MEDICOR CANCER CENTRES

October 3, 2014

Ms. Margaret Obermeyer
Investigator
The College of Physicians and Surgeons of Ontario
80 College Street
Toronto ON M5G 2E2

File # MMO/93778

Dear Ms. Obermeyer:

Re: Response to IOP

Thank you very much for allowing me to respond to the report of the IOP.

I am a family physician/palliative care physician who has been in practice for 20 years. In 2006, I founded the first private integrated cancer clinic in Canada (Medicor Cancer Centres), where we provide cancer care combining traditional and off-label therapies.

Before responding specifically to the IOP's report, I would like to bring to the attention of the Committee that my CAM practice has been the subject of numerous reviews by the CPSO, often as a result of complaints by other physicians.

I want the ICRC to know that I am committed to the care of my patients. I have a very low volume patient-centered practice. I deal with patients with honesty, integrity, and transparency. I believe that I fulfil an important role in offering patients alternative cancer therapies, which also have a reasonable risk/benefit profile. In accordance with the ideals of the CAM policy, I actively participate whenever possible in expanding the body of medical knowledge evolving in this area through publishing my findings in reputable journals.

I am committed to ongoing self-assessment and continuous learning, including implementing suggestions made by the College. I am continuously assessing these opportunities and embrace the ability to enhance my practice.

In the case of past complaints and past peer assessments, I have viewed each of these as an opportunity for growth and learning, and I believe that I have done so.

The ICRC has carefully scrutinized my practice against the College's policy on Complementary and Alternative Medicine. On each occasion, I have been found to be in compliance with that policy.

For example, in 2007, in response to a complaint by another physician, the CPSO investigated my off-label use of a promising of new cancer treatment dichloroacetate ("DCA"). In that case, the ICRC concluded that:

> *Dr. Khan is a specialist in family medicine, but this does not suggest that he has insufficient education, knowledge or skills to treat patients with cancer.*
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> ...
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> *It would appear that patients seeking treatment at Dr. Khan's clinic have already sought conventional treatment and therefore could reasonably be expected to more than adequately informed about traditional choices available to them.*
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> ...
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> *...there is no information to suggest that Dr. Khan is attempting to mislead his patients about the potential risks involved in treating them with DCA.*
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> ...
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> *The Committee is of the opinion that Dr. Khan is in compliance with CPSO and other guidelines and standards with respect to the off-label use of DCA as a cancer therapy.*

In 2010, the CPSO conducted a peer review by two physicians, a palliative care specialist and an oncologist.

> *"Dr. Khan does have an extensive library of articles on the use of the agents he prescribes, namely dichloroacetate, low-dose naltrexone, tetrathiomolybdate, and ribavirin. These consist largely of preclinical studies addressing pharmacokinetics and safety testing and some phase I-II clinical trials. Dr. Khan reports informing all patients that these agents are not standard therapy and that all patients are asked to sign a consent form that dearly identifies these treatments as experimental and indicates they are not considered generally accepted treatment..."* ***[oncologist reviewer]***
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> *"I reviewed the CPSO policy on complementary treatment (dated Feb 2004). In my opinion, Dr. Khan's practice is in keeping with the policy with respect to treating patients in that he does not misrepresent the evidence supporting the treatment he prescribes and does not provide detailed information clearly identifying the uncertain benefit and potential toxicities."* ***[oncologist reviewer]***

Most recently, after a public complaint and a Section 75 Investigation into my use of DCA for a patient with thyroid cancer who refused conventional treatment (surgery), despite my recommendation to her that she pursue this rather than complementary treatment, the ICRC released a decision. Despite an

exhaustive review of clinical issues, the only issue raised by the ICRC was whether I am properly using the palliative care billing code.[1] In its decision dated June 13, 2014, the ICRC concluded:

> *The Committee is satisfied that the clinical care provided by Dr. Khan was consistent with the College's policy on Complementary/Alternative Medicine (No. 3-11).*
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> ....
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> *According to the College policy on Complementary/Alternative Medicine (No. 3-11), the practitioner must advise the patient that the treatments are unproven, and therefore may or may not be effective. The signed consents of* [the patient] *are also clear that the treatment's effectiveness is unproven.*

As I hope the ICRC can appreciate, it is disheartening to be the subject matter of repeated complaints by other physicians with respect to my use of Complementary/Alternative therapies. While I can certainly appreciate that there is sometimes a lack of understanding on the part of conventional physicians with respect to these treatments, the patients in my practice are treated with dignity and respect, they are well informed, and their choices are honoured after a careful discussion of the risks, benefits, and limitations of a treatment.

Response to IOP, Complaint from Dr. Trinkaus

1) The patient, her family and I were all aware of the "standard" therapy for colon cancer at Mrs. Karamitsos' stage (second line FOLFIRI), with a failure rate of 96%, progression free survival being "similar in both arms", (i.e. no better with the FOLFIRI treatment arm in the published study), and potential serious side effects. As a result the patient was in a position to explore alternative therapy. The patient gave her written informed consent as indicated in her charts.

2) Whether the IOP feels the FOLFIRI regimen with a 96% failure rate is "widely accepted" and "supported by guidelines" is irrelevant. The patient rejected this therapy after discussing risks and benefits with her own oncologist Dr. Trinkaus. She had an absolute right to choose her own therapy. In fact, CPSO policy states that any CAM therapeutic option must "possess a favourable risk/benefit ratio". The "widely accepted" second line FOLFIRI itself fails to meet this criterion.

3) Mrs. K was aware that carboplatin + mesna was not standard of care. This is confirmed by the signed consent form.

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[1] While I continue to believe that I am appropriately using the palliative care billing code, and this was supported by another oncologist, I anticipate that I will be engaging in further discussions with the Ministry about this particular issue.

4) While remote supervision of Mrs. K's therapy by Dr. Matsumura and his team was certainly unusual, no evidence has been presented by the IOP that supports the notion that it falls below accepted standards. In fact, the IOP opined that the patient was not harmed in any way, and I have already presented ASCO standards that affirm that email orders for chemotherapy are acceptable. There is no Canadian regulation prohibiting the supervisory relationship of the Berkeley team in overseeing Mrs. K's therapy, which was administered personally by me.

5) The IOP has accused me of "not demonstrating clinical competence in prescribing and supervising chemotherapy." This statement is unclear. Is he/she stating that I displayed a lack of competence, and if so, what was the evidence for that? As I explained, I did not prescribe the therapy. It was prescribed by the Berkeley team who are experts and developers of the therapy, and who provided ongoing supervision. In my own office, I have safeguards in place to monitor patient safety during administration. I am always in the office when chemotherapeutic agents are being administered to patients. There is the requisite resuscitation equipment located on site, although thankfully, no patient has ever had a serious adverse reaction. I would suggest that I am in a much better position to administer chemotherapy, under the supervision of other physicians, than many other health care practitioners, including nurses in remote areas, who administer chemotherapy on their own, supervised remotely.

6) "Formal training" in oncology is not a condition of administering the carboplatin + mesna therapy. I have already asked the CPSO Physician Advisory Service about prescribing cytotoxic therapies myself, and I was never advised such a condition existed. (Attached is a copy of advice I received for prescribing Vidaza). In this case, I was not even prescribing the therapy myself, and I was working under the very team that developed this therapy over the past 25 years. Oncologists are allowed to prescribe powerful psychiatric medications for example, which have life threatening side effects, such as suicide. Yet they do not need "formal training" in psychiatry.

7) There is no requirement for Dr. Matsumura to have personally met the patient. I have met the patient in person and conveyed all of the pertinent history, physical, lab tests, imaging report etc. to Dr. Matsumura and his team. Pertinent information is conveyed to the team on a regular basis for all "SAFE" chemo patients. All lab tests and imaging are copied to the Berkeley team. The IOP has not indicated how a personal meeting with Dr. Matsumura would have changed the course of therapy, or improved the patient's response. Since it is acknowledged that the patient was not harmed, it is not clear if there would have been any anticipated benefit of a personal meeting.

8) Chemotherapy symptoms were documented in the chart at each visit, as can be seen by referring to the patient chart. The IOP may expect many side effects with conventional chemo, and be surprised at their absence in the chart. However, that is not a charting deficiency; it merely reflects the low side effects of the therapy. If the committee feels that a more detailed account of pertinent negatives should be charted, I would be happy to add a formal assessment such as ESAS questionnaire with every "SAFE" chemo cycle for all patients.

9) The IOP is correct that there was no documentation of GFR calculation, because it was not calculated (or more correctly, estimated) by a formula. The standard of care in Ontario is to estimate GFR, however the IOP apparently did not notice that we measured GFR by a 24 hr urine collection with serum creatinine, which is more accurate than eGFR. In other words, we were above the standard of care, resulting in a more accurate and safe carboplatin dose.

10) The CPSO CAM policy does not require published literature to support the proposed therapy. Dr. Matsumura's internal data on response rates in stage 3 and stage 4 cancers of various types (including colon) is supportive of this regimen. Also, now that the CPSO has all the "SAFE" chemo patient charts, it is a simple matter to confirm that there is good evidence to support this therapy. Our analysis indicates a remarkable 81% response rate by modified RECIST definitions*, in patients who are almost all stage 4 and mostly on second or third line therapy.

**Some patients do not fit RECIST definitions because RECIST is undefined for chemo-immunotherapy and RECIST is undefined for patients who are N.E.D. ("no evidence of disease") but have a high circulating tumour cell count. For chemo-immunotherapy, if tumours display no shrinkage but an absence of perfusion on colour Doppler or loss of metabolic activity on PET scan after therapy (indicating necrosis), that is classified as a response. For N.E.D patients, a reduction of circulating tumour cell count > 50% is classified as a response.*

The IOP has made many significant criticisms and accusations that are not supported by existing policies as far as I am aware. It seems to me that the IOP may not understand the concept of chemo-immunotherapy or "protected" chemotherapy (body protected by mesna).

The IOP also disregarded the fact that I use a more accurate GFR measurement than the eGFR standard of care used in most hospitals. Rather than making a positive comment about that, he/she accused me of a deficiency.

I find this IOP report very concerning and disheartening. It would appear I am being held to a non-existent standard. It is my sincere wish that the ICRC will carefully consider my comments and not accept the IOP's report, given the inherent inaccuracies and limitations.

As I indicated at the outset of this letter, I remain open to suggestions for improvement, and I continue to believe that I treated this patient in accordance with all College policies. I value the privilege afforded to me to practice medicine, and respect the guidance of the College.

Sincerely,

Akbar Khan