STATEMENT OF DECISION

Respondent:	**Andrew Katelaris**
Complainant:	Dr Kerry Chant, NSW Ministry of Health

Confidential information has been removed pursuant to section 41B of the *Health Care Complaints Act 1993*

1. The Complaint

1.1 On 21 October 2015 the Health Care Complaints Commission (the Commission) received a complaint from Dr Kerry Chant, Chief Health Officer and Deputy Secretary, Population and Public Health, NSW Ministry of Health. Dr Chant complained that Dr Andrew Katelaris, a de-registered medical practitioner, had provided an intraperitoneal injection of what was claimed to be 12g of cannabis oil (THC and CBD oil or cannabidiol in a 2:1 ratio) to a 56 year old female with metastatic ovarian cancer, which resulted in her prolonged hospitalisation at Calvary Mater Hospital, Newcastle.

1.2 Concerns were reported to Dr Chant by a clinical pharmacologist at Calvary Mater, Dr A, who advised that the patient had been injected by Dr Andrew Katelaris at the Wellness Clinic in Newcastle on 2 September 2015 and for two days following the injection and prior to her presentation at the hospital, had reported experiencing significant and frightening hallucinations and vomiting and had not eaten.

1.3 The patient had presented to Calvary Mater on 4 September 2015 with fevers, a painful distended abdomen (requiring opiates), vomiting, dehydration and confusion. During her stay she developed a low grade peritonitis thought to be secondary to peritoneal irritation and required albumin and red cell infusion. Due to her long bed stay and general frailty, she was discharged to a rehabilitation facility on 21 September 2015. It was reported that hallucinations, confusion and abdominal pain were present throughout the patient's hospital stay and that elements of altered mental state had persisted as at the time of the complaint.

1.4 It was also reported that Dr Katelaris had visited the patient during her hospitalisation and was allegedly seeking access to her blood results and asking the patient to come to the Wellness Clinic to be looked after. Wellness Clinic employees also reportedly visited the patient in hospital, bringing her alternative health foods and vitamins.

1.5 Dr Chant noted in her complaint that she had also been made aware of a second patient with ovarian cancer who had been injected intraperitoneally at the same time by Dr Katelaris and who was admitted to John Hunter Hospital for a few days with similar symptoms to those experienced by the first patient.

1.6 Dr Chant summarised the concerns about Dr Katelaris' conduct as being that he had provided a treatment as an unregistered health practitioner that had led to the hospitalisation of two patients, that he had attempted to interfere with necessary care while a patient was recuperating, that he had used high

THC products manufactured in an unknown environment that had led to symptoms requiring the prolonged hospitalisation of two patients and that he had potentially exploited vulnerable people.

1.7 On 16 November 2015, Calvary Mater identified the first patient, Ms K, and provided the Commission with her clinical records.

1.8 The Commission wrote to John Hunter Hospital seeking the identity and clinical records of the second patient alleged to have been injected intraperitoneally with cannabis oil by Dr Katelaris at the Wellness Clinic and admitted to the hospital around 4 September 2015. On 23 March 2016 John Hunter Hospital identified the patient as Ms M and provided the records of her admission between 4 and 7 September 2015 to the Commission.

1.9 Ms K died on 21 February 2016.

2. Issues

2.1 The Commission investigated the following issues:

- Whether Dr Andrew Katelaris breached the Code of Conduct for non-registered Health Practitioners ('the Code of Conduct') by administering intraperitoneal injections of cannabis oil to two patients suffering metastatic ovarian cancer and in his management of their adverse reactions to that administration;

- Whether Dr Katelaris poses a risk to the health or safety of members of the public.

2.2 The relevant clauses of the Code of Conduct, as set out in Schedule 3 to the *Public Health Regulation 2012*, in this case are:

- Clause 3(1): a health practitioner must provide health services in a safe and ethical manner;
- Clause 3(2)(c): a health practitioner must not provide services that he or she is not qualified to provide;
- Clause 3(2)(i): a health practitioner must encourage his or her clients to inform their treating medical practitioner (if any) of the treatments they are receiving;
- Clause 5(1): a health practitioner must not hold himself or herself out as qualified, able or willing to cure cancer or other terminal illnesses;
- Clause 5(2): a health practitioner may make a claim as to his or her ability or willingness to treat or alleviate the symptoms of these illnesses if that claim can be substantiated;
- Clause 7(1): a health practitioner must not attempt to dissuade clients from seeking or continuing with treatment by a registered medical practitioner;
- Clause 7(2): a health practitioner must accept the right of his or her clients to make informed choices in relation to their health care;
- Clause 7(3): a health practitioner should communicate and cooperate with colleagues and other health care practitioners and agencies in the best interests of their clients;
- Clause 11: a health practitioner must not diagnose or treat an illness or condition without an adequate clinical basis;

- Clause 15: a health practitioner must maintain accurate, legible and contemporaneous clinical records for each client consultation.

3. Respondent

3.1 Dr Andrew Katelaris (PhD) was a registered medical practitioner in NSW until December 2005 when the then Medical Tribunal ordered his deregistration for inappropriate prescribing practices in relation to drugs of addiction and prescribed restricted substances, the breach of a number of conditions on his registration, including a prohibition against his own use of cannabis, and his inappropriate supply of cannabis to various persons. In relation to the latter allegation, Dr Katelaris admitted supplying cannabis to people for the control of symptoms of illness. He said that he had supplied cannabis to about 12 people who were very ill, in some cases terminally. He admitted knowing that this conduct was in contravention of the *Drug Misuse and Trafficking Act 1985* and that he had no legal authority to supply the cannabis. Dr Katelaris maintained before the Tribunal that he was involved in a "pilot study" to demonstrate a medically effective form of cannabis and that he had been acting compassionately.

3.2 In its December 2005 decision the Medical Tribunal noted that Dr Katelaris had also made it clear in his submissions that he proposed to continue to carry out research into the medical use of cannabis and the Tribunal found that he showed no concern that he had no legal authority to carry out such research, or approval from an ethics committee, or authority from the NSW Department of Health to supply cannabis to any persons. The Tribunal found that Dr Katelaris had acted in deliberate defiance of legal restrictions and ethical standards of practice and had demonstrated a refusal to accept that he was bound by the same laws and restrictions that govern all other medical practitioners and by ethical rules and obligations which all reputable practitioners would recognise as binding on them.

3.3 Dr Katelaris was unsuccessful when he applied to the Medical Tribunal in 2009 for a review of the decision to deregister him. Following the 2005 Tribunal decision he had been convicted of cultivating a commercial quantity of cannabis and as a result of comments directed towards and about the jury at the end of the trial, he was found guilty of two counts of contempt. The 2009 Tribunal noted Dr Katelaris' continued inability to acknowledge any fault or error on his part in relation to both the criminal offences and the professional misconduct for which he had been deregistered in December 2005 and found that he had not discharged his onus of persuading the Tribunal that he was a fit and proper person to be registered as a medical practitioner. Dr Katelaris has not sought a review of that order.

3.4 Since that time, Dr Katelaris has continued to engage in activist efforts to legalise cannabis for medicinal use and his own research into "*the emerging science of cannabis, its use in childhood epilepsy, pain management, cancer, and many other illnesses*"[1]. He works as a practitioner at the Wellness Clinic in Newcastle, which is run through an organisation called the Church of Ubuntu, self-described as an "*alternative community designed to give needed support to patients and their families challenged by such things as cancer, leukemia, epilepsy, MS, fibromyalgia, and more*". On the Church of Ubuntu website, a short video called "The Pot Doctor" notes that despite the fact that

[1] Cannabis Hemp Guide, September 2015, www.cannabishempguide.org

cannabis use has been highly restricted by the Australian Government since the 1920's, Andrew Katelaris "*continues to grow, promote and prescribe the plant medicinally to both adults and children*".

4. Investigation

4.1 The Commission obtained evidence during this investigation from the following sources:

- Complaint from Dr Kerry Chant dated 15 October 2015;
- Clinical records for Ms K from Calvary Mater Hospital for the period 4 to 20 September 2015;
- Clinical records for Ms K provided by her treating oncologist, Professor B, under cover of his letter to the Commission dated 22 December 2015;
- Clinical records for Ms M from John Hunter Hospital for the period 4 to 7 September 2015;
- Email from Andrew Katelaris to Ms K, sent 31 August 2015, titled "Research Proposal: Novel treatment for malignant ascites"
- The Cannabis Hemp Guide, online monthly publication, September 2015;
- Decision of the Medical Tribunal in *Re Dr Andrew Katelaris*, dated 15 December 2005;
- Decision of the Medical Tribunal in *Dr Andrew Katelaris and the Medical Board*, dated 16 October 2009;
- Church of Ubuntu website: www.churchofubuntu.org;
- File note of telephone conversation between Commission Investigation Officer and Ms M on 1 April 2016;
- File note of telephone conversation between Commission Investigation Officer and Ms K's sister on 10 May 2016;
- Email from Ms M to the Commission dated 23 May 2016, attaching "Research Proposal: Novel treatment for malignant ascites" provided to Ms M by Dr Katelaris prior to treatment;
- Transcript of interview with Dr Andrew Katelaris at the Commission on 21 June 2016;
- Written submissions compiled on behalf of Ms K and her family by Ms K's sister, dated 19 August and received by the Commission 8 September 2016.

5. Summary of Evidence

Evidence concerning Ms K

(i) Professor B's clinical record

5.1 Ms K was diagnosed with stage 3c ovarian cancer in early March 2015, confirmed as stage 4 by needle biopsy. She was 56 years old. On diagnosis, she had an elevated CA125 level of 5714 and palpable groin nodes indicative of metastatic adenocarcinoma, as well as abdominal ascites associated with the tumour, causing swelling and discomfort. She was noted to be keen on pursuing complementary therapies as well as mainstream medical treatment for her cancer. Upfront surgery was not recommended as appropriate, but upfront chemotherapy was recommended as highly likely to improve the ultimate surgical outcome and her overall fitness. Her desire to pursue complementary therapies was encouraged as long as this did not "*impose unreasonable restrictions on proven therapy*".

5.2 Between 12 June and 12 August 2015 her tumour marker (CA125 level) steadily fell from 4200, to 3100, to 2400, to 1700 as she underwent cycles of chemotherapy over that period.

5.3 In April 2015 she was noted to have lost about nine kilograms over the previous month and between 23 April and 13 August 2015, the evidence indicates she lost another approximately five kilograms in weight. In the eight weeks between 13 August and 14 October 2015, which covers the period in which she received intraperitoneal cannabis oil from Dr Katelaris and her subsequent hospitalisation, her weight dropped by another approximately nine kilograms.

5.4 On 27 October 2015, Professor B, Ms K's oncologist, wrote to her GP to say that Ms K "*has clearly had major toxicity from unconventional treatments*", noting that she was given intraperitoneal cannabis oil and THC on 2 September which provoked crampy intra-abdominal pain with vomiting and psychotropic disturbance. He noted her admission to Calvary Mater Hospital on 4 September for intravenous fluids and antibiotics, her discharge on 28 September and further episodes of vomiting which prompted readmission to hospital. He noted that she was not presently fit to have further trials of chemotherapy and that if Ms K's condition continued to deteriorate at the rate it had done in the last few weeks, he considered her survival to be measured in weeks to months.

5.5 Professor B advised the Commission that an unregistered practitioner had accompanied Ms K to two appointments with him; the first occasion he believed to be on 10 June and the second, 14 October 2015. He said that Ms K had told him on the second occasion about the administration of intraperitoneal cannabis oil and tetrahydrocannabinol on 2 September 2015 and the subsequent complications and that Dr Katelaris had "*expressed distress*" at the complications of the intraperitoneal injection.

(ii) Ms K's timeline of IP cannabis oil treatment and hospitalisation

5.6 Ms K kept a written record or journal of her involvement with Dr Katelaris and his intraperitoneal administration to her of cannabis oil, a copy of which she provided to her oncologist in October 2015. This timeline, with accompanying photographs, is also included in the written submissions provided to the Commission by Ms K's sister.

5.7 Ms K recorded that in April 2015 she contacted a Newcastle journalist about an article he had written concerning a woman whose breast cancer had apparently gone into remission following her use of medical cannabis oil. The journalist put her in touch with a person, 'BJ', who was apparently able to supply Ms K with medical cannabis oil for pain and nausea and who introduced her to a naturopath at the Wellness Clinic in Newcastle. The naturopath in turn introduced Ms K to Dr Katelaris who was described by Ms K as "*working extensively using medical cannabis oil for epileptic children and also for some cancer patients*".

5.8 Ms K had her first paid Skype consultation with Dr Katelaris on 19 April 2015, during which he discussed alternatives to chemotherapy, including the use of medical cannabis oil, following her proposed debulking surgery. She remained in contact with the naturopath and Dr Katelaris between May and August 2015 through email and the occasional telephone call, found both practitioners caring and concerned about her health and her trust in Dr Katelaris' advice grew.

5.9 On 13 August 2015, Ms K recorded that she had her second paid consultation with Dr Katelaris and that he accompanied her to an appointment with her oncologist, Professor B. She stated that it was after this consultation that Dr Katelaris told her:

> *of the option of trialling a new medical cannabis oil treatment where he is planning to experiment with injecting highly concentrated medical cannabis oil via IP into the peritoneal cavity with a view to more directly targeting of the cancer tumours with a view to possibly killing the cancer cells that have been creating my chronic ascites. Andrew explains that this experiment is based on the research work on medical cannabis oil done by Dr Guzman of the University of Madrid.*

He apparently encouraged her to do her own research into Dr Guzman's work and decide whether she wanted to go ahead and take part in the 'trial'.

5.10 On 20 August 2015, Ms K noted that she was desperate to get rid of her chronic ascites, which was persisting despite four chemotherapy cycles and a continuing drop in her tumour marker levels. Her next round of chemotherapy was due to commence on 10 September 2015 and she recorded wanting to get her ascites drained as soon as possible before then. However she also noted "*to enable a proper trialling of Dr Katelaris IP medical cannabis oil I need to have the ascites present 'pre-drain' to see if the oil will work on reducing it*".

5.11 Because her next round of chemotherapy was scheduled for 10 September 2015, Ms K noted there was only "*a short window of time to undertake Andrew's trial*" and that he accordingly scheduled it for 2 September at the Wellness Clinic in Newcastle. He told her that another patient with ovarian cancer and chronic ascites would be travelling down from Nimbin to participate in the trial as well.

5.12 Ms K decided to undergo the trial after researching Dr Guzman's work, but she had concerns about a number of aspects of the trial, including the sterility and constituents of the oil and how the treatment would be conducted and she emailed Dr Katelaris a number of questions on 31 August 2015.

5.13 By email that day Dr Katelaris told Ms K that he was writing up the protocol and would provide it to her that evening, including information about exactly what and how much would be injected into her. In response to her question as to whether he had injected humans or animals with the proposed substance previously and if so, what the outcome was, he stated "*I have told you several times this is the first experience we will have*". In response to her question as to how he knew an intraperitoneal injection of the substance would be medically safe if she was the first person he had ever trialled the substance on, he stated that the "*cannabinoids are intrinsically safe in any dose. My main concern is to disperse the medicine without causing irritation*".

5.14 Dr Katelaris assured Ms K that alcohol would be used to sterilise the injecting equipment and he also stated that "*cannabis oil is strongly bactericidal*" and that although he had little to worry about on that count, he would pass the solution through a 0.2 micron filter if he could obtain one. In response to her question about side effects, specifically whether she would feel "*stoned*" and her concern about the impact of THC on her existent depression which he attributed to the disease and the chemotherapy, Dr Katelaris stated "*it is a big THC dose but should be balanced by the CBD and the fact that most will remain localised in the peritoneum for a while and not act centrally*".

5.15 Dr Katelaris told Ms K that only a single treatment was envisaged as long as her tumour was responsive and he advised that the success of the treatment would be measured by a "*combination of ascites reduction, markers and imaging depending on the situation as it develops*". He told her that 24 hours of observation should be adequate following the injection. To Ms K's concern that the "experimental substance" may affect her next round of chemotherapy scheduled for 10 September, by, for example, causing an inflammatory reaction or infection that even further lowered her neutrophil count, he responded that she would not be treated if she was neutropenic.

5.16 Significantly, Ms K told Dr Katelaris that she would like to let her oncologist, Professor B, know that she was undertaking the experiment and that it was a choice she had taken of her own free will, so that he could be informed about what was going on. She also wanted to be able to record any improvements from the experiment prior to her next scheduled chemotherapy cycle and report on any illness or other side effects that may have a bearing on that next cycle. She told Dr Katelaris specifically that she would be uncomfortable keeping this information from Professor B as it may have a bearing on her upcoming chemotherapy and surgery. Despite Ms K's concerns, Dr Katelaris told her "*I would prefer you defer until after the procedure. Then, especially if it went well I would discuss the matter with Prof myself*".

5.17 Ms K recorded having attended the Wellness Clinic accompanied by her friend on 2 September 2015. By the time she arrived, the other participant in the trial had already received an intraperitoneal injection. She noted that she was not given any 'waiver' forms to sign prior to her treatment. Dr Katelaris' 'medical support team' consisted of a nurse (albeit one then "*having a break from nursing*"), a naturopath and other Wellness Clinic staff and volunteers. She recorded receiving a local anaesthetic, having a cannula inserted and then being injected intraperitoneally with two x 20ml of the oil and gently rocked from side to side "to distribute the oil".

5.18 Ms K described then experiencing, within approximately 10 to 15 minutes following the injection, "*excruciating gut pain that keeps moving across my diaphragm causing very painful contractions. I then get a referred pain that starts in my liver then moves to a sharp stabbing pain in my left shoulder. Then the pain moves back to my gut*". This was accompanied by cycles of violent vomiting and within 20 to 30 minutes, she stated that she was completely "stoned" and dropping in and out of lucidity.

5.19 In response to Ms K's request for pain relief, she was offered oral cannabis oil capsules by someone at the Wellness Clinic and eventually the pain was so extreme, even after taking Panadol and Buscopan, that Ms K took one, which provided some relief.

5.20 Ms K recorded that the following day, due to her ongoing vomiting, her blood pressure began dropping and Dr Katelaris put her on a saline drip and administered intravenous Vitamin C. She discovered later that the other patient experienced very similar physical reactions to the oil as hers and that Dr Katelaris was moving between the two women to check on them. Ms K recorded that in her lucid moments, she expressed concern to the Wellness Clinic staff monitoring her that no one was making a clinical record of her reaction, fluid loss due to vomiting or fluctuating lucidity. She was told they were "*remembering*" and would make notes later.

5.21 On 4 September 2015 Ms K was still vomiting intermittently and experiencing abdominal pain and fluctuating lucidity. She recorded that the other patient was also having problems and that Dr Katelaris decided to take them both to hospital. Ms K was taken to Calvary Mater and the other patient to John Hunter Hospital.

5.22 Ms K recorded that by good fortune, Calvary Mater was scheduled to commence a research project in November 2015 into the use of medical cannabis oils for pain and nausea relief and the Registrar called the manager of that project, Dr A, who cautioned against the kidney flush he proposed. Dr A advised that such a procedure may distribute the oil throughout Ms K's body in an uncontrolled way because the carrying agent was medical coconut oil. The decision was taken to manage her conservatively and she was put on intravenous fluids, pain relief and antibiotics.

5.23 Ms K recorded that 5 days after the intraperitoneal injection, she was still vomiting, heavily "*stoned*" and in and out of lucidity, although her abdominal pain had greatly reduced. Her appetite was suppressed and she found it difficult to keep food down.

5.24 Ms K recorded that at some point during the first week of her admission, Dr Katelaris visited her in hospital and told her he was "*annoyed with himself*". He told her that the oil he had been planning to use on both patients, with "*known*" THC and cannabinoid levels was sourced from the US but had been held up in customs. Rather than postpone the trial, he had made up his own oil, but was unable to laboratory test the THC and cannabinoid levels. She noted that neither patient had been told about this prior to the injection of the untested oil.

5.25 Dr A took urine and blood samples to measure Ms K's THC and cannabinoid levels on 11 September 2015. Ms K noted that the "*cut-off level for measuring high levels of THC in urine mg/ml are **15**. My THC levels, taken one week after admission are **4000**!*"[2] Around this time her CA125 levels were also measured and had dropped to 1100 and she has recorded in her timeline that they were still at this low level post-discharge and despite having missed her scheduled fifth cycle of chemotherapy on 10 September 2015. However on 16 September 2015 she had 2.5 litres of ascites fluid drained and was given a blood transfusion due to very low haemoglobin levels.

5.26 On 20 September 2015, Ms K was considered well enough for transfer to her local hospital, where she stayed for another eight days. Ms K recorded that because her stoma had been completely inactive for over two weeks due to eating so little, the hole had closed over with skin growth. She recorded still feeling very sick, weak and heavily "stoned", having difficulty eating and having lost over eight kilograms in weight from the time of the trial to her hospital discharge.

5.27 By 2 October 2015, Ms K's CA125 levels had climbed back up to 2200 and by 4 October, with uncontrolled vomiting and bad abdominal and bowel pain, she realised she had a bowel blockage, called an ambulance and was readmitted to her local hospital. She stayed there for the next three days during which time she lost more weight, acquired a chest infection and her closed stoma hole burst

[2] Calvary Mater Hospital pathology records for Ms K report a THC confirmation level of 3734 ng/mL for a urine specimen collected on 9 September 2015, when cut-off level for 11-nor-carboxy-THC is 15 ng/mL; on 16 September, her THC level was > 4000

open. She recorded that her next consultation with Professor B would be on 14 October 2015, where she would learn what options remained for treatment and where Dr Katelaris would come to meet Professor B and answer any questions he may have about the cannabis oil trial.

(iii) Calvary Mater Hospital Records

5.28 Ms K's clinical records contain a handwritten note addressed to the admitting officer from Dr Andrew Katelaris, dated 4 September 2015 and presumably sent with Ms K to hospital in the ambulance. He has written:

> *[Ms K] is a friend of mine, visiting Newcastle from Windsor. She has ovarian cancer with recent chemotherapy. She has a colostomy due to past obstruction. No bowel movement + distension + vomiting.*
>
> *4pm Pulse 100 RM*
>
> *Temp 38° (no rigour) (sic)*
>
> *P.u(?)-noon*
>
> *Thank you for caring. Phone 0414……. Please keep me updated.*
>
> *Dr Andrew Katelaris MD.*

Significantly, there is no mention of the intraperitoneal cannabis oil he administered two days previously, nor of the full clinical picture from 2 September 2015 onwards. There is a clear attempt to suggest that she is a personal friend, rather than a patient, that he is (incidentally) a medical practitioner and that the fairly superficial clinical information he sets out is only what would be known to and observed by him as a medically qualified friend.

5.29 The deliberate failure to provide a full and accurate clinical picture that would implicate Dr Katelaris in the administration of cannabis oil to Ms K is also evident from the ambulance electronic medical record contained within Ms K's clinical record, where the case description includes the following:

> *Pt lying in bed at friends health and wellbeing centre, has been there for a couple of days. Recent chemo for ovarian Ca 20/8/15. Pts friend/Dr gave 2000mls IV fluids yesterday and IV Vit C today. Pt has also been receiving alternative treatment from this Dr since wednesday (sic). Paramedics unsure of what the treatment is.*

Similarly, Ms K's presenting problem on admission is recorded in the notes as being "*referred by MO febrile post chemo*".

5.30 It is not until 1925 hours the evening of her admission that it is recorded that she had "*alternative therapy this week including 'marijuana injection into abdomen'*" and has been unwell with increasing abdominal tenderness since that time. The impression at that examination was that she had sepsis of unknown origin and possibly bacterial peritonitis in view of the injection. Later that evening further history is recorded in the progress notes, including that the "*doctor*" who administered the "*marijuana injection*" is Dr Andrew Katelaris "*MD*", running a health centre in the Hunter region using "*alternative Rx*" and that he is

deregistered. The medical registrar has noted *"? criminal negligence by Andrew Katelaris"* in the records.

5.31 The progress notes from this time record Ms K as being in considerable pain on movement, very drowsy and lethargic, vague, confused and tolerating only a small amount of food. On 7 September, Ms K's sister travelled down to see her and stay nearby and on 8 September in view of Ms K's ongoing confusion, the hospital tried to contact Dr Katelaris to ask him for details of the cannabis trial. Dr Katelaris visited Ms K later that day and according to the nursing notes, wanted Ms K to come to the Wellness Clinic to be looked after. Ms K's sister is recorded as being unhappy with his visit and with the proposal that Ms K be discharged the following day.

5.32 On 9 September a medical officer discussed the recent *"trial"* with Dr Katelaris and recorded that the patient was given 12g of mixed cannabinoid (CBD to THC in a 2:1 ratio) diluted with saline and given intraperitoneally. He noted that it was *"reportedly aseptic technique but conducted in domestic environment"* and that both Ms K and another lady had developed severe abdominal cramping, vomiting and disorientation within 15 minutes of the injection, with the symptoms persisting for two days before they were taken to hospital. As a result of that history, Ms K was reviewed by consultant, Dr A, and her clinical impression of Ms K's ongoing condition was cannabinoid toxicity with or without bacterial peritonitis, with a plan to test blood and urine samples for the cannabinoid concentration and a proposed intraabdominal washout. That day the notes also record that a *"friend"* from the Wellness Clinic had brought in a green smoothie for Ms K, the ingredients of which apparently included hemp seeds and hemp and frankincense oil. Ms K was advised not to consume this in view of her possible cannabinoid toxicity.

5.33 On 10 September, the clinical team, including Dr A, determined that the probable cause of Ms K's inflammatory reaction was chemical irritation of the peritoneum and that it was unlikely that a washout would be able to lavage the fat soluble injection of cannabinoids and coconut oil out of Ms K's abdomen. It was noted that Ms K's drowsiness had significantly improved but that the toxicology team were now involved due to Ms K's cannabis toxicity.

5.34 On 11 September Dr Katelaris was recorded as visiting Ms K and was overheard questioning her about her pathology results and stating that he would find out what laboratory they were sent to in order to get them himself. Staff intervened and told him he had no authority to access the results and that it was a matter for Ms K whether she wished to inform him of them. After he left, the clinical nurse consultant spoke to Ms K about Dr Katelaris' behaviour and Ms K is recorded as having said *"she understood how difficult it was to get trial data on this subject for her condition"* but also that she would not participate in the injections again. She was appreciative of the efforts of staff to protect her interests.

5.35 On 12 September, Ms K's *"friend"* from the Wellness Clinic visited again and asked a nurse for Ms K's blood results. She was told she was not allowed to have the information. She then took a photograph of a trolley with lollies and chocolates for sale on the ward and complained at length that sugar causes cancer and that it was disgusting to be selling such items. After she left, Ms K requested copies of her blood results but was told that she would be informed of these by a medical officer, but not given copies.

5.36 By 15 September, during Dr A's review, Ms K was noted to have had a gradual improvement in cognition, with her hallucinations and vomiting settling. Ms K gave permission for repeat testing of her CBD/THC levels and for the de-identified publication of her results in a medical journal. She was advised that the illegal nature of the cannabis use had been reported and she was advised not to take products from the Wellness Clinic due to a lack of knowledge concerning their safety. On this occasion, Ms K told Dr A about the second patient from Nimbin and her similar presentation to John Hunter Hospital.

5.37 That day, Ms K was again visited by a "*friend*" from the Wellness Clinic, who brought her lunch, including another green smoothie which the friend assured nursing staff was made from vegetables. Ms K was reported to have vomited following the lunch and was noted to be very drowsy and lethargic after the meal. She was told that the "*powdered vitamin C*" could not continue to be brought in due to potential interactions and that the doctors need to be informed.

5.38 Dr Katelaris visited later that day and the nursing notes record that as he was discussing the success of his trials and programs with Ms K, the nurse took the opportunity to ask him what had gone wrong in Ms K's case. The notes record that his tone and body language became very aggressive as he asked the nurse why she thought something had gone wrong. She recorded pointing out Ms K's very high THC levels and confusion, which Dr Katelaris disputed until Ms K interrupted to agree she had been confused. Once Dr Katelaris left, the nurse also recorded asking Ms K how she felt having been part of an experimental procedure with no human clinical trial. Ms K is recorded as saying she gave informed consent, but that she had experienced more pain than expected, had concerns about the effect on her memory and cognition and that while she took into account the fact that Dr Katelaris was "*a zealot*", she had been surprised by his lack of protocol for follow up and felt he was not prepared in a way she had not expected. She said that at that stage she would not consider having the treatment again.

(iv) Ms K's sister's submissions

5.39 Ms K's sister prepared extensive and relevant written and pictorial submissions for the Commission which were received in final form on 8 September 2016. These provide an overview of Ms K's diagnosis, mainstream cancer treatment and involvement in Andrew Katelaris' 'trial' and include a number of emails between Ms K and the Wellness Clinic preparatory to her treatment there, transcribed text messages between Ms K and Dr Katelaris during her post-trial hospitalisation and an 'impact statement' describing the effect on Ms K's family of the events of the period from Ms K's cancer diagnosis to her death.

5.40 Ms K's sister has compiled the submissions in such a way that the account of what happened to Ms K is given as much as possible in her own words, derived from a collation of her notes, correspondence, emails, phone texts and drafts. Relevant evidence from those submissions that is additional to that contained in Ms K's timeline and clinical records will be set out in what follows.

5.41 By email dated 18 April 2015, attaching copies of the CT scan and ultrasound confirming her diagnosis, Ms K asked 'BJ' at the Wellness Clinic for more information about medical cannabis oil as a treatment for cancer, what the Church of Ubuntu does and what support and advice the 'group' can provide her. She noted in this email that she had spoken to a Newcastle Herald journalist

who had contacted the Clinic on her behalf. In his response the following day 'BJ' told Ms K that the Clinic offers:

> *professional Medical and Herbal based assistance with consultation in person in Newcastle, via skype and/or telephone…We supply full plant extraction MC oil for variety of ills. The whole plant is the way creation gave it to us, and this is what we aim to have in a concentrate. Please don't be too taken up with the whole cbd hysteria around at the moment, as we have been doing this for a few yrs now and with the aid of some of the best 'old timers' in Australia and USA, we aim to offer this gift from creation in all its amazing qualities.*
>
> *We dont have testing facilities here in Aus altho our 'organic trials' have been successful across a wide range of ills….hopefully soon we will have people consuming Cannabis raw as a vegetable, as it is the most important vegetable on the planet (sic).*

5.42 Emails evidence an arrangement for Ms K to have a consultation by Skype with Dr Katelaris and the Director of the Clinic, a naturopath, on 23 April 2015, at a cost of $150. The Director of the Clinic claimed that as the Clinic was "*already flooded with requests for help*" they had "*chosen not to have a public profile as we doubt we could keep up with the demand – hence you can't Google the clinic at this stage*".

5.43 Following the first Skype consultation, emails over the next month evidence arrangements for the provision of medicinal cannabis oil to Ms K for her immediate use. This is evidently distinct from the ultimately trialled intraperitoneal injection. Ms K was advised by the Clinic's Director:

> *you can get through the oil makers we work with – a 50ml bottle of MC -diluted with MCT (coconut oil in refined form) for $150 which for your situation should last 2-3 weeks and may act as immune support, potential tumour shrinkage (unknown for individual cases which is what Andrew was trying to explain on the phone yesterday), and provide relief for any pain, nausea or loss of appetite. The concentrated doses you were discussing with Andrew is another discussion for another time.*

5.44 In June 2015, Ms K's queries about the cannabis oil she had purchased from the Church of Ubuntu were in terms of its efficacy for pain relief at the dose recommended, whether she should continue to take it under the tongue or rectally and whether she was likely to get a bit 'stoned' if she increased the dose. The Clinic's Director advised her to increase the dose to help with the pain, to mix the oil with juice if she couldn't stand the taste and to experiment with rectal administration because this would enable a dramatic dose increase without the side effects.

5.45 On 19 August 2015, Ms K made notes about a telephone conversation she had with Dr Katelaris following his introduction of the idea of trialling intraperitoneally injected cannabis resin to attack Ms K's ascites. He had raised this as an idea following the appointment with Professor B to which he had accompanied Ms K

on 13 August 2015, but not in front of Professor B[3]. Ms K recorded having questioned him about where previous trials had been conducted and by whom and Dr Katelaris telling her she was not listening: "*I have told you a dozen times we are entering new territory*". In answer to where she might find previous research, he told her that she had an analytical mind and to do her own research on the internet, and finally, that previous experiments had been conducted by Dr Guzman in Spain involving injectable cannabis resin to shrink a brain tumour, but that she would be the first person it had been used on as an IP injection. He told her to use it when all her other options had been exhausted, but not to get too sick or run down and he told her he was not trying to 'sell' it to her; it was her choice.

5.46 Ms K's sister has noted at this point that Dr Katelaris' 'medical advice' in preparation for the experimental 'treatment' included his insistence that he would be unable to determine whether it had worked to reduce the ascites fluid unless the ascites was present and that he therefore counselled and 'pressured' her not to have an ascites drain, which her sister stated she had desperately needed at that point. Ms K acquiesced and her decision not to have the ascites fluid drained reportedly caused her "*a great deal of pain, nausea, bloating and discomfort for a matter of weeks before the 'treatment'*".

5.47 The evidence indicates that Ms K was excited to be going ahead with the trial and that she understood that it was experimental, but that she also had a number of pertinent questions she wanted answered before agreeing to proceed. On 31 August 2015 Dr Katelaris provided his responses to specific questions (as discussed at paragraph 5.13 and following) and provided her with what he termed a "*Research Proposal: Novel treatment for malignant ascites*" which he appears to have written that day. In it he described the following method for the proposed administration of the oil:

> *The patient will be placed supine and suitably draped. Local antisepsis provided with chlorhexidine*
>
> *Local anaesthetic infiltrated at injection site, 2 cm below umbilicus in the midline*
>
> *A 21 guage catheter will be introduced using "Z" tracking to minimise the risk of leakage.*
>
> *A suitable dose (10-20gm) of cannabis resin incorporating equal parts of THC and CBD will prepared in 20ml of warmed MCT oil and instilled slowly into the peritoneum. The patient will be gently rolled left to right to distribute the oil, the cannula removed and closed with steristrips.*
>
> *The patient to be observed for 24 hours post procedure.*

5.48 Dr Katelaris' 'research proposal' noted that this was a "*novel procedure which has yet to be reported by any researcher*" and that as such, there was uncertainty associated with the procedure and its possible outcomes. However, in relation to possible risks, he asserted "*cannabis is an exceedingly safe substance with no reported organ toxicity*" and that the psychotropic effect of the THC would be

[3] The submissions include evidence that Ms K paid Dr Katelaris $175 to accompany her to the consultation with Professor B on 13 August 2015, which included a contribution to his travel costs

"*minimised due to low systemic availability and modulated by co-administered CBD*". He further noted, as part of his 'disclaimer' that "*as it is being applied against a life threatening disease with no alternate treatment option and holds out the reasonable prospect of results the risk/benefit ratio is considered favourable*". He indicated his authorship of the proposal as "*Dr Andrew Katelaris MD*".

5.49 Ms K's sister was in daily attendance on Ms K during her hospitalisation at the Calvary Mater from 7 September 2015 onwards. She was a witness to the times when Dr Katelaris visited her sister and has described in her submissions his insistence on knowing whether Ms K's tumour marker tests had been done and what the results were or when Ms K would get those results so that she could advise him. She described the occasion on 11 September 2015 during which Dr Katelaris sought to have a private conversation with Ms K during a visit, but could be overheard by Ms K's sister and a nurse. Dr Katelaris was heard asking Ms K about her CA125 test and the delay in getting results. He told her they were her results, that she had a right to them and that he would drive her right then to the pathology lab where she could demand they give them to her or he could get them for her himself. As corroborated by the hospital records, at this point the nurse had to intervene to point out how ill Ms K was, that she had procedures scheduled and that the only people with a right to those results were Ms K, her next of kin and her doctors.

5.50 The submissions also include emails between Ms K and Dr Katelaris after the trial and resulting hospitalisation. The day of her transfer from Calvary Mater to her local hospital, on 20 September 2015, Ms K wrote to Dr Katelaris and told him that she would be providing him with all of her hospital medical tests and blood results when these were done and she advised him she would let him know the date of her next appointment with her oncologist so that he could join her there to answer any questions he might have about the experiment that she couldn't answer.

5.51 Significantly, in this email, she described what she had suffered as a result of the trial but also what she continued to hope might be its benefit. Her entreaty to Dr Katelaris bears quoting at length:

> *This experience has really knocked me flat Andrew. I've had a lot of vomiting & gut pain. Been through drips, drugs and blood transfusion. Had high temp & fever on & off over the 2 weeks in Mater. I've also had an ascites drain (2.5ltrs). Not a lot removed but it's made me more comfortable.*
>
> *Only time will tell & the blood test if the oil has actually managed to knock out some of the cancer cells. I'm praying for that.*
>
> *I really hope you will organise some sort of clinical notes & observations on what actually happened to [Ms M] and me side effects wise with this oil while we were in your care Andrew?*
>
> *It would be such a waste for [Ms M] & I to have gone through all the pain & sickness only to have no 'observations' or 'research' notes kept on what happened to us.*

5.52 The submissions include transcriptions of text messages from Ms K's phone (which remains in her sister's possession) during the period of Ms K's

hospitalisation and after discharge home. Messages sent by Dr Katelaris to Ms K are brief to the point of terseness and primarily query the results of her blood tests. The text messages drafted by Ms K to Dr Katelaris during the period she was in Calvary Mater were not all delivered, apparently due to the lack of reception within the hospital. Particularly towards the end of her stay at that hospital, Ms K attempted unsuccessfully on a number of occasions to send Dr Katelaris an update on her progress and imminent transfer to her local hospital, as well as the emotional impact of what she had been through as a result of his 'treatment'. One such undelivered text message drafted on 18 September 2015 reads in part:

> *still have temp. but they can't ID the pathogen. I'm very physically weak have lost a lot of weight & am still feeling a bit 'stoned'. Can't believe I have lost 2 weeks of my life in hospital with my reactions from this treatment? How's [Ms M] recovering? Im just coming up for air now & trying to make sense of the journey….This experience has really wiped me out physically & emotionally Andrew.*

5.53 Eventually on 21 September 2015, Ms K was able to get sufficient reception to send a text message to Dr Katelaris and advised him of her transfer to another hospital, of her continued weakness, breathlessness, lack of appetite, need to build up health and weight once home and her hopes for discharge. Dr Katelaris' only response was "*OK*". Similarly, two days later, when Ms K described in a text to him her exhaustion, frailty and inability to be discharged due to the lack of arrangements in place for home help, his response was again only "*OK*".

5.54 Dr Katelaris' response was more effusive when Ms K texted him her CA125 results on 23 September 2015, which remained lowered from levels recorded during her last chemotherapy cycle. The text messages also indicate Ms K's desire to have Dr Katelaris accompany her to her next appointment with her oncologist and his agreement to do so with sufficient 'warning'. Unfortunately Ms K's health deteriorated again and arrangements to see Professor B needed repeated changing. On 2 October 2015, Ms K texted Dr Katelaris:

> *Hi Andrew. Still bed ridden, still feeling slightly 'stoned' & short term memory recall terrible. 53kg & struggling to eat & keep food down to get weight back on. Now just got the CA125 results from yesterday & they are back to 2200. Feeling absolutely heartbroken. What was all this suffering & illness for to end up back at the same place with my tumour count?*

Dr Katelaris responded merely "*That is bad news. See you soon*".

5.55 The remaining text messages continue in this vein with Dr Katelaris providing minimal responses to Ms K's health updates and communication from her to him tapering away. The final exchange occurred on 17 December 2015, when Ms K told Dr Katelaris that she had resumed chemotherapy but had been very ill. She told him her CA125 levels had been as high as 23,500 but had dropped to 15,500 following the resumption of chemotherapy and that she now needed full time care at home. She said to him in this text:

> *Feeling pretty bummed about the whole cannabis oil experiment. Not because it failed but because the side effects were so severe & put me into a lengthy hospital stay which then led to additional complications like weight loss, lung infection & blocked stoma. Had almost 2 months*

(Sept/Oct) with no chemo & that's allowed the cancer to go gang-busters again. I lost so much ground during that time.

I'm feeling tired & worn down by the illness & all the treatments but I very much want to live & will continue to fight the cancer with whatever means work for as long as I can.

5.56 The response from Dr Katelaris was characteristically brief and unengaged: "*Thanks for the update. I hope the next reports better health. Best wishes*". He did not have any further communication with Ms K.

Evidence concerning Ms M

(i) Communication with Ms M

5.57 Ms M advised the Commission during a telephone conversation that she had only met Dr Katelaris the weekend before the cannabis oil trial on 2 September 2015, at a medical cannabis 'symposium' in Nimbin. She said she had heard Dr Katelaris speaking about another woman with ovarian cancer, Ms K, who was participating in the trial and she had accordingly approached him and asked to be involved. She said she would have liked more time beforehand and didn't do much research, but was assured that there was no risk of organ damage or of overdosing.

5.58 Ms M told the Commission that she still has ascites but has no option for surgery because of the type of ovarian cancer she has. She has asked Dr Katelaris for further injections and has encouraged him to do the trial again, using smaller doses more gradually, but said that he is reluctant because of what happened to Ms K, who reacted more severely than she did. She said that she uses small doses of cannabis oil daily and that she has noticed her ascites is reduced and her daily activities are more manageable. She spoke highly of Dr Katelaris and the staff at the Wellness Clinic.

5.59 Ms M provided the Commission with a copy of the same 'research proposal' as was given to Ms K and set out in an email her views in relation to what she termed a "*brilliant novel trial*". Ms M told the Commission that:

It is my belief that had Dr Katelaris been permitted, rather than being declined his request by regulatory authorities to test the quality & potency of the material prior to commencing the trial, it would have raised safety measures, preventing the outcome that ensued.

Being permitted to test the material would have contributed to a less stressful experience for both candidates in the trial; it would have improved the trial results & as well as contributing to a greater chance of success; benefiting both participants, as well as other women condemned to suffering this condition, where conservative medicine offers no hope with a limited framework of undignified, costly, useless, hopeless alternatives.

Ms M's email to the Commission is in effect a submission in support of Dr Katelaris' work and a request that the initial trial not be 'shelved' or aborted or considered a failed attempt. She notes Dr Katelaris' longstanding position as an advocate and educator in relation to medical cannabis and industrial hemp and praises his assistance and support to many distressed parents of children with

epilepsy whose quality of life she asserts is greatly improved by his treatment. Of particular concern to the Commission in the circumstances of this matter, is her claim that there have also been "*outstanding, promising results from other patients diagnosed with brain cancers & pancreatic cancers, that Dr Katelaris has been treating with M.C*".

(ii) Clinical records from John Hunter Hospital

5.60 Ms M's clinical records from John Hunter Hospital record that on 4 September 2015 she attended the Emergency Department, accompanied by a "*friend*" called Andrew. She presented with increasing drowsiness over the previous 24 hours and a noted history of ovarian cancer. A collateral history was taken from Andrew, who, it was noted had only met the patient a week before at a Nimbin festival.

5.61 The Triage notes record two days of profuse non-bilious vomiting and dry retching and one day of increased drowsiness. During the history taking, it was noted that Ms M kept falling asleep and was unable to complete sentences. "*Andrew*" told the ED RMO that he had noticed when driving Ms M to the hospital that whenever he braked, she complained of abdominal pain. He said she had flown from Mullumbimby to visit him. Nowhere in the history given by Dr Katelaris to the ED is it mentioned that he had injected her intraperitoneally with cannabis oil as part of an experimental treatment for her malignant ascites, or that he had medical qualifications, albeit he was not a registered medical practitioner.

5.62 As a result of Dr Katelaris' withholding of critical information, the true clinical picture could not be understood and the initial working diagnoses were possible hepatic encephalopathy, spontaneous bacterial peritonitis, electrolyte abnormality and intracerebral event. Ms M was, due to her condition, noted to be a poor historian when she was reviewed later on the first day of her admission by an Obstetrics and Gynaecology Registrar and the picture became no clearer. The Registrar felt that the abdominal pain was secondary to her ascites and her increasing drowsiness due to progressive disease. The progress notes record that Ms M was sent for a brain CT, was hypotensive and required continuous stimulation to stay awake.

5.63 The following day Ms M was noted to remain drowsy, to be unable to give a coherent history and was considered not competent to give consent, however it was ascertained that she had stage 4 low grade serous ovarian cancer diagnosed in 2002 and that she had refused conventional treatment. The cause of her drowsiness was still unknown. It was noted that the blood test results showed a few abnormalities, but nothing consistent with the current symptoms. Attempts were made to get in contact with Ms M's next of kin.

5.64 On 6 September 2015 the progress notes record that Ms M was visited by a friend from Newcastle who brought in a 'health' smoothie and a brown rice pudding. On review that day, Ms M's was noted to have shown some improvement and the working diagnosis was a presumed urinary tract infection. It was noted in the record that she denied the use of any complementary or alternative medicines.

5.65 Later that day Ms M's brother arrived from Sydney. The doctors at the hospital recorded having a frank discussion with him in which they told him their view that his sister's current presentation was part of her ongoing deterioration due to ovarian cancer and that if it were left untreated, it would end her life. Ms M was

refusing analgesia for her pain and declining antibiotics and her brother was told that sepsis would be the outcome of leaving the UTI untreated. After being left alone with his sister to discuss her treatment options, Ms M's brother disclosed to reviewing medical officers that his sister had been trialing high dose THC treatment, but that he was unsure of the details.

5.66 On 7 September 2015 Ms M was transferred by air to Mullumbimby. She was noted not to be orientated to day or date, to be very slow and unsteady with mobility and to remain drowsy and slightly febrile. She had refused all offered treatment, but earlier that day consumed a green shake brought in by a "*friend*".

Dr Katelaris' evidence

5.67 Dr Katelaris attended the Commission for an interview on 21 June 2016 as required by coercive notice. At the outset Dr Katelaris took issue with the complaint against him on the grounds that he views himself as a "*scientific independent researcher*" and not as a clinician or healthcare provider and he therefore does not recognise the Commission's jurisdiction over him. On being shown a copy of his research proposal to trial a novel treatment for malignant ascites, Dr Katelaris conceded that he had administered an experimental *treatment*. He told the Commission that Ms K, in a very advanced stage of malignant peritoneal disease, had almost pleaded with him to do something for her and as his usual responses about "*diet and so on*" seemed foolish in the circumstances, he decided to try to introduce the cannabis oil to the sequestered site where the ascites are. He said the decision to try and do this caused him much anxiety and many sleepless nights, in which he thought to himself "*Can I actually do this? Will it help the women?*" Later in the interview he expanded on the "sleepless nights and pacing" and told the Commission that he had been "*investigating my own inside whether I had the balls to do it … knowing, too, that if things turned to shit that the system would come down on me like a ton of hot bricks*".

5.68 He said that a significant issue was how to prepare the medicine, with concerns that an aqueous alcohol solution, which was what had been used in Spain in research involving brain tumours, was problematic in combination with the substantial dose of cannabis he was proposing to use, in terms of its potential production of an unstable mental situation in the recipient. He decided to pay a third party supplier, raising what he called a substantial amount of money via crowdfunding, to supply a cannabinoid mix equivalent to that used in the experimental work in Spain. This was a three parts to two ratio of CBD to THC, with which he believed he could manage the psychotropic effects.

5.69 Dr Katelaris told the Commission (on the presumption the Commission was unaware of his background) that he had previously had licenses to cultivate cannabis for medical research and for industrial production. He said he had been approaching Sydney University for years to assist him with the batch testing of some of the cannabis samples he had been using in his experiments, to get confirmatory analysis of what his suppliers were telling him, some of whom he noted could be "*shady customers*".

5.70 Dr Katelaris said that when he got the oil from the supplier for use in the trial on Ms K and Ms M, he was assured it was in a 3:2 ratio, but he had no way of testing that. He claimed that Sydney University agreed to do so, using high pressure liquid chromatography (HPLC). He claimed that at his urging, Sydney University first approached the Ministry of Health, NSW (the Ministry) for what he called a

"*s.23(4)(b) licence*" under the *Drug Misuse and Trafficking Act*, explained what they were doing and why they wanted the cannabis tested. The Ministry allegedly refused to sign the licence, even though it had done so for many other cases, and the sample was not tested by Sydney University.

5.71 Dr Katelaris claimed that he informed Ms K and Ms M that he was "*flying blind on this trial*" and would be a lot happier if he had an analysis of the oil. He ordered the components to do his own thin layer chromatography (TLC) testing from overseas, but they were held up in Customs. He claimed that because "*the ladies' conditions were sort of going down*" and they both wanted to go ahead even though he told them he could only look at the physical characteristics of the oil and not its phytochemistry, that is what they did.

5.72 Dr Katelaris said that "*the irony of the situation*" was that he was able to test a sample of the oil kept aside for that purpose just a week later, when the TLC equipment got through Customs, and it turned out to be "*eight to one THC and that was a clear explanation of the exaggerated psychotropic effect that the ladies suffered*".

5.73 Dr Katelaris told the Commission that the biggest problem and the reason he won't be repeating the trial (even though Ms M is pressuring him to repeat the process and Ms K saw a halving of her tumour markers), was that he "*lost control of the data*". Although his evidence on this point was unclear, it appeared to the Commission that Dr Katelaris was blaming Ms K's sister for preventing him from continuing to treat Ms K and that because of her interference he lost both "*control of the data*" and the opportunity to promote his dietary guidelines and the use of "*ketogenics*" to Ms K and he understands that within three weeks her tumour markers had started an inexorable rise from which she did not recover.

5.74 Not only did Dr Katelaris seek to blame Ms K's sister, he placed responsibility for the failure of the experiment squarely at the feet of the Ministry for refusing to allow Sydney University to test the sample of oil he wanted analysed. His argument was to the effect that had HPLC testing been applied and he had discovered the 8:1 ratio, he would have "*backed away. I wouldn't have done an eight to one because that's not even the experiment we want. We didn't want to get these ladies out of their tree. We wanted to impact their ovarian cancer.*"

5.75 Another problem Dr Katelaris encountered was his choice of carrying agent, namely MCT (medium chain triglycerides) or coconut oil, which he otherwise considered an excellent and specific solvent for cannabis. He noted that both women had developed serious abdominal cramping pain within minutes of injection, with shoulder tip radiation. He claimed to have waited after injecting the first woman and to have checked in with her after 20 minutes to ask whether, if she had known the pain she would be in before she started, she would have embarked on the process. Her answer that it wasn't that bad and that she could do it persuaded him to proceed. Apparently believing that this decision demonstrated his ability to chart a reasonable course between risk and risk-avoidance, he told the Commission:

> *We're not cavalier and I'm not stupid. I might be – and I'm not reckless. Right? There may be – there's always a grey area between bold and stupid, but I like to stay in one of those shades of grey, not in a black or white sort of area.*

5.76 As Dr Katelaris noted, unfortunately the pain that had been mild for the first half an hour escalated once both women were injected and then the vomiting started. He said he stayed with the women for two and a half days. He claimed to have then surmised what is now his understanding, that both women had a chemical peritonitis. He wondered whether that was caused by the MCT carrying agent, some of the impurities in the resin or the fact that the resins "*were an unchartered territory*". He then told the Commission that it was the chemical peritonitis that would preclude him from doing it again, even though "*we got a 50 per cent reduction in tumour marker and [Ms M] is doing tolerably well – we haven't fixed her. She's doing tolerably - and wants it done again*". Dr Katelaris then said to the Commission:

> *Despite that, my threshold for repeating something as fraught as that and that – I have to call that at the fraught end. By giving a person a little cap of oil to see how they react is one thing, injecting it – you know, there's a one-way street. So before I do that again, I'd probably want hospital backing….*
>
> *And I would, yes, even sort of drag my feet backwards a bit and watch what other people do for a while…*
>
> *I've got enough on my plate. That was two ladies that were sort of on my case, I have to say. Well, I'm not blaming them…*

5.77 Dr Katelaris agreed that he had drafted the 'research proposal' in response to the request of the two women for treatment, in order to "*formalise*" what was proposed. He was asked who was his intended audience for his findings, following the trial but repudiated that concept, explaining as follows:

> *say we got a really strong signal of effectivity, right, then I'd make a noise and sort of more or less coerce the system.*

He then suggested that he may in fact have contemplated an "*audience*" for his research,

> *if I got like better than a 50 per cent transient increase, like which is all we got – I mean, I don't want to overplay that. That wasn't enough to keep me pushing…And the ladies suffered too much…It was bad enough looking after them, right, let alone being them…*
>
> *let's say by some miracle they both responded dramatically and didn't need further paracentesis, I'd take them to the media…*
>
> *But I wouldn't go through the proper channels where I've been sort of bogged down for 20 years. If we actually got a convincing – not just a 50 per cent response, but a durable response, like with physical symptoms, i.e., reduction of recurrent ascites, that's your measure of whether you're winning or not. Right? No, you'd hear me from the tops of the rooves. That would be my audience.*

5.78 Dr Katelaris was asked what he had told the two subjects about the risks of being involved in his experimental treatment. He told the Commission that the critically important fact to remember about cannabis is that it is the only clinically active pharmaceutical substance which has an unrecorded lethal dose measurement ('LD50'). He said he told the women that they might "*spin out, like green out plus,*

plus, plus" but they would "*always come back*". He said he told them "*it won't kill you, but… you're on uncharted waters*".

5.79 Dr Katelaris agreed that he used a "*huge dose*" of cannabis in his experimental treatment and he was asked to quantify. He told the Commission that his problem was that he couldn't get access to analytical facilities, other than rudimentary ones and that consequently, he couldn't be certain of the potency. Because of the lack of certainty about this and possible contaminants, he noted that he was "*just not going to do it again off that end of the black market…without analytical support*".

5.80 Dr Katelaris was asked why he went ahead with the experiment without the analytics and without confirmation of the CBD/THC ratio. He said it was because "*the ladies said, 'Look we're dying,' basically*". When he was asked whether that was in fact the case for Ms M, he answered that Ms M was actually much better at taking health advice than Ms K and that she was on a rigid vegetarian diet and really looking after herself. He said she was "*like a late ring in*". He noted that she had heard him speak at a symposium in Nimbin and made a point of coming to see him wanting "*some novel treatment*".

5.81 Dr Katelaris was asked about his first consultation with Ms K. Significantly, he explained that he had needed to know what he was dealing with and he said:

> *I mean you've got to ask your basic questions. I may be deregistered, but I mean I know the basic common sense approach to medicine. You know what the person is, what they've got and what they're taking.*

The Commission notes at this point that Dr Katelaris did not extend this "*common sense approach to medicine*" to his interactions with his medical colleagues at Calvary Mater and John Hunter Hospitals. He failed to provide a timely and accurate clinical history to those into whose care he placed Ms K and Ms M, although he was uniquely placed and evidently obliged to do so given the inability of both patients to provide a proper history because of the psychotropic effects of the untested cannabis he had administered to them.

5.82 Dr Katelaris told the Commission that he did not keep the notes he had made about Ms K after her death, as "i*t wasn't a clinical interaction. It was a science interaction*" and he considers there to be a difference in clinical responsibility between the two. He agreed that he had accompanied Ms K to her oncologist, Professor B, on two occasions and he explained he had done this because he had an "*ulterior motive*", In the event that he got a positive result in the experiment, he wanted to be able to go to Professor B and say "*Look mate, look at this. What are we going to do about it? I want to do the next one with you here*".

5.83 Dr Katelaris was asked why he persisted in describing cannabis as a "*safe and effective herbal medication*" given what the Commission termed a "*catastrophic*" outcome for both women. He completely and somewhat angrily repudiated the use of the word "*catastrophic*", challenging its applicability to a situation that saw a "*50 per cent reduction in tumour markers until we lost control of it*". He said that the three days of serious vomiting were just "*a standard chemo reaction*" and that he gave his treatment to people "*on the edge of a life*". In the case of Ms K, he told the Commission that "*she was chosen because, despite what everyone would say…you've had three bowel obstructions and recurrent ascites….You're not going to live very long. Because each time they cut her*

open, they made more adhesions, I mean, I'm not blaming the surgeons. It's just a problem that had no solution". Essentially, he appeared to be saying that the outcome for Ms K was not catastrophic because she was going to die a humiliating death from bowel obstruction in any event and her symptoms post-injection were similar to a severe response to chemotherapy. By way of explanation, he told the Commission "*If it was on a well person like with no symptoms and you say, 'I just want to see what happens if I give you this', that would be catastrophic*". Significantly, Dr Katelaris did not seek to extend this argument to Ms M's situation.

5.84 Dr Katelaris told the Commission that the injections took place at the Newcastle clinic because he wanted to administer the cannabis oil in a place that was calm and clean. He said that he stayed on the premises with the women for about 20 out of 24 hours each day after the injection and that it was the ongoing and serious emesis that concerned him enough to arrange for both women to go to hospital. What pushed him to act was that Ms K developed a temperature and he called an ambulance as soon as it crept over 37.5°C.

5.85 Dr Katelaris said that he cannot remember the whole chronology of the night, but he claimed to have accompanied Ms K to Calvary Mater Hospital *and* to have taken Ms M himself to John Hunter Hospital. He said the reason for the two different hospitals was as simple as one woman having private health insurance and the other not.

5.86 Dr Katelaris was asked whether he told Calvary Mater Hospital about the cannabis oil and he replied "*On presentation. How could you not?*" It was pointed out to him that he did not tell anyone about it at John Hunter Hospital. Dr Katelaris then told the Commission that he thought he did, as he had at the first hospital, but that the conditions hadn't presented for him to do so and he didn't want to tell an intern. Dr Katelaris told the Commission:

> *I mean at the first one the registrar just walked in and I more or less said, "Come and listen to this", you know.*

Dr Katelaris was asked whether he had been "*up-front*" at the Calvary Mater Hospital and he answered:

> *Not up-front. I gave specific and exact….once you had three days of vomiting and a bit of a temperature coming on, that sort of clouded it you know. Were we dealing with neutropenia? Were we getting into serious trouble…It was just beyond my capacity to manage. I needed laboratory support, basically. I could have managed it with - say I could get some blood tests. I could have managed it reasonably well…but it was just all too marginal without the blood support.*

The Commission interprets Dr Katelaris' evidence on this important point to be that he certainly informed Calvary Mater Hospital about the fact that Ms K had been given cannabis oil, but that in his view, that was not really the significant clinical information. The problem was more what might have been causing her temperature and vomiting and that was something only blood tests could reveal. That had to be sorted out so that was the information he was specific about. And while Dr Katelaris *intended* to tell doctors at John Hunter Hospital, he didn't ever get the opportunity to tell someone senior and he was not going to tell an intern.

5.87 Later in the interview the Commission returned to this point and put to Dr Katelaris that in relation to Ms M, he had not been at all forthcoming to the hospital about what had happened to her. He said he thought he had been, "*because what's the point of not?*" and then conceded that obviously "*the message didn't get through*". It was pointed out that he must have known that there were many differential diagnoses being considered, including hepatic encephalopathy, electrolyte abnormality, even an intracerebral event, for which she had a brain CT and that even four days after the injection she was considered not competent to give consent and the doctors still couldn't work out what was wrong with her. It wasn't until two days after admission and when Ms M's brother told the hospital about the THC treatment that they began to piece the clinical picture together. Dr Katelaris claimed he had spoken to a registrar straight away on presentation and that he wasn't trying to cover up what he had done.

5.88 Dr Katelaris was asked directly what his responsibility was to make the "*experiment*" safer. He answered that he could have waited until he got an analysis but then directed blame again at the government that had prevented the testing. When asked why he didn't wait or postpone the trial until his testing kit arrived, he answered *"[T]hey'd all be dead. They were too far advanced, but once cachexia sets in, once you've had three bowel obstructions, you haven't got time*". Again, Dr Katelaris obfuscated when answering the Commission's question as to how Ms M's clinical picture before the trial could approach that description. On the one hand, he acknowledged that she had managed her disease for 11 years with diet and meditation, while on the other he claimed that she was "*sick of carrying 10 litres of ascites around…that's why she wanted to be part of it*".

5.89 Dr Katelaris expressed his anger at the supplier of the resin used - "*I think you could hear me cursing him when I rang up….I mean, I consider that was a stab in the back…We were shafted basically*". Then, once again, he blamed his inability to test the resin, noting that it was "*infuriating to have the test within your grasp and have your sample sitting on the same desk as an HPLC machine and not allowed to let it happen*". But when it was put to him that *he* didn't then say to himself, "*if you can't test, you can't do*", he returned again to his excuse that "*this was a life threatening condition*" and that he wouldn't have done it for anyone with a life expectancy of more than 12 months but that there was essentially no other option for these women.

5.90 Pursuing the thrust of Dr Katelaris' own argument, it was put to him that to get the consent of the two women to continue to be involved in these circumstances, he would have had to say something to them along the lines of "*We'll go ahead with this even though I haven't been able to test because you're dying anyway*". Dr Katelaris responded:

> *Hang on. These women? Let's stay with [Ms K] because I had a lot more discussion. I mean, [Ms M] sort of jumped in, whereas Ms K – she was funny because she was very anxious. I mean you can't be 40 and dying of a malignant disease and not be somewhat anxious. I mean it's not a pleasant situation. And, yes, we had quite a few discussions, but most of them ended up with me saying, "Look, it's an unknown" – you know, really reiterating in softer terminology.*

The Commission notes, contrary to Dr Katelaris' account, that both women were 56, that Ms M's ovarian cancer had been diagnosed 13 years earlier and there

was no evidence of deterioration and that Ms K was scheduled to commence another cycle of chemotherapy on 10 September 2015 and had told Dr Katelaris that she therefore had a small window of opportunity before then to try his experimental treatment. Indeed, Dr Katelaris later told the Commission that he had had no "*significant concerns for [Ms M's] health…even though she's frail and mildly hepatic, she has an excellent constitution*".

5.91 Dr Katelaris told the Commission that he wanted to know how both women had fared after his experiment "*out of a sense of human decency*". He was asked how he had checked up on Ms K in hospital and whether he had looked at her blood results and progress notes. He told the Commission that it wasn't his position to check up on her, although he appreciated that she "*posed a very difficult diagnostic problem because it was the thing that made me bring her to hospital*". Although he claimed to have taken "*meticulous care*", he worried, from his past research in microbiology and sepsis, that he might have given her a peritonitis and he wasn't going to "*let her die of that when she can be saved by a bit of IV*". He noted that it "*was just a chemical peritonitis because all the cultures were extremely negative, which was good*".

5.92 When Dr Katelaris claimed to have known the results of Ms K's blood cultures from discussing the issue with some of the doctors at the hospital, he was asked whether he had been working with the medical team at Calvary Mater. While Dr Katelaris wouldn't say "*working*" with them, he asserted the following:

> *there was some professional courtesy and I must admit, the attitude appeared to me to change dramatically when the CA-125 result came in…there was a fair bit of hostility before that…. Like I was public enemy number 1 sort of thing…You can just feel the daggers and things…But when the CA-125 result came in, everyone softened up and says there may be something…I wish we had just a more honest, open sort of system where they could do that…Just imagine how I'd be received if she was cured?*

5.93 Dr Katelaris then claimed that by his rudimentary or 'back of envelope' calculations, the numbers from the tissue culture work seemed to indicate that apoptosis or cancer cell suicide could be achieved by getting cannabis oil at the right concentration into the sequestered area of the ascites. He told the Commission that he wouldn't have got involved in cannabis and cancer except that people keep coming to him. He asked rhetorically what you do when you get a phone call every day from someone whose 15-year-old has brain cancer. Evidently, his response is not to say that he can't help and he told the Commission that he had actually had some significant responses to oral cannabis in some brain tumours, but other tumours, such as gut and ovarian, had not responded in the same way.

5.94 Dr Katelaris told the Commission that he gave his assurances that he would not be repeating what happened with Ms K and Ms M in the future. His reasons for this were that:

> *even though there was a small indicator of activity, it's too – it's not a procedure for a one-man band. Right? It's a procedure to be done in a hospital setting and, to tell you the truth, I wouldn't even put in a proposal for it because the indicators of effectiveness were not overwhelming enough…what's the point of going through that if it's only a transient thing.*

5.95 Dr Katelaris said that to repeat the experiment he would have to see a better indication that he was going to have a toxic effect against the cancer. He was asked how he would see that indication without another trial like the one he had undertaken. He said that animal work was probably all that was available to him but that he had done plenty of it and can handle animals. He said it wasn't a "*crusade*" for him because even though ovarian cancer is a disaster, it doesn't affect as many people as "*something I can do better at elsewhere*". In a final attempt to explain his motivations with the experiment, he told the Commission:

> *I won't say I was dragged into, they made me do it, that's unfair, right, but you have to understand this wasn't a cavalier action by someone who wants personal glory. I was actually trying to save someone – not only these individuals' lives, but break open that sort of glass ceiling that stops proper research being done for them.*

6. Findings and Determination

(i) Breach of the Code of Conduct for non-registered health practitioners

6.1 For the purposes of the Code of Conduct for non-registered health practitioners, 'health practitioner' and 'health service' have the same meaning as they have in the *Health Care Complaints Act 1993* (the Act). The Act defines 'health practitioner' as "*a natural person who provides a health service (whether or not the person is registered under the Health Practitioner Regulation National Law)*" and defines 'health service' by setting out a non-exhaustive list of services, whether provided as public or private services. Relevantly for this matter, the list includes "*services provided in other alternative health care fields*".

6.2 Notwithstanding Dr Katelaris' assertion that he was not engaged in a "*clinical interaction*" when he administered an intraperitoneal injection of cannabis oil to two women for the "*novel treatment of malignant ascites*" associated with their ovarian cancer, the Commission finds that his administration of cannabis oil as a "*novel treatment*" and his management of the clinical complications for both women that resulted, constituted services provided in an alternative health care field. The Code of Conduct for non-registered health practitioners is applicable to his activities, irrespective of his characterisation of himself as a researcher and his 'trial' as scientific rather than clinical.

6.3 The Commission finds that Dr Katelaris provided health services to two women in an unsafe and unethical manner and that the extent and nature of his breaches of the Code of Conduct are so egregious, and his insight so deficient, that he poses a serious risk to the health and safety of the public.

6.4 The Commission finds that in response to Dr Katelaris' significant self-promotion about the benefits of cannabis oil he was achieving in the treatment and alleviation of cancer and associated symptoms, somewhat coincidentally, two 56 year old women with ovarian cancer and ascites approached him in 2015 for help. The Commission finds that Dr Katelaris saw this as an opportunity to try to introduce cannabis in a way that had not been tried before, namely, via intraperitoneal injection, to see whether it would have an impact on a cancer he had not dealt with before. The Commission finds that he devised a hasty, ill-conceived and unsafe clinical trial of this experimental treatment, which would give him the 'protection' of a disclaimer if things went badly, but personal accolades and good publicity if things went well. The Commission finds that Dr Katelaris was in breach of Clause 5 of the Code of Conduct, which requires that a health practitioner must not hold himself out as qualified, able or willing to cure

cancer or other terminal illness and that any claim as to his ability or willingness to treat or alleviate the symptoms of those illnesses must be able to be substantiated.

6.5 The Commission finds that both of these women were particularly vulnerable due to their cancer diagnosis. The evidence is clear that both women placed their complete trust in Dr Katelaris and believed that he wanted to help them above anything else and that their safety and comfort, including in Ms K's case, her mental and emotional stability, were paramount. The Commission finds that throughout the trial and its aftermath, Dr Katelaris' primary motivations were self-promotion and self-protection and that he repeatedly put his own interests before those of the two women involved and thereby provided a health service in an unethical manner in breach of Clause 3(1) of the Code of Conduct.

6.6 The Commission finds that Dr Katelaris has either willfully misrepresented to the Commission, or inexcusably failed to inform himself, of the clinical situation and prognosis for these women prior to his administration of cannabis oil to them on 2 September 2015. He repeatedly described the condition of both women as rapidly deteriorating to excuse his decision not to wait until the cannabis resin he had bought from a third party supplier could be tested to measure its potency and ensure that the CBD/THC ratio was safe. Dr Katelaris told the Commission that he couldn't postpone his 'trial' to ensure the cannabis was first tested and found safe because the women were running out of time and would have died if he did not go ahead. The Commission does not accept this as an accurate clinical picture for either woman.

6.7 The Commission notes that at the time of the cannabis trial, Ms K had metastatic ovarian cancer with significant ascites, but also that between June and August 2015, and certainly during the period in which Dr Katelaris knew her, her CA125 levels had steadily dropped from 4200 to 1700 as a result of chemotherapy treatment. She was due to have her next chemotherapy cycle on 10 September 2015 and her oncologist, who was aware of her interest in complementary therapies, had encouraged this as long as it did not impose unreasonable restrictions on proven therapy. The Commission finds, contrary to Dr Katelaris' evidence, that far from telling him she was "*basically dying*" and therefore begging him to proceed with the experiment even though he hadn't tested the cannabis, Ms K took very considered and proactive steps to ensure herself of the safety of the proposed trial and that it would not interfere with her scheduled conventional treatment.

6.8 The Commission notes that Ms M had lived with a diagnosis of low grade ovarian cancer since 2002, that she had declined conventional treatment but was managing her health with diet and alternative therapies. There was no evidence that her condition was deteriorating at the time of the trial and Dr Katelaris himself noted that he had no significant concerns for her health and that in fact her constitution was excellent. The Commission therefore finds that Dr Katelaris' decision to proceed with the administration of untested cannabis oil was unsafe and unethical and completely without clinical justification, in breach of Clause 3(1) of the Code of Conduct.

6.9 The Commission finds that Dr Katelaris did not explain to Ms K that he had been unable to test the cannabis he proposed to use, or ask her whether she wished to go ahead in the circumstances, and that she did not learn about this situation until during the first week of her hospital admission. The Commission finds that only two days before the scheduled treatment, Dr Katelaris reassured Ms K that cannabinoids are safe in any dose, that there would be no adverse effects from the THC due to the balancing effect of the CBD and that he had no concerns

about the sterility of the procedure. He gave these assurances when he was not in a position to allay any of her fears given that there had not been and would not be any testing of the resin he had bought on the black market.

6.10 The Commission therefore finds that Dr Katelaris administered cannabis oil to Ms K without her informed consent and that it is more likely than not on the available evidence that she would not have proceeded if she had known that the substance had not been tested for its CBD/THC ratio, potency or possible contaminants. The Commission accepts Ms K's evidence that neither woman was informed of this problem before the injection was administered. The Commission finds that the failure to obtain informed consent for the injection of cannabis oil was in breach of Clause 7(2) of the Code of Conduct that requires that a health practitioner must accept the right of his client to make informed choices in relation to their health care.

6.11 The Commission finds that Dr Katelaris' conduct was particularly unsafe and unethical when he asked Ms K to defer telling her oncologist about the experiment until after it had been done, despite her professed discomfort at keeping any information from Professor B that may have a bearing on her upcoming chemotherapy and surgery. The Commission finds that Dr Katelaris wanted to avoid any scrutiny from his medical colleagues beforehand, not because of the ethical and scientific indefensibility of his approach, but to be able to boast of his success on the off-chance that it worked. The Commission finds that Dr Katelaris was therefore in breach of clause 3(2)(i) of the Code of Conduct that requires a health practitioner to encourage his client to inform their treating medical practitioner of the treatments they are receiving.

6.12 The Commission finds that Dr Katelaris' conduct was also unsafe and unethical when he told Ms K to defer having her ascites drained before her next round of chemotherapy, because he wanted her ascites to be present to ascertain whether the oil would work to reduce it. Given the absence of any ability to measure the effects of his 'treatment', either on Ms K's tumour marker levels or on her ascites and the complete lack of scientific rigour and legitimacy to the methodology of this 'clinical trial', the Commission finds that there was no justifiable reason to prevent Ms K from having her ascites drained when she wished this to happen and that this caused her even more unnecessary discomfort. The Commission finds this aspect of Dr Katelaris' conduct to be a breach of Clause 7(1) of the Code of Conduct that requires that a health practitioner must not attempt to dissuade clients from seeking or continuing with treatment by a registered medical practitioner.

6.13 The Commission finds that Dr Katelaris' decision to proceed with the administration of the cannabis oil in circumstances where he had not tested the cannabis, where, as the Commission has found, the women involved did not know that they were being injected with untested oil, where the critical CBD/THC ratio and therefore the potential psychotropic effects were unknown, and where he used admittedly "*huge doses*" of cannabis, was without clinical justification, was unsafe and unethical and resulted in serious clinical complications for both women. The Commission finds that his decision to proceed in the circumstances, allegedly because the two women were on the "*brink of death*" and time was running out, was in breach of Clause 11 of the Code of Conduct that requires that a health practitioner must not diagnose or treat an illness or condition without an adequate clinical basis.

6.14 The Commission finds that Dr Katelaris was deceitful in his dealings with both Calvary Mater and John Hunter Hospitals and that he was dishonest to the Commission about what he had disclosed to both hospitals and their medical

staff. The Commission finds that Dr Katelaris deliberately withheld important clinical information that would have brought him professional discredit and possibly criminal sanction, namely that he had injected untested cannabis oil intraperitoneally two days earlier as an experimental alternative treatment for ovarian cancer and ascites, and that it had gone terribly wrong.

6.15 The Commission finds that his letter to Calvary Mater Hospital is actively deceitful in that it suggests that Ms K's presenting condition may have something to do with her recent chemotherapy and says nothing about the injection of cannabis oil two days earlier. The use of "*MD*" is designed to give the letter a clinical legitimacy that Dr Katelaris' deregistered status does not warrant. Given Ms K's mental state and confusion and the fact that the paramedics were not aware of the nature of the alternative treatment she had received, Dr Katelaris' letter, signed as though from a medical practitioner, was the most important clinical information available to the hospital on her admission.

6.16 The Commission also finds that he further misled medical staff when the Calvary Mater Hospital had to contact him to ask about the cannabis trial, some five days after Ms K's admission. The Commission accepts that this may have involved Dr Katelaris telling a registrar about what had happened, but certainly not that it was accurate information or that he volunteered it on Ms K's presentation, as he asserts. The clinical notes record his advice that he gave a CBD/THC cannabinoid mix in a 2:1 ratio, diluted with saline. This does not accord with his evidence either that he intended to give a CBD/THC in a 3:2 ratio to control the psychotropic effects, or that approximately a week after the injection he tested a sample of the mix and found it consisted of an 8:1 ratio, which would explain the exaggerated psychotropic effects.

6.17 The Commission finds that Dr Katelaris deliberately withheld material clinical information from the medical staff at John Hunter Hospital, this time deliberately withholding his medical qualifications when giving Ms M's history, and that the effect of this was to tie up scarce hospital resources and time, to subject Ms M to unnecessary investigation and to potentially interfere with the most timely and effective treatment for her symptoms. The Commission finds this aspect of Dr Katelaris' conduct in relation to both women to be a breach of Clause 7(3) of the Code of Conduct that requires that a health practitioner should communicate and cooperate with colleagues and other health care practitioners and agencies in the best interests of his client.

6.18 The Commission finds that this conduct was highly unethical and completely inexcusable on a number of levels. Dr Katelaris effectively decided what the medical practitioners at two major hospitals needed to know in order to provide the necessary emergency treatment to both women whose health and safety his own conduct had imperiled. He put his own reputational interests before the health and safety of these women. He caused unnecessary confusion to extremely busy hospital staff and interfered with or caused a delay in the delivery of appropriate medical care by failing to assist in the development of a timely and accurate diagnosis for both women. His conduct displays both his contempt for his registered medical colleagues and his clear inability to admit fault and face the consequences. It demonstrates his recourse to dishonesty in the interests of self-protection.

6.19 The Commission finds that Dr Katelaris made and kept no clinical records in relation to his treatment of either woman and that this is unethical and inexcusable conduct, particularly in the context of administering a novel treatment under the guise of a trial. It is a failing that caused particular distress to Ms K, who told him directly that it would have been such a waste for her and

Ms M to have gone through all the sickness and pain they suffered, only to have no "*research*" or observations kept on them. This failing is a breach of Clause 15 of the Code of Conduct that requires a health practitioner to maintain accurate, legible and contemporaneous clinical records for each consultation.

6.20 The Commission finds that Dr Katelaris attempted to access Ms K's blood test results and tumour marker levels when he visited her in hospital, in order to obtain the only results his 'clinical trial' would ever provide him or his subjects. The Commission finds this conduct demonstrates the trial's complete lack of scientific legitimacy and credibility and illustrates Dr Katelaris' unethical approach to medicine. The Commission also finds that Dr Katelaris has overstated the benefits he achieved with the injected cannabis oil for Ms K, noting that a reading of 1100 does not constitute a 50% reduction in the tumour marker from the pre-trial level of 1700. The Commission finds this to be another illustration of the lack of clinical rigour in Dr Katelaris' general approach to his treatment of cancer with cannabis.

6.21 The Commission finds that Dr Katelaris conducted a purported clinical trial of medicinal cannabis that he was not qualified to conduct as a deregistered medical practitioner without a license or ethics approval. The Commission finds that he provided a purportedly novel treatment that he was not qualified to provide as a deregistered medical practitioner without the ability to test the substance to be used, to monitor the progress of the patients, to measure the results of the treatment or to respond to any side effects or clinical emergency. This constituted the provision of a health service in breach of Clause 3(2)(c) of the Code of Conduct that requires that a health practitioner must not provide services that he is not qualified to provide.

(ii) Risk to public health and safety

6.22 In finding that Dr Katelaris poses a risk to the health and safety of members of the public, the Commission takes into account the following matters:

- Dr Katelaris has failed to acknowledge or accept that the outcome of his experiment was catastrophic to both women and that his serious errors of judgement were responsible for causing them unnecessary pain and abdominal discomfort, severe vomiting, extreme disorientation and prolonged hospitalisation, including unnecessary diagnostic testing in Ms M's case and in Ms K's, a serious deterioration in her condition that meant she could not resume scheduled conventional treatment until it was too late;
- Dr Katelaris appears to have decided that because the two women had a diagnosis of ovarian cancer with ascites, there was no other treatment option for them and he was therefore ethically free to try whatever he felt might work;
- Dr Katelaris' clinical trial was completely lacking in scientific legitimacy and clinical rigour at every stage of its inception and execution and was unauthorised and unregulated;
- Dr Katelaris ignored the clearly expressed wishes of Ms K that the trial be safe, properly observed, monitored and documented and that it not interfere with her conventional treatment;
- Dr Katelaris has failed to accept responsibility for any of the clinical decisions made during the course of the experiment and afterwards, and has sought to blame everyone but himself for what went wrong. Dr Katelaris has directed blame towards the two women for pleading with

him to help them and 'forcing' him into the trial. He has blamed the black market supplier of the cannabis resin for misleading him as to its potency and the Ministry for refusing Sydney University a licence to test it for him. He has blamed Customs for holding up the components of his own testing equipment and the two women again for being on the brink of death and the urgency of their situation forcing him to proceed with the experiment without having first tested the cannabis. He has blamed Ms K's sister for what he termed his loss of control of the data, which control was actually his unauthorised access to blood results ordered by the hospital and his pressure on Ms K to provide them to him. He has blamed Ms K and her sister for not allowing him to continue guiding Ms K's recovery with diet and other alternative therapies and therefore allowing her condition to deteriorate inexorably. He has blamed the 'system' for the fact that clinical staff at Calvary Mater Hospital could not acknowledge openly and honestly that they were impressed by the reduction in Ms K's CA125 levels that he achieved;

- Dr Katelaris actively deceived clinical staff at both hospitals by giving inaccurate and incomplete histories for both women, omitting any mention of injected cannabis oil, in the interests of self-protection and against the interests of both women, with no respect for his registered medical colleagues and inconsiderate of scarce hospital resources;
- Dr Katelaris has an unjustified belief in his own pioneering courage and ability to treat cancer and/or alleviate its symptoms with cannabis given his lack of involvement in or contribution to any properly conceived, evidence-based, authorised and ethical clinical trial;
- Dr Katelaris has been dishonest to the two subjects of his experiment, dishonest to clinical colleagues to save himself professional embarrassment and possible criminal sanction, and dishonest to the Commission in an attempt to protect his professional reputation. The Commission has no confidence that he is telling the truth when he claims that he has no intention of repeating the injection of cannabis oil in future;
- The Commission has determined that Dr Katelaris' conduct demonstrates completely deficient clinical skill, care and knowledge and contempt for the basic ethical obligations of all health practitioners. Irrespective of questions of *legality* in relation to Dr Katelaris' cannabis use in the health services he provides, the Commission finds his administration of cannabis by any route, in the treatment of cancer and/or the alleviation of its symptoms, to be fundamentally unsafe and unethical.

Section 40 submissions

6.23 The Commission wrote to Dr Katelaris on 21 September 2016, proposing to take action under sections 41A and 41B of the *Health Care Complaints Act 1993* ("the Act") and inviting submissions under section 40 of the Act.

6.24 No submissions were received from Dr Katelaris within the statutory timeframe and the Commission has accordingly determined to proceed with the action proposed.

Decision

6.25 The Commission has determined that Andrew Katelaris has breached the Code of Conduct for non-registered health practitioners and that his conduct poses a risk to the health and safety of members of the public. Accordingly, the Commission proposes to make the following prohibition order under section 41A(2)(a) of the *Health Care Complaints Act 1993* ("the Act"):

> Andrew Katelaris is permanently prohibited from injecting cannabis or any of its derivatives, either by itself or mixed with any carrying agent to any person. Andrew Katelaris is permanently prohibited from supplying or administering cannabis or any of its derivatives to any person for the treatment, or purported treatment of cancer.

6.26 The Commission issues the following public statement under section 41A(2)(b) of the Act:

> The NSW Health Care Complaints Commission conducted an investigation into a complaint that Andrew Katelaris, a deregistered medical practitioner, administered intraperitoneal injections of cannabis oil to two women with ovarian cancer in September 2015, which resulted in serious adverse reactions and their prolonged hospitalisation.
>
> The investigation found that Andrew Katelaris breached the Code of Conduct for non-registered Health Practitioners and provided health services in an unsafe and unethical manner when:
>
> (i) he devised a hasty, ill-conceived and unsafe clinical trial of injected cannabis oil as a treatment for malignant ascites;
>
> (ii) he obtained cannabis resin from the black market and did not ensure that it been analysed for its potency and potential contaminants before administering it by injection;
>
> (iii) he did not obtain informed consent from the women to whom he administered untested cannabis oil in that he did not explain he had been unable to test it first;
>
> (iv) he told one of the women to defer telling her oncologist about the experiment until after it had been done, even though she expressed her discomfort at keeping back any information that may have a bearing on her upcoming chemotherapy and surgery;
>
> (v) he told one of the women to defer having her ascites drained because he needed to have her ascites present to test whether his trial had worked, even though he had no means of measuring this result;
>
> (vi) he administered huge doses of untested cannabis via intraperitoneal injection and caused foreseeably serious complications for both women;
>
> (vii) he withheld the fact that he had intraperitoneally injected cannabis oil when giving the clinical history for both women to hospital medical staff;
>
> (viii) the incomplete and inaccurate clinical histories he gave to two hospitals caused unnecessary confusion to extremely busy hospital staff and interfered with or caused a delay in the delivery of appropriate medical care to both women;

(ix) he took and kept no clinical notes, measurements or observations in connection with the 'trial';

(x) his 'trial' lacked authorisation, ethics approval, scientific legitimacy and credibility;

(xi) he provided a purportedly novel treatment that he was not qualified to provide as a deregistered medical practitioner without the ability to test the substance to be used, to monitor the progress of the patients, to measure the results of the treatment or to respond to any side effects or clinical emergency;

(xii) he put his own interest in self-protection and self-promotion ahead of the health and safety of two vulnerable women suffering from ovarian cancer.

The Commission is satisfied that Andrew Katelaris poses a risk to the health or safety of members of the public.

The Commission therefore makes the following prohibition order:

> Andrew Katelaris is permanently prohibited from injecting cannabis or any of its derivatives, either by itself or mixed with any carrying agent to any person. Andrew Katelaris is permanently prohibited from supplying or administering cannabis or any of its derivatives to any person for the treatment, or purported treatment of cancer.

6.27 The Commission will provide a copy of this Statement of Decision to the following organisations under section 41B(3)(b) of the Act:

- Australian Health Practitioner Regulation Agency (AHPRA);
- Each professional council in NSW;
- The NSW Ministry of Health:
  - (i) Population and Public Health Division;
  - (ii) Pharmaceutical Regulatory Unit.

6.28 The Commission makes this Statement of Decision publicly available.

Tony Kofkin
Director of Investigations
Health Care Complaints Commission

24 October 2016