General Practitioner, Dr C

A Report by the

Health and Disability Commissioner

(Case 06HDC12164)

Parties involved

Mrs A	Consumer (deceased)
Mr A	Consumer's husband
Mr B	Complainant/Consumer's son
Ms B	Complainant's partner
Dr C	Provider/General practitioner
Dr D	General and intestinal surgeon

Complaint

On 11 August 2006, the Commissioner received a complaint from Mr B about Dr C's care of his late mother, Mrs A. The following issue was identified for investigation:

- *The appropriateness of the care provided by Dr C to Mrs A.*

An investigation was commenced on 9 March 2007. The investigation was delayed by several months while awaiting an initial response from Dr C, and further delayed while awaiting expert advice.

Information reviewed

Information from:
- Mr B
- Dr C

Mrs A's:
- Clinical records from the District Health Board
- Nursing records from two Hospices
- Death certificate and cremation documents.

Responses to the provisional opinion were received from:
- Mr B
- Dr C

- Independent expert advice was obtained from Dr Steve Searle, general practitioner.

Information gathered during investigation

Overview
Mrs A was Dr C's patient for approximately eight years from 1 May 1995 until her death in 2003. She had multiple medical conditions and consulted Dr C frequently.

From late 2002, Mrs A's family noticed that she had lost weight, and was experiencing tiredness and a lack of appetite. Several aspects of blood test results taken in August and November 2002 were abnormal and subsequent tests in February and May 2003 reported further abnormalities. Mrs A was referred for a liver ultrasound in June 2003 which showed a mass on the right side. In July 2003, Mrs A underwent a liver biopsy which found advanced cancer in her liver. The primary site of the cancer could not be identified. In light of her poor prognosis, Mrs A was referred for palliative care. She died later that year.

Following her death, her son, Mr B, queried whether his mother's cancer could have been diagnosed earlier and treated, given the frequency with which Mrs A consulted Dr C over the eight years she was his patient.

Dr C
Dr C is a general practitioner. He trained in the United Kingdom, and is registered with the Medical Council of New Zealand under a general scope of practice requiring him to work within a collegial relationship. Dr C is a member of the Royal College of General Practitioners in the United Kingdom. He is currently participating in a training programme towards becoming a Fellow of the Royal New Zealand College of General Practitioners.[1]

When Mrs A first came under Dr C's care on 1 May 1995, he was practising at a medical centre. Both Mr and Mrs A remained with Dr C when he shifted his practice to another medical centre in May 2000.

Mrs A
Mrs A was 72 years old when she started receiving care from Dr C. He describes her medical history and the initial period of her care as follows:

> "When I took over the care of [Mrs A], she had already been treated for chronic hypertension for more than 10 [years] with blood pressures ranging from 130/80[mm/Hg] to 200/100[mm/Hg]. Related to this and in the presence of mild hyperlipidaemia, she had suffered a myocardial infarction in 1986 and a right sided cerebrovascular accident in 1989.
>
> She also had suffered from chronic gastritis, allergic rhinitis, vulvitis associated with urinary frequency, arthritis of her neck, spine and knees, chronic plantar

[1] Specialist qualification in general practice which allows a doctor to practise vocationally/independently.

> fasciitis, chronic constipation with diverticula disease affecting her distal colon and had had the removal of basal cell papilloma. She had had an appendicectomy and Caesarean section."

Over the eight years Mrs A was his patient, Dr C dealt with her approximately 40 medical conditions. A list of Mrs A's medical conditions was provided by Dr C during the investigation. In addition to those stated above, they included duodenal ulcer, hypertension, insomnia, irritable bowel syndrome, obesity and stress incontinence. Mrs A's son, Mr B, disagrees that his mother had so many medical conditions. According to him, "she suffered from the same sorts and numbers of medical conditions that afflict most elderly women — nothing more and nothing less".

According to Dr C, many of Mrs A's diverse medical conditions "required close attention" and "were in part affected by her excessive weight". Although Mr B acknowledged that his mother "may have been overweight", he queried Dr C's use of the word "obesity", and supplied two photographs taken of his mother in 2001 and January 2002 to support his view that his mother "[did] not look obese to [him] as a layman".

Dr C stated that Mrs A was "a frequent attender" at his surgery presenting several times each month. His records show that between May 1995 and August 2003, Mrs A visited his surgery on "some 150 occasions" and he "arranged some 232 laboratory or X-ray tests". In addition, Dr C recorded Mrs A's blood pressure and weight during some of her visits.

Consultation chronology

Mrs A consulted Dr C on many occasions over the eight years she was his patient. This report focuses on Dr C's treatment of Mrs A in the period leading up to her diagnosis of cancer until her passing. Accordingly, only the consultations relevant to those issues are discussed.[2]

Weight monitoring between 1998 and 2002

Mrs A was 1.61 metres tall and her ideal weight ranged between 51kg (Body Mass Index of 20) and 64kg (BMI of 24). Dr C monitored Mrs A's weight formally (using a computerised recall system) as part of the cardiovascular risk assessments and Well Woman Checks[3] he conducted. The timing of these weight checks varied from six months to three years depending on the level of risk found at each assessment.

Dr C stated that between 1998 and 1999, he also monitored Mrs A's weight "informally" over 62 visits. However, the details of these are not documented in his notes except for three occasions when Mrs A's weight gain placed her outside her ideal weight range. During a visit on 28 April 1998, Dr C recorded that Mrs A weighed 75kg (equating to a BMI of 28.9). Dr C measured her weight again on 2 November 1998 and observed that it had dropped slightly to 74kg (BMI of 28.5). Mrs A's weight remained stable at 74kg

[2] See also Appendix B1 – review of the clinical notes of Dr Searle's report.

[3] Health screening programme designed for women over the age of 40 and post-menopausal women.

when she was weighed again a year later on 21 December 1999. Although Mrs A saw Dr C frequently over the next three years, he did not record her weight again until 21 October 2002. She had lost considerable weight at that stage and returned to her ideal weight range with a new weight of 60.5kg.

In relation to his monitoring of Mrs A's weight between 1999 and 2002, Dr C stated:

> "During the period from 1999 to November 2002 [Mrs A] weighed 74kgs which was above her ideal weight and she was encouraged by myself and my staff to reduce her weight in order to benefit her general health. There was no pathological or sinister element to the weight loss during this period.
>
> …
>
> Between December 1999 and October 2002, [Mrs A] was overweight from my measurements and measurements by her specialists. She was counselled during this period and encouraged to lose weight through diet and appropriate exercise. Laboratory tests were performed on a regular basis monitoring her various medical conditions and excluding pathological processes associated with obesity or pathological weight loss."

According to Dr C's records, Mrs A's weight remained stable at 60.5kg when she was weighed four months later on 14 February 2003. In contrast, Mr B stated that, as a family, they had noticed that between late 2002 and early 2003, Mrs A experienced a steady decline in her weight and a loss of appetite, and became increasingly lethargic. To monitor Mrs A's weight, Mr B's partner began weighing Mrs A on a weekly basis. She also began accompanying Mrs A to her consultations with Dr C and provided him with her recordings of Mrs A's weight. However, Dr C's notes do not contain any information from Ms B.

Following the February 2003 entry in Dr C's notes, Mrs A's weight was not recorded for four months until 20 June 2003 when she weighed 56kg (a 3.5kg weight loss). She lost a further 1.5kg and weighed 54.kg a month later on 22 July 2003. This was the last record of her weight in Dr C's notes. Shortly afterwards, her diagnosis of cancer was confirmed and she was referred for palliative care.

August 2002

Dr C ordered a number of blood tests for Mrs A on 22 August 2002, including iron studies, liver function, B_{12} and folate. The tests included carcinoembryonic antigen (CEA).[4] Mrs A consulted Dr C on 27 August after she had fallen over and struck a table.

[4] Antigen found in the blood of patients suffering from colon cancer and other diseases and otherwise normally found in fetal gut tissue. CEA is a tumour marker normally performed to follow up on known cancer in a patient.

October 2002
During a consultation on 21 October 2002, Mrs A reported several occasions of constipation. Dr C discussed the management of this and prescribed Coloxyl with Senna tablets. He documented in his notes "gastritis, acute/chronic lethargic, frail and chr [chronic] constipation". This is the only entry pertaining to this consultation. The clinical records do not contain any previous references to constipation or reference to his discussions with Mrs A about her reported constipation. Dr C advised me that his diagnosis of chronic constipation was based on the notes from Mrs A's previous GP (which refer to constipation in November 1989 and diverticula disease in February 1990, May 1990 and June 1991) and her consultation with him on 13 February 2001, when she presented with rectal bleeding from haemorrhoids associated with chronic constipation.

The consultation included a weight check, ordering urine tests, and an examination of Mrs A's skin, eyes, mouth, chest, breasts, abdomen and rectum. However, Dr C's notes do not state why a general clinical examination was performed on this occasion. He also omitted to record the findings from his examination and whether a chaperone was present.

Dr C advised me that his diagnosis at this time was chronic intermittent gastritis and lethargy associated with her chronic medical conditions. He initiated the investigations "to exclude anaemia and vitamin deficiency hypothyroidism" owing to Mrs A's age, general frailty, chronic constipation and multiple medical conditions.

On 23 October 2002, two days after seeing Dr C, Mrs A was admitted to a regional hospital's Emergency Department with an acute gastric bleed. A gastroscopy indicated a large 2cm x 2cm duodenal ulcer without any fresh bleeding, or blood in her stomach or duodenum. Gastric biopsies were taken and Mrs A was placed on one week of triple eradication therapy for *Helicobacter pylori.* On 28 October 2002, Mrs A was discharged from hospital with follow-up instructions to return for another gastroscopy in six weeks' time.

On 31 October 2002, three days after her discharge, Dr C reviewed Mrs A. The notes of the consultation record, "back from hospital well [blood test]". He advised during the investigation that at this consultation he ascertained that she "felt generally well with no ongoing symptoms". Dr C noted that he prescribed omeprazole[5] in light of her duodenal ulcer, and added in his notes gastro-oesophageal reflux, duodenal ulcer and a history of haematemesis (vomiting of blood) associated with aspirin or NSAID (non-steroidal anti-inflammatory drug) under Mrs A's list of clinical diagnoses/medical warnings.

November 2002
On 22 November 2002, Mrs A presented with pain in her right knee owing to chronic arthritis (chondrocalcinosis). Dr C ordered hip and knee X-rays and prescribed Paradex (an analgesic). (The X-ray reports on 10 December 2002 confirmed joint space loss in Mrs A's hips and knees consistent with osteoarthritis.) According to Dr C, Mrs A had

[5] Proton pump inhibitor used in treating dyspepsia, peptic ulcers and gastroesophageal reflux disease.

"no abdominal symptoms" on this occasion although Dr C did not document this observation in his notes. Dr C advised that in light of Mrs A's duodenal ulcer, he ordered stool tests to investigate the presence of *Helicobacter pylori*, occult blood, pathological bowel bacteria and parasites. He also requested a test for carcinoembryonic antigen. However, Dr C did not record his basis for ordering this test or any suspicion he may have had regarding Mrs A's health.

Several of Mrs A's test results reported on 29 November 2002 were abnormal. They included an elevated erythrocyte sedimentation rate[6] of 38mm/hr (normal range being 2–25mm/hr), and an elevated ferritin[7] of 404µg/L (normal range being 25–300µg/L). Her liver function was mildly abnormal with an elevated GGT[8] enzyme level of 63U/L (normal range 5–50U/L). Mrs A was negative for *Helicobacter pylori* and parasites.

Mrs A's haemoglobin level of 114g/L was "borderline low" (normal range being 115–165g/L) although her red cells, white cells and platelets appeared normal. Amongst the batch of tests ordered was one for cancer specific antigen (CEA). The laboratory confirmed that Mrs A's CEA result was normal and included in its report a note advising Dr C that "CEA is not suitable as a screening test for primary diagnosis of tumours". In response to the test results, Dr C documented in his notes a reminder to review Mrs A's liver function in three months' time (in February 2003) and her renal function in six months' time (in May 2003).

December 2002

On 12 December 2002, Mrs A returned to hospital for a follow-up gastroscopy and gastric biopsy, and was diagnosed with "inflammation, chronic, mild" in her stomach and gastric antrum.[9] A copy of the report was sent to Dr C. He noted that there was no evidence of any acute inflammation, dysplasia or malignancy, or of any Helicobacter organisms.

Based on the report, Dr C considered that Mrs A's gastritis (in October 2002) was probably related "to dietary factors, excessive gastric acidity, *Helicobacter pylori* or the use of aspirin and NSAID medications". He states that during a consultation on 23 December 2002, he told Mrs A to avoid excessive irritant foods, remain a non-smoker, avoid excessive alcohol, aspirin and NSAIDs, and to continue using omeprazole as directed. These discussions are not documented in the medical record. The notes record that Mrs A had her Well Woman Check, that her cardiovascular risk was mild, and that Dr C discussed chondrocalcinosis and hormone replacement therapy with her. It was

[6] ESR measures the rate at which red blood cells (erythrocytes) settle out of suspension in blood plasma, measured under standardised conditions. The ESR increases if certain proteins in the plasma rise, as occurs in rheumatic diseases, chronic infections and malignant disease, and is a non-specific index of inflammation.

[7] Iron storage protein found in the liver, spleen and bone marrow.

[8] Gamma-glutamyltransferase. It is often elevated above normal in hepatitis and other conditions that cause liver damage.

[9] A portion before the outlet which is lined by mucous membrane and does not produce acid.

noted that she could not tolerate non-steroidal anti-inflammatory medication and she was prescribed Celebrex. Blood pressure was recorded, but not weight. A private referral (possibly to an orthopaedic surgeon) is noted.

Care in 2003

January 2003
On 15 January 2003, Mrs A attended an outpatient clinic at hospital accompanied by her husband. She was reviewed by a consultant general surgeon, who discussed with her the findings from her gastroscopy and gastric biopsy a month earlier. Although Mrs A reported "feeling better" and was "eating her food", she complained of "a whole lot of various aches and pains around her abdomen". Mr A informed the general surgeon that his wife had not regained any weight since her discharge from hospital in October 2002.

In his report to Dr C, the general surgeon stated that he did not investigate Mrs A's weight concerns but he offered to review her again if Dr C considered it necessary. The general surgeon gave Mrs A a further prescription of omeprazole and advised her to continue taking it daily.

Dr C did not refer Mrs A back to the general surgeon. In relation to the follow-up care thereafter, Dr C stated:

> "Following [the] consultant surgeon's assessment on the 15th January 2003, [Mrs A] was seen by me some ten times over the next four months for unrelated other medical conditions.
>
> Although she had complained to [him] of various aches and pains around her abdomen, when I assessed her on these ten occasions, which included the 16 January 2003, she had no symptoms of weight loss or abdominal pain and her weight was recorded on 14th February 2003 as 60.5kg with a BMI of 23.15, well within her normal weight range and demonstrating no weight loss whatsoever since her previous measurement of 60.5kg on the 21st October, 2002."

February 2003
On 17 February 2003, Dr C ordered further blood tests for Mrs A without documenting the basis for his investigation. Dr C's request included a test for cancer specific antigen but not Mrs A's liver function despite the reminder in his notes on 29 November 2002. Compared with the results in November 2002, the February 2003 readings showed further abnormalities in Mrs A's ESR (51mm/hr — above the normal range of 2–25mm/hr) and ferritin level (513µg/L — above the normal range of 25–300µg/L). Her C-reactive protein (9mg/L) was also above the normal range of 0–5mg/L. (It had previously been at the upper normal limit of 5mg/L in November 2002.) Mrs A's cancer specific antigen test was normal. As it had done in the report of November 2002, the laboratory reminded Dr C that it was not a suitable investigation for the primary diagnosis of tumours.

In relation to the February 2003 test results, Dr C commented:

> "These results might have been consistent with iron excess, inflammation or tissue necrosis.
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> At that time, I was treating [Mrs A] for an infected lesion on her left lower leg, which had inflammation and necrosis associated with cultured growths of staphylococcus aureus [bacteria], proteus mirabilis [bacteria] and skin flora.
>
> [Mrs A's] elevated ferritin was consistent with iron excess associated with her heterozygous state for genetic haemochromatosis[10] previously diagnosed in September 2000 and confirmed on 21st October 2002.
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> There was no significant rise in her ferritin levels over the period from January 2000 to May 2003, apart from a single result in November 2002, after which the levels restabilised to [Mrs A's] normally slightly elevated level from her genetic heterozygous state at around 300–500µg/L."

March–April 2003

In March 2003, Mrs A consulted Dr C for problems in the lower part of her left leg and was referred to an orthopaedic surgeon. Details of this are not relevant to the investigation and are not discussed further.

On 23 April 2003, Mrs A presented for a flu vaccination. Dr C recorded in his notes that Mrs A had had "variable periods of 1–2/52 [one to two weeks of] feeling wo[nd]erful or unwell with various aches" but did not specify what type of aches she had experienced. He noted in the medical record that she was concerned her condition might be due to her hormone replacement therapy or Lipex (a drug to lower cholesterol). Dr C advised her to stop hormone replacement therapy "and see". Her weight was not recorded on this occasion.

May–June 2003

On 22 May 2003, Mrs A underwent repeat blood and liver function tests. There were further abnormalities in Mrs A's ferritin level (545µg/L compared to 513µg/L in February 2003 with the normal range being 25–300µg/L) and C-reactive protein (14mg/L compared to 9mg/L in February 2003 with the normal range being 0–5mg/L). Her liver function results (having been mildly abnormal in November 2002) were grossly abnormal and showed a GGT enzyme level of 528U/L (well above the normal range of 5–50U/L). Mrs A's ESR remained stable at 51mm/hr. It was outside the normal range of 2–25mm/hr, as it had been in the November 2002 reading.

According to Dr C, the "abnormal liver function tests suggested for the first time, the presence of a mixed hepatocellular[11] and cholestatic[12] pathology". He scheduled a

[10] A rare genetic disease that results in the over-abundance of iron in the body tissues. Organs affected include the liver, brain, heart and kidneys. Complications include liver dysfunction, diabetes, changes in skin pigmentation, heart problems and arthritis.

[11] Pertaining to or affecting liver cells.

review with Mrs A four days later on 26 May 2003, to discuss the abnormal blood and liver function results, and advised her of the need for an urgent liver ultrasound examination. He also made a note to recheck the blood test in one month.

Liver ultrasound

The liver ultrasound performed a fortnight later on 10 June 2003 showed a discrete mass in the right lobe of Mrs A's liver measuring approximately "75 by 77mm in diameter". In light of her abnormal liver function test results, the radiologist considered metastasis, hepatomas[13] within the liver and cirrhosis (liver disease) as possible diagnoses and advised Mrs A to consult a gastroenterologist.

The following day (11 June 2003), Mrs A met Dr C to discuss the results of her liver ultrasound and the follow-up required. Owing to the lack of gastroenterologists providing private consultations in the region, Dr C was concerned about the likely delay in diagnosing and treating Mrs A and arranged for her to consult a general surgeon instead. Mrs A agreed and an urgent appointment was arranged for 26 June 2003 with Dr D, a general and intestinal surgeon. However, it appears from Dr C's records that he did not send Dr D any written referral prior to Mrs A's appointment with him.

Dr C arranged further laboratory tests on 20 June 2003, prior to Mrs A's assessment by Dr D. Dr C measured her weight and blood pressure, but no other clinical notes were made. He advised me that the tests were done to monitor the progress of the previously abnormal laboratory tests on 22 May. He stated that he conveyed the results to Dr D "immediately prior to his assessment to assist him in his consultation with the knowledge of fresh laboratory information".

On 26 June 2003, Mrs A saw Dr D, who noted that she had "a poor appetite and [had] lost about 2 stone in weight over the past two years". He also noted that Mrs A "looked a little slim and fragile" and had "occasional pain in her right hypochondrium".[14] On examination, Dr D observed that Mrs A's abdomen was "soft with some tenderness on the right side" and her liver felt "palpable and enlarged". In his report to Dr C, Dr D advised that the mass in the right lobe of Mrs A's liver was "likely to [be] either a primary or metastatic deposit". Dr D's follow-up plan included ordering an urgent liver biopsy and CT scan of Mrs A's upper abdomen and reviewing her again thereafter.

On 15 July, the notes record that Mrs A had a poor appetite, "try pred[nisone]" for 14 days. Dr C reviewed Mrs A again on 22 July. The notes record, "poor appetite lost 2.5kg". Her weight and height were recorded, and blood tests ordered. Dr C advised me that he performed laboratory tests that day to monitor her progress in light of her previous abnormal results and to exclude a primary liver tumour as suggested by her ultrasound result. He further advised:

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[12] Tending to diminish or stop the flow of bile.

[13] Carcinoma derived from liver cells.

[14] The upper lateral portion of the abdomen situated beneath the lower ribs.

> "I monitored her vitamin and iron levels together with her coagulation factors in view of her previous history of a bleeding duodenal ulcer and the new finding of abnormal liver function."

Liver biopsy

A month later, on 28 July 2003, Mrs A underwent a liver biopsy, which confirmed the presence of tumour cells in her liver. The radiologist's findings were "necrotic metastatic carcinoma" and additional investigations were conducted to determine its primary site. On 1 August, the radiologist excluded metastatic breast carcinoma from her diagnosis and advised (in a supplementary report) that the primary possibilities included Mrs A's lung, pancreas, bile duct, stomach and distal oesophagus. However, despite conducting further investigations, the radiologist was unable to determine the primary origin of the tumour and recorded in her additional supplementary report (on 25 August) a finding of "metastatic adenocarcinoma[15] of undetermined primary site".

Follow-up care

On 4 August 2003, Dr C noted that Mrs A's weight had improved to 55kg following the liver biopsy.

On 5 August, Mrs A consulted Dr C to discuss the liver biopsy results. Ms B accompanied Mrs A for this visit. The notes record "d/w tumor in liver — metastic spread — unknown [primary] ? bowel ? lung." Dr C advised that at this appointment they discussed Mrs A's results and treatment options, including Iscador — an alternative treatment for cancer using mistletoe extracts. Ms B recalls Dr C mentioning Iscador "briefly" during the consultation and printing a letter for Mrs A about "the use of Iscador in the treatment of your cancer". Ms B also recalls Dr C asking Mrs A to contact him if she wanted to consider this therapy. However, there is no record of the details of the discussion concerning Iscador in Dr C's notes.

The letter that Dr C gave Mrs A explains the composition of Iscador, its mode of action, its uses and contraindications, side effects, compatibility with other medications, method of application, use of Iscador in specific situations, complimentary therapy and evolution of the Iscador preparations. The letter discusses "the effectiveness of Iscador preparations" and, with regards to inoperable tumours and secondaries, notes:

> "Apart from the striking improvement in general condition and analgesic action (pain relieving action) cessation of tumour growth has frequently being noted and on occasion also tumour regression. Inoperable tumours may well become operable."

[15] A form of cancer that involves cells from the lining of the walls of many different organs of the body.

Under the heading "evolution of the Iscador preparations", the letter states:

> "… Work has been continued within Europe and the United States, where they have been found to be an exciting, successful and naturally based way of stopping, controlling or preventing the abnormal growth of cells found within cancer."

Dr C advised me that the information was given to Mrs A during the consultation "in all good faith" and that he "did not have a vested interest" in Mrs A pursuing this therapy. Instead, Dr C wanted to inform Mrs A of alternative options, particularly as he was aware that Iscador therapy was discussed within their local community's cancer support group, and offered by several general practitioners in the vicinity.

Two days later, on 7 August, Mrs A had a chest X-ray (ordered by Dr C for "suspected lung primary"). The X-ray found no evidence of cancer in her lungs. Mrs A consulted Dr D on 8 August 2003 prior to her appointment with Dr C that afternoon. In relation to the visits on 5 and 8 August, Dr C stated:

> "I explained to [Mrs A] that the biopsy had shown a metastatic cancer affecting her liver, the precise primary at that time being either bowel or lung. Following our discussion, I made a referral to [a] Hospice and also to [Dr D] detailing the results of the biopsy.
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> [Dr D] met with [Mrs A] regarding the results of the liver biopsy on 8th August 2003. He discussed the findings with her and recommended palliative care with the help of [a] Hospice. I arranged to meet with [Mrs A] that same afternoon to support her and to discuss options available to her.
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> We discussed [Dr D's] advice that she had metastatic cancer originating from a primary site,[16] the precise location of which was uncertain and that sadly no curative therapy was available.
>
> Following our discussion, and with her consent I made referrals to community occupational therapy and to the local 'living with cancer' support group.
>
> I provided [Mrs A] with detailed information regarding other possible treatment options, including dietary advice and Iscador natural therapy for her condition."

Palliative care

On 11 August 2003, Dr C referred Mrs A to the hospice. Owing to her need for full nursing care, Mrs A was transferred to another hospice a fortnight later on 29 August. During her admission to both hospices, Dr C visited several times. Mrs A died in the second hospice.

[16] In Dr D's report on 8 August 2003, he advised Dr C that the liver biopsy "confirmed metastatic carcinoma possibly from the lung or bowel".

Certification of Mrs A's death
Shortly afterwards, Dr C was notified of Mrs A's death, and drove approximately 17 kilometres from his home to the hospice to certify Mrs A's death. Dr C recorded in the hospice's medical notes "Died @ 7.30am. 0900 certified dead." Dr C stated that he cancelled all appointments with other patients that morning to visit Mrs A "promptly after her death" and supplied a copy of his appointment book, which showed "call out" for slots between 8.40 and 9.50am.

The death certificate that Dr C completed records Mrs A's cause of death as "metastatic carcinoma of bowel 4 months". This differs from the radiology reports in August 2003, which were inconclusive regarding the primary metastatic site. It is unclear when Dr C received the additional supplementary report from the radiologist confirming that the primary site could not be determined. The certification of Mrs A's cause of death was subsequently queried by Mr B (discussed below).

Other matters
Mr B and Ms B stated that following Mrs A's death, no attempts were made by Dr C to express his condolences to Mr B's father notwithstanding that Mr B's father was also a patient of Dr C.

On 30 September 2003, a fortnight after Mrs A's death, Mr B telephoned Dr C's surgery to request a copy of his mother's death certificate. His request was not attended to. Two months later, on 3 December 2003, Mr B wrote to Dr C but did not receive a reply. Following a second telephone call to Dr C's surgery on 6 January 2004, his staff recorded in Mrs A's notes "2nd request for copy of certificate of 'cause of death' for mum made today. 2nd note left for [Dr C] to action today". A copy of Mrs A's death certificate was then sent to Mr B.

On 23 February 2004, Mr B wrote to Dr C querying his basis for certifying Mrs A's cause of death as metastatic carcinoma of the bowel of four months' duration. The next day (24 February 2004), Dr C sent a five-page letter to Mr B, which included the results of Mrs A's liver function test on 22 May 2003, the liver ultrasound report of 10 June 2003, and the findings from the liver biopsy on 28 July 2003. However, Dr C did not respond directly to Mr B's query regarding the certification of his mother's cause of death. Dr C stated at the end of his letter that he had "spent some time responding to [Mr B's] letter" and enclosed an invoice for $90.

Three months later, on 19 May 2004, Mr B sent a cheque for $90 and a third letter to Dr C querying the management of his mother's cancer. Mr B commented that the information provided by Dr C did not support Dr C's diagnosis of bowel cancer and reiterated his query about Dr C's certification of his mother's cause of death. Mr B also queried why it took so long for Dr C to diagnose Mrs A's cancer given that she had consulted him frequently for eight years. Mr B stated:

> "My concern is that it took you until 7 August 2003 to make your diagnosis by which time you were limited to palliative care rather than remedial care. [In your

> letter] you detail the number of times you saw my mother and the number of tests you conducted. Despite this and despite the obvious symptoms (eg. weight loss, tiredness, loss of appetite and constipation) exhibited since late 2002 you still did not come up with any solution. It seems to me that you did very little and continually reassured my mother that everything was alright because the blood tests were satisfactory. It was not until the abnormal blood test on 22 May 2003 that the alarm bells began to ring for you. Then it took you another two months to make your final diagnosis on 7 August 2003.
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> To my mind, as a layman, it seems that you should have been more proactive given the number of times you saw my mother and the symptoms she presented. Because of inaction any chance of remedial care was lost."

Dr C did not respond to Mr B's third letter, and subsequently clarified that he had perceived this letter "as one of general comment rather than requesting a response". Two years later (three years after Mrs A's death), Mr B made the complaint about Dr C that triggered this investigation.

Changes and review of practice

Since the events in question, the style and location of Dr C's practice has changed considerably from a large multi-doctor medical centre with a central administration team to a closer-knit solo general practice. Dr C now has a practice administrator solely focused on his practice, who "serves to prevent delays in obtaining documents, with closer attention to follow-up and despatching of documents to individual patients".

Dr C advised me that over the past year, his practice has been "under the close scrutiny and monitoring of the Medical Council". This has included regular performance competence reviews, daily external electronic monitoring of his clinical notes by independent general practitioners, attending weekly meetings with his collegiate supervisor to address shortcomings in his practice, and participation in a monthly peer review group approved by the Medical Council. In addition, Dr C is also undergoing an educational programme with progression towards becoming a Fellow of the Royal New Zealand College of General Practitioners. (Refer to Appendix C for a copy of Dr C's response to my provisional opinion for details of the changes he has made and the review he is undergoing with the Medical Council.) Dr C stated that "overall, [his] practice is under what might be term[ed] 'a very tight rein'".

Independent advice to Commissioner

Independent expert advice was obtained from Dr Steve Searle, general practitioner. Dr Searle's advice is attached as Appendix A.

Comment was obtained from the Medical Director of the New Zealand Cancer Society on the use of Iscador natural treatment with cancer patients. The Medical Director's comments are attached to this report as Appendix B4.

Responses to provisional opinion

The following parties responded to my provisional opinion:

Mr B
Mr B commented on several aspects of his mother's care including Dr C's documentation and management of her medical conditions, weight loss and blood tests. The relevant points have been incorporated in the "information gathered" section of this report. In addition, Mr B requested that the cause of death on his mother's death certificate be amended to "metastatic cancer primary site unknown". (I have recommended that Dr C follow this up in the "Recommendation" section of my report.)

Mr B also stated:

> "… Clearly in my mother's case, [Dr C's] standard of care has been less than could reasonably be expected from a competent medical practitioner. He has let my mother (and my father) down.
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> …
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> … I have approached [this case] 'with a heavy heart' but have believed that it was something I had to do for mum, who was a very special person."

Dr C
Dr C submitted a comprehensive response to my provisional opinion. (I have enclosed his response in full as Appendix C as it is a model response for providers who are responding to serious criticisms of their care.) He accepts the criticisms in my provisional opinion "with a sincere sense of deep regret". Although Dr C felt at the time that he was doing his best to care for Mrs A, on review, he concedes that there were deficiencies in his practice including his standard of record-keeping, and his ordering and interpretation of tests. In addition, Dr C acknowledges that he did not provide Mrs A with adequate information about Iscador, and accepts that he should have responded more promptly and appropriately to Mr B's requests for information following his mother's death.

Dr C stated that since the events in question, he has changed the style and location of his practice considerably, and has been actively engaged in a review process of his practice for more than a year. He also commented that his practice has been "under the close scrutiny and monitoring of the Medical Council" and outlined the steps he is taking towards becoming a Fellow of the Royal New Zealand College of General Practitioners.

As part of his response, Dr C enclosed a cheque of $90 (to refund the charge of his report of February 2004) and included a written apology to Mr B in which he stated:

> "I am endeavouring in my new practice to learn from this experience and prevent these problems occurring in future to others."

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4

Right to Services of an Appropriate Standard

(1) Every consumer has the right to have services provided with reasonable care and skill.
(2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

RIGHT 6

Right to be Fully Informed

(1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including —

…

(b) an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and

…

(e) any other information required by legal, professional, ethical, and other relevant standards; …

Other relevant standards

New Zealand Medical Association's "Code of Ethics" (March 2002)

> "*Responsibilities to the Patient*
>
> …
>
> 4. Doctors should ensure that every patient receives appropriate investigation into their complaint or condition, including adequate collation of information for optimal management.
>
> 5. Doctors should ensure that information is recorded accurately and is securely maintained.
>
> …
>
> 16. Doctors should recommend only those diagnostic procedures which seem necessary to assist in the care of the patient and only that treatment which seems necessary for the well-being of the patient."

Cole's *Medical Practice in New Zealand* (Medical Council of New Zealand, 2001):[17]

> "*The medical record*
>
> An important part of a good doctor–patient relationship is the keeping of a proper medical record. It is a tool for management, for communicating with other doctors and health professionals, and has become the primary tool for continuity of care in many large practices, as well as in hospitals. To fulfil these tasks the record must be comprehensive and accurate. … Poor record keeping may be a form of misconduct.
>
> …
>
> *Inadequacy of patient records as a form of misconduct*
>
> A doctor is expected as part of quality of service to maintain adequate records. It is in the patient's interest that past events are accurately recorded for the doctor and for others such as locums. It may be vital in a drug dosage issue. … The absence of a permanent record makes the task of establishing the truth very difficult."
>
> The Medical Council of New Zealand's publication *Good Medical Practice — A Guide for Doctors* (2000) states:

[17] Page 80.

"Good clinical care

2. Good clinical care must include:

- an adequate assessment of the patient's condition, based on the history and clinical signs, and if necessary, an appropriate examination;
- providing or arranging investigations or treatment when necessary;
- taking suitable and prompt action when necessary; …

3. In providing care [a doctor] must

…

keep clear, accurate and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed;

…

- prescribe only the treatment, drugs or appliances that serve the patient's needs."

The Medical Council of New Zealand *Statement on Complementary and Alternative Medicine* (April 1999, reviewed October 2002) states:

"The Council expects that any doctor who embarks upon a mode of investigation or treatment of patients that is not based upon evidence of effectiveness acceptable to the Colleges and the Council will,

…

(2) In treating patients:

…

(c) Provide sufficient information to allow patients to make informed choices

…

(d) Not misrepresent information or opinion. Patients must be made aware of the likely effectiveness of a given therapy according to published and accepted information, notwithstanding the medical practitioner's individual beliefs.

…

(3) In advancing knowledge, and providing treatments in areas of uncertainty where no treatment has proven efficacy:

(a) ensure that their patients are told the degree to which tests, treatments or remedies have been evaluated, and the degree of certainty and predictability that exists about their efficacy and safety."

Breach — Dr C

Overview
Mrs A required frequent care and prolonged consultations during the eight years she consulted Dr C. Caring for an elderly patient with many and varied medical conditions can be a challenging task for a general practitioner. However, Dr C is subject to Rights 4(1) and 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code). Dr C was required to provide services to Mrs A with reasonable care and skill, and in accordance with legal, professional, ethical and other relevant standards. Those standards include statements and guidelines issued by the Medical Council of New Zealand and the New Zealand Medical Association. In addition, Dr C was required to provide Mrs A with full information about her treatment options, in accordance with Right 6(1) of the Code.

In my view, three aspects of Dr C's care of Mrs A fell below an appropriate standard of care: his record-keeping; his ordering and interpretation of laboratory tests, and follow-up systems; and the information he gave Mrs A about Iscador natural treatment. The reasons for my view are discussed below.

Documentation
In accordance with Right 4(2) of the Code, and relevant standards from the New Zealand Medical Association (NZMA) and the Medical Council of New Zealand (set out above), medical practitioners have an ethical and professional duty to maintain adequate records as part of good quality care. Records are an essential tool for patient management, for communicating with other doctors and health professionals, and for ensuring continuity of care.

As noted by Dr Steve Searle, my independent general practitioner advisor, adequate notes allow for a more reliable comparison of findings than simple memory of events should a patient return for review of the same or different problems. The standard of the medical record can, therefore, have a significant impact on the current and future care of patients.

Dr Searle strongly criticised Dr C's record-keeping in this case. I agree with my advisor that Dr C's notes of his consultations with Mrs A are, in the most part, woefully inadequate.

Given the limited information in the clinical notes, Dr Searle was unable to comment in detail on the standard of care that Dr C provided to Mrs A. In particular, it was difficult for Dr Searle to advise exactly what investigations should have occurred at various points of Dr C's care. For example:

- Dr Searle considered weight loss a key issue in this case but was unable to ascertain from Dr C's notes exactly when Mrs A's weight loss became a cause for concern. On 21 December 1999, Mrs A weighed 74kg, which appears to have been above her ideal weight range. When her weight was next recorded on 21 October 2002, Mrs A

had lost 13.5kg and weighed 60.5kg. Although I accept Dr C's comment that Mrs A returned to her ideal weight range in late 2002, I am concerned that for almost three years, Dr C failed to document Mrs A's weight when she presented many times with various medical problems. Mrs A's weight remained stable at 60.5kg when it was next recorded on 14 February 2003. From then until 20 June 2003, she lost a further 3.5kg but her weight was not recorded between these dates despite several worrying results from her blood tests in February and May 2003. In short, the lack of documentation makes it very unclear what Dr C did to monitor Mrs A's weight during this period, although it is clear that there was concern about Mrs A's weight loss. In my view her weight should have been monitored and recorded.

- Dr Searle was unclear about Dr C's basis for ordering blood tests on numerous occasions including 26 January 2001, 13 February 2001, 19 November 2001, 22 April 2002 and 22 August 2002, as he did not document his reasons for initiating further investigations (this issue is also discussed below). In relation to the tests on 22 August 2002, it is clear that Dr C suspected "that something might seriously be wrong with Mrs A", because in addition to other tests (including iron levels and inflammatory markers) he also ordered a test for carcinoembryonic antigen. Carcinoembryonic antigen tests are usually done to follow up cancer in patients. However, Mrs A had not been diagnosed with cancer at this stage. No notes were recorded on this date to explain why Dr C ordered those tests or what his suspicion was.

- Dr C failed to document his basis for performing a general clinical examination on 21 October 2002 and his findings from this examination.

- On 22 November 2002 Mrs A presented with pain in her right knee. The month earlier she had been in hospital for the treatment of a duodenal ulcer. Dr C advised me that Mrs A had "no abdominal symptoms" at the time, but this is not recorded in the notes.

- During a consultation on 5 August 2003, following the diagnosis of cancer, Dr C recorded "d/w tumor in liver — metastatic spread — unknown [primary] ? bowel ? lung". That day Dr C sent a letter to Mrs A regarding Iscador natural therapy. Dr C advised me that he provided Mrs A with detailed information regarding other possible treatment options, including dietary advice and Iscador. However, there is no record of those discussions. Dr C provided Mrs A with an information sheet about Iscador, but any supplementary verbal information provided during discussions at that consultation should have been recorded.

I am concerned by the numerous deficiencies in Dr C's documentation of his care of Mrs A. It appears that Dr C supplemented his notes, in his response to the complaint, with explanations based on his recall. It is very difficult to establish the extent to which his explanations are based on the clinical record, as opposed to his memory of events. I note that at the time Dr C responded to the complaint, more than three years had passed since the events. The absence of a permanent and contemporaneous record makes the task of

verifying the accuracy of his recall many years after the events very difficult. The paucity of notes has impeded my investigation into whether Dr C provided appropriate clinical care to Mrs A.

Although Dr Searle advised that it is unlikely that Mrs A's cancer could have been diagnosed earlier even if Dr C had kept good notes, I agree with my expert that recording symptoms, signs and basic examination findings would have provided Dr C and other doctors to whom he referred Mrs A with a clearer clinical picture of her condition.

Proper record-keeping is an essential part of good quality care and is one aspect of practice that is basic to clinical competence. I acknowledge my advisor's comments on aspects of Dr C's record-keeping that were appropriate. However, the overall paucity of information in Dr C's records raises serious questions about his professional competence and would undoubtedly be viewed with moderate to severe disapproval by his peers and registration body. Dr C's record-keeping did not comply with professional standards. In this respect, he did not provide services to Mrs A with reasonable care and skill and, in my view, breached Rights 4(1) and 4(2) of the Code.

Dr C accepts my findings that his record-keeping was deficient. He acknowledges that he should have recorded Mrs A's symptoms, and his examination findings, in the clinical notes.

Ordering of tests and investigations
Dr C stated that over the eight-year period he cared for Mrs A, he arranged approximately 232 laboratory tests and X-rays. There are several aspects of Dr C's ordering of these tests that are of concern: the appropriateness of the tests ordered; Dr C's interpretation of the test results; and his follow-up systems.

Dr Searle noted that Mrs A's symptoms, complaints, and the results of clinical examination findings are not well documented in the clinical record. It is therefore difficult to determine what investigations Dr C should have carried out at various times. However, there appears to be a departure from the appropriate standard of care in the ordering and interpretation of tests.

On many occasions throughout 2001 and 2002 Dr C ordered various blood tests. However, the basis for his ordering many of those tests is unclear. For example:

- On 22 August 2002, Dr C ordered a test for carcinoembryonic antigen, a test that is usually done to follow up known cancer in a patient. Given that Mrs A had not been diagnosed with cancer at this time, it is unclear why Dr C ordered that test. If it was ordered to pick up cancer, the ordering of the test was inappropriate. As noted by my advisor, this test is not suitable as a screening test for detecting unknown cancers or, as also noted in the laboratory report, for the primary diagnosis of tumours. Yet the test was repeated in November 2002, and February and May 2003, with no explanation in the clinical record of the reason why it was ordered or of any suspicion Dr C had about Mrs A's health.

- On 13 February 2001, Mrs A presented with visible bleeding per rectum. However, during this appointment Dr C ordered a faecal occult blood test. This is a test to check for non-visible blood in the bowel motions. As stated by my advisor, because bleeding was already known to have occurred, there was no point in a test to check for non-visible blood. Either no test should have been done or, if there was ongoing concern, she should have been further investigated through a sigmoidoscopy, for example, or a specialist referral.

- A haemochromatosis gene test that had been ordered in September 2000 was re-tested in July 2001. It was inappropriate to repeat this test because the gene does not change.

In addition to these discrete incidents, the extent to which tests were ordered without documented reasons is concerning. I agree with my advisor that it is not how much a patient is investigated, but rather the appropriateness of the investigations and the interpretation of them. Indeed, the New Zealand Medical Association Code of Ethics clearly states that doctors have a responsibility to their patient to recommend only those diagnostic procedures that seem necessary in the care of the patient. In this case, it appears that the sheer number of tests ordered by Dr C was not consistent with his responsibility to Mrs A under the NZMA Code of Ethics.

Indeed, the volume of tests Dr C ordered may have made it harder for him to focus on what was important. Dr C stated that "laboratory tests were performed on a regular basis monitoring [Mrs A's] various medical conditions and excluding pathological processes associated with obesity or pathological weight loss". Dr Searle was concerned that this statement suggests an over-reliance on laboratory tests. I agree with Dr Searle that Dr C needs to consider other more effective strategies for investigating a patient's symptoms and signs apart from relying on laboratory tests alone.

My advisor also expressed concern about Dr C's interpretation and response to some of the more relevant findings in the test results, e.g., the change in weight and liver function tests. Dr Searle commented that Dr C's statement about the use of tests to monitor Mrs A's various medical conditions and exclude pathological processes associated with obesity or pathological weight loss implied that Dr C believed that the tests would exclude pathological processes. As noted by Dr Searle: "[T]ests are in fact probabilistic results and don't fully include or exclude things as a rule and need to be interpreted in the context of the patient's symptoms and signs and other salient parts of the clinical picture including other investigations." For example, Dr C may need to undertake other investigations or arrange a referral for a specialist opinion, should his patient's signs or symptoms indicate such a need.

My advisor expressed concern about Dr C's follow-up systems. For example, Dr C recognised the need for ongoing monitoring of Mrs A's liver function after mildly abnormal results on tests in October and November 2002. He wrote a reminder in his notes on 29 November 2002 to order another liver function test in three months' time. However, he omitted to follow this up when he ordered a range of blood tests on 17

February 2003, despite the fact that the liver function test was the one test that did appear to need repeating. Furthermore, on 17 July 2001 Dr C requested a repeat test for haemochromatosis gene testing. As noted earlier, this test had previously been performed in September 2000. Because genes do not change, the repeat test was wasteful.

Guided by my expert advice, my view is that Dr C did not provide Mrs A with an appropriate standard of care in relation to his ordering and interpretation of laboratory tests, and in relation to his follow-up systems. Accordingly, in my view Dr C breached Rights 4(1) and 4(2) of the Code. I consider that Dr C's departure would be viewed with moderate to severe disapproval by his peers. Dr C accepts my criticisms and acknowledges that this aspect of his care was also deficient.

Information about Iscador treatment
Mrs A consulted Dr C on 5 August 2003, accompanied by Ms B. The consultation notes record that Dr C and Mrs A had a discussion about the tumour in her liver. The notes record: "d/w tumor in liver — metastatic spread — unknown [primary] ? bowel? lung". Ms B stated that during the consultation, Dr C mentioned Iscador "briefly" to Mrs A and printed her a letter. Dr C advised me that he also provided Mrs A with dietary advice and detailed information regarding other possible treatment options. However, Dr C's notes do not record any specific discussions he had with Mrs A during this visit.

The letter that Dr C gave to Mrs A about Iscador explains the composition of Iscador, its mode of action, its uses and contraindications, side effects, compatibility with other medications, method of application, use in specific situations, complementary therapy and evolution of Iscador preparations. The letter discusses "the effectiveness of Iscador preparations" and provides information to support the use of Iscador. The letter does not include information about accepted medical opinion on Iscador, or critical information regarding its efficacy as a treatment for cancer patients.

Dr Searle advised that Iscador is not a medically recognised and accepted form of treatment. In a situation where treatment is not generally accepted to be evidence-based and of proven value, as is the case with Iscador, this should be pointed out to the patient and independent advice offered. My advisor's view is supported by the New Zealand Cancer Society.[18] The Medical Director for the New Zealand Cancer Society (who is also on my panel of expert radiation oncologists) confirmed that Iscador is a complementary therapy and is not evidence-based. In his view, the prescription of Iscador is not a dereliction of a doctor's duty, but doctors recommending Iscador need to point out to their patients that it is a complementary therapy and not evidence-based, so that the patient can make an informed choice whether to accept the treatment. The Medical Director also noted that it is important for doctors to document the details of any such discussions with patients in their treatment notes.

[18] See Appendix B4 — New Zealand Cancer Society's views on the use of Iscador.

These experts' views are in line with the Medical Council of New Zealand's 'Statement on Complementary and Alternative Medicine' (April 1999, reviewed October 2002), and the views of the Medical Practitioners Disciplinary Tribunal in *Director of Proceedings v Dr R W Gorringe*[19] (released in August 2003, the same month as Dr C recommended Iscador to Mrs A, and therefore an indicator of the standard applicable at that time). The Medical Council's Statement provides that any doctor who embarks upon a mode of treatment that is not based upon evidence of acceptable effectiveness must provide the patient with sufficient information to make an informed choice, including the effectiveness of the therapy according to published and accepted information, and the degree to which tests, treatments, or remedies have been evaluated, and the degree of certainty and predictability that exists about their efficacy and safety. In the *Gorringe* case the Tribunal stated: [20]

> "The Tribunal is of the view that where a registered medical practitioner practises '*alternative*' or '*complementary*' medicine, there is an onus on that practitioner to inform the patient not only of the nature of the alternative treatment offered but also the extent to which that is consistent with conventional theories of medicine and has, or does not have, the support of the majority of practitioners."

My advisor commented that Dr C's lack of documentation of any explanation he may have provided on Iscador (that the treatment is not a medically recognised and accepted form of treatment) is a moderate departure from an appropriate standard of care. In the absence of documented evidence that Dr C provided Mrs A with adequate information about Iscador, and Ms B's recollection that Dr C mentioned Iscador "briefly", I conclude that Dr C did not provide Mrs A with adequate information.

Mrs A had a clear legal right to adequate information, under the relevant standards, case law and, most specifically, Right 6(1) of the Code. In my view, Dr C's failure to provide Mrs A with that information was a breach of Right 6(1) of the Code.

Dr C accepts my findings, and has taken steps to improve his information disclosure and documentation practice.

Adverse comment

Supply and charge of Iscador

From the information that Dr C provided during the investigation, it was unclear to my expert whether Dr C himself intended to supply and charge Mrs A for Iscador. Dr C subsequently clarified that he offered Iscador "in good faith" and "had no vested interest whatsoever" in Mrs A procuring the therapy.

However, given his inadequate documentation, Dr C risked appearing to have a vested interest in Iscador treatment. It would also have been prudent for Dr C to suggest

[19] MPDT Decision No: 237/02/89D.

[20] Paragraph 52.

alternative avenues for purchasing Iscador and to document in his notes that he had done so. The importance of such documentation was discussed in case 04HDC06861. Dr C has taken on board my criticisms regarding the circumstances in which he offered Iscador to Mrs A, and made changes to this aspect of his practice.

Provider's response to complaint
A fortnight after Mrs A's death, her son telephoned Dr C on 30 September 2003 to request a copy of his mother's death certificate. After receiving it three months later, he sent two letters on 23 February 2004 and 19 May 2004 to query Dr C's diagnosis and management of his mother's cancer. Given the length of time Dr C was Mrs A's doctor, it is understandable that her family had questions regarding how her care was managed.

I am concerned by the manner in which Dr C responded to Mr B. First, Dr C delayed providing Mr B a copy of the death certificate. It was only after Mr B documented his request and telephoned Dr C's surgery a second time that Dr C sent him a copy of the death certificate. This was three months following Mr B's initial telephone call on 30 September 2003 — a considerable length of time to action a simple request. Dr C accepts that it took him "an excessive period of time" to provide this information.

Secondly, Mr B was invoiced $90 when Dr C sent a written reply the next day on 24 February 2004. Although I acknowledge that he had "spent some time" responding to Mr B's letter of 23 February 2004, in my view it was unprofessional of Dr C to charge Mr B for his services in these circumstances. Mrs A had been a long-time patient and Dr C had done very little up to that point to resolve Mr B's concerns (apart from sending him a copy of the death certificate). Sending an invoice was insensitive and likely to cause offence — as indeed it did. It did little to restore Mr B's trust and confidence in his mother's doctor. Dr C has since refunded the $90 to Mr B.

Thirdly, Dr C ignored Mr B's letter of 19 May 2004 when he had further questions about Dr C's management of his mother's cancer. Mr B clearly wanted answers to several unresolved issues. Dr C acknowledges that he should have replied to Mr B's second letter and offered a face-to-face meeting. He clarified that he did not do so at the time as he perceived Mr B's May 2004 letter "as one of general comment rather than requesting a response from [him]".

In my view, Dr C missed the opportunity for low-level resolution of Mr B's outstanding concerns. Had Dr C responded appropriately, it may have assisted Mr B in dealing with his grief and provided him with closure. It might also have prevented him from escalating his concerns to my Office. I have drawn to Dr C's attention his obligations under Right 10(3) of the Code, which requires a health care provider to facilitate the fair, simple, speedy, and effective resolution of complaints. Dr C accepts my criticisms and is "deeply sorry" that he "let [Mr B] down" at a time when he was grieving and wanting answers.

In my view, Dr C's offer of Iscador treatment and the manner in which he dealt with Mr B, together with his failure to provide services of an appropriate standard, raises serious questions about his professional competence. However, I am satisfied from reviewing his response that appropriate steps are being taken to address these deficiencies, and note

that his practice is "currently under a regime of close monitoring and surpervision" by the Medical Council.

Concluding comments

The events surrounding Mrs A's diagnosis of cancer and death have obviously been distressing for her family. Their questions about the appropriateness of the care Dr C provided are understandable. However, I accept Dr Searle's advice that despite the various departures in Dr C's standard of care, it is unlikely that Mrs A's cancer could have been diagnosed earlier or treated differently, even if her symptoms and signs had been adequately documented and the appropriate investigations ordered. Dr Searle commented that "pancreatic cancer and cancer of unknown primary site both have poor outcomes". He further advised:

> "My best summation is that [Mrs A's] weight loss was either initially because of her duodenal ulcer alone, or because of her ulcer and the possibility of an undiagnosed cancer of unknown origin. It was not possible in my opinion to have diagnosed her cancer prior to her liver function becoming abnormal. Even if an ultrasound was done immediately after her liver function became mildly abnormal this would have only found the cancer in her liver sooner (or missed it if it was still too small) and would not have enabled any curative treatment of any underlying cancer. … In this particular case I do not consider there was likely to have ever been symptoms or signs that if investigated in a different manner would have led to a different outcome.
>
> …[P]ancreatic cancer and cancer of an unknown primary site both have poor outcomes despite aggressive attempts at investigations and management. Overall, pancreatic cancer has a poor prognosis. By the time someone has symptoms, goes to their doctor and is diagnosed, the disease is often quite advanced. Cancer of unknown primary site (CUP) ranks as the fourth most common form of cancer deaths and represents both a diagnostic and management challenge …"

Put simply, Mrs A's final clinical outcome would very likely have been the same even if she had received better care from Dr C. However, this does not alter the fact that his care and record-keeping were substandard.

Actions taken

In response to my provisional opinion, Dr C provided Mr B with a comprehensive written apology for his breaches of the Code. Dr C apologised for each aspect of his care that was found wanting, including the manner in which he handled Mr B's requests for

information following Mrs A's death. Dr C outlined in detail the steps he is taking to address the deficiencies discussed in my report. He is deeply sorry for the shortcomings in his care. He has also refunded Mr B $90 for the charge he previously levied for his report in February 2004.

I commend Dr C for his gracious and sincere apology, and for his unreserved admission of responsibility. It is a pity that it took this investigation and the prospect of disciplinary proceedings for him to respond in this way. Nevertheless, the manner in which Dr C has responded to my provisional opinion, and the actions he has taken, are a good example for other providers responding to care deficiencies identified during a complaint and investigation process.

Recommendation

I recommend that Dr C lodge a statutory declaration with the Registry of Births, Deaths & Marriages (Registry) to amend the cause of death on Mrs A's death certificate to "metastatic cancer — primary site unknown". The amended death certificate from the Registry is to be forwarded to my Office for sending to Mr B.

Non-referral to Director of Proceedings

I initially proposed referring Dr C to the Director of Proceedings in accordance with section 45(2) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken. My decision was based on the severity of Dr C's breaches of the Code, which highlighted significant competence concerns. I considered that disciplinary proceedings would be in the public interest, to punish unacceptably poor practice, maintain professional standards, and protect public safety. I also proposed referring Dr C to the Medical Council with a recommendation that it undertake a review of his competence.

However, in light of Dr C's response to my provisional opinion, I am satisfied that he has learnt salutary lessons from this case, and appropriate steps have been put in place by the Medical Council to address any public safety concerns about his practice. I note that Dr C's practice is currently under "a very tight rein", and that he is receiving close monitoring and supervision from the Medical Council. Although Dr C's apology was made belatedly, it is a relevant factor to weigh when considering the need for punishment. In my view, the public interest does not support referral of Dr C to the Director of Proceedings.

Follow-up actions

- A copy of this report will be sent to the Medical Council of New Zealand and the Royal New Zealand College of General Practitioners.

- A copy of this report, with details identifying the parties removed, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A

Independent advice to Commissioner

The following expert advice was obtained from Dr Steve Searle, general practitioner:

"**Report on complaint file 06/12164**

This report has been prepared by Dr S J Searle, under the usual conditions applying to expert reports prepared for the Health and Disability Commissioner. In particular Dr Searle has read the guidelines for Independent Advisors to the Commissioner (Ref. 1) and has agreed to follow them. He has been asked to provide an opinion to the Commissioner on case number 06/12164.

He has the following qualifications: MB. ChB (basic medical degree Otago University), DipComEmMed (a post graduate diploma in community emergency medicine — University of Auckland), FRNZCGP (Fellow of the Royal New Zealand College of General Practitioners — specialist qualification in General Practice which in part allows him to practise as a vocationally registered practitioner). As well as the qualifications listed Dr Searle has a certificate in family planning and a post graduate diploma in sports medicine. He has completed and renewed a course in Advanced Trauma — ATLS (Advanced Trauma Life Support). He has worked in several rural hospitals in New Zealand as well as in General Practice and accident and medical clinics and currently works in his own practice as well as in the Emergency Department in Dunedin Hospital and at an after hours clinic in Dunedin. He is also involved in local search and rescue missions and training.

Dr Searle is not aware of any conflict of interest in this case — in particular he does not know the health provider(s) either in a personal or financial way. Dr Searle has not had a professional connection with the provider(s) to the best of his knowledge.

Basic Information:

Patient concerned:
[Mrs A] (dec).

Nature of complaint:
Whether [Dr C] provided an appropriate standard of care to [Mrs A] (dec).

Complaint about:
[Dr C], general practitioner.

Also seen by:
[Dr D], general and gastrointestinal surgeon, and various hospital and hospice medical and nursing staff.

Purpose
To provide independent expert advice about whether [Dr C] provided an appropriate standard of care to [Mrs A] (dec).

[At this point, Dr Searle lists the précis of the background of the case and the issue being investigated. These have been omitted for the sake of brevity.]

Documents and records reviewed:
Supporting Information

- Copy of [Mr B's] letters to [Dr C] dated 3 December 2003 and 23 February 2004, marked 'A' (Pages 1–2).
- Copy of [Dr C's] response to [Mr B] dated 24 February 2004, marked 'B' (Pages 3–8).
- Copy of [Mr B's] letter to [Dr C] dated 19 May 2004, marked 'C' (Pages 9–10).
- Copy of [Mr B's] letter of complaint dated 5 August 2006, with enclosed documents certifying [Mrs A's] death, marked 'D' (Pages 11–18).
- Copy of HDC's notification letter dated 9 March 2007 to [Dr C], marked 'E' (Pages 19–23).
- Copy of [Dr C's] response to HDC dated 15 April 2007 with enclosed charts and lab report dated 28 July 2003, marked 'F' (Pages 24–69).
- Copy of [Mrs A's] clinical records from [Dr C], in a folder marked 'G' (Pages 70–277).
- Copy of [Mrs A's] records dated 11 August–17 September 2003 from [the first] Hospice, marked 'H' (Pages 278–329).
- Copy of [Mrs A's] records dated 29 August–15 September 2003 from [the second] Hospice, marked 'I' (Pages 330–375).
- Copy of clinical records provided by [Dr D], general and gastrointestinal surgeon, marked 'J' (Pages 376–381).
- Copy of cremation documents, marked 'K', pages 382–388.

Possible missing information
I do not think there is any missing information. I had thought there might have been separate hand written clinical notes in addition to the computer print out (see my comments in Appendix B1), but it has been confirmed with [Dr C] that there are no other notes.

Quality of provider's records or lack of them

There are limited clinical notes recorded by [Dr C]. Whilst he has provided what has been described as clinical records (Supporting information marked 'G') they are in fact minimal and at times no notes recording presenting symptoms or examination findings (see appendix B1 for my more detailed review of the notes). In the opinion of myself and several other General Practitioners (Ref. 3) it is clear that [Dr C] thought that something might be seriously wrong with [Mrs A] on at least one occasion when he ordered laboratory tests (see laboratory request form 22 Aug 2002 — supporting information page 212), but no clinical notes were recorded at this time to indicate why he had such a suspicion.

Whilst certain aspects of the records are good this does not make up for the absence of information about symptoms and signs. Good information [Dr C] provided included the following;

1. Patient identification (Name, Date of birth)
2. Records of immunisations
3. Blood pressure and weight recordings
4. Accident details
5. Long term medications
6. Long term classifications (or problems)
7. Medical warnings
8. Records of tests ordered, referrals made, and prescriptions written.

Adequate notes are important for many reasons. These reasons include allowing more reliable comparison of findings than simple memory of events should a patient return for review of the same or a different problem by the same doctor. Notes are critical for informing another doctor in the practice, or a locum, of the prior status of the patient, which can have a large impact on the current and future care of patients.

Medical record-keeping is one aspect of practice that the Medical Council of New Zealand (Ref. 4) considers basic to clinical competence of all doctors — it is listed under their "Communication" domain of medical practice. The Medical Council also has a statement on "The maintenance and retention of patient records" (Ref. 5). I think it is worth stating the first part of what this contains:

Records form an integral part of any medical practice; they help to ensure good care for patients and also become critical in any future dispute or investigation.

1. Maintaining patient records

(a) Records must be legible and should contain all information that is relevant to the patient's care.

(b) Information should be accurate and updated at each consultation. Patient records are essential to guide future management, and invaluable in the uncommon occasions when the outcome is unsatisfactory.

Simple recording of symptoms and signs, or their absence (when relevant), would in my opinion have helped clarify events. This is not only useful for medico-legal purposes, but would have also been useful to any locum doctors, and also to [Dr C] himself, when seeing [Mrs A] in the future for comparative purposes. On top of this, I think records are useful for ongoing education and quality improvement — if other doctors regularly review the notes of a particular doctor, then they can help that doctor review the standard of their care.

Describe the care as documented and describe the standard of care that should apply in the circumstances

Taking a full history and documenting the relevant parts of this — previously commented on above as being inadequate and see also comments in Appendix B1.

Do an appropriate examination
Because the symptoms or complaints of the patient are not well recorded in this case, it is difficult to comment on what examination(s) should have occurred at various times.
Order appropriate investigation(s) — Because the symptoms or complaints of the patient are not well recorded in this case, and the examination findings are similarly not well recorded it is difficult to say exactly what investigation should have occurred at various times. Extensive comment is made about this in Appendix [B2]. Myself and my colleagues (Ref. 3) would consider that there would appear to be a departure from an appropriate standard of care in the ordering and interpretation of tests in this case. In particular there could well be an over reliance on tests. In the context of [Dr C's] comments about his ordering of tests we would view this as a moderate to severe departure suggesting the possibility that [Dr C] needs to review his practice in this area.

Decide on appropriate management and implement this or seek advice and/or refer on for such management. Other than ordering tests, and prescribing medication there are a wide range of management options such as advising patients when to come back or not (see below), referring patients to specialists, getting patients back at a certain time interval for review, and lifestyle and other treatments — a full list is beyond the scope of this report. Whilst [Dr C] did refer [Mrs A] to specialists at times and did have various recalls in place for follow-up, the lack of notes about symptoms and signs makes it difficult to comment on what advice was appropriate or not.

Give the patient appropriate advice on follow-up, and any new symptoms to watch out for that might need earlier follow-up. There appears to be no notes about what if any follow-up advice was given to [Mrs A].

Have appropriate systems in place to reduce errors

This is where there is great potential to improve the management for all patients. Doctors are human and errors can occur — however they can be minimised and/or the effects of these errors reduced or mitigated by having systems in place to check for errors and if possible to take action to prevent harm or to prevent sub-optimal outcomes for patients.

A gene test which had already been ordered in Sep 2000 was re-tested in this case — as the gene does not change this is not an appropriate test to repeat — this could have been done as a simple oversight and does not adversely affect individual patients care however it is wasteful and this could indirectly affect all patients' care. I think it is difficult for doctors to have a system that automatically checks for such waste but rare tests are not ordered often and doctors could do a quick search (that the computer systems they have easily allow) to check they have not already ordered such tests. The other system that could occur is for the laboratory to check gene tests have not already been done on a patient before performing them — this is probably the best way to avoid this sort of waste as sometimes one doctor will order a test without being aware that another doctor had previously ordered the same test.

[Dr C] did use recall systems for some aspects of patient care such as reminder systems for influenza vaccination and blood pressure checks (supporting information pages 174 to 178). This is a good standard of care as it avoids things being forgotten.

It may be useful for [Dr C] to have some sort of peer review system in place that includes another doctor or group of doctors, reviewing his notes to see if they are adequate and also reviewing what tests and other management or investigation plans [Dr C] utilises. This sort of system of reviewing actual practice is likely to pick up on aspects of practice that traditional continuing medical education (attending meetings on specific topics or reviewing the latest research) is not necessarily going to address. Some doctors in various specialities, including general practice, are already doing this, but it is not yet a compulsory part of maintenance of professional standards.

Describe in what ways if any the provider's management deviated from appropriate standards and to what degree

The main departure from an appropriate standard of care was the lack of adequate documentation of symptoms and examination findings. I consider this to be a moderate to severe departure from an appropriate standard of care.

As previously mentioned there is also a moderate to severe departure from an appropriate standard of care in the ordering and interpretation of laboratory tests.

Answering Questions put to me by the Commissioner's Office

Expert Advice Required

To advise the Commissioner whether, in your professional opinion, the care provided to [Mrs A] by [Dr C] was of an appropriate standard.

1. Please comment generally on the standard of care that [Dr C] provided to [Mrs A].
The lack of notes about symptoms and signs makes it difficult to comment on this in any detail. I believe that from the information available that the comments I have made elsewhere in this report cover this issue.

If not covered above, please answer the following questions and include reasons for your view:

2. Please comment on the standard of [Dr C's] clinical assessments/examinations of [Mrs A] between October 2002 and September 2003.
The lack of notes about symptoms and signs makes it difficult to comment on this in any detail. Of note [Dr C] diagnosed "gastritis" on 21 Oct 2002 and prescribed appropriate medication for this (somac — similar to and a very acceptable and usual alternative to the losec (omeprazole) the hospital put her on a few days later). Her duodenal ulcer that caused her to be admitted to hospital on 23 Oct 2002 is for most purposes treated in a similar way to "gastritis". Of particular note [Mrs A's] weight was 60.5kg on 21 Oct 02 and the same on 14 Feb 03 — this would be partly reassuring consistent with the duodenal ulcer having been the cause of her weight loss prior to 21 Oct 02. I also note the surgeon who saw her on 15 Jan 03 (supporting information page 269) noted that [Mrs A] had not gained weight and various other symptoms but considered at that stage it was reasonable to wait and see how she got on but would be happy to review things if symptoms continued. On 23 April 2003 it was noted that [Mrs A] had "variable periods of 1–2/52" (1 to 2 weeks) "feeling wonderful or unwell …" This does not particularly suggest anything concerning going on, but the notes are not in sufficient detail to really comment much further. A weight measurement does not appear to have been recorded at this time. It is not clear to me why blood tests were checked on 22 May 03 (as opposed to checking them sooner or later) but these did detect a change in liver function. After that appropriate follow-up investigation such as the ultrasound and referral to a specialist after the result of the ultrasound did occur. Further care after this appears to have been satisfactory but once again the lack of notes about symptoms and signs makes it difficult to comment on this in any detail.

(*If applicable*) What further investigations should [Dr C] have requested during this period or at any earlier stage?

Because of the lack of notes about symptoms and signs it is difficult to comment on this in any detail. What it is possible to say is that simple things such as recording symptoms and signs and basic examination findings may have helped give a better picture of what was happening. Of note her weight was not recorded between 21 Dec 1999 and 21 October 2002, and it was not recorded between 14 Feb 2003 and 20 June 2003. I think it is clear at these times that there was concern about weight loss and that when [Mrs A] attended measuring her weight should have occurred. Also of note although a number of blood tests were done on 17 Feb 2003 the liver function tests were not repeated. There had been a mildly abnormal part to her liver test (raised GGT enzyme) on prior tests in October and November. I am not clear why [Dr C] was doing the blood tests on 17 Feb 2003 but the one test that did appear to need repeating, the liver functions, was not done. On the other hand other tests such as the CEA test were not indicated — I have commented on this issue in Appendix B2 of this report. The liver function tests were rechecked on 22 May 2003.

3. Was the care provided by [Dr C] to [Mrs A] between October 2002 and September 2003 appropriate?
Because of the lack of notes about symptoms and signs it is difficult to comment on this in any detail. The problems with under and over ordering tests mentioned above and not focusing on the relevant findings and rechecking those in a timely manner (the change in weight and liver function tests) is a moderate departure from an appropriate standard of care.

4. Was [Dr C's] documentation of an appropriate standard? I have commented on this earlier. There was a lack of adequate documentation of symptoms and examination findings. I consider this to be a moderate to severe departure from an appropriate standard of care.

If, in answering any of the above questions, you believe that [Dr C] did not provide an appropriate standard of care, please indicate the severity of his departure from that standard.

This has been commented on above.

5. Are there any aspects of the care provided by [Dr C] that you consider warrant additional comment?
Iscador treatment was offered to [Mrs A] by [Dr C] on 5 August 2003 (supporting information pages 240 to 244). However, the appropriateness of such treatment is beyond the immediate scope of this report. I have therefore incorporated my comments on Iscador in a supplementary report to avoid distracting the reader from the key issues in this case.

The death certificate diagnosis was inaccurate in that the cause of death was stated as "metastatic carcinoma of bowel". However [Dr C] received a letter from the Surgeon [Dr D] on 8 August 2003 (supporting information page 277) stating that "… the biopsy of the liver has confirmed metastatic carcinoma from

possibly the lung or bowel". After that a chest x-ray was normal. This meant concluding that the primary cancer was bowel cancer was not unreasonable. [Dr C] wrote in a letter to [the first] Hospice 8 August 2003 "…metastatic lesion in the left lobe of the liver probably from a bowel primary" (supporting information page 245). This was a correct statement at the time it was made. I asked a group of colleagues (Ref. 2) if they considered the inaccurate statement of the cause of death to be a problem. If [Dr C] had the full histology results (which he may not have) then there was disagreement between my colleagues as to if the inaccurate statement of the cause of death was a problem. Of note the nature of the cause of death (cancer) was correct. Also there was reason, in the absence of the final histology result, to believe it could have been from bowel cancer as stated above. As far as I can tell the final histology results may not have been sent to [Dr C] — the results print out of all the results sent to his practice does not have any results between the 23 Jul 2003 and 04 Aug 2003 (page 116 of supporting information) — the biopsy happened on 28 Jul 2003. However in [Dr C's] letter to [Mr B], 24 Feb 2004, (supporting information page 5) [Dr C] does appear to have the histology result — but I am not sure if he obtained this before or after [Mrs A's] death. Myself and my colleagues (Ref. 2) consider it would be slightly better if the cause of death was accurately stated as metastatic cancer primary site unknown. I do not think it is critical to have the death certificate changed but if either [Dr C] or the family wish this to occur then it would be reasonable for [Dr C] to arrange to have the certificate amended.

[Dr C] states on page 37 of the supporting information "… [Mrs A] suffering from metastatic carcinoma of an unknown primary site being either pancreas, bile duct, stomach or distal oesphagus…" and also later on the same page states "The precise site within the bowel of the primary cancer was not included on the certificate, as it was not known with certainty, but probably was the pancreas." I think that he means by this that he considers the pancreas to be part of the bowel. This is not common usage of the term bowel. However of note embryologically the pancreas does develop from the gut and hence can be considered to be a related organ. The term "bowel cancer" can refer to cancer of the intestine in any site — usually the large bowel or colon, but certainly could include the rectum. However cancer of the pancreas is not usually considered a type of bowel cancer. Options for primary site for the diagnosis could have included Small intestine, Colon, Rectosigmoid junction & rectum — all of which could possibly be termed bowel cancer — however the histology did not suggest those sites. The alternative sites would be Pancreas, or Unknown primary site — neither of which would normally be termed "bowel cancer" and both of these terms are coded separately to the above mentioned types of bowel cancer on most cancer registers.

The definition of abnormal weight loss could be considered to be a key issue in this case. When [Mrs A's] weight loss could be considered abnormal was an important consideration. A full definition of abnormal weight loss is beyond the scope of this report. However another way of looking at this issue would be to

consider the concept of un-explained weight loss. I do not think [Dr C's] notes allow an adequate conclusion to be made as to if there was un-explained weight loss prior to May 2003. Of note prior to October 2002 weight loss could have been explained by the duodenal ulcer. There was then no weight loss between Oct 2002 and February 2003.

Conclusion:
The lack of adequate documentation of symptoms and examination findings is the major issue. There are also problems with the under and over ordering of blood tests. In particular at times [Mrs A's] weight was not recorded when it should have been and on at least one occasion her liver function tests were not rechecked when they should have been.

Note on causation:
Obviously the family have been concerned that if [Mrs A] had been diagnosed earlier that she might have been able to be cured or have a better outcome. Her diagnosis based on the ultrasound and biopsy results however mean it is possible to conclude that alternative care would not have improved her final outcome.

I would note that one of the principles of giving advice to the Health and Disability Commissioner is that the "outcome of the care is irrelevant" — it may be that there was no departure from the accepted standards but the care still resulted in an adverse outcome for the consumer. Conversely there may have been no adverse outcome for the consumer but the care may have been substandard.

Also there may have been departures from an acceptable standard of care but those departures may not have changed the outcome of care. I think this is the situation here. Whilst there was inadequate documentation of symptoms and signs I do not think if this was done in an adequate manner that [Mrs A's] cancer could have been diagnosed earlier or treated any differently. There was also an apparent incorrect focus on requesting some laboratory tests that were not indicated and potentially falsely reassuring — but I do not consider that if these were performed appropriately that [Mrs A's] cancer could have been diagnosed earlier or treated any differently. A similar situation applies to the possibility of repeating the mildly abnormal liver function test earlier.

My best summation is that [Mrs A's] weight loss was either initially because of her duodenal ulcer alone, or because of her ulcer and the possibility of an undiagnosed cancer of unknown origin. It was not possible in my opinion to have diagnosed her cancer prior to her liver function becoming abnormal. Even if an ultrasound was done immediately after her liver function became mildly abnormal this would have only found the cancer in her liver sooner (or missed it if it was still too small) and would not have enabled any curative treatment of any underlying cancer. Strategies for scanning patients head to toe to check for unknown cancer have not been successful and indeed can be harmful as often

minor abnormalities are found that need invasive tests to check out and these invasive tests can harm or even kill patients. My understanding is that with weight loss that turns out to be cancer related [to] only about half of patients [that] have a symptom that localises where the problem might be (e. g. weight loss and cough with say lung cancer). In this particular case I do not consider there was likely to have ever been symptoms or signs that if investigated in a different manner would have led to a different outcome.

For example the two main possibilities of either pancreatic cancer or cancer of an unknown primary site both have poor outcomes despite aggressive attempts at investigations and management. Overall, pancreatic cancer has a poor prognosis. By the time someone has symptoms, goes to their doctor and is diagnosed, the disease is very often quite advanced. Cancer of unknown primary site (CUP) ranks as the fourth most common cause of cancer deaths and represents both a diagnostic and a management challenge (Ref. 6). Patients present with nonspecific systemic complaints of short duration (weight loss, anorexia, malaise, fatigue), not contributing to organ-site localization. The primary tumor remains unidentified in greater than 80% of antemortem series, despite an aggressive endoscopic/positron emission tomography — based workup, and in 30%–70% of postmortem autopsy series, highlighting the regression of the primary as one of the hallmarks of this clinical entity. With the exception of a minority of treatable subsets, CUP is characterized by resistance to combination chemotherapy: responses occur in less than one fourth of patients and are short-lived.

My view that the outcome would not have been changed by different care however does not change my conclusions about the standard of care.

Recommendations:

The main departure from an appropriate standard of care was the lack of adequate documentation of symptoms and examination findings. I consider this to be a moderate to severe departure from an appropriate standard of care. [Dr C] should review his standard of record keeping.

Myself and my colleagues (Ref. 3) would consider that there would appear to be a moderate to severe departure from an appropriate standard of care in the ordering of tests in this case. This suggests that [Dr C] needs to review his practice in this area.

I do not think it is critical to have the death certificate changed but if either [Dr C] or the family wish this to occur then it would be reasonable for [Dr C] to arrange to have the certificate amended — 'metastatic cancer primary site unknown' would be a more accurate statement than 'metastatic carcinoma of bowel'. [Dr C] should also consider reviewing how he uses the term bowel cancer as it would not normally be used to include pancreatic cancer.

The local laboratory should consider checking gene tests have not already been done on a patient before performing them to avoid waste. This is probably the

best way to avoid this sort of waste as sometimes one doctor will order a test without being aware that another doctor had previously ordered the same test. This recommendation should be sent to all laboratories in New Zealand although I believe some laboratories might already be carrying out this recommendation.

[Dr C] should also consider having another doctor, or group of doctors, review his records on a regular basis.

References

(1) Guidelines for Independent Advisors — Office of the Health and Disability Commissioner — Appendix H of the Enquiries and Complaints Manual — effective date: 1 September 2003.

(2) Discussion of the death certificate with a group of five general practitioners (this discussion occurred on a separate occasion to the discussion below (Ref. 3).)

(3) Discussion of the laboratory tests ordered (in particular those in the supporting information pages 180, 181, 184, 185, 206, 209, 212) with a group of six general practitioners (unaware of the information in reference 2 above).

(4) http://www.mcnz.org.nz/

(5) Medical Council of New Zealand statement on "The maintenance and retention of patient records".

(6) Cancer Medicine: Case Discussions — Cancer of Unknown Primary Site: Missing Primary or Missing Biology?, George Pentheroudakis, Evangelos Briasoulis, Nicholas Pavlidis; The Oncologist, Vol. 12, No. 4, 418-425, April 2007; doi:10. 1634/theoncologist. 12-4-418, © 2007.

Dr Stephen J. Searle 11 September, 2007"

Appendix B1 — Review of the clinical notes

When I first scanned through the information sent to me to check there was no obvious missing information I thought a record of symptoms and signs might have been kept elsewhere (it was common practice for example to hand write this information but keep other information on computer). Supporting information G appeared to have no record of symptoms or signs recorded. The printout of the clinical notes (pages 70 to 169 of the supporting information) largely is a list of vaccinations, blood pressure readings and weight recordings along with a list of prescriptions written, lab results, and referral letters and one or two other miscellaneous items — these are all good things to have recorded but usually alongside this information symptoms and signs are recorded to put the other information in context. For this reason I requested that [Dr C] be asked if [he] had any other separate hand written notes — the H&DC investigator confirmed with him that there were no other notes. On closer review I found that the font size of some of the notes recording symptoms and signs was smaller than that of the other notes making the space they took up on the print out smaller than it otherwise normally would be. Also the nursing and doctors' notes were both (appropriately) printed out so that what notes I had originally seen I had thought were not [Dr C's], but only those of his nurse. These two factors made the bulk of the notes appear to contain very little notes about symptoms and signs compared to the other types of information mentioned above.

I note in the supporting information page 31, that [Dr C] states he examined many things on 21st October 2002 including breasts and rectal examination. This is not recorded in the notes and should have been. In particular it is not clear what the indications for these examinations were and if a chaperone was present or if one was offered and declined. In particular routine breast examination is of no benefit in screening for, or checking just in case, there might be a breast cancer. If there was a lump then this should have been documented and investigated.

I have taken the trouble to list the following notes that I found within pages 70 to 169 of the supporting information for the time period Feb 2001 to Jul 2003 as this helps clarify as best as possible what symptoms and signs were recorded. I have kept abbreviations and spelling mistakes and clarified my interpretation in brackets — the use of abbreviations is perfectly acceptable and common medical practice. I have put in bold the notes that were relevant or could be directly relevant to her weight loss or general health prior to June 2003.

> 22 Jul 2003 "has appt for [Mrs A] on Monday poor appetite lost 2.5kg c 4 ex bx nose cut horn" (this last part being abbreviations meaning in my opinion "see her for an excision biopsy of her nose which had a skin lesion resembling a cutaneous horn") — on this occasion a weight and height was recorded and various blood tests ordered.
>
> 15 Jul 2003 "poor apetite try pred 14/7" (the "pred" meaning prednisone a type of steroid and the "14/7" meaning 14 days.)

20 Jun 2003 blood pressure and weight recorded and blood test ordered but no clinical notes.

11 Jun 2003 "d/w u/s — refer gastro recheck fbt refer [Dr D] seeing [Dr D] 26 June 10. 40am" (meaning discussed with the patient re ultrasound and referrals and rechecking a blood test).

26 May 03 "seen specialist — offered her knee replacement and hip replacement — mild hepatitis-rec 1/12 — u/s liver" (the last part meaning a blood test had shown a disturbance in her liver function and the "rec 1/12 — u/s liver" meaning recheck the blood test in 1 month and order an ultrasound of the liver).

23 Apr 03 "has had variable periods of 1–2/52" (1 to 2 weeks) "feeling wonfderful"(wonderful) "or unwell with various aches — thinks hrt" (hormone replacement therapy) "or lipex" (a drug for lower cholesterol) "or the combination may cause it — adv stop hrt" (advised to stop the hormone replacement therapy) "and see" "lt" (left) leg healed well now.

17 Mar 03 "letter out to [local orthopaedic surgeon]" (there is a little bit of information in that letter (a referral to an orthopaedic surgeon) saying she has painful knees and their effect on her but this information is not in the actual notes).

Jan to March 2003 — various notes about skin wounds and skin lesions (see the very end of this appendix for a full list) — notes not relevant to the issues in this case.

23 Dec 02 "WWC — cvra mild d/w chondrocalcinosis d/w hrt — ct 2x/wk

bse — refer [local orthopaedic surgeon] — cant tolerate nsaids — pvte ref — trial celebrex od"

(I think this translates to Well Women Check — cardiovascular risk mild discussed with her re chondrocalcinosis, discussed with her re hormone replacement therapy — continue two times a week; breast self examination — refer [local orthopaedic surgeon] ([local orthopaedic surgeon] being I think a local orthopaedic surgeon) can't tolerate non-steroidal anti-inflammatory medication — private referral — trial celebrex once a day (a type of non-steroidal anti-inflammatory with lower risk of gastrointestinal side effects than most other similar medication).

(of note blood pressure recorded on this occasion but not her weight)

2 Nov 02 "sore rt knee — aches at nt — xray try paradex" (meaning sore right knee aches at night try paradex (a type of medication with paracetamol and another medication in it for pain relief)).

31-Oct-02 "back from hospital well bt" (bt meaning blood test).

21-Oct-02 "gastritis — constipated — acute/chronic lethargic — frail — going to hydro 2x/wk chr constipation" weight 60. 5 (kg)

8 Oct 02 "bp check — infl of rt little finger"

10 Sep 02 "d/w scoliosis — has appt with [local orthopaedic surgeon] try ken inj having physio 2x/wk try orthotics"

27 Aug 02 "seen [local orthopaedic surgeon] referred for physio

toppled over yesterday — struck a table — contusion rt upper chest ?post rib # sl tenderness rt hip no # palpable xray no # seen adv refer physio" (rt = right, ?=possible, post=posterior, #= fracture/broken)

April to July 02 various notes about calf wound and dressings and a skin biopsy.

26 Jun 02 "hand sore at base of thumb"

20 May 02 "rt wrist swelling and painful — uses wrist to lift herself 3/7 try wrist support — xray" (an xray and blood tests ordered)

Dec 01 to Apr 02 various notes about hands, wrists and back

Jan 01 to Dec 01 various notes about back, bladder, bezalip medication, wrists, feet/toes/ankle.

26 Mar 01 "feverish 37. 7 e/c n urti — e/c n chest abdo clear — temp has been 39 — adv fluids — stop ees c 2/7"

13-Feb-01 "n2 to scalp/ dorsum of hands

haemorrhoids — pr bleeding — check stools

cvra mild risk mild o/w for ht" (n2 meaning liquid nitrogen, pr meaning per rectum, cvra meaning cardiovascular risk assessment, o/w meaning over weight and ht meaning height). (although as far as I can tell her weight was not checked on this occasion and it was last checked before this on 21 Dec 1999 when it was 74 and it was rechecked again on 21 Oct 2002 when it was 60. 5kg).

Other notes/records included;

25 Jun 2003, 06 Jun 2003, 20 May 03, 2 Apr 2003, 28 Feb 2003, 23 Sep 02,22 Aug 02, 2 Apr 02, 7 Jan 02, 11 Oct 01, 17 Apr 01, — on all these occasions repeat prescriptions written but no clinical notes — it is unclear if [Mrs A] was seen or not — on some occasions it can be appropriate to write prescriptions

without seeing patients. And 10 Jul 02 and 6 May 02 (on these occasions notes about a wound but not about the repeat medication).

At times various recalls were used as demonstrated in the clinical notes on various occasions e. g. 01 Jul 03 Recall letter for a blood test — this is a good standard of care to have a reminder system so repeat tests are not forgotten.

Jan to March 2003 — various notes about skin wounds and skin lesions

(I have listed these notes below so that it is clear that I have considered them — but I have not written out my interpretation of these notes as I do not believe they contain any relevant information)

11 Mar 03 "abr to lt lower leg — d n attending — n2 to scalp taking hrt 2x/wk try MWT

26-Feb-03 "abr to lt lower leg — still has discharging area after 7/52 — last lesion took 6/12 to heel — use a support stocking"

20-Feb-03 "clean/dress wound rt lower leg. Clean and dry

PN clea redress still sl soreness with mild cellulitis c 4 n2

17 Feb 03 "rof face and lt hand

Clean dress wound rt lower leg. Small amount of discharge

PN Clean redress proteus and stap isolated — resistant to erythromycin"

14-Feb-03 "ralts forehead and hand

wound lt lower leg discharging and tender. Swab sl cellulitis

pn clean/dress"

7 Feb 03 "wounds clean/dry forehead — lt wrist

wound lt lower leg — painful ?early cellulitis = pn clean/redress"

5 Feb 03 "Cleaned with saline covered with dry dressing rt 2/7 review will change dressing at home

ex bx ?bcc lt forehead ex bx cut horn lt wrist c 4 cod 2/7 warned small scar pt accepts this"

21 Jan 03 "rof lt lower leg

healing well n2 to sks — BCC lt face and scc lt hand c 4 ex bx"

Appendix B2 — Comments on investigations or tests ordered

Because the symptoms or complaints of the patient are not well recorded in this case and the examination findings are similarly not well recorded, it is difficult to say exactly what investigation should have occurred at various times. Examples of investigations ordered were as follows:

22 Aug 02 various blood tests with a note about a repeat prescription but no other notes. The blood tests included a test for carcinoembryonic antigen which is a test that is usually done to follow-up known cancer in a patient. Given she did not have known cancer this test was probably done in case it might pick up a type of cancer. This test is not however good at detecting unknown cancers. Of note even the result from the lab states that it "is not suitable as a screening test for the primary diagnosis of tumours". Myself and my colleagues (Ref 3.) are concerned that [Dr C] was inappropriately reassured by a normal result of this test. Other tests ordered on this date such as iron levels and inflammatory markers (ESR, CRP) also suggest [Dr C] was concerned that there might be something more seriously wrong (my opinion and that of my colleagues (Ref 3.).

20 May 02 tests for inflammation and Rheumatoid factor (possibly appropriate as notes made stating wrist swelling and painful).

29 Apr 02 various blood tests and no clinical notes other than a recording of blood pressure which on its own would not justify the test ordering.

19 Nov 01 various blood tests and no clinical notes other than a recording of blood pressure which on its own would not justify the test ordering.

17 Jul 01 various blood tests in the context of an infected left toe. Tests included haemochromatosis gene testing which had already been ordered in Sep 2000 — as the gene does not change this is not an appropriate test to repeat — this could have been done as a simple oversight and does not adversely affect individual patients care however it is wasteful and avoiding waste is commented on later in this report under the heading "have appropriate systems in place to reduce errors".

13 Feb 2001 Faeces occult blood test. This is to check for non-visible blood in bowel motions. At this time the notes stated "PR bleeding" meaning bleeding per rectum had been visible. Thus bleeding was already known to have occurred and there was no point checking for non-visible blood. Myself and my colleagues (Ref 3.) considered that either no test should have been done (probably a reasonable option for this patient), or if there was concern that there was something other than the "haemorrhoids" was the cause of bleeding then other investigation such as sigmoidoscopy (inspection of the lower bowel with a special instrument called a sigmoidoscope) or specialist referral should have occurred, or have been discussed with the patient.

26 Jan 2001 various test ordered including iron stores, blood count and inflammatory marker, but no clinical notes made.

[Dr C] made the comment (page 31 of supporting information) "Laboratory tests were performed on a regular basis monitoring her various medical conditions and excluding pathological processes associated with obesity or pathological weight loss". Myself and my colleagues (Ref. 3) are concerned that this statement suggests an over reliance on laboratory tests. For example [Dr C] possibly needs to consider referral for specialist opinions or investigation prior to obtaining abnormal laboratory tests should the symptoms or signs indicate such a need. There are also other strategies that can be used such as strict follow-up and follow-up advice that can be more useful than laboratory tests alone. [Dr C's] apparent approach to laboratory testing in combination with the lack of notes about symptoms and signs made us concerned that [Dr C] may need to review his practice both in the areas of note taking and that of ordering and interpretation of laboratory tests. Myself and my colleagues (Ref. 3) would consider that there would appear to be a departure from an appropriate standard of care in the ordering of tests in this case and in the context of [Dr C's] comments we would view this as a moderate to severe departure suggesting the possibility that [Dr C] needs to review his practice in this area.

Of note numerous tests were ordered for [Mrs A] by [Dr C]. [Dr C] points this out himself on page 40 of the supporting information. However he does not seem to recognise that the issue is not how much a patient is investigated but rather the appropriateness of the investigations and the interpretation of them. On the one hand [Dr C] states "… I would not suggest to a patient of the infallibility of medical tests to reveal any problem whatsoever." (Page 39 of supporting information.) This is good in that he appears to recognise the limitations of tests. However earlier in the same letter (page 31 of supporting information) he states "Laboratory tests were performed on a regular basis monitoring her various medical conditions and excluding pathological processes associated with obesity or pathological weight loss". To me this implies that he did think his tests "excluded" pathological processes. Tests are in fact probabilistic results and don't fully include or exclude things as a rule and need to be interpreted in the context of the patient's symptoms and signs and other salient parts of the clinical picture including other investigations. I am also concerned that the sheer number of tests [Dr C] ordered may have made it harder to focus on what was important. For example [Dr C] stated in explaining his assessment of [Mrs A] in Oct/Nov 2002 that "Following receipt of her laboratory tests I arranged ongoing monitoring of her liver function tests in 3 months …" (supporting information page 32). This to me suggests he was concerned about her liver function and recognised the need for follow-up, but 3 months later in February 2003 he ordered several tests but not liver function tests. I consider that most of the other tests had probably no clear indication and possibly distracted him from the need to arrange ongoing monitoring of her weight and liver function.

Appendix B3 — Supplementary report on Iscador treatment

[Mrs A] was offered Iscador treatment by [Dr C] (letter dated 5 August 2003 from [Dr C] to [Mrs A], marked pages 240 to 244 in the supporting information provided). It is not clear to me that [Dr C] had explained to [Mrs A] that Iscador is not a medically recognised and accepted form of treatment. In a situation where a treatment is not generally accepted to be evidenced based and of proven value, this should be pointed out to the patient and independent advice offered (e. g. from a cancer society or a reliable consumer group). I am unsure about the New Zealand Cancer Society's views on Iscador,[21] and its website (www.cancernz.org.nz) does not contain any information or links to related websites on this treatment. However, overseas cancer societies do not support the use of Iscador, and a summary of their reviews is included below. I think that [Dr C's] lack of documentation of any explanation he may have provided on Iscador (that this treatment was not a medically recognised and accepted form of treatment) is a moderate departure from an appropriate standard of care. This is particularly so when his letter to [Mrs A] states "… has shown the effectiveness of Iscador preparations to be as follows …" implying that Iscador is effective when this is either not the case or has not yet been proven to be the case.

If Iscador was to be offered as a treatment, then I think [Dr C] needs to ensure that he offers his patients alternative avenues for purchasing Iscador. In other words, information on other health practitioners who could and do supply Iscador should be given to his patients to provide them with options as to who they obtain the Iscador from. It is not clear from the supporting information that [Dr C] would be providing (and presumably charging for) Iscador treatment. If it was his intention to provide the treatment himself, then there is a risk of him having a vested interest — trying to sell the Iscador for financial gain. I think if [Dr C] was offering something (Iscador) that he had a vested interest in, or that could be construed as him having a vested interest in, then it was even more important than usual for him to offer alternatives for the same or similar treatment and to document in the notes that he had done so. I consider his lack of documentation of offering alternative options in this context a moderate departure from an appropriate standard of care.

Iscador
Iscador is an extract of mistletoe first proposed for the treatment of cancer in 1920 by Rudolph Steiner (1861–1925), who espoused many occult beliefs. Steiner founded the Society for Cancer Research (the Society) to promote mistletoe extracts and occult-based practices he called anthroposophical medicine. A 1962 report by the Society claimed that the time of picking the plants was important because they react to the influences of the sun, moon, and planets. Various mistletoe juice preparations have been studied with the hope of finding an effective anticancer agent. However, in 1984, the expert working group of the Swiss Society for Oncology concluded that there was

[21] See Appendix B4 for the Cancer Society's views, which were provided by its Medical Director to the HDC investigator.

no evidence that Iscador was effective against human cancers [Ref. 1]. To date, more than 30 clinical studies have investigated mistletoe as a cancer treatment. The National Cancer Institute (of the United States of America) has concluded: "Reports of improved survival and/or quality of life have been common, but nearly all of the studies had major weaknesses that raise doubts about the reliability of the findings." [Ref. 2]

References:

Ref 1.) Working group on unproven methods in oncology. Iscador. File No. 10E. Bern: Swiss Cancer League, 1984.

Ref 2.)[http://www. cancer. gov/cancertopics/pdq/cam/mistletoe] Mistletoe extracts (PDQ): Overview. NCA Web site.

http://www.cancer.gov/cancertopics/pdq/cam/mistletoe)

Dr Stephen J. Searle 11 September, 2007.

Appendix B4 — New Zealand Cancer Society's views on the use of Iscador

On 28 August 2007, the HDC investigator contacted the New Zealand Cancer Society's Medical Director (who is also on the Commissioner's panel of radiation oncology experts) for comment on how doctors should discuss the use of alternative treatments with cancer patients. On 29 August 2007, the Medical Director stated:

> "The Cancer Society's stance is that patients should seek orthodox opinions from oncology and palliative care specialists before embarking on complementary therapies. Although the Cancer Society acknowledges that patients do use complementary medicines, these should be used in conjunction with palliative treatment.
>
> A few doctors do prescribe Iscador and doing so is not a dereliction of their duty. However, because Iscador is a complementary therapy that is not evidenced based, doctors need to point this out to assist patients to make an informed choice on whether or not to accept such treatment. It is also important for doctors to document the details of any such discussions with patients in their treatment notes."

Appendix C — [Dr C's] response to the provisional opinion

[Dr C] responded to the provisional opinion as follows:

> "I acknowledge your provisional opinion on my management and treatment of the late [Mrs A] dated 11th January 2008.
>
> With a sincere sense of deep regret regarding the level of care I provided to this patient, I accept the recommendations that you make.
>
> I felt at the time that I was doing my best to care for [Mrs A] with her multiple medical conditions, but on review I concede that there were deficiencies in my Practice including that of record keeping, which was found not to be up to the standard expected in terms of the recording of symptoms and findings at my examinations.
>
> I also accept that I should have responded more promptly and appropriately to [Mr B] in the manner as highlighted in your opinion in terms of procuring for him copies of the New Zealand Death certificate and a copy of the Medical Certificate of Causes of Death, which took me an excessive period of time to obtain for him.
>
> Since that time I have changed my style and location of my practice considerably from the large multi-Doctor medical centre of […] with a central administration team to a closer net solo General Practice at […] with a practice administrator solely focused upon my own practice. This serves to prevent delays in obtaining documents, with closer attention to follow up and dispatching of documents to individual patients.
>
> Although I responded to [Mr B's] letter of 23rd February 2004 in good time on the following day, 24th February, 2004, I did not respond to his further letter of 19 May, 2004 as I perceived this latter letter as one of general comment rather than requesting a response from me.
>
> In retrospect this was a missed opportunity where a face to face meeting might have resolved his outstanding concerns.
>
> I will apologise to [Mr B] in writing and refund the ninety dollars that he paid me for my reports to him in a separate letter that I have already prepared.
>
> You recommend that I review my practice in light of the shortcomings that you have identified.
>
> That action of review I am actively engaging and have been doing so on an ongoing basis for more than a year.

For the past year, my practice has been under the close scrutiny and monitoring of the Medical Council.

I have had regular Performance Competence Reviews in my last and new practice and will have a further competence review in March 2008.

I have daily external electronic monitoring of my clinical notes by independent GP practitioners with a weekly review of those records being reported to the Medical Council.

I am attending weekly meetings with my collegiate supervisor specifically to address identified shortcomings, which include focusing upon improving clinical record keeping. My collegiate supervisor provides written reports to the Medical Council on a three monthly basis.

I am to demonstrate to the Medical Council that I am meeting the continuing professional development required by a doctor working in General Practice.

Currently the number of my practice consultations are limited to no more than 20 per day or 100 per week.

I must protect the time available as a result of limiting patient consults to develop my personal medical education.

I am affiliated to the Royal New Zealand College of General Practitioners and am actively progressing upon the training pathway to obtaining fellowship of the College.

I am attending and actively participating in the RNZCGP GP Registrars' seminar programme throughout 2008.

I also attend and am actively involved in a monthly peer review group which has been approved by the Medical Council, with verification of attendance on a monthly basis.

I am required to prepare for and sit the examination Primex in November 2008.

I have attended independent psychiatric and neuropsychiatric assessments with favourable results.

Overall my practice is under what might be termed 'a very tight rein'.

I further note your comments and those of your advisers about my advice to patients concerning Iscador therapy.

At the time, this preliminary information document was presented to [Mrs A] in all good faith and I did not have a vested interest in her pursuing this therapy at a later date if she so wished.

I desired to inform her of possible other treatment modalities open to her, particularly as I knew that Iscador therapy is discussed further within our local 'Living with cancer' course run by the Cancer Society that I had actively recommended to her. I was aware that few patients have any initial knowledge regarding this treatment, but that it is provided to a number of patients by several GPs in my area.

I take on board the criticisms made regarding the circumstances of this advice and have taken steps to ensure that the future information provided, together with my medical records, note clearly that the patient has been advised that Iscador therapy is not generally accepted as being evidenced based and further that my information hand out now clearly states that reports of improved survival and/or quality of life have been common, but the form of studies raise doubts over the proven reliability of these findings, as concluded by the National Cancer Institute of USA."