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HEALTH SCIENCES CENTRE

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Margaret Obermeyer
Investigations and Resolutions
College of Physicians and Surgeons of Ontario

Dear Ms. Obermeyer,

I, Yoo-Joung Ko, am a duly licensed physician in the province of Ontario. I am currently a staff medical oncologist at the Sunnybrook Odette Cancer Centre in Toronto where I have practiced for the past 10 years. Prior to 2004, I was a staff medical oncologist at the Beth Israel Deaconess Medical Center in Boston, where I completed my subspecialty training in Hematology/Oncology. I am an Assistant Professor in the division of Medical Oncology in the Department of Medicine at the University of Toronto. My clinical practice is limited to the treatment of gastrointestinal malignancies, of which colorectal cancer accounts for the majority of cases.

I have been informed and understand that although the College has retained me to provide an independent opinion, my duty is not to the College, nor is it to the member under investigation, but rather to assist the Inquiries, Complaints and Reports Committee and the Discipline Committee. I have reviewed the medical files that have been provided to me by the College from Dr. Khan's practice. The summaries of each of the case files are summarized below along with my respective findings for each case. The findings will also refer to the in person meeting with Dr. Khan and his attorney on January 22, 2015 at which you were also present. I have also reviewed the audio recording from that meeting and the additional files and the response letter that was subsequently provided.

1) H S
This patient with metastatic lung cancer was initially treated with Alimta and cisplatin x 4 cycles with stable disease at a different clinic. The patient was treated with alpha lipoic acid and DCA in December 2012. The patient received Mesna and carboplatin (260mg) from July 2013. Assessment note from July 24, 2013 in SOAP format, which was very difficult to read (due to the handwriting) but suggests "extensive discussion, supp. psychotherapy" for 3 days. Received Mesna and carboplatin (300mg) on July 30, 2013. The Medicor clinic note from Aug 6, 2013 states, "decreased air entry" on right side but left side was "okay". The clinical assessment suggested a left pleural effusion or partial collapse secondary to encasement of tumor of left main bronchus but chest x-ray suggested disease on right side. The August 7 note suggested that the patient was "responding to therapy". On august 27, 2013, the patient received Mesna and Carboplatin (300mg). The clinic note from August 27, 2013 suggested "significant benefit from SAFE chemo with decreased tumor in lungs. The CXR showed "large improvements with SAFE chemo". On Sept 11, 2013, this patient received Mesna and

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carboplatin (300mg) and on Oct 1, 2013, she received Mesa + carboplatin (300mg). She was then seen at Southlake on September 21, 2013 for bilateral leg swelling and SOB and was found to have bilateral DVTs and PE's at which time, she was started on Lovenox. The patient apparently deteriorated on October 7. The CT scan from Southlake revealed extensive disease in the right lung disease with mediastinal and left hilar adenopathy.

It was very difficult to determine patient's prior cancer history and treatments from the notes included in the chart. The dosing of carboplatin was not clear in terms of whether it is based on AUC or mg/kg. The interpretation of "significant benefit with decreased tumor" in August does not seem to have any obvious basis as the CT angiogram performed in September, 2013 when compared to the August scan did not show any difference (I do not have any reports from august or prior to august). The basis for clinical classification of the tumor response as a partial response is not obvious.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

2) R O
The patient was diagnosed with Non-hodgkin's lymphoma and was previously treated with at least 2 different regimens. The medical history was complicated by a perforated bowel. The patient was not eligible for an allogeneic transplant due to progressive disease. DCA offered but unclear from chart if the patient received this.

Clarification has been received that the patient did not receive DCA.

In this case, there is no evidence that he did not meet the standard of practice of either a cancer or CAM physician. There is no display of a lack of knowledge, skill or judgment. There was no risk of harm in this case.

3) L N
This patient had a GBM which was resected and subsequently treated with chemoradiation. The patient was seen at Medicor for consideration of DCA therapy. The notes were sparse and very difficult to read. No copies of imaging reports were in the provided files but there was a note attributing the results as being due to "DCA, chemo and radiation".

It was difficult to determine the history of cancer and treatments from the files in the chart. The notes were sparse and difficult to read due to the handwriting.

Copies of MRI scans May, August, December 2011 were subsequently provided which

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were not in the original files provided by the college.

In this case, there is no evidence that he did not meet the standard of practice of either a cancer or CAM physician. There is no display of a lack of knowledge, skill or judgment. There was no risk of harm in this case.

4) B R
This patient had a vulvar melanoma excised with negative sentinel node. The patient was recommended to undergo monitoring of "CTC" levels to determine aggressiveness of therapy.

It was unclear what test was being ordered and for what indication. I cannot determine if the patient received any treatment under Dr. Khan from the provided files.

The patient received DCA. Apparently all files were provided to the college but were not in the files that I reviewed.

In this case, there is no evidence that he did not meet the standard of practice of either a cancer or CAM physician. There is no display of a lack of knowledge, skill or judgment. There was no risk of harm in this case.

5) M N
This patient had a GBM treated with temozlomide. Dr. Khan suggested measuring CTC levels to determine if CTC was positive for disease monitoring purposes. The recommendation was for DCA after temozolomide therapy and SAFE chemo if there was a subsequent recurrence. No further data was available from the chart.

In this case, there is no evidence that he did not meet the standard of practice of either a cancer or CAM physician. There is no display of a lack of knowledge, skill or judgment. There was no risk of harm in this case.

6) M H
This patient had metastatic ovarian cancer diagnosed 2010 treated with TAH-BSO and taxol/carbo x 6 cycles. The pathology report from Hamilton Health Sciences centre was in chart confirming a diagnosis of clear cell carcinoma. She was treated by Dr. Gagovski with mega nutritional IV therapy, low dose chemotherapy with insulin potentiation. The patient had recurrent disease 2 years later and taken back to the OR for dissection of the right pelvic sidewall. She had been treated with zoledronic acid for hypercalcemia. The Medicor clinic note from 2014 suggested that patient "failed to respond to DCA". There is an IV treatment record of DCA on July 23, 2014.

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This is one of the few charts reviewed that had the original pathology report. The documentation was insufficient to allow an accurate determination of the treatment course at Medicor.

In this case, there is no evidence that he did not meet the standard of practice of either a cancer or CAM physician. There is no display of a lack of knowledge, skill or judgment. There was no risk of harm in this case.

7) G B
There was a typed note from 4/17/2014. The patient had a low grade follicular lymphoma diagnosed 2005. DCA + AveUltra or HonoPure was recommended. The patient was from Cape Town, South Africa.
The consent had been signed although I could not determine if the consult was performed in person or not. I could not determine if the patient received any treatment at Medicor.

Patient received oral DCA at home in South Africa.

I cannot determine if the care given met the standard of a cancer doctor due to the lack of details. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

8) A K
The patient had a diagnosis of bladder cancer. The biopsy report from 14/07/2011 noted a diagnosis of superficial papillary urothelial carcinoma with no evidence of muscle invasion. A cystoscopy report from January 30, 2013 reported no evidence of recurrence. According to the note from Nov 2012, the patient had a recurrence in 2012 treated with a repeat TURBT and intravesical chemotherapy. The recommended plan suggested DCA therapy. The patient was treated with DCA in Nov 2012. The clinic note from May 2013 suggested "TCC, resolved after DCA". The plan recommend was to start LDN.
This patient had superficial bladder cancer that was completely resected. There are no records of the actual DCA treatment. It was unclear how it was determined that the patient was recurrence free due to the DCA rather than from conventional therapy. The patient experienced toxicity in terms of neuropathy and neutropenia.

I am still unclear as to how it was determined that the patient is recurrence free due to DCA. The patient had at least 2 TURBTs with intravesicle mitomycin in 2012. I do not see the ultrasound report of the 20x7mm tumor prior to DCA. It is noted that OHIP was billed for a palliative care code K023 on multiple occasions although a patient with superficial bladder cancer is not generally considered to be palliative.

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9) E J

This patient had superficial bladder cancer in 1999, which required multiple resections. The patient was then found to have a lung mass in 2009, which was resected and found to be bladder cancer. Therapy with Gem/cis was started prior to the patient travelling to Mexico for treatment in 2010. The patient received radiation therapy to chest wall metastasis in 2010. The patient was found to have a pancreatic mass in 2012 and a EUS cytology report from April 22, 2013 showed a neuroendocrine neoplasm in the pancreas. The initial plan suggested was DCA therapy then LPN. The patient developed neuropathy and received some sort of treatment for neuropathy. The patient also received SAFE chemo in 2013 and 2014. The Medicor clinic note from May 8, 2014 stated "new CT no abn" despite the imaging report suggesting progression (CD rom not available).

I was very difficult to determine clinical course of patient based on the files in the provided. There is significant paucity of clinical detail in notes. The dosing of carboplatin varies from AUC 3 to AUC 5. I could not determine how the dose of chemotherapy was determined from the documentation of GFR calculation. There was no chemotherapy flowsheet.
Dr. Khan subsequently clarified that the "no abnormality" referred to the brain CT rather than body CT.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

10) W P

This patient had a diagnosis of metastatic pancreatic cancer. The diagnosis was based on imaging from Fort McMurray and a EUS biopsy. A small liver metastasis was noted on initial MRI imaging. The initial note recommended SAFE chemotherapy pending approval from Dr. Matsumura's team. This recommendation is instead of standard therapy with FOLFIRINOX. The patient was treated with SAFE chemo on November 5, 2013. The note from November 7 suggested that the increased pain could be a sign of response. The patient experienced increased pain and required increasing doses of both opioid and Lyrica. The nausea and vomiting was attributed to edema in the tumor causing duodenal narrowing. The note from Feb 4, 2014 noted increased pain and a decreased performance status. This assessment concluded that patient "responded to

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therapy" but deterioration was after missed chemo doses rather than progressive disease. The suggestion was to undergo a celiac plexus block and then have the therapy changed to DCA.

Although there was "pending approval" from Dr. Matsumura's team, there was no documentation of subsequent involvement from the Berkeley team. There was no documentation of the method the dose of carboplatin is calculated. There is no documentation of how the tumor response was determined. There was no base line imaging or tumor marker assessment. From the notes, it was likely that patient was experiencing tumor progression causing increased pain, nausea and vomiting.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case, there is concern that the misinterpretation of nausea and vomiting as due to tumor inflammation displays lack of knowledge about pancreatic cancer and the common complications. In this case, the conduct did not expose the patient to harm or injury.

11) R A
This patient was diagnosed with SCLC in 2011. The patient was treated with chemo radiation in addition to whole brain radiation. The patient sought care at Medicor in August 2012, as patient was concerned about risk of recurrence. The patient was recommended to have measurement of circulating tumor cells and treatment of LDN, DCA, TM. The patient was initially treated with DCA and circulating tumor cells was measured and used as surrogate for tumor response. The patient was started on SAFE chemotherapy in 2013.

*There was no documentation for cycle 2 dosing of carboplatin, which was reduced to 300mg from 450mg (AUC 3: (89.4+25)*4=340mg). Renal function was not checked at each cycle. Serum creatinine was noted to vary between 66 and 76. There was no documentation of radiologic restaging in the file.*

Dr. Khan has subsequently provided copies of bloodwork that were not initially present in the file provided to me. The patient has undergone repeat CXR and abdominal ultrasounds rather than CT due to patient request. These were not present in the initial file. The Carboplatin discrepancy was clarified but there is no written record of while the dosing was such.

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12) H P
This patient had a sarcoma with progression on 2nd line chemotherapy. The patient received DCA at another clinic. The patient had an ECOG performance status of 3 or 4 as noted on baseline assessment. The treatment was approved by Dr. Mastsumura. The patient was given carboplatin AUC 1.5 from September 2013 to January 2014.
There was no baseline imaging performed. The requisition from Dr. Khan for MRI on 11/29/2013 indicated patient was receiving "experimental chemo" and to assess response. There was no documentation that prior records were examined. Records are sparse for last cycle (7). There was no documentation regarding any palliative care discussion.

The MRI spine performed on Dec 14 was ordered by Dr. Shenouda not by Dr. Khan. The baseline MRI from April 2013 is too far from the start of chemotherapy (September) to be useful.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

13) A B
Patient AB was an international patient from Northern Ireland. She had stage IV breast cancer and stage II ovarian cancer. She was started on SAFE chemotherapy. The patient experienced persistent nausea and vomiting through most cycles. On cycle 5 (Jan 2014), the patient was given IV ceftriaxone at the same visit as SAFE chemotherapy. The patient was noted to have a fever (38 C). Bloodwork from Feb 18 showed AST, ALT >5x ULN. She was started on DCA in March 2014. The patient passed away on March 11, 2014 despite the notes from March 7 stating that patient was weak but treatment went ok.

There was no documentation of comprehensive review prior detailed cancer history. There was no baseline imaging or tumor markers. There is inadequate documentation regarding patient's symptoms and signs in the weeks prior to death. No rationale for changing from SAFE chemo to DCA. There was no apparent discussion about end of life care.

The response from Dr. Khan is noted but the copy is not on file. Ongoing email communication was apparently done but not documented separately.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

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14) M L
The patient from New Brunswick had metastatic esophageal cancer to nodes and liver initially diagnosed 2013. In the initial consult, there is a note that "notes, abdominal ultrasound report, CT scan report, CXR report, FPT, blood test and pathology report have been reviewed". The patient was started on SAFE chemotherapy in August, 2013. The note from October 2, 2013 stated a "chemo effect (tumor necrosis)". The patient experienced persistent but intermittent epigastric pain. An assessment from Nov 1, 2013 suggested a barium swallow, but then the cause was determined to be "partially secondary to anxiety, partial inflammation due to treatment" although inadequate food intake noted. The patient was given IV ceftriaxone during cycle 8 as "aspiration pneumonia" suspected. The patient continued on SAFE chemo on January 14, 2014 after patient having an esophageal stent inserted. An ultrasound on Dec 12, 2013 demonstrated a mixed response as compared to scan from Oct 31,2013 but notes lesions in seg 4a, 6,7,8. The baseline ultrasound from July 12, 2013 demonstrated only 2 liver mets in right lobe of liver. The patient was noted to have passed away on Feb 21, 2014.

There is no documentation of GFR calculation on any chemotherarpy order. Cycle number (2) is not noted on chemotherapy order sheet. The symptoms were concerning for disease progression during course of SAFE chemotherapy. There is misinterpretation of progressive dysphagia as tumor inflammation. Although patient was likely at risk of obstruction, no documentation of weight during followup visits and for adjustment of chemotherapy dose. There was inadequate disease assessment during course of care.
The lack of GFR calculation was apparently due to preprinted orders. Cycle 2 orders were reprinted and was missing due to apparent misfiling. Missing weights were apparently intentional as it was not used in calculation GFR. It is important to note that measuring weight is more than for chemotherapy calculations.

I do not believe that the care given in this case met the standard of a cancer doctor. The disease assessment does not meet the standards expected in the care of a cancer patient. The care may have met the standards of a doctor practicing CAM. The care in this case does display lack of knowledge of the natural history of esophageal cancer. In this case, the conduct did not expose the patient to harm or injury.

15) A C
This patient was diagnosed with carcinoma of unknown primary. The patient sought multiple opinions. The patient had been treated with Taxotere and radiation therapy in Ottawa. The patient was seen by Dr. Khan June 17, 2014 but there is no evidence patient received any treatment.

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The patient was not treated by Dr. Khan.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

16) T M

This patient had metastatic colorectal cancer. A CT scan from 6/10/14 demonstrated metastasis in lung, nodes, liver and bone with progression since Nov, 2013. The patient was started on DCA on July 15, 2014 but no further follow-up was noted. The patient passed away on September 20, 2014.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

17) R T

Patient RT had prostate cancer on androgen ablation. His PSA was less than 1.0 in 2013. He was seen by Dr. Khan on Nov 20, 2013. An assessment stated that SAFE chemo would be reviewed but recommended only if there was progression.

No documentation of treatment.

I cannot determine if the care given met the standard of a cancer doctor. The care does meet the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

18) M G

Patient MG had metastatic NSCLC with brain mets treated with radiation therapy. The patient was seen by Dr. Khan on April 4, 2013 and recommended to receive LDN while on chemo and DCA after chemo. A CT scan from July 15, 2013 performed in Sudbury demonstrated worsening lung nodules and suspicious lung metastasis. The patient was started on SAFE chemo on Aug 20,2014. A note from Nov 29, 2013 attributed back pain to "chemo effect against bone met". Bloodwork from Nov 25 shows ALT AST 2-3x ULN. The last treatment on Dec 11 and the clinic note stated patient was "ok". The patient passed away on January 14, 2014.

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There is no documentation of GFR calculation. Cycle of chemotherapy (2) was not indicated on order sheet. There was no restaging of disease while on therapy. Carboplatin was given after progression on Taxol and Carboplatin.
GFR was measured by a 24-hour urine collection on Aug 16, 2013. No software was apparently available for calculating SAFE chemo doses. Cycle 2 was missing due to changes in customized pre-printed orders.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

19) G K
Previously reviewed.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

20) K B
The patient had a Whipple procedure Aug 1, 2012, which revealed a T3 N1 adenocarcinoma of pancreas. The patient was started on adjuvant gemcitabine. KB was first assessed at Medicor on Oct 11, 2012. It is unclear if patient was treated with LDN. A note from Nov 11, 2013 stated that patient was on DCA. The patient was started on SAFE chemo Jan 21, 2014. There was either no or minimal notes outlining symptoms or physical findings between cycle 2 and 4. Neurologic symptoms including weakness and vision loss was noted with left sided visual loss noted on April 15, 2014. A MRI request was sent to Guelph and chemo held. The patient was treated again on April 29th but no note was made of MRI or neurologic results other than carotid Doppler being ordered. The patient passed away July 6, 2014. Note from? (not certain due to handwriting) June 12, 2014 notes weakness ? ascites.

There is no documentation of any weight changes during course of SAFE chemotherapy between January and May 2014. There is no baseline imaging or followup imaging to assess disease response except a CXR on 2/21/2014 (not known to have lung mets). There is documentation of MRI ordered by Dr. Khan but no follow-up is noted.
Additional records have been provided by Dr. Khan. I do not believe that an ultrasound Doppler provides adequate information regarding tumor blood flow. Contrast enhanced Doppler ultrasound can be useful or an enhanced CT scan should be used.

The care given does met the standard of a cancer doctor in terms of disease

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assessment The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

21) Y P
Patient YP had a liposarcoma diagnosed in 2010 treated with multiple resections, RFA and chemotherapies. The initial consult at Medicor was done on Oct 28, 2013. The patient was seen again July 11, 2014 after a "CR" from Ifosfamide. The patient was started on SAFE chemo July 15, 2014.

No GFR calculation was noted on 1st cycle order.

A clarification has been provided by Dr. Khan.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

22) J F
Patient JF had metastatic melanoma to brain. The patient was treated with surgical excision. The patient had a recurrence excised but experienced an early nodal recurrence. The patient was treated with XRT and IFN. The patient then developed brain metastasis soon thereafter. The patient was initially seen at Medicor on April 7, 2011. The patient was started on oral DCA during radiation. The headache improvement was thought to be related to treatment effect. There is a gap in patient visits to Medicor until 2012. The patient started on IV DCA in 2012 which continued until 2013 while the patient was being treated at Sunnybrook.

This patient has more detailed notes than any other patient. It is very difficult to determine if patient was benefiting from DCA given that the patient was also receiving conventional therapy.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

23) A Y
This patient had lung cancer with brain metastasis. The response measured by circulating tumor cell measurement. A CT scan in December demonstrated an

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increased LUL mass growing into hilum/mediastinum. Brain metastasis was detected in March 2014 and was treated initially with Prednisone 100mg.

The documentation lacks any symptoms or physical exams. Due to the paucity of details in the file, it is difficult to determine the treatment course.
Dr. Khan has provided a long copy of email exchanges with the patient.

The care given in this case does not meet the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does display lack of common practice of treatment brain metastasis with steroids (the usual steroid dose is dexamethasone 4 mg q6h). In this case, the conduct did not expose the patient to harm or injury.

25) L L
This patient had metastatic breast cancer. The patient was treated with Mesna + Carbo and Gem.
It is very difficult to determine prior history from the documents provided.

Dr. Khan has provided a transcribed copy of the history rather than a copy.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

26) F H
Patient FH had ovarian cancer and cervical cancer. The patient received Carbo/Mesna/Gem.

There is significant lack of details in clinic notes. It is very difficult to determine how tumor response or clinical benefit was determined by Dr. Khan.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

27) J F (2)
This patient had metastatic melanoma. The patient was treated with DCA then SAFE chemotherapy.
The consent was signed only by patient and not the staff physician. IV lidocaine given for pain – this is unusual.

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IV lidocaine was apparently used to mitigate vein irritation which is highly unusual. Dr. Khan admits to omitting the dose in the note.

I cannot determine if the care given met the standard of a cancer doctor. The care may have met the standards of a doctor practicing CAM. The care in this case does not display lack of knowledge, skill or judgment. In this case, the conduct did not expose the patient to harm or injury.

Dr. Khan provides care for cancer patients through his Medicor clinic where he offers complimentary alternative medicine such as DCA and SAFE chemotherapy. For the latter, he has collaborated with the team from the Berkeley Institute in California. Most, if not all patients are discussed by email with the Berkeley team. At Medicor, he mixes and administers the chemotherapy himself without additional team members such as pharmacists or oncology nurses. He provides email and phone communication to his patients and family members. All patients sign a consent form for treatment and communication at the beginning of their visits. Dr. Khan has developed a preprinted chemotherapy order sheet which is still being modified. Dr. Khan imports both carboplatin and Mesna from the United States.

To summarize, in the majority of the patient charts reviewed, the level of documentation falls below the standard of a cancer physician such as a medical oncologist and it likely falls below the level of a physician practicing CAM. There are several instances where there is concern that Dr. Khan is unaware of the complications of some of the cancers (gastric outlet obstruction in pancreas cancer, esophageal obstruction in GE junction tumours) and he misinterpretation of some of the symptoms. However, I do not believe that the outcomes would have be different in these cases nor do I believe that the patients were significantly harmed.

The lack of detail in the patient charts makes this review challenging at best. The lack of detail makes it very difficult to determine the course of events in the patient charts. Several of the records that were missing were provided to the college at a later time. Many of the written records lack sufficient detail for an outsider reviewer to determine the course of the patient. For example, many of the patients have complicated cancer histories for which they were treated at other centres but these records are not in the chart at Medicor. This is in contrast to when a patient is referred to another cancer centre, all the records for their treatment, scans, and medical notes are sent with them. In the case of the charts that I reviewed, the majority of the charts do not have copies of their pathology or of their prior treatments. Furthermore, with the exception of a few charts, there is no documented acknowledgment that Dr. Khan has reviewed the prior medical charts. There is no consistent radiologic imaging performed at baseline or during therapy to assess radiologic response. In more than one patient, the symptoms and signs are worrisome for disease progression but are attributed to tumor inflammation suggesting clinical benefit. From my perspective, Dr. Khan's

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interpretation of the imaging and clinical results are unconventional. For example, his attribution that the liver metastasis in patient KB are non-viable due to lack of perfusion on an ultrasound would not be considered standard medical practice. Dr. Khan has extensive email communication with the patients and/or family members. Although some of these were provided to the College, they were not routinely kept in the medical chart as part of the patient's record.

Dr. Khan administers Carboplatin and Mesna intravenously. As he administers the medication himself, there is no process of a double check that is recommended by most oncology societies such as Cancer Care Ontario (including specific patient, dose, drug etc). This is important despite the small numbers of patients in his practice. Although Carboplatin is being administered as a CAM, it is still remains important to have the safety checks in place. As I have not visited Medicor, I would recommend that his practice of chemotherapy administration be reviewed by qualified pharmacists and nurses to further review the treatment processes used at Medicor.

Dr. Khan imports the medication (Carboplatin and Mesna) himself from the United States. It is unclear what role the Berkeley institute has with the used medications as the chemotherapy orders specify certain lot numbers. I believe that in Canada, a drug establishment license is required for the importation of medications. As I am not an expert in this regulation, I would suggest that either someone from the College of Pharmacy or other relevant regulatory body review the drug procurement process at Medicor to confirm that it meets the proper guidelines.

Dr. Khan uses Carboplatin and Mesna under the complementary alternative medicine policy (CAM). He believes that this is being recommended in the patient's best interests and he does often acknowledge the patient's autonomy in choosing CAM. However, it is unclear if there is conflict of interest with the importation of SAFE chemotherapy and whether there is an additional charge for Carboplatin and Mesna that are otherwise available through existing Canadian wholesale drug distributors. This can be clarified by Dr.Khan if he can provide further details about the role of the Berkeley Institute and provision of Mesna and Carboplatin. Furthermore, according to CAM policy, physicians are still expected to reach a conventional diagnosis. In several cases, patients' symptoms were attributed due to tumor inflammation rather than due to tumor progression, an approach that would generally not be considered to be standard. Furthermore, the CPSO CAM policy states that "physicians must never inflate or exaggerate the potential therapeutic outcome that can be achieved ....". The Medicor website quotes that "with low side effects and strong responses seen in 80-90% of stage 4 cancers, this therapy is sure to generate some excitement as word of it gradually spreads through the community" which could be seen as a misrepresentation of the benefits of SAFE chemotherapy. In most areas of cancer medicine, such reports of success would indeed be considered to be outstanding but this is seldom seen.

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In summary, Dr. Khan administers carboplatin and Mesna under the CPSO complimentary alternative medicine policy. Although the regimen is unconventional, the clinical efficacy claims to be somewhat optimistic without the support of significant medical evidence aside from case reports. It is certainly accepted in the medical community to offer off-label use of medications but they are often supported by a higher level of evidence. The purported mechanism of action (immune mediated) of this combination is the rationale that Dr. Khan uses to explain some of the symptoms that patients are experiencing. However, the medical records suggests that the symptoms are related to disease progression. Dr. Khan has made efforts to monitor patients and provides open and timely access to patients and their caregivers. However, these records are not kept in the medical charts and the quality of record keeping appears to be insufficient. As these are potentially dangergous medications, it is important to ensure that adequate safety checks are put in place (e.g. patient identification double checks, proper drug labeling and storage) which appear to be lacking at Medicor. Whether his practice is in compliance with the CPSO CAM policy can be clarified by a response from Dr. Khan regarding conflict of interest and whether the information provided about SAFE chemotherapy is considered to be a misrepresentation.

Yours truly,

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