nevertheless obligated to comply with relevant Ethical Guidelines.
- [74] The submissions for the PCC repeated the principles relevant had this been an intervention study, but with the alternative submissions applicable to an observational study if this were found to be the case by the Tribunal.
- [75] The submissions referred to four specific instances of non-compliance with the applicable Ethical Guidelines, described as the “*most obvious instances*”: namely conflict of interest, inducement and exploitation, want of informed consent, and study and protocol design. These are dealt with separately now.

Conflict of interest

- [76] The Ethical Guidelines for Intervention Studies refers at paragraph 4.19 to the potential for compromise of the study design or conduct if an investigator has a conflict of interest.
- [77] Potential conflict of interest may arise, it is said in paragraph 4.20, if the investigator is remunerated for participant recruitment or has a commercial interest in the intervention or financial links to the study sponsor.

- [78] The PCC submitted, and the Tribunal accepts, that the 50% shareholding by Dr Feller in PureCure is a conflict of interest (described in the submissions as “*glaringly obvious*”) which Dr Feller was obligated to manage.
- [79] As Dr Feller himself has acknowledged, he failed to disclose that conflict of interest to patients who were participating in the TKG trial. That was exacerbated when participants had to pay for the TKG from 1 January 2017.
- [80] It is the justification for that that the submissions on Dr Feller’s behalf have emphasised. It was said, on his behalf, that Dr Feller did not declare his shareholding to participants because he did not consider that to be relevant; that he was not an independent researcher; and that he was a director/employee of the company manufacturing the product; with there having been no perceived or actual conflict of interest.
- [81] The Tribunal does not accept that that was the case and does accept the submission for the PCC that Dr Feller did have that conflict of interest.

Inducement and exploitation

- [82] In his evidence Professor McMillan referred to the Informed Consent Form used by Dr Feller which was produced to the Tribunal by Mr Dunbar. That includes:
- “You will be provided with study Solution at no cost, for as long as you require it. We will NOT be able to pay for your travel costs or for time lost from work, should that occur. You will not be given any money or gifts to participate in this research”.*
- [83] The Tribunal accepts Professor McMillan’s evidence that the implication from that statement, because the trial was open-ended with no end date, was that the trial and free access to TKG would continue until the patient stopped taking it or died.
- [84] The Tribunal also accepts Professor McMillan’s opinion that the costs of producing and distributing TKG must have been known to Dr Feller at the time he enrolled patients into the trial; and the statement quoted from the Informed Consent Form is therefore false and misleading.
- [85] Finally, the offer of free treatment contained in that Informed Consent Form was, as Professor McMillan said, a way of encouraging patients to try the product, TKG, and they might be strongly motivated to pay for it once they had

started using it despite that this was not the basis on which they entered the trial. The Tribunal accepts Professor McMillan's view that this could be viewed as exploitative.

- [86] These matters combined affirm that there was inducement as provided in the NEAC Guidelines; and that there was exploitation by Dr Feller of his patients in the process used by him to have them pay for the TKG product.

Informed consent

- [87] This topic is covered extensively in the Ethical Guidelines for Intervention Studies at paragraphs 6.6 – 6.23.
- [88] There is provision (at paragraph 6.8 and 6.9) for the entitlement for people “*to make free and informed decisions about their participation in a study*” and the requirement for “*sufficient competence to make that decision...*”. Paragraph 6.13 imposes the obligation on an investigator to design and conduct studies to maximise the validity and quality of participants' informed consent.
- [89] In his evidence Professor Hampton referred to several documents containing written statements made by Dr Feller. These were an article titled “*The science of anolyte: electrochemical activation (ECA)*” written by Dr Feller in August 2016; the “*Informed Consent Form*” authored by Dr Feller; and a letter written in February 2017 to the members of the Complaints Triage Team.
- [90] Professor Hampton analysed some 11 extracts from those documents and expressed the opinion that these “*these comments display a disturbing lack of understanding of the product that [PureCure was] selling*”.
- [91] For his part, Professor McMillan referred to the Informed Consent Form and the duty on doctors to provide high quality, evidence-based information about the treatment and the uncertainties of it. Professor McMillan referred to page 1 of the Information Sheet and a statement of belief that the TKG had significant potential value in helping individuals with cancer. He referred to the fact that no supporting literature is referred to in the Information Sheet nor any literature that Dr Feller had provided to substantiate the claim that “*A large body of published research indicates that this should be the case*”.
- [92] Professor McMillan also referred to the Information Sheet which included: “*After successful trials in animals, and external human conditions, [TKG]'s chemical properties were perfected for internal human use*”. Professor

McMillan said that this was a misleading way to describe what happened and that, using the term “*trial*”, implied that properly conducted clinical trials had been held and that the results of those trials had been published.

[93] Finally, Professor McMillan, concluded with an opinion that the Information Sheet Dr Feller provided to patients would not enable them to understand the uncertainties and lack of evidence base for the treatment and fell short of the standard required by the MCNZ statement *Information, Choice of Treatment and Informed Consent*.

[94] The Tribunal finds that there has been by Dr Feller non-compliance with the applicable Ethical Guidelines in the context of providing informed consent to participants in the trial by Dr Feller.

Study and Protocol Design

[95] In this context the PCC relied on the NEAC Guidelines and specific provisions of paragraphs 2.8, 5.3, 5.4, 5.5, and 5.6. These paragraphs referred to a “*control*” group and an “*intervention*” group; to every question being based on a thorough review of relevant literature; to the studied design being the best one suited to answer the study question while minimising harm, maximising benefit and meeting other ethical standards; to the ethical importance of scientific soundness; and to the sufficiency of the intended number of participants to generate reliable findings.

[96] The PCC relied on the evidence of Professor McMillan which included that the clinical study was not justified by a thorough review of relevant literature. The supporting literature, Professor McMillan said, included a 2009 Ph.D. thesis from the University of Pretoria and two Papers by one H A Kaoud. The first Kaoud Paper was found by Professor McMillan to be in an open access, pay-to-publish journal listed on a list of predatory journals and the article did not, in his opinion, meet the standard required. The second article by that author was not, in Professor McMillan’s opinion, sufficiently credible to justify a Phase II trial.

[97] The PCC relied also on Professor McMillan’s opinion that Dr Feller’s clinical trial lacked a clear and adequately specified study question and without that, it could not have succeeded as a study.

[98] The Tribunal accepts the PCC submission that the evidence given by Professor McMillan that the use of the phrases “*of significant potential value in helping*

individuals with cancer” and *“helping individuals with cancer*” in the Informed Consent Form was too vague for an Information Sheet or a protocol for patients taking part who were at the end stage of cancer and might interpret such a phrase as halting the progress of the cancer or putting them into remission.

[99] Professor McMillan referred also to the extract from the Information Sheet that the

“... endpoints of this Trial relate to 1) the quality of your life and your sense of health and well-being, both before, and after you began taking TKG001. and 2) your longevity as predicted by your original doctors, compared with actual”.

[100] Professor McMillan expressed the opinion, which the Tribunal accepts, that a patients’ subjective sense of health and quality of life tells nothing about whether there is a substantial beneficial effect from TKG, nor whether it has any effect upon cancer remission. Measuring actual longevity, Professor McMillan said, against that predicted by an oncologist would tell very little and that what was needed was a comparison of how people fare when taking TKG compared to not.

[101] The Tribunal accepts this evidence and the submissions from the PCC that these extracts also indicate non-compliance with the NEAC Guidelines.

[102] Finally, the Tribunal accepts the evidence of Professor McMillan and submissions for the PCC that there was non-compliance with the NEAC Guidelines, there having been no attention to statistics and the number of participants needed; no study end date; and no control group.

[103] It accepts Professor McMillan’s opinion and the submission that Dr Feller’s TKG trial fell well short of the standard that is required by the NEAC Guidelines and the Declaration of Helsinki and well short of what should reasonably be expected of a doctor involved in research.

[104] The Tribunal finds that Dr Feller failed to obtain the necessary HDEC approval for the TKG trial and further failed to meet the necessary ethical standards that he was obligated to meet whilst conducting the trial.

[105] The Tribunal finds particular 7 made out and that this separately amounts to malpractice and negligence on Dr Feller’s part and was conduct bringing discredit to his profession and is therefore professional misconduct under section 100(1)(a) and (b) of the HPCA Act.

Particular 8 – supply or sale of TKG

[106] This particular addresses the period between 16 July 2016 and 9 July 2017 and alleges that Dr Feller supplied and/or assisted in the supply of TKG or otherwise encouraged its use in the circumstances listed in the sub-particulars. These refer to the use of influence or position, failure to obtain informed consent, failure to disclose a financial interest or shareholders' interest, inclusion of vulnerable or terminally ill patients in the patient group, and acting in contravention of the Health Information Privacy Code 1994 (HIPC).

Influence to recruit – sub-particular (a)

[107] Professor McMillan's evidence was that it was clear that Dr Feller was conducting a clinical trial and his status as a doctor would have played a role in the recruitment of patients to the trial. That is not unusual or unacceptable, he said, provided that the doctor's involvement in the clinical trial conforms to the expectations of a doctor.

[108] When, however, the doctor's behaviour falls short of what is reasonably expected when they are involved in research and their role aids recruitment, that is a different matter, he said. There is an expectation that the doctor conducting the clinical trial will do so in a methodologically and ethically acceptable way.

[109] The PCC relied on a set of emails provided to it by Dr Feller and the medical information of study participants as further evidence of Dr Feller's having encouraged the use of TKG.

[110] The Tribunal accepts the PCC submission that Dr Feller used his status as a medical doctor to legitimise the study to the patients taking TKG. The combination of references to Dr Feller as a doctor and beliefs in the potential value of the product in the Informed Consent Form had the effect of legitimising the product, TKG, as a trial to many patients.

[111] The description of the study in the Informed Consent Form referred to Dr Feller and his "*over three decades of Private Practice experience*" with reference to his role as Principal Investigator or Sub-investigator in over 220 clinical trials in the United States of America. The Tribunal accepts that Dr Feller did use his role as a medical practitioner to influence potential users of TKG to join the trial

that he was involved in and to recruit them to it. It finds that sub-particular 8(a) is made out on the facts.

Failure to obtain informed consent – sub-particular (b)

- [112] This issue is allied to the informed consent question in the context of ethical requirements under the NEAC Guidelines referred to in the context of particular 7, but is addressed here in the context of misconduct by Dr Feller as a medical practitioner in the supply or assistance of supply or encouragement for use of the product, TKG.
- [113] In the present context the PCC relied on the Code of Health and Disability Services Consumers' Rights promulgated under the Health and Disability Commissioner Act 1994 (HDC Act).
- [114] Right 9 of that Code provides that it is to apply to consumers participating in research. Right 6 provides aspects of information that consumers have the right to and would expect to receive including an explanation of available options, advice of time estimates, notice of proposed participation in teaching or research, and any other information required by other standards.
- [115] Reliance is placed by the PCC on the evidence of Professors Hampton and McMillan referred to above in the context of particular 7 on this topic.
- [116] The Tribunal accepts the PCC submission that the information in the Informed Consent Form in question and the articles and further information relied on by Dr Feller provided inaccurate and insufficient information for individuals to be fully informed in their giving of consent to participation in the trial.

Failure to disclose financial/shareholders interest – sub-particular (c)

- [117] It is the case for the PCC that Dr Feller supplied, sold, and encouraged the use of, TKG in circumstances where he failed to disclose to patients participating in the TKG trial that he had a financial interest in PureCure. These patients were those to whom he supplied and sold TKG.
- [118] Again there is very significant overlap with the allegations and evidence in the context of particular 7, non-compliance with NEAC Guidelines. This decision has already explored the factual background to Dr Feller's interest in and financial links to PureCure, the promoter of the TKG trial. The Tribunal has

already accepted the PCC submission that Dr Feller's 50% shareholding in PureCure is a "*glaringly obvious conflict of interest*".

[119] As also noted, the factual background is largely non-contentious. The financial records for PureCure produced to the Tribunal show a receipt from sales of TKG of approximately \$327,000.00. The product was sold in 2 litre bottles for \$100.00 and 4 litre bottles for \$200.00 each; and the Tribunal accepts the PCC submission that "*this is not an insignificant sum*".

[120] It further accepts the submission that Dr Feller's failure to disclose his financial shareholding interest in these circumstances is a serious breach of the standard expected of a medical practitioner.

Vulnerable patient group – sub-particular (d)

[121] The allegation is that the patient group included vulnerable and/or terminally ill patients to whom Dr Feller owed a greater duty of care pursuant to the HDEC guidelines.

[122] In his evidence Professor McMillan said:

"End stage cancer patients should likewise be considered a vulnerable research population because they are facing the prospect of death unless some way of halting the progress of their cancer can be found. This means that there is a significant risk of this research population being manipulated or exploited..."

[123] The evidence from Professor Hampton included these statements:

"Hypochorous acid consumed orally will react in the mouth and throat and will not reach tumours".

...

"Mixing the solution with milk will lead to the immediate loss of the Hypochorous acid. I agree this will improve palatability, and it will also prevent any direct damage to cells lining the mouth and throat. Of course, what is left for consumption is an expensive formulation of milk and salt water".

[124] The Tribunal accepts the submission from the PCC concerning the sales information from PureCure's records (the company in which Dr Feller had the 50% shareholding) of sales totalling approximately \$327,000.00.

[125] The submission was that Dr Feller, in supplying, selling and encouraging the use of, TKG in those circumstances, owed a greater duty of care to those

vulnerable patients and was exploitative and unethical. That submission is accepted by the Tribunal.

**Contravention of the Health Information Privacy Code 1994 (HIPC)
– sub-particular (e)-**

[126] Rule 4 of the HIPC provides that:

*“Health information must not be collected by a health agency
(a) by unlawful means; or
(b) by means that in the circumstances of the case,
(i) are unfair ...”*

[127] The commentary on this rule 4 includes:

“HEALTH RESEARCH inducements that could be regarded as constituting undue influence should not be offered to research participants to provide information. Any reward for participation in health research (monetary or otherwise) should be approved by an ethics committee. Researchers who are in positions of power over individuals should not use their position to influence the decisions of individuals to provide personal information for research purposes”.

[128] In a letter dated 14 February 2017 to the Complaints Triage Team Dr Feller included:

“Each individual returned the Interview Template and Informed Consent... before they participated”.

[129] An attachment included in a bundle of the documents sent by Dr Feller to the MCNZ on 28 February 2017 included:

“PureCure interview form. Required to be completed by every participant prior to starting treatment. The Form provides me with the information I need to decide if the participant is eligible.”

[130] Given the vulnerability of Dr Feller’s patients and the increased risk of manipulation and coercion, the PCC submitted that he was in a position of power over the participants. Further, that in the circumstances where insufficient and inaccurate information was given to patients to enable them to provide informed consent, health information was unfairly obtained in breach of the HIPC.

[131] The Tribunal accepts those submissions and that there has been a contravention of the HIPC by Dr Feller in the supply or assistance in supply of TKG or otherwise encouragement in the use of TKG by Dr Feller either directly or through PureCure.

[132] While the Tribunal finds that this is malpractice as defined by the HPCA Act, it finds this is not of sufficient severity severally to warrant disciplinary sanction. This is because the compliance with that Code could be said to be a secondary aspect to the unfair inducement itself.

Particular 8: summary

[133] The Tribunal finds that each of the five particulars in sub-particulars a) – e) in particular 8 are circumstances of supply or assistance of supply or other encouragement in use of TKG by Dr Feller. The particular 8 and its sub-particulars cumulatively and severally (excepting for sub-particular (e)) are malpractice and negligence on Dr Feller's part and warrant disciplinary sanction.

The Charge: general

[134] The Charges are laid under section 100(1)(a) and/or (b) of the HPCA Act. These provide that orders can be made by the Tribunal if, after conducting a hearing, it finds that the practitioner has been guilty of professional misconduct because of any act or omission that amounts to malpractice or negligence in relation to the scope of practice in respect of which the practitioner was registered at the time of the conduct or because of any act or omission that has brought or was likely to bring discredit to the profession in which the practitioner practised at the time of the conduct.

[135] If negligence or malpractice is alleged that must be established as behaviour which falls seriously short of that which is to be considered acceptable and not mere inadvertent error or oversight or even carelessness.

[136] Discredit to the profession involves a breach of an objective standard with the question to be asked being whether reasonable members of the public informed and with knowledge of all the factual circumstances, could reasonably conclude

that the reputation and good standing of the profession in question was lowered by the behaviour of the practitioner.¹

[137] In considering any charge of misconduct under the HPCA Act the Tribunal must, having found acts or omissions in question which were misconduct or likely to bring discredit to the relevant professional, also consider whether the acts or omissions in question are of such severity as to warrant a disciplinary sanction for the purpose of maintaining standards, protecting the public, or punishing the practitioner.²

[138] The onus of proving the Charges lies on the PCC. The standard is the balance of probabilities. The more serious the allegation, the higher the level of proof required.

[139] The PCC submitted that essentially what is at issue in this case is that of a doctor who designed and conducted a clinical trial after failing to comply with his ethical and professional obligations. Dr Feller's failures, as charged, it was submitted, represent a significant departure from the standards expected of a medical practitioner and require an appropriate disciplinary response from the Tribunal. There were, of course, no submissions by Dr Feller or on his behalf as he did not attend the hearing.

Discussion

[140] The Tribunal must consider the Charge as a whole but sub-particulars 6, 7 and 8 in the context of the further allegations in particulars 9 and 10. Essentially the factual background in particulars 1 – 5 have been found made out; the allegations in particular 6 concerning the clinical study or trial in the absence of necessary approvals has been found to be made out in all its particulars; the allegation in particular 7 of failure to comply with guidelines has been found to be made out; and all five allegations in particular 8 of supply for, assistance in supply, or other encouragement in the use of, TKG have been found made out.

[141] The fundamental obligation when conducting the TKG trial for Dr Feller as a registered medical practitioner is expressly covered in *Good Medical Practice* at paragraph 81:

“When designing, organising or carrying out research:

¹ *Collie v Nursing Council of New Zealand*; [2001] NZAR 74 at [28].

² *PCC v Nuttall*; 8/Med04/03P.

- *make sure that a properly accredited research ethics committee has approved the research protocol, and that the research meets all regulatory ethical requirements...*

[142] Paragraph 56 provides:

“Be honest and open in any financial or commercial dealings with patients, employers, insurers or other organisations or individuals”.

And paragraph 58:

“If you have a conflict of interest, you must be open about the conflict, declaring your interest. You should also be prepared to exclude yourself from related decision making”.

Paragraph 57 includes:

“You must not allow any financial or commercial interests to affect the way you prescribe for, treat or refer patients”.

This expressly includes that doctors do not exploit patients’ vulnerability or lack of medical knowledge when making charges for treatment or services. There is the express requirement in paragraph 31 that doctors familiarise themselves with the Code of Health and Disability Services Consumers’ Rights (CHDSCR) and with the HIPC.

[143] Paragraph 32 provides:

“With rare and specific exceptions you should not provide treatment unless:

- *the patient has received all the information that a reasonable patient, in that patient’s circumstances, would expect to receive about the condition and treatment options, including the expected risks, side effects, costs and benefits of each option; and*
- *you have determined that he or she has an adequate understanding of that information; and*
- *you have provided the patient with an opportunity to consider and discuss the information with you; and*
- *the patient has made an informed choice; and*
- *the patient consents to treatment”.*

[144] Relevant paragraphs in *Information, choice of treatment and informed consent* are:

“30. All research must be approved by an accredited ethics committee before patients are invited to participate and give consent to involvement in the study. There is special responsibility when a proposal includes investigative research or a trial of treatment. You also have an ethical

duty to share knowledge and to teach and learn throughout your career. Nevertheless, under Right 9 of the Code informed consent is necessary whenever a patient participates in research. If any form of the research is changed or amended once informed consent has been obtained you must renew the patient's informed consent.

"31. If the treatment is part of research, it is the responsibility of the investigating doctor to take all reasonable steps to enable the patient to understand the full implications of the treatment, especially the uncertainties. Written consent from a patient is required for research."

[145] In the MCNZ Paper *Statement on complementary and alternative medicine* there is provision in paragraph 10 concerning the information to be given, and at paragraphs 12 and 13 the endorsement by the MCNZ of the following extract from *Gorringer*³, a decision of the Medical Practitioners Disciplinary Tribunal:

"...there is an onus on the practitioner to inform the patient not only of the nature of the alternative treatment offered but also the extent to which that is consistent with conventional theories of medicine and has, or does not have, the support of the majority of practitioners."

[146] The PCC also relied on Guidelines in the New Zealand Medical Association Code of Ethics. The status of that Code and the extent to which it may have been binding on Dr Feller was not explored in submissions from the PCC.

[147] The PCC was unable to refer the Tribunal to another case directly comparable to the present one but did refer to *Leach*⁴ where a nurse sought sick leave from her employer on the grounds that her son was unwell with cancer. That later proved to be wrong with the nurse's misconduct including the fabrication of an email purporting to come from a doctor at a child's hospital. She failed to engage in the Tribunal process. Her registration was cancelled with conditions on re-registration, order for censure, and an order for contribution to costs.

[148] The PCC also referred to the conflict of interest and exploitative conduct aspects of *Wilson*⁵, the case of a doctor charging patients with a margin between 177% – 316%. Those charges were found to be exploitative of the patients even although they were willing to pay that sum for the medication. This conduct was found to bring discredit to the medical profession.

³ MPDT237/02/89D

⁴ 389/Nur11/179P

⁵ 314/Med10/145P

[149] On the subject of want of informed consent, the PCC referred to *B v Medical Council*⁶ and the extract:

“... the provision of inadequate information in a situation where the patient needs that information for his or her decisions affecting treatment or investigation, will almost always be professional misconduct or conduct unbecoming”.

[150] Reference was also made to *Dr N*⁷, the case of a medical practitioner practising at a beauty clinic who treated an elderly patient with an injection of a product. The patient suffered an adverse reaction to the product and the doctor was found to have failed to obtain the patient’s informed consent. That failure consisted in failing to advise the patient that the product was an unapproved medicine and that there were risks. The doctor also failed to seek out any peer-reviewed articles or clinical data prior to administering the product. Such failure was found to amount to misconduct as malpractice or negligence or otherwise bringing discredit to the profession. The Tribunal ordered conditions on the doctor’s scope of practice for a period of 2 years and ordered censure and a fine.

[151] It is important for the Tribunal to consider other relevant cases to achieve some uniformity in outcome. Reference must also be had to applicable codes of practice for a health practitioner. They are not, however, the sole criteria by which the Tribunal must reach its decision. The Tribunal must decide whether, having regard to the facts as found, there has been malpractice or negligence on the part of Dr Feller or conduct on his behalf which brought, or he was likely to bring, discredit to his profession. Those terms are extensively defined in the decisions of the High Court and of the Tribunal.

[152] Dr Feller embarked on a clinical trial of this product, TKG. There had been the background to the product introduced to him by the local farmer as mentioned earlier. In collaboration with the farmer, Dr Feller, as a medical practitioner, formed the company PureCure for the express purpose of trialling the product over time and later selling it. TKG was produced in substantial quantities. Documents were prepared, including Informed Consent documents and other documents promoting and describing the product and Dr Feller’s interest in it.

⁶ Noted in [2005] 3 NZLR 810

⁷ 535/Med12/225D

- [153] There was one prominent New Zealander who was expressly approached by Dr Feller's colleague and co-shareholder in PureCure, Mr Vernon Coxhead, namely the late Sir Colin Meads, the former All Black. Otherwise, however, the evidence is that all other participants were encouraged into participation in the trial of the product by Dr Feller and his associates through the company, PureCure.
- [154] While the product was given without charge initially, it was then established that there would be a charge and over the period of time significant funds were generated from the sale of this product. In fact the product was valueless and completely ineffective and, as Professor Hampton so succinctly put it, once it reached the mouth and throat of the participant was no more than "*an expensive formulation of milk and salt water*".
- [155] The circumstances constituted an intervention study by Dr Feller and there were significant breaches of the guidelines applicable to any such study. Even if it were only an observational study, for the reasons given, there were breaches of such standards. Necessary approval from the HDEC was required as the relevant accredited ethics organisation. Dr Feller failed to seek or obtain this at any stage.
- [156] Particular 6 is found made out as malpractice and negligence on Dr Feller's part as a medical practitioner and as conduct bringing discredit to his profession.
- [157] Independently of approvals required, Dr Feller was required to comply with the NEAC Guidelines being the relevant ethical guidelines for clinical research studies. He failed to do so adequately and indeed significantly.
- [158] Particular 7 is found made out as malpractice and negligence on Dr Feller's part as a medical practitioner and as conduct bringing discredit to his profession.
- [159] During the period between 19 July 2016 and 6 July 2017 Dr Feller used his influence as a medical practitioner to recruit or encourage patients to participate; he failed to provide adequate and accurate information to those patients so as to obtain the proper informed consent from them; and he failed to disclose his financial and shareholder interests in PureCure. Dr Feller owed a greater duty of care to the vulnerable and terminally ill patients involved in the trial. Dr Feller unfairly induced patients to provide their health information as a prerequisite to obtaining TKG as required by the relevant Privacy Code (the HIPC).

- [160] Particular 8 in all its five sub-particulars cumulatively and severally (except sub-particular (e)) are found made out as malpractice and negligence on Dr Feller's part as a medical practitioner and as conduct bringing discredit to his profession.
- [161] Finally, the authorities require that the Tribunal assess whether disciplinary sanction is required for this misconduct. It has no hesitation in so finding. There were a significant number of patients involved. Those patients were misled by the information they were given and their consent was not properly informed. When charging commenced the patient's interests were further compromised to the financial benefit of Dr Feller as a shareholder in PureCure. There was a risk that patients' health could be compromised by their reliance on this product possibly to the exclusion of other medical treatment for their condition. They were vulnerable patients given their state of health and life expectancy. The misconduct warrants disciplinary sanction. The one exception is particular 8(e) which the Tribunal finds severally does not warrant such sanction. That decision was announced to the hearing and submissions then made by the PCC as to penalty.

Penalty

The PCC position

- [162] Having made general submissions on legal matters and relevant cases, the PCC submitted that it was proportionate and necessary for Dr Feller's registration as a medical practitioner to be cancelled. This would, it was said, ensure the protection of the public and the maintenance of professional standards. Dr Feller should be prevented, it was submitted, from any further exploitation of vulnerable members of the public and removal from the register would ensure that his influence would discontinue.
- [163] Cancellation of Dr Feller's registration would assist in delegitimising the TKG trial conducted by Dr Feller and assist in dispelling the supposed beneficial effects that had been claimed to have been made. Emphasis was placed on Dr Feller's response to the matter and that he had indicated no acceptance of any misconduct. It was said that the essence of Dr Feller's response was that he had made some minimal procedural errors but had complied with fundamental ethical requirements. While the Tribunal accepts that that was the essence of his response, it does not accept that that response was in any way accurate.

- [164] A strong message must be sent to the profession, it was said, to the effect that fundamental breaches of ethical requirements of the kind involved here would not be tolerated.
- [165] Cancellation need not, it was said, be permanent, and Dr Feller could return to New Zealand and seek to resume practice, with the MCNZ evaluating his fitness to practise at the time.
- [166] Aggravating factors included the vulnerable patient group in question, the scale of misconduct, the extensive experience claimed by Dr Feller, and Dr Feller's failure to respond or appear before the Tribunal suggesting, it was said, a lack of insight on his part.
- [167] Also mentioned was a South Carolina State Board of Examiners Final Order made in 2005 where it was found that Dr Feller had violated the Rules and Regulations of the Board of Medical Examiners. He had obtained certain medications by fraud and deception for his own use and, it was found, engaged in dishonourable, unethical and professional conduct that is likely to deceive, defraud, or harm the public. The record shows that Dr Feller was fined the sum of USD\$10,000.00, was publicly reprimanded, and had conditions on his practice (from which he was released by separate Order in 2008).
- [168] In exploring whether there was any other alternative to cancellation of registration, the PCC submitted that the penalty of suspension would be ineffective in the circumstances. Dr Feller is overseas and looks to be practising in South Carolina, USA. A suspension in New Zealand would serve as little protection to the public. Following any period of such suspension it would be open to Dr Feller to return to New Zealand and apply for a practising certificate.
- [169] It was further submitted that any suspension order would indicate a view that there is a real possibility of rehabilitation and would be an inadequate penalty to mark appropriately the Tribunal's condemnation of Dr Feller's misconduct.

Discussion

- [170] The available penalties for the Tribunal are:⁸
- a) That registration be cancelled.

⁸ Section 101 of the HPCA Act

- b) That registration be suspended for a period not exceeding 3 years.
- c) That the health practitioner be required, after commencing practice following the date of the order, for a period not exceeding 3 years, to practise his or her profession only in accordance with any conditions as to employment, supervision, or otherwise specified.
- d) Censure.
- e) A fine of up to \$30,000.00 (but not if he or she has been convicted of a relevant offence or damages have been awarded against him or her – not the case here).
- f) Costs.

[171] The principles behind penalty orders of the Tribunal as clearly set out on the basis of authorities⁹ are:

- a) What penalty most appropriately protects the public.
- b) The important role of setting professional standards.
- c) A punitive function (although this is not the principal purpose behind in the order but may be a secondary consequence. This topic is discussed further below).
- d) Rehabilitation of the health professional.
- e) That any penalty imposed is comparable to other penalties imposed upon health professionals in similar circumstances.
- f) Assessing the health practitioner's behaviour against the spectrum of sentencing options that are available and trying to ensure that the maximum penalties are reserved for the worst offenders.
- g) An endeavour to impose a penalty that is the least restrictive that can reasonably be imposed in the circumstances.
- h) Whether the penalty proposed is fair, reasonable and proportionate in the circumstances presented.

[172] In *A v Professional Conduct Committee*¹⁰ the High Court said that four points could be expressly and a fifth by implication taken from the authorities namely:

⁹ *Roberts v Professional Conduct Committee of the Nursing Council of New Zealand* [2012] NZHC 3354; *Katamat v PCC* [2012] NZHC 1633 at paragraph 49 and *Joseph v PCC*; [2013] NZHC 1131 at [65] – [66]; *Singh v Director of Proceedings*, [2014] NZHC 2848 (esp. paragraphs [56] – [60] and [66])

¹⁰ *A v Professional Conduct Committee* [2008] NZHC 1387 at [81]

“First, the primary purpose of cancelling or suspending registration is to protect the public, but that ‘inevitably imports some punitive element’. Secondly, to cancel is more punitive than to suspend and the choice between the two turns on what is proportionate. Thirdly, to suspend implies the conclusion that cancellation would have been disproportionate. Fourthly, suspension is most apt where there is ‘some condition affecting the practitioner’s fitness to practise which may or may not be amenable to cure’. Fifthly, and perhaps only implicitly, suspension ought not to be imposed simply to punish.”

[173] The Court went on:¹¹

“Finally, the Tribunal cannot ignore the rehabilitation of the practitioner: B v B (HC Auckland, HC 4/92, 6 April 1993) Blanchard J. Moreover, as was said in Giele v The General Medical Council [2005] EWHC 2143, though ‘... the maintenance of public confidence ... must outweigh the interests of the individual doctor’, that is not absolute – ‘the existence of the public interest in not ending the career of a competent doctor will play a part.’”

[174] The Tribunal is also mindful of the remarks of Randerson J in *Patel v Dentists Disciplinary Tribunal*¹². That case involved an appeal by a dentist whose name had been removed from the register by the Dentists Disciplinary Tribunal in relation to charges arising from his treatment of an elderly couple for whom he carried out crown and bridge work, accepted by the Court as being “*grossly incompetent and completely unacceptable*”¹³.

[175] In discussing the purpose of disciplinary proceedings, the Court said:

“[28] The Dentist Act does not provide any guidance on this subject but I am satisfied that the following statement of principle by Eichelbaum CJ in Dentice v Valuers Registration Board [1992] 1 NZLR 720, 724-725 is apposite in this case:

Although, in respect of different professions, the nature of the unprofessional or incompetent conduct which will attract disciplinary charges is variously described, there is a common thread of scope and purpose. Such provisions exist to enforce a high standard of propriety and professional conduct; to ensure that no person unfitted because of his or her conduct should be allowed to practise the profession in question; to protect both the public and the profession itself against persons unfit to practise; and to enable the

¹¹ At [82]

¹² Auckland HC; AP77/02; 8/10/02;

¹³ Paragraph 32

professional calling, as a body, to ensure that the conduct of members conforms to the standards generally expected of them; see, generally, Re A Medical Practitioner [1959] NZLR 784 at pp 800, 802, 805 and 814. In New Zealand, such provisions exist in respect of medical practitioners, barristers and solicitors, dentists, architects, pharmacists, real estate agents and a number of other professionals and callings, as well as valuers; ...

[29] *In the light of those general purposes, it is also relevant to consider the purpose of the removal of a practitioner's name from a professional register. There is authority for the proposition that removal from a professional register has a protective purpose and is not designed to punish the professional concerned: Re A Medical Practitioner [1995] 2 QBR 154, 164. Plainly, removal from the register does serve to protect the public but it also serves the function identified in Dentice of maintaining professional standards and maintaining public confidence in the standing of the profession. It also acts as a deterrent to the individual concerned and others in the profession.*

[30] *The consequences of removal from a professional register are ordinarily severe and the task of the Tribunal is to balance the nature and gravity of the offences and their bearing on the dentist's fitness to practise against the need for removal and its consequences to the individual: Dad v General Dental Council at 1543. As the Privy Council further observed:*

Such consequences can properly be regarded as inevitable where the nature or gravity of the offence indicates that a dentist is unfit to practise, that rehabilitation is unlikely and that he must be suspended or have his name erased from the register. In cases of that kind greater weight must be given to the public interest and to the need to maintain public confidence in the profession than to the consequences of the imposition of the penalty to the individual.

[31] *I respectfully adopt the observations of the Privy Council and would add that it is incumbent on the Tribunal to consider carefully the alternatives available to it short of removal and to explain why the lesser options have not been adopted in the circumstances of the case. As well, while absolute consistency is something of a pipe dream, and cases are necessarily fact dependent, some regard must be had to maintaining reasonable consistency with other cases. That is necessary to maintain the credibility of the Tribunal as well as the confidence of the profession and the public at large”.*

- [176] Of importance amongst these principles are first the necessity for the Tribunal, if it is to consider cancellation of registration, to articulate why other alternatives would be inadequate; and secondly, to consider seriously questions of rehabilitation.
- [177] The Tribunal has noted the aggravating factors stressed for the PCC and taken these and the matters that had been advanced on Dr Feller's behalf at earlier stages by his then lawyers into account.
- [178] What the Tribunal is faced with in this case is that Dr Feller has acted in the ways set out in this decision but has since left New Zealand and is no longer practising here. There is evidence that he has returned to South Carolina or elsewhere in the United States of America and may be practising there. There is no adequate evidence about that and he has certainly not attended to explain his position.
- [179] Dr Feller's failure to attend the hearing by the Tribunal has first indicated his disrespect for the disciplinary process that has been undergone and the role of the Tribunal in seeking to make orders which are most effective in the circumstances. Secondly, the Tribunal has not been able to assess with any accuracy Dr Feller's personal position or his professional ambitions or future. Those are significant matters for the Tribunal to take into account.
- [180] The Tribunal accepts the PCC submission that, in the absence of Dr Feller or his giving any such explanation and in his absence from New Zealand, any order suspending him or imposing conditions on his practice would be significantly, if not completely, ineffective. A period of suspension must relate to the practitioner's time in New Zealand and the things that can be significantly addressed during that period of suspension to ensure better practice for the future and compliance with all ethical and legal requirements. Those might include completion of an appropriate course or courses; time for reflection; consultation with peers and other support networks; and other relevant conditions. Conditions imposed on practice in New Zealand only come into effect at some indeterminate time in the future when, and if, Dr Feller resumes practice here.
- [181] Furthermore, an order for suspension has deterrence considerations for both the practitioner and the profession of which he or she forms part. If the consequence of a suspension is that a practitioner is not prevented from practising for the

period because of absence from New Zealand, it becomes nugatory. It may be that, had Dr Feller attended and explained his position or shown some acceptance and awareness of the issues involved or been able to participate in some formulation of outcome that would address the issues, the Tribunal could have considered an order other than cancellation of registration, such as suspension and or imposition of conditions on Dr Feller's practice for a relevant period. That has not occurred, however, and that is a primary reason why those outcomes are not available to the Tribunal to consider in this case.

[182] This issue has been addressed before by the Tribunal. In *Augustine*¹⁴, the medical practitioner had returned to the United States of America and did not attend the hearing of the charges against him. The charges included forging prescriptions for himself and his wife and writing prescriptions for his wife for a drug of dependence. The Tribunal described that there were serious questions to be answered concerning his health condition and his intentions for any further practice in New Zealand and said:

“134. In addition to that, given his absence from New Zealand now and his stated intention not to return to practise here, the Tribunal has considered carefully whether its concerns could be addressed by any order short of cancellation of Dr Augustine's registration. If he is not to practise in New Zealand any longer, then a suspension order would be nugatory. Likewise would any conditions on any resumption of practice. Those outcomes are practically not available to the Tribunal. The case compares in that regard with Fernando¹⁵ where the medical practitioner had been absent from New Zealand for many years and, in considering suspension, the Tribunal said:

Before reaching that conclusion, we have of course considered other options such as suspension. In this regard, it should be recalled that the Practitioner has not lived or practised in this country for years. That fact alone suggests that suspension would not be apt.

135. What the Tribunal can do effectively, however, is cancel his registration so that, if he ever does wish to return to New Zealand and practise, he can make appropriate application and the full situation then, including any dependence his wife may have (or indeed his own medical condition) can be considered

[183] The matters to which the Charge and this decision refer are significantly serious. Vulnerable and terminally ill patients became involved in this clinical trial and

¹⁴ 968/Med17/411P

¹⁵ 860/Med16/352P

the use of TKG when they were hoping for some positive outcome for them. There may well have been for them a reliance on this product such that they did not take other medical advice, assistance or treatment that could have been beneficial and so the consequence for them may have been significantly compromised by being involved in the use of this product. These are serious matters and they go to the heart of medical practice and in particular the trial of a new product. Dr Feller has embarked on this clinical trial, found to be an intervention study, with completely inadequate compliance with guidelines and a significantly likely negative outcome for his patients.

[184] In all the circumstances of the case the Tribunal has concluded that it has no option but to order cancellation of Dr Feller's registration. Questions of any rehabilitation into the profession in New Zealand or of conditions or otherwise on practice can be addressed if ever Dr Feller returns to New Zealand and seeks registration and to practise as a medical practitioner here. That order for cancellation is included below.

[185] There is no benefit in considering any orders under section 102 of the HPCA Act which relate to conditions to be complied with before any application for re-registration is made because they cannot be realistically addressed either.

[186] There needs to be an order for censure to express the Tribunal's significant disquiet about the events and the misconduct on Dr Feller's behalf and that is ordered below.

[187] There also needs to be an order for payment of a fine of \$5,000.00. This is because cancellation of Dr Feller's registration as a medical practitioner in New Zealand will not prevent him from earning income elsewhere, and in particular in the United States of America to which he has returned. There would be no monetary consequence flowing from cancellation of his registration accordingly; and the Tribunal determines that an order for fine should be made against him. This is a proportionate response.

Costs

[188] The PCC sought an order for costs and, having referred to various authorities, advised the Tribunal that its costs including investigation and preparation amounted to some \$64,500.00. The Tribunal must also consider its own costs estimated to be some \$28,939.00. This is approximately \$93,500.00. The

Tribunal finds that those sums are costs reasonably incurred in the circumstances. The PCC sought an order for contribution to those costs of 60%.

Section 101 of the HPCA Act provides in this context:

“... the Tribunal may—

....

(f) order that the health practitioner pay part or all of the costs and expenses of and incidental to any or all of the following:

(i) ...

(ii) any inquiry made by a professional conduct committee in relation to the subject matter of the charge:

(iii) the prosecution of the charge by ... a professional conduct committee, ...:

(iv) the hearing by the Tribunal”.

[189] There are two statements of principle drawn to the Tribunal’s attention from decisions in the High Court. The first of these is *Cooray v Preliminary Proceedings Committee*¹⁶:

“It would appear from the cases before the Court that the Council [the MCNZ that then had jurisdiction in the matter] in other decisions made by it has in a general way taken 50% of total reasonable costs as a guide to a reasonable order for costs and has in individual cases where it has considered it is justified gone beyond that figure. In other cases where it has considered that such an order is not justified because of the circumstances of the case, and counsel has referred me to at least two cases where the practitioner pleaded guilty and lesser orders were made, the Council has made a downwards adjustment”.

[190] The second case mentioned is *Vatsyayann v Professional Conduct Committee of the New Zealand Medical Council*¹⁷. There it was said¹⁸:

“So far as costs orders were concerned, the Tribunal correctly addressed a number of authorities and principles. These included that professional groups should not be expected to bear all the costs of a disciplinary regime and that members of the profession who appeared on disciplinary charges should make a proper contribution towards the costs of the inquiry and a hearing; that costs are not punitive; that the practitioner’s means, if known, are to be considered; that a practitioner has a right to defend himself and should not be deterred by the risk of a costs order; and that in a general way 50% of reasonable costs is a guide to an appropriate costs order subject to a discretion to adjust upwards or downwards...”

¹⁶ Wellington HC: AP 23/94; 14/9/95; Doogue J;

¹⁷ [2012] NZHC 1138

¹⁸ Paragraph 34

- [191] The Tribunal has been given no information about Dr Feller's means or whether he can or cannot meet a reasonable contribution towards costs. One element of financial information that the Tribunal has is the return there has been to PureCure from the sale of the product, TKG, and therefore the resultant return to Dr Feller. That is not to say Dr Feller is to be penalised by any costs order, but it does give a small indication of some resources.
- [192] In this case the conduct of the hearing has not been in any way facilitated by Dr Feller and the PCC has had to incur the cost of all preparation and presentation of the case to the Tribunal. The PCC on behalf of the Tribunal incurred the cost of obtaining an Order for Substituted Service from the District Court. The information provided eventually by Dr Feller to the PCC was not properly collated and included significantly irrelevant material which had to be analysed and filtered.
- [193] Any costs not met by Dr Feller will be met by the profession and that must be taken into account.
- [194] It is appropriate that Dr Feller make a greater contribution to costs and the Tribunal fixes this at 60%, which is the sum of \$56,100.00 which is ordered below.

Name suppression

- [195] The Tribunal made at the hearing, and now confirms, an order for non-publication of the names and all details of the medical conditions of any of the patients involved in the trial by Dr Feller. One exception to that is the late Sir Colin Meads as his name is in the public domain already from publicity having been given to his use of the product. Another prominent New Zealander was mentioned briefly in correspondence. The Tribunal has no evidence or information about this person nor any application for non-publication of his name. Submissions from a news medium resisted any order for non-publication of that person's name but agreed that it was appropriate that there should be an order for non-publication of the documents which contain his name. That seems an appropriate course to the Tribunal and an order is made accordingly.

Result and orders

[196] The Charge against Dr Feller is made out in all its particulars as misconduct as malpractice and negligence and conduct bringing discredit to his profession.

[197] The registration of Dr Feller as a medical practitioner is ordered to be cancelled.

[198] Dr Feller is ordered to be censured in the matter.

[199] Dr Feller is ordered to pay a fine of \$5,000.00.

[200] Dr Feller is ordered to pay the sum of \$56,100.00 towards the costs of the PCC and the cost of the Tribunal in this matter to be divided as to 66%, \$37,026.00 , to the PCC and 34%, \$19,074.00, to the Tribunal.

[201] The Tribunal confirms the order for non-publication of the names of the patients involved in the trial except for the late Sir Colin Meads. It makes an order prohibiting the publication of such parts of the documents produced to the Tribunal as contain reference to [].

[202] The MCNZ is requested to send a copy of this decision and any other material that the MCNZ considers appropriate to the appropriate authorities in the State of South Carolina and the Federation of State Medical Boards in the United States of America so that those authorities there are fully conversant with the matters raised in this decision.

[203] Pursuant to section 157 of the HPCA Act the Tribunal directs the Executive Officer:

- a) To publish this decision, and a summary, on the Tribunal's website;
- b) To request the MCNZ to publish either a summary of, or a reference to, the Tribunal's decision in its next available publication to members, in either case including a reference to the Tribunal's website so as to enable interested parties to access the decision.

DATED at Auckland this 17th day of October 2019



.....
 David M Carden
 Chairperson
 Health Practitioners Disciplinary Tribunal

SCHEDULE

Pursuant to sections 81(2) and 91 of the Act, the Committee charges Dr Mitchell Dean Feller as follows:

Background

1. At all material times, Dr Feller was a registered Medical Practitioner, carrying on work as a general practitioner in Hawera.
2. On or about 19 July 2016, Dr Feller and an associate incorporated PureCure Limited (**PureCure**).
3. At all material times, Dr Feller was listed as a director of PureCure, owning a 50% shareholding in that company.
4. The commercial activities of PureCure included the company manufacturing, supplying and selling the product 'Te Kiri Gold' (**TKG**).
5. The active ingredient in TKG is hypochlorous acid.

Clinical trial

6. Between 19 July 2016 and 6 July 2017, Dr Feller developed and/or conducted a clinical study and/or clinical trial (**Trial**) involving TKG. The Trial was undertaken by Dr Feller in circumstances where he failed to seek and/or obtain the necessary approval from the relevant accredited ethics committee/organisation, namely The New Zealand Health and Disability Ethics Committees (**HDEC**), in circumstances including where:
 - (a) human participants were recruited in their capacity as consumers of health or disability support services; and/or
 - (b) human participants were recruited in their capacity as volunteers in clinical trials; and/or
7. In undertaking the Trial, Dr Feller failed to adequately follow and/or comply with the relevant ethical guidelines for clinical research studies, [deleted at hearing]:
 - i. The National Ethics Advisory Committee guidelines; [deleted at hearing]
 - ii. [deleted at hearing]

Supply/sale of TKG

8. Between 19 July 2016 and 6 July 2017, Dr Feller supplied and/or assisted in the supply of TKG, or otherwise encouraged the use of TKG, in circumstances where:
 - (a) he used his influence and/or position as a medical practitioner to recruit and/or encourage patients to participate in the trial; and/or
 - (b) he failed to obtain informed consent from patients in that he did not provide sufficient and/or adequate and/or accurate information to patients concerning TKG; and/or
 - (c) he failed to disclose that he had a financial and/or shareholders interest in PureCure; and/or
 - (d) the patient group involved in the Trial included vulnerable and/or terminally ill patients, to whom he owed a greater duty of care, pursuant to HDEC guidelines; and/or
 - (e) he acted in contravention of the Health Information Privacy Code 1994, in that he unfairly induced patients to provide their health information as a prerequisite to obtaining TKG.
9. The Committee charges that Dr Feller's conduct, as particularised at paragraphs 6 to 8 above (inclusive), breached Medical Council statements including *Good Medical Practice*, and/or *Statement on Information, choice of treatment and informed consent*, and/or *Statement on Doctors and CAM (complementary and alternative medicine)*.
10. The conduct alleged at paragraphs 6 to 8 above (inclusive) amounts to professional misconduct in that, whether separately or cumulatively, it:
 - (a) amounts to malpractice or negligence in relation to his scope of practice pursuant to section 100(1)(a) of the Act; and/or
 - (b) has brought or is likely to bring discredit to the profession, pursuant to section 100(1)(b) of the Act.