

## ONTARIO PHYSICIANS AND SURGEONS DISCIPLINE TRIBUNAL

**Citation:** *College of Physicians and Surgeons of Ontario v. Khan*, 2022 ONPSDT 5

**Date:** February 7, 2022

**Tribunal File No.:** 17-002-I

### BETWEEN:

College of Physicians and Surgeons of Ontario

- and -

Dr. Akbar Nauman Khan

### FINDING REASONS

**Heard:** January 20-22, February 18-20 and March 2-4, 2020, in person and September 21, 22, 24 and 25, October 5, 7 and 8 and November 2-3, 2020, by videoconference

### Panel:\*

Mr. Peter Pielsticker (chair at time of decision)

Mr. Mehdi Kanji

Dr. William King (chair at time of hearing)

Dr. Deborah Hellyer

Dr. Susanna Yanivker

\* Dr. King and Dr. Hellyer were unable to participate in the decision. The remaining panel members give the decision pursuant to s. 4.4 of the *Statutory Powers Procedure Act*.

### Appearances:

Mr. Peter Wardle, Mr. Evan Rankin, Ms. Morgana Kellythorne, Ms. Jessica Amey and Ms. Webnesh Haile, for the College

Ms. Marie Henein, Ms. Lauren Mills Taylor and Ms. Sydney Hopkins, for Dr. Khan

Mr. David Rosenbaum, Independent Legal Counsel

### RESTRICTION ON PUBLICATION

The Tribunal ordered, under ss. 45-47 of the Health Professions Procedural Code, that no one may publish or broadcast the name or any information that would identify the names of patients or any information that would identify patients referred to during the Tribunal hearing or in any documents filed with the Tribunal. There may be significant fines for breaching this order.

## **Allegations**

[1] The Notice of Hearing alleged that Dr. Khan committed an act of professional misconduct:

1. under paragraph 1(1)33 of Ontario Regulation 856/93 made under the *Medicine Act, 1991* ("O. Reg. 856/93"), in that he has engaged in conduct or an act or omission relevant to the practice of medicine that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional; and

2. under paragraph 1(1)2 of O. Reg. 856/93 in that he has failed to maintain the standard of practice of the profession.

[2] The Notice of Hearing also alleged that Dr. Khan is incompetent as defined by subsection 52(1) of the Health Professions Procedural Code (the Code), which is Schedule 2 to the *Regulated Health Professions Act, 1991*, SO 1991, c. 18.

## **Response to Allegations**

[3] Dr. Khan denied all the College's allegations in the Notice of Hearing against him.

## **Overview and Background**

[4] Dr. Khan is a family physician by training, who worked in Toronto providing palliative care to patients before opening a clinic called Medicor Cancer Centres. Portions of his care through Medicor were billed through the Ontario Health Insurance Plan (OHIP) while some treatments, tests and costs for communications with patients and their families were paid out-of-pocket by patients.

[5] This case pertains to the care and treatment Dr. Khan provided to 12 patients living in Ontario and other provinces, between 2012 and 2017 at Medicor. Particular focus is placed on Dr. Khan's use of the medications SAFE chemotherapy, low-dose naltrexone (LDN), dichloroacetate (DCA) and his use of unapproved investigations ONCOblot and CTC to diagnose, monitor and treat cancer in his patients.

[6] Other matters before the Tribunal include:

- a request by Dr. Khan to limit public access to various documents and *in camera* (non-public) testimony given by Dr. Khan and other witnesses;
- the allegation that Dr. Khan failed to cooperate in providing the College with the chart of Patient A, and the charts of 12 other pediatric patients for the purposes of a section 75 investigation being conducted by the College; and
- Dr. Khan's OHIP billing practices and use of OHIP billing codes when caring for cancer patients.

### **Dr. Khan's Background**

- [7] Dr. Khan graduated from the University of Toronto in 1992 and completed his family medicine training in 1994. Initially, he worked at the Addiction Research Foundation as a research associate, and he also practised in addictions medicine. Dr. Khan began working at Scarborough General Hospital where he joined the palliative care team that provided home visits for patients. He did this work from 1994 until 1997 when the Scarborough General Hospital palliative care team dissolved. At this time, Dr. Khan opened what he described as a charitable corporation called Palliative Interdisciplinary Network (PALIN) with his friend who was also a family care physician. In this practice, Dr. Khan and his colleague took over the palliative care patients who had previously been under the umbrella of care at Scarborough General. He did this work from 1999 to 2007. Throughout the years he practised palliative care, Dr. Khan also worked as a surgical assistant for numerous surgical specialties, and from 1995 to 1997 Dr. Khan was also the team physician at the University of Toronto Scarborough Campus where he provided students with medical care.
- [8] In the spring of 2006, Dr. Khan opened the Medicor Cancer Centres. Initially, Dr. Khan provided conventional medical care to his patients, many of whom required palliative care for their illnesses, including cancer. Over time Dr. Khan expanded his practice to include an integrative approach which combined complementary and alternative medicine (CAM) and therapies with his patients' conventional medical care. He hired a naturopath who also provided care to some of his Medicor patients.

- [9] In 2007, Dr. Khan became interested in a medication called dichloroacetate (DCA) which is typically used to treat metabolic disorders in children. (Metabolic disorders are a group of diseases that involve abnormal metabolism processes at the cellular level). Dr. Khan began offering DCA to patients as an alternative way of treating cancer. At the hearing, Dr. Khan estimated that since he began offering it, he has treated 3,000 patients with DCA.
- [10] As he expanded his practice, Dr. Khan began offering a low dose regimen of a medication called naltrexone (LDN for low dose naltrexone), which is commonly used in addiction care. It is also used to treat patients with autoimmune diseases and for fibromyalgia and chronic fatigue syndrome. Dr. Khan used LDN for treating cancer.
- [11] In June of 2013, Dr. Khan met with Kenneth Matsumura who, according to Dr. Khan, is a medical doctor and scientist in the United States. Dr. Matsumura told Dr. Khan about a cancer treatment called "SAFE chemotherapy," which he developed in 1992. Following this meeting, in July 2013 Dr. Khan began offering SAFE chemotherapy to his patients. Patients pay \$4,200 USD for one cycle of SAFE chemotherapy, and an additional consultation fee of \$650 for Dr. Matsumura's team at the start of therapy. The patients to whom this hearing pertains received anywhere between five to 24 cycles of this treatment from Dr. Khan.

## **THE ISSUES**

- [12] The issues to be decided by the Tribunal are as follows:

### **Part A - Standard of Practice and Incompetence**

- [13] Standard of Practice: Did Dr. Khan fail to maintain the standard of practice in the care and treatment he provided to the 12 patients whose care was at issue in this hearing? (In conjunction with this, we address whether a ban on publication of a document that related to SAFE chemotherapy, and testimony in relation to that document, that the Tribunal ordered during the hearing, should remain in place.)
- [14] Incompetence: In his care of the 12 patients whose care was at issue in this hearing, did he display a lack of knowledge, skill or judgment of a nature or to an

extent that demonstrates that he is unfit to continue to practise or that his practice should be restricted?

#### Part B - Disgraceful, Dishonourable or Unprofessional Conduct

- [15] With regard to his OHIP billing practices at Medicor, did Dr. Khan engage in any acts or omissions relevant to the practice of medicine that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional?
- [16] Did Dr. Khan's delay in providing the chart of A, and/or his failure to provide the charts of other pediatric patients to the College investigator, constitute acts or omissions relevant to the practice of medicine that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional?

#### **Burden of Proof**

- [17] The College has the burden of proving allegations of professional misconduct and incompetence against a member. As affirmed by the Supreme Court of Canada in *F.H. v. McDougall*, 2008 SCC 53, there is no sliding scale for the standard of proof in civil cases. Rather, there is only one standard of proof, and that is proof on a balance of probabilities. This is very different from the standard of proof "beyond a reasonable doubt" that is applied in criminal cases. In all civil matters, regardless of the nature of the allegations, evidence must be clear, convincing and cogent to satisfy the balance of probabilities test. Although the panel should be mindful of, and take into account, the seriousness of the allegations and the consequences or inherent improbabilities in the evidence, the Supreme Court of Canada has affirmed that these considerations do not alter the standard of proof required: *F.H.* at paras. 40, 45-46.

#### **THE FACTS AND EVIDENCE**

##### Oral Evidence

- [18] We heard testimony from 10 witnesses.

*The College presented three physicians who were accepted as expert witnesses:*

*Witness #1 - Dr. Jawaid Younus - Expert Witness for the College*

- [19] Dr. Younus obtained his medical degree in 1985 from the King Edward Medical College in Lahore, Pakistan, where he began his clinical work in oncology and hematology. In the early 1990s he travelled to the Boston University School of Medicine where he enrolled in the Masters and PhD programs. His PhD training was cut short due to his acceptance into the internal medicine residency training program (completed 1991-1994) at the Metrowest Medical Center in Massachusetts. However, he was able to complete his Masters degree in public health, and a second Masters degree in molecular biology. Following his residency, Dr. Younus did a fellowship in hematology and oncology at the Medical University of South Carolina in Charleston (1994-1996), which was followed by a second residency program at the Memorial University of Newfoundland in St. John's where he obtained his qualifications for internal medicine and medical oncology under the Royal College of Physicians and Surgeons of Canada in 2001.
- [20] In 2002, Dr. Younus joined the staff at London Health Sciences Centre as a medical oncologist, where he continues to provide clinical care to patients. Since 2002, he has also been a professor at the University of Western Ontario's Schulich School of Medicine and Dentistry, where he is currently an associate professor in the Department of Oncology, Division of Medical Oncology.
- [21] Dr. Younus estimates that 80% of his work focus is dedicated to the management of patients with cancer. He holds cancer clinics three days per week where he diagnoses and treats patients through conventional diagnostic tests and medical therapies, along with some complementary treatments.
- [22] Dr. Younus distinguished between complementary medical treatments, which are therapies that fall outside the realm of conventional therapies and are used in addition to conventional treatments, and alternative therapies, which are used in place of an accepted conventional therapy.
- [23] While his practice does not include alternative medical therapies, Dr. Younus explained that due to his longstanding interest in CAM therapy, along with his previous research experience in complementary medicine, he was recruited onto

the Canadian National Team on Complementary Therapy and Alternative Care in 2001 as its only medical oncologist/hematologist. This group consists of a wide range of health care professionals who look at how CAM will be looked at in the literature to be investigated further.

- [24] Dr. Younus's work at the London Regional Cancer Program involves advising patients about complementary and alternative therapies for cancer they may be interested in. In addition to looking after his own patients, other consultants refer their patients to Dr. Younus to have discussions about CAM. The other 20% of Dr. Younus's work is spent in research, education and teaching. Broadly speaking, his research focuses on three areas: supportive care, breast cancer and lung cancer. In addition to his numerous peer-reviewed journal publications on conventional medicine, Dr. Younus has conducted research in complementary medicine. Four notable studies include: whether ginseng could improve chemotherapy-induced fatigue in cancer patients; whether hypnosis could improve hot flashes in post-menopausal women; whether therapeutic touch could prevent radiation dermatitis; and a study to estimate and better understand the prevalence of complementary therapy on adult cancer patients and physicians' perspectives in Newfoundland. The goals of the latter study were to make physicians aware that they should be asking patients about CAM and of possible interactions between CAM and conventional therapies, and to learn how to integrate CAM into medical care.
- [25] CAM research continues to be an area of interest for Dr. Younus. He has recently completed two studies on CAM therapy. The first asked if naturopathic polyherbal treatment could counteract the appetite loss and anorexia experienced by some patients receiving chemotherapy and the other study looked at whether homeopathic drops and ointment could improve lymphedema.
- [26] Dr. Younus also co-authored a book chapter on herbal medicine in the 2007 publication, *Enhancing Cancer Care: A practical guide to complementary support*.
- [27] Dr. Younus teaches medical trainees and has given numerous presentations to faculty, researchers and colleagues at departmental rounds and for the purpose of their continuing medical education (CME). In addition to internal medicine and oncology, his teaching responsibilities involve educating trainees on CAM and its

relationship to oncology. He has presented numerous sessions at his departmental rounds as well.

- [28] The College tendered Dr. Younus as an expert witness in the diagnosis and treatment of cancer. In response, counsel for Dr. Khan sought to exclude Dr. Younus's testimony concerning Dr. Khan's care, on two bases: due to issues with respect to his "Acknowledgement of Duty as an Expert" form, and on the basis that his expertise in the conventional treatment and diagnosis of cancer did not qualify him to give opinion evidence about the types of alternative modalities that Dr. Khan used. (Counsel did not object to Dr. Younus testifying about conventional therapy.)

*Exclusion of Dr. Younus as an expert witness on the basis of the Acknowledgement of Duty form*

- [29] In April 2018, Dr. Younus provided the College with a written report in which he reviewed Dr. Khan's care of Patient B. At the time, Dr. Younus had not signed the Acknowledgement of Duty as an Expert form, which Rule 12.05(3) of the Rules of Procedure of the Discipline Committee (as the Tribunal was then called) requires every expert to sign,<sup>1</sup> and which rule 12.05(4) 6 states must be contained in an expert report. He did not sign this Form until January 13, 2020. Counsel for Dr. Khan objected to the admissibility of Dr. Younus's report and Dr. Younus testifying as a witness due to his failure to comply with this Rule.
- [30] Counsel for the College argued in response that Dr. Younus testified he was aware of and understood his duty and that while attachment of the form was desirable and a technical requirement, it was possible to give leeway on the matter such that Dr. Younus should not be disqualified as an expert for this reason alone.

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<sup>1</sup> In the form, the expert acknowledges that their duty is to provide opinion evidence in relation to the proceeding that is fair, objective and non-partisan and that is related only to matters that are within their area of expertise; and to provide such additional assistance as the panel may reasonably require, to determine a matter in issue. The expert acknowledges that this duty prevails over any obligation which they may owe to any party by whom or on whose behalf they are engaged.

[31] Counsel for the College placed into evidence the letter of appointment dated March 7, 2018 from Ms. Lisa Mueller, an investigator with the College, to Dr. Younus, which outlined Dr. Younus's duties and informed him of the requirement to acknowledge his duties when providing his opinion. Dr. Younus confirmed that his understanding of his duties from that letter was similar to his understanding of his duties as described in the Acknowledgment form he signed in January 2020. He explained that "as an assessor, I was to provide an independent opinion about this case, unbiased, and only solely focused on the evidence or the case that was provided to me."

*Alleged Limitation on Dr. Younus's scope of expertise and his qualifications to testify regarding complementary and alternative medicine (CAM)*

[32] On questioning by counsel for Dr. Khan, Dr. Younus confirmed that his research was in conventional and complementary medicine, not alternative medicine. He further confirmed that he had not personally been involved in research on the medication LDN or the ONCOblot test, nor had he used either within his practice. Dr. Younus clarified that the College asked him to evaluate Dr. Khan's care of the patient in question, not to specifically express an opinion on LDN and ONCOblot.

[33] Counsel for Dr. Khan established that Dr. Younus, notwithstanding his lack of personal experience in the use of LDN and the ONCOblot test, provided the College with an opinion on these modalities in the course of his review of Dr. Khan's care.

[34] Dr. Younus also testified that his duty to his own patients is to evaluate and provide an opinion on the evidentiary basis and science of therapies, including alternative and complimentary, that may be brought up by his patients interested in these types of treatments. This would typically involve a literature review of the treatment of interest and a discussion with the patient. He used a similar approach to arrive at his opinions on the use of LDN and ONCOblot in reviewing Dr. Khan's care of Patient B. In the case of ONCOblot, he also discussed the test with colleagues in his own field to learn if any of them used the test or had specific experience using or referring patients to use the test.

[35] We deliberated on both issues and concluded that Dr. Younus would be permitted to testify and give opinion evidence.

- [36] In failing to sign an Acknowledgement of Duty form and failing to include a statement of acknowledgement of duty in his report, Dr. Younus technically breached Rule 12. However, we did not find the breach to be sufficiently egregious that it should disqualify Dr. Younus from testifying. Further, based on his testimony, we were satisfied that Dr. Younus understood his responsibilities and duty when he reviewed Dr. Khan's care for the purposes of his 2018 report.
- [37] Regarding Dr. Younus's scope of testimony, there was no dispute between the parties that Dr. Younus has expertise in the conventional diagnosis and treatment of cancer. We were satisfied based on the evidence that Dr. Younus also has the "special or peculiar knowledge" required by the caselaw (*R. v. Mohan*, [1994] 2 SCR 9) to evaluate the efficacy of different therapies based on the scientific process, including alternative therapies, regardless of whether he personally provides them in his own practice. Dr. Younus's overall expertise and knowledge on these matters exceeds the knowledge of the members of the Tribunal and we therefore concluded that his expertise would be of assistance to us. We therefore agreed to accept Dr. Younus as an expert in the diagnosis and treatment of cancer and to hear his evidence, including his opinion on Dr. Khan's care of Patient B and the use of LDN and the ONCOblot test in her care. We indicated that Dr. Khan would have the opportunity, at the appropriate time, to make submissions as to the weight to be given to Dr. Younus's testimony.

*Dr. Younus as an expert witness*

- [38] We accepted Dr. Younus as an expert witness in the diagnosis and care of cancer patients. We concluded that he was unbiased in general and did not have a specific bias against CAM therapies. We were further assured on this matter given that, since early in his career, Dr. Younus appears to have had and continues to have a personal interest in CAM therapy. This is evident from his statements at the hearing, his willingness to have interactions and assist his patients when they are seeking CAM therapies, his own research into complementary care and his teaching on the subject. We placed significant weight on the evidence given by Dr. Younus and found it to be of great assistance. We noted that although his expertise lay in conventional medical diagnosis and care of cancer patients, his foundational knowledge of cancer, science and evaluation of scientific literature provided a basis to evaluate various therapies pertinent to the care of patients

with cancer, including CAM therapies, LDN and diagnostic tests such as ONCOBlot. We found Dr. Younus's testimony to be thoughtful, concise and clear. He appeared to pause and consider his answers before speaking and seemed comfortable telling us when he did not know the answer to a question being asked. While critical of Dr. Khan's care, his assessments were well articulated, balanced and fair.

*Witness #2 - Dr. Donna Johnston - Expert for the College*

- [39] Dr. Johnston graduated from the medical program at Queen's University in 1995. She received training in pediatrics at the University of Ottawa's Children's Hospital of Eastern Ontario (CHEO) from 1995-1998, after which she did fellowship training in pediatric hematology oncology at the Fred Hutchinson Cancer Research Center and the University of Washington's Children's Hospital and Regional Medical Center from 1998-2001. Her fellowship involved both clinical training and research, which included significant time in the laboratory. Following her fellowship training, she joined the staff at CHEO in 2001 as an assistant professor. She is currently a full professor in the Department of Pediatrics, and the division chief for pediatric hematology oncology at CHEO, where she divides her time between clinical oncology work, research, teaching and some administration.
- [40] Dr. Johnston's practice includes the diagnosis and care of children with cancer, and she has experience in pediatric palliative care as she was a member of the pediatric palliative care team until her oncology workload increased. Currently, Dr. Johnston is CHEO's sole pediatric neuro-oncologist.
- [41] Dr. Johnston's teaching duties include clinical and formal lecture-based education of medical students, residents, fellows and clinicians seeking CME. She is the recipient of numerous awards, including for her work in teaching.
- [42] Although her practice is a conventional medicine practice Dr. Johnston also has extensive experience with CAM, as her patients frequently request CAM or naturopathic therapies. For this reason, she regularly collaborates with a naturopathic doctor, Dr. D. Seely, who runs the Ottawa Integrative Cancer Centre (OICC). Dr. Johnston explained that she and Dr. Seely work closely together with the goal of providing the best outcome for patients who wish to receive both

chemotherapy and CAM or natural therapies, to ensure that the therapies do not interact by exacerbating or mitigating the effects of chemotherapy.

[43] Dr. Johnston has published extensively, including on the subject of pediatric brain cancer. She has also published in the field of complementary and alternative medicine in pediatric oncology. Additionally, Dr. Johnston has significant experience in evaluating and assessing scientific studies, including those that deal with diagnosis and treatment options for pediatric cancer. She has been a reviewer for over 30 scientific journals and numerous grant funding proposals.

[44] Further to her clinical and academic appointments, Dr. Johnston holds other notable positions which include, but are not limited to:

- chairing the specialty committee in pediatric hematology oncology at the Royal College of Physicians and Surgeons of Canada;
- clinical investigator (formerly principal investigator) for the Children's Oncology Group trials where there are currently approximately 45 clinical trials open; and
- member of the Canadian Pediatric Brain Tumor Consortium, a 15-member group of Canadian neuro-oncologists who collaborate on research and challenging patient cases.

[45] We accepted Dr. Johnston as an expert in the diagnosis and treatment of pediatric cancer without objection from Dr. Khan. We admitted as exhibits, both her May 14, 2018 report on Dr. Khan's care of Patient A, and her February 1, 2020, reply to the report of Dr. Kerbel, who was an expert witness for Dr. Khan.

[46] In assessing Dr. Johnston's evidence, we recognized that she is highly experienced and well-informed in the care of pediatric oncology patients, particularly children with neuro-oncological disease and in research, including laboratory-based and clinical trial research.

[47] Although the majority of her clinical work and research has been in the field of conventional medicine, Dr. Johnston did not appear to have a bias against CAM, and we were further reassured on this point since Dr. Johnston frequently

collaborates closely with a CAM practitioner and has also conducted researched in the area of CAM.

- [48] In weighing Dr. Johnston's evidence, we gave the greatest weight to her evidence concerning the clinical care of patients with neuro-oncological disease, and on the principles of medical and scientific research as they pertained to cancer care. We felt that her experience in these areas and as a clinician would allow her to evaluate various cancer therapies and the scientific rigour upon which they are founded, and that this would extend to the evaluation of CAM therapies as they pertained to cancer care, including Dr. Khan's care of Patient A.
- [49] We found her testimony to be thoughtful, concise and clear. She appeared to pause and consider her answers before speaking and seemed comfortable telling us if she did not know the answer to a question.
- [50] Her assessments of Dr. Khan's care were also well-articulated, balanced and fair. Her evidence was helpful to us.

*Witness #3 - Dr. Richard Tozer - Expert Witness for the College*

- [51] Dr. Tozer graduated from McMaster University's medical program in 1990, after he obtained his doctorate in biochemistry from the University of Western Ontario in 1987. Between 1990 and 1993, he did his residency training in internal medicine at McMaster University, where he remained to do his medical oncology fellowship training from 1993 to 1995. Between 1995 and 1997, Dr. Tozer did further research training through the Terry Fox Fellowship at the Institute for Molecular Biology and Biotechnology, McMaster University and at the Hamilton Regional Cancer Centre. Dr. Tozer is currently a fellow of the Royal College in both internal medicine and medical oncology.
- [52] Since 1997, Dr. Tozer has been a staff oncologist at the Juravinski Cancer Centre (Juravinski). Since 2011, he has been the Chief of Oncology, Division of Medical Oncology at Hamilton Health Sciences Corporation, where he oversees 60-80 hospital staff.
- [53] Dr. Tozer explained that medical oncologists treat cancer, including hematological cancers, with systemic therapy or radiation. At his hospital, the medical

oncologists report to him, whereas surgical oncologists, who treat cancer with surgery, report within the Department of Surgery.

- [54] Dr. Tozer divides his time between clinical oncology work, teaching and his Chief of Medical Oncology duties.
- [55] His current clinical practice includes the diagnosis and treatment of various cancers with a focus on sarcoma, breast cancer and melanoma.
- [56] Between 1999 and 2014, Dr. Tozer was the hospital's Head of Supportive Care for oncology, where he continues to function in a primary leadership role. Dr. Tozer explained that in this position, he oversees the numerous aspects of cancer care required to assist cancer patients through the cancer journey in the best possible way. Key aspects include clinical nutrition, pain and symptom management, palliative care and psycho-oncology, which at present includes social work, psychology, psychiatry and mental health nursing.
- [57] For eight years, Dr. Tozer was Director of the Medical Oncology residency training program at McMaster University. His teaching experience included the education of medical students, residents, fellows, nursing students and physician assistants, and the supervision of PhD students. Currently, Dr. Tozer is the chair of Morbidity and Mortality Rounds, gives regular academic half-days and receives invitations to speak from other departments, such as internal medicine and surgery.
- [58] For several years, Dr. Tozer has also provided end-evaluations for Pathway 3 and Pathway 4 candidates (physicians with non-Canadian medical certification applying for Ontario certification). He has experience doing both peer assessments and formal evaluations for the College as well.
- [59] Dr. Tozer's research on cancer has been published in numerous peer-reviewed medical and scientific journals, and he has contributed to a number of peer-reviewed books on cancer.
- [60] Currently, Dr. Tozer sits on the board of Wellwood, a community-run organization that provides support to patients through meditation, yoga, tai chi, reiki educational sessions and support groups. Prior to this position, Dr. Tozer

travelled throughout Ontario and the country as an external reviewer for the branches of Wellspring, an organization similar to Wellwood. The focus of this work was to provide quality assurance evaluations by reviewing the organization's programming, volunteers, members and board.

[61] Dr. Tozer explained that his clinical work requires familiarity with CAM because at any time, approximately 70% of his cancer patients will be receiving CAM therapy, and he must ensure that there are no dangerous interactions between these treatments and their conventional therapies.

[62] Dr. Tozer testified that acupuncture is provided to cancer patients at Juravinski, and the palliative care team is running a study on the effects of cannabinoids in relation to standard narcotics for the relief of pain from metastatic cancer, predominantly prostate and breast.

[63] Dr. Tozer is the recipient of numerous honours and educational grants, and his other current notable past and current positions include, but are not limited to:

- current position with the Medical Oncology Examination Board at the Royal College where he was chief examiner for the examination board for medical oncology for five years;
- current Associate professor at McMaster University in the Department of Oncology;
- College work involving the evaluation of non-Canadian medical graduates, peer review and formal opinions as he is providing in the case of Dr. Khan.

[64] Similar to her objection to the testimony of Dr. Younus, counsel for Dr. Khan took the position that Dr. Tozer could only be qualified as an expert in the diagnosis of cancer and the treatment of cancer with conventional modalities, and not in the treatment of cancer through alternative means, on the basis that Dr. Tozer had no experience in alternative therapies other than acupuncture. We were satisfied based on the evidence that Dr. Tozer was well qualified to give expert testimony, without his testimony being limited as requested by Dr. Khan. Although his clinical work, research and teaching have been in the field of conventional medicine, he has made it his business to understand the CAM treatments that many of his

patients are using. We therefore accepted Dr. Tozer as an expert in the diagnosis and treatment of cancer.

- [65] We gave significant weight to Dr. Tozer's evidence concerning the clinical care of patients with cancer and on the principles of medical and scientific research.
- [66] We found Dr. Tozer's testimony to be thoughtful, concise and clear. While he did at times express frustration at some of the clinical decisions made by Dr. Khan, in several instances, he also gave credit to Dr. Khan when he believed the patient care he provided was good and met the standard of practice.
- [67] Overall, while critical of Dr. Khan's care, Dr. Tozer's assessments were well-articulated and we understood the reasons behind his criticisms and concerns. This led us to conclude that his assessments were balanced and fair and we found that his evidence was helpful to us.

*Dr. Khan presented two witnesses who were accepted as expert witnesses:*

*Witness #4 - Dr. Robert Kerbel - Expert witness for Dr. Khan*

- [68] Dr. Kerbel obtained his Bachelor of Science in Life Sciences from the University of Toronto in 1967. In 1972, he obtained his doctorate in microbiology and immunology from Queen's University. For his PhD work, Dr. Kerbel studied T cells and B cells and their interaction with each other, after which he became a postdoctoral fellow at the Department of Cancer Biology in the Chester Beatty Research Institute.
- [69] Dr. Kerbel began his academic career in 1975 as an assistant professor at Queen's University. He moved to the University of Toronto in 1985 and is currently still a professor there.
- [70] Dr. Kerbel has extensive experience as a cancer researcher and has consulted widely in this field, including internationally. While he has occasionally participated in cancer research at the clinical level, notably on two occasions, the vast majority of his research has been at the pre-clinical level. However, numerous clinical investigators from around the world have asked him to work in an advisory capacity on the scientific aspects and trial design of clinical cancer research.

- [71] Currently, Dr. Kerbel is a Senior Scientist of the Biological Sciences Platform at the Sunnybrook Research Institute, Sunnybrook Health Sciences Centre, where he has studied a wide spectrum of conventional cancer drugs and treatments. A great deal of his work has involved metronomic therapy, which involves conventional, mostly off-patent drugs being used in an unconventional dosing regimen. Most recently, he has turned his attention to immunotherapy in which he studies pre-clinical models of human tumours grown in immunocompetent mice.
- [72] Prior to his current laboratory appointment, Dr. Kerbel held numerous research-related positions, which include:
- Director, Biological Sciences Program, Sunnybrook and Women's College Health Sciences Centre, Toronto-Sunnybrook Regional Cancer Centre, Toronto;
  - Director, Division of Cancer Biology Research, Sunnybrook Health Sciences Centre, Toronto; and
  - Head, Division of Cancer and Cell Biology, Samuel Lunenfeld Research Institute, Mt. Sinai Hospital, Toronto.
- [73] While he has been on numerous grant review panels, Dr. Kerbel has also been the recipient of a number of grants, both national and international, including from the National Cancer Society Research Institute, the Medical Research Council, the Canadian Institute of Health Research, the Canadian Breast Cancer Foundation, the Prostate Cancer Foundation (in the UK) and the National Institute of Health in the United States.
- [74] Dr. Kerbel has published extensively and internationally, and his work has been cited over 67,000 times, which is reflected in his "H-factor" of 116. H-factor is a metric of the number of times a researcher's publications have been cited by other researchers. An H-factor of 100 is considered to be very high and few researchers in Canada have H-factors greater than 80 or 90. Dr. Kerbel was also listed amongst the top 1,000 scientists in the world, living or dead, in terms of the H-factor and the number of times his publications have been cited.

- [75] Dr. Kerbel's work also involves education at the undergraduate and postgraduate levels, and he has supervised many students including those at the doctoral and postdoctoral level.
- [76] Dr. Kerbel has been a keynote speaker at many scientific meetings around the world and over his career he has given over 900 lectures at centres such as Harvard University, the MD Anderson Cancer Center in Texas and the Memorial Sloan-Kettering Cancer Center in New York, to name a few.
- [77] Dr. Kerbel's work has garnered many awards, honours and distinctions including a Tier I Canada Research Chair in Tumour Biology, Angiogenesis and Antiangiogenic Therapy from 2001 to 2015. His expertise has been sought by numerous editorial boards for publications from around the world, particularly in publications focused on cancer research. His current appointments include the International Journal of Cancer, Current Cancer Drug Targets, EMBO Molecular Medicine and Molecular Cancer Therapeutics.
- [78] We accepted Dr. Kerbel as an expert in cancer biology and research. We found his testimony to be enthusiastic, detailed and balanced. We placed significant weight on his evidence and found it to be of great assistance in elucidating various aspects of cancer biology, immunotherapy, research, the scientific process and the impact of therapies on tumour growth.

*Witness #5 - Dr. Mark Rosenberg, Expert Witness for Dr. Khan*

- [79] Dr. Rosenberg is a medical doctor who, before entering medical school, had completed a Masters of Science in Physiology at the Georgetown University Graduate School in Washington, DC. He received his medical degree from Georgetown University in 1988. Upon completion of the degree, he did a transitional internship at Fitzsimons Army Medical Center, followed by an Emergency Medicine residency at the Brooke Army Medical Center. He was board certified by the American Board of Emergency Medicine in 1994 and became a fellow of the American College of Emergency Physicians in 1996.
- [80] Dr. Rosenberg completed his "pay back" to the military (for having paid his way through Georgetown) as the Assistant Chief of Emergency Medicine at Walter Reed Army Medical Center. After that, he moved to Florida where he continued

his work in emergency medicine as the Assistant Director at Westside Regional Medical Center and eventually at the Bethesda Hospital in Boynton Beach, Florida.

- [81] In the early 2000s, Dr. Rosenberg opened a practice focusing on preventative medicine and health. He continued his emergency work alongside his preventative medicine practice. Dr. Rosenberg continued his work in emergency medicine until approximately 2005. At that point, the diagnosis of advanced cancer in a person close to him became the impetus for his interest and subsequent reading on cancer and cancer treatments. This led to his current practice, which he carries on through a company called Advanced Medical Therapeutics, where he is the sole physician. Currently, 85% of Dr. Rosenberg's work consists of treating patients with cancer, many at the advanced stage and the other 15% focuses on preventative care for age-related disease. Dr. Rosenberg estimates that each year he treats 400 patients with cancer. He describes himself as an "integrative cancer therapy practitioner," which he says is a combination of conventional and alternative types of treatments.
- [82] Dr. Khan tendered Dr. Rosenberg as an expert in integrative cancer therapy. There was no objection from the College, and we qualified him as such.
- [83] In his cross-examination after being qualified and after testifying in chief, Dr. Rosenberg confirmed that he has no formal postgraduate training or qualifications in biology, chemistry or oncology, and that most of his expertise in the field of cancer is self-taught. He also confirmed that he holds no medical qualifications in this province, has never practised in Ontario or Canada, is not familiar with the standard of medical care in this province, nor is he familiar with the College, or the College's CAM policy.
- [84] Over the years, Dr. Rosenberg's interest in cancer has led him to conduct his own research on cancer therapies, including the treatment of two patients with an experimental agent that he administered in South America because he was unable to treat these patients in the United States due to regulatory restrictions.
- [85] According to Dr. Rosenberg's *curriculum vitae*, he is "currently completing pre-clinical studies (with Harvard affiliates) with a novel drug targeting cancer stem cells." He confirmed in his testimony that the "Harvard affiliates" refers to faculty

members at Harvard who are co-owners with him of a company called Hillstream BioPharma.

- [86] Dr. Rosenberg conceded on cross-examination that he has strong views on how cancer is treated in the United States. He has spoken out against the American Medical Association, the FDA, State Boards of Medicine and pharmaceutical companies, stating that they "...knowingly allowed and even promoted the continued use of an ineffective treatment strategy (chemotherapy) for advanced stage cancer for over two decades," which "has caused the needless suffering and premature deaths of millions of children, women, and men." He also published an article in which he stated that:

Also, approximately 2/3 of as oncologist's income comes from the administration of chemotherapy. In summation, oncologists are merely pawns in the system, manipulated by the pharmaceutical industry.

- [87] We note however, that Dr. Rosenberg's concerns regarding the pharmaceutical industry did not prevent him from attempting to participate in this industry. He has on a number of occasions attempted to start numerous, now defunct, biotech/pharmaceutical companies. He is currently a 4.5% owner of Hillstream BioPharma, and he has various patent applications which are pending.
- [88] Based on his testimony and publications, we were aware that he had strong negative views about conventional cancer care and chemotherapy due to its limitations in curing cancer, and we understood that he may have a bias against conventional medicine. We were also aware that Dr. Rosenberg did not have education, training nor any formal qualifications in conventional cancer treatment. We also considered the fact that Dr. Rosenberg has never qualified to practise or practised medicine in this province and that he was not familiar with the standards set out by the College nor with the CAM policy. However, we found that when questioned, Dr. Rosenberg did not attempt to hide his views on conventional therapy, his lack of qualifications in conventional cancer care or his lack of familiarity with healthcare standards in this province, and we found his testimony to be honest and forthright when questions about these and other topics were put to him.

[89] While we put limited weight on Dr. Rosenberg's evidence on conventional cancer care, we found him to be an honest and credible witness. We were comfortable putting weight on his evidence concerning integrative medicine in general, particularly on the ONCOblot test, which is a test that he had used in his own practice. Additionally, we were aware from a photograph of Dr. Rosenberg and Dr. Khan, arm-in arm, together at a Las Vegas conference in 1993, that Dr. Rosenberg already had a relationship with Dr. Khan before he testified at this hearing, and before he generated his January 11, 2020 report pertaining to Dr. Khan's care, although we do not know the extent of that relationship or whether or how it may have influenced Dr. Rosenberg's testimony and report on Dr. Khan's care. We cautiously placed moderate to significant weight on this report and testimony with regard to his general views on integrative medicine and ONCOBlot testing in the diagnosis of cancer. However, due to Dr. Rosenberg's lack of qualifications in conventional cancer care and his lack of knowledge of the medical standards set by the College, we lowered the weight we placed on Dr. Rosenberg's assessment and views of Dr. Khan's knowledge, skill, judgment and Dr. Khan's overall care of the patient discussed in Dr. Rosenberg's report.

*Witness #6 - Patient B - Witness for the College*

- [90] Ms. B is a 61-year-old woman who began seeing Dr. Khan in 2017. Ms. B testified about her experience and the impact of Dr. Khan's care during the time when he diagnosed her with leukemia and provided her with treatment for this cancer.
- [91] Despite being clearly distressed, and at times tearful during certain periods of her testimony, Ms. B gave clear answers to the questions posed to her. We found Ms. B to be open and forthright about her time under Dr. Khan's care and about numerous personal details in her life. Although she acknowledged the significant and lasting negative impact that Dr. Khan's care has had on her life and her family, she did not appear to harbour ill will towards Dr. Khan. She did not attempt to impugn Dr. Khan by exaggerating or twisting events and facts to intentionally paint him in a negative light, nor did she express any anger towards him.
- [92] Rather, we found that Ms. B gave detailed answers to the questions posed to her by counsel and we believed that her testimony was very likely an honest and accurate account of the time period in her life under Dr. Khan's care and of her

experience as Dr. Khan's patient. We found her testimony to be of significant assistance in clarifying important details of Dr. Khan's care of her, and in bringing to life the human story and challenges faced by patients during the diagnosis and treatment of serious disease. Ms. B's testimony served as an important reminder of the lasting impact that a physician can have on their patient, particularly when treating them for cancer and other serious illnesses.

*Witness #7 - Mr. S, father of Patient A and Witness # 8 - Mrs. S, mother of Patient A – Witnesses for Dr. Khan*

[93] Mr. S and Mrs. S testified about their experience during the time their son, A, was diagnosed and treated for brain cancer. Their testimony included evidence on the care provided by Dr. Khan, as well as other physicians.

[94] Both parents gave us highly personal accounts of their experiences. It was evident that they attempted to make the best decisions they could for their son based on the information available to them and their understanding and beliefs of what their son would have wanted. During their testimony, A's parents' love for their son was obvious and they gave us an opportunity to learn about A and the many unique qualities that made him a special child. A's parents' intent, related actions and decisions in the interest of supporting their son and preserving his quality of life throughout his cancer journey were not in question, nor were they the subject of this hearing.

[95] It was evident that reliving the events of their son's diagnosis and treatment and eventual death was extremely difficult for both parents. However difficult it was, both Mr. and Mrs. S gave honest and detailed answers. Although they testified separately, the details of events described by each parent were similar. We believe that they gave us an accurate account of the events and how they experienced them.

*Witness #9 - Dr. Khan*

[96] During this hearing, Dr. Khan testified with regard to the allegations in the Notice of Hearing, and with respect to his care and actions as they pertained to each of the 12 patients whose care was at issue.

- [97] Dr. Khan was calm and courteous to counsel, even when under rigorous questioning. Throughout portions of his testimony, he paused to reflect before answering questions and seemed comfortable admitting if he did not know the answer to a question or did not recall certain details. However, we noticed that on numerous occasions, if a potential answer or testimony risked putting him in a negative light, Dr. Khan attempted to side-step some of the questions posed to him. This made him appear evasive.
- [98] As will be discussed in more detail below, it was also evident that documentary evidence did not back up portions of his testimony. This also brought his credibility into question.
- [99] With regard to reliability around some topics, we felt that Dr. Khan sincerely attempted to provide testimony to reflect the best of his recollection and we believed his testimony on those topics. However, around other topics, as will be discussed, we did not find Dr. Khan's testimony to be reliable nor credible, and at times, Dr. Khan was intransigent in the face of evidence which contradicted his testimony.
- [100] Dr. Khan appeared to be skilled at understanding his audience and comfortable with presenting them with a narrative that included inaccurate communications and selective omissions of key information. Dr. Khan said what he wished to his patients, but at this hearing he presented us with numerous explanations to justify his inaccurate communications.

*Witness #10 - Mr. D. Dunlop - Witness for Dr. Khan*

- [101] Mr. Dunlop is a retired police officer who worked in the police force for 32 years before retiring in 2011. As a police officer, he gained experience in surveillance and intelligence, and he specialized in the field of hate crimes. He was also in charge of an investigative unit that investigated a multitude of offences, including homicide. He received a number of commendations for his police work, including a 25-year Exemplary Medal from the Governor-General.
- [102] After his retirement, he became a licensed private investigator. He is the founder and chief investigator of the company Inquisitive Intelligence Investigations Inc., which primarily conducts investigations for law firms.

[103] Dr. Khan's lawyers contacted Mr. Dunlop to investigate the Ottawa Integrative Cancer Centre (OICC) and to ascertain whether it provided certain treatments, particularly DCA, to patients. Mr. Dunlop understood that the clinic was founded by a naturopathic doctor, Dr. Seely. Mr. Dunlop's firm employed various methods of investigation including a review of the OICC website, some of their documents and an undercover visit to the clinic. During his visit to the OICC clinic, Mr. Dunlop made inquiries about DCA while posing as an uncle inquiring about treatment for his nephew, a pediatric patient with non-Hodgkin's lymphoma. He got various documents and brochures relating to the types of care provided by the OICC.

[104] We found Mr. Dunlop's testimony to be frank and accurate based on his recollection. He seemed comfortable admitting instances when he did not recall the answer to a particular question.

## **Part A - Standard of Practice and Incompetence**

### Background Information

[105] The standard of practice issues in this hearing span numerous aspects of Dr. Khan's clinical care, including his analysis of the science and data underlying his proposed treatments and claims, his communications with patients, his medical investigations and his diagnoses and therapies. Various College policies and legal authorities are pertinent. Key background information and excerpts from relevant policies are provided.

*The following excerpts define the framework for expectations of physician care:*

#### *The College's CAM Policy (Policy Statement #3-11)*

[106] One of the main areas of focus was Dr. Khan's use of complementary and alternative medications and tests, as well as his use of conventional medications in an unconventional or "off-label" manner.

[107] The expectations and standards to which a physician must adhere when offering these types of therapies and diagnostic tests as part of their practice are outlined

in the College's CAM policy.<sup>2</sup> Below are key excerpts from the CAM policy which have relevance to this hearing:

### Terminology

**Conventional Medicine:** Refers to the type of treatment, diagnostic analysis and conceptualization of disease or ailment that is the primary focus of the curricula of university faculties of medicine. It is sometimes referred to as traditional medicine or science-based medicine and is the type of medicine that is generally provided in hospitals and in specialty or primary care practice.

**Complementary/Alternative Medicine (CAM):** Refers to a group of diverse medical practices and products that are not generally considered part of conventional medicine. They are also sometimes referred to by other terms, such as non-traditional and non-conventional. The boundaries between CAM and conventional medicine are not absolute and some specific CAM practices may become incorporated into conventional medicine.

...

Patients have the right to make health care decisions that accord with their own values, wishes and preferences. This includes decisions to pursue complementary/alternative medicine either as an adjunct to conventional medicine, or instead of conventional medicine. The *Medicine Act, 1991* states that physicians shall not be found guilty of professional misconduct or incompetence solely on the basis that they practice a therapy that is non-traditional or that departs from the prevailing medical practice.

...

### A. General Expectations for Physician Conduct

The general expectations for physician conduct expressed in this section mirror existing obligations contained in the Practice Guide.

Grounded in principles of ethics and professionalism, these expectations translate into specific obligations for physician conduct:

...

#### i) Act in Patients' Best Interests

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<sup>2</sup> The CAM policy has since been amended. All references are to the policy in effect at the time of the events.

...

ii) Respect Patient Autonomy

...

iii) Refrain from Exploitation

...

iv) [Manage] [c]onflicts of Interest

...

These principles and obligations are applicable to all medical practice, and represent the foundation of good medical practice.

...

B. Specific Expectations for Physician Conduct

...

1) Practicing CAM

This section applies to all physicians who practise CAM, either as the primary focus of their practice, or as a component of their conventional practice.

When physicians are practising CAM, the College expects that they will do so competently, in keeping with their legal, professional and ethical obligations.

i) Clinical Competence: Knowledge, Skill and Judgment

Physicians must always act within the limits of their knowledge, skill and judgment and never provide care that is beyond the scope of their clinical competence.

This expectation applies equally to treatments or therapies that the physician recommends to patients and those which patients request.

...

All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science.

Clinical Assessments

Physicians providing CAM must conduct a clinical assessment of the patient.

Any clinical assessment of a patient must involve taking an appropriate patient history, and performing or ordering any necessary medical or laboratory examinations or investigations that are required to obtain relevant and comprehensive information about the patient's ailment or condition.

...

If physicians also reach a CAM diagnosis, that diagnosis must be based on the clinical assessment conducted and other relevant information, be supported by sound clinical judgment and be informed by evidence and science.

CAM diagnoses that do not satisfy these requirements are not acceptable diagnoses.

### iii) Treating the Patient: Therapeutic Options and Informed Consent

Physicians must always have valid informed patient consent to authorize therapeutic intervention. Physicians must also evaluate and analyze all available therapeutic options, in accordance with the expectations set out below.

#### Therapeutic Options

Any CAM therapeutic option that is recommended by physicians must be informed by evidence and science, and it must:

- Have a logical connection to the diagnosis reached;
- Have a reasonable expectation of remedying or alleviating the patient's health condition or symptoms; and
- Possess a favourable risk/benefit ratio based on: the merits of the option, the potential interactions with other treatments the patient is receiving, the conventional therapeutic options available, and other considerations the physician deems relevant.

Physicians must never recommend therapeutic options that have been proven to be ineffective through scientific study.

#### Informed Consent and Communication

The provision of CAM must be authorized by valid informed consent, in accordance with the legal and policy requirements set out in the *Health Care Consent Act, 1996* and the Consent to Medical Treatment policy.

The College expects that through the consent process, physicians will convey the following to patients:

- The extent to which the CAM diagnosis reached (if applicable) is supported by the conventional medical community;
- Their rationale for recommending the therapeutic option in question;
- Reasonable expectations about the clinical efficacy of the therapeutic option;
- Whether the therapeutic option is supported by the conventional medical community, along with the level of support provided by the CAM community;
- A description of how the therapeutic option compares to conventional medical interventions that would be offered to treat the same symptoms or condition (comparison of risks, side effects, therapeutic efficacy, etc.); and
- Accurate information about the conventional therapeutic options that would be offered to treat the same symptoms or condition.

The details of the consent process, including the above information, should be documented in the patient's medical record.

[108] The policy also states that in order for patient consent to be informed, physicians must always provide patients with accurate and objective information about the available therapeutic options. Physicians must never inflate or exaggerate the potential therapeutic outcome that can be achieved, misrepresent or malign the proven benefits of conventional or CAM treatment or make claims regarding therapeutic efficacy that are not substantiated by evidence. It is a principle of good practice that physicians provide their professional opinion in an accurate and objective manner, substantiated by fact and sound clinical judgment. Clinical concerns must always be highlighted.

*The College's Consent to Treatment Policy (Policy Statement #3-15)*

[109] Physicians must comply with the expectations set out in the College's Consent to Treatment Policy when obtaining consent for treatments. Physicians must obtain valid consent before treatment is provided. For consent to be valid it must:

- be obtained from the patient if they are capable with respect to the treatment or from the incapable patient's substitute decision-maker;
- be related to the treatment;

- be informed;
- be given voluntarily; and
- not be obtained through misrepresentation or fraud. Physicians must be frank and honest when interacting with patients, including when conveying the information about the proposed treatment.

[110] These College policies will be referred to throughout this document as they are the basis for many of the issues to be discussed.

## **Part B - Standard of Practice**

### Standard of Practice of the Profession - Dr. Khan's Use of SAFE ® Chemotherapy

[111] Dr. Khan prescribed SAFE chemotherapy to 10 of the patients whose care was at issue in this hearing. Although we will address the allegations specifically with regard to each patient, we thought it appropriate to assess generally whether Dr. Khan's reliance on SAFE chemotherapy met the standard of practice.

### *Background Information and Terminology*

[112] Throughout this hearing we heard testimony about clinical trials, including pre-clinical, and phase 1, 2, 3 and 4 clinical trials (sometimes referred to as phase I, II, III, IV trials).

[113] Dr. Younus confirmed that these trials are necessary for a therapeutic option to be informed by evidence and science:

The prospective randomized clinical trials have been the gold standard of evaluating the efficacy of any given treatment, for any given oncological diagnosis. These trials are run with a very specific set of parameters to be exercised every single time a patient is recruited into the study, and goes through Phase I through Phase II, and Phase III, requiring at each step of investigation a certain set of parameters to be evaluated, so the next step become easier and feasible to be done.

[114] Each trial phase provides data that allows scientists and clinicians to establish specific information about the proposed therapy. Dr. Tozer gave information about phase 4 trials conducted after the drugs are approved for use.

### *Pre-Clinical Trials/Studies*

- [115] Pre-clinical trials or studies do not occur in humans and are typically conducted either *in vitro* or *in vivo*. In *in vitro* studies, cells in a petri dish are exposed to treatments and monitored for their response. In *in vivo* studies, live animals or animal systems are exposed to treatments and monitored for their response.
- [116] Dr. Younus testified that while *in vitro* and *in vivo* level studies are useful for learning about biological information, processes and diagnostic pathways, they are “not enough to recommend something from that level to be transported into the level of using that medicine for humans.”

### *Phase 1 Clinical Trials*

- [117] Dr. Kerbel explained that primarily, phase 1 trials are conducted to establish safety, tolerance, toxicity and drug dosages ahead of phase 2 trials. A phase 1 trial will include patients with different types of cancers, and in various stages of treatment. Some of the patients accepted into phase 1 trials have often been pre-treated with other medications. Dr. Johnston explained that in essence “you give a drug, and you watch for side effects. And then if you don’t see many side effects, then you can escalate the dose and you basically build up [until] you reach toxicity to figure out what dose is tolerated.” Dr. Younus explained that a phase 1 trial, from a “conventional medicine point of view, only provides the findings about the toxicity, side effects, and the dose that can be used in the human trials.”

### *Phase 2 Clinical Trials*

- [118] Dr. Kerbel explained that phase 2 trials usually consist of a small number, typically 20, of therapy-naïve patients (meaning they have not been previously exposed to any therapy) who have one specific type of cancer (e.g., breast cancer or colon cancer). Phase 2 trials try to measure the efficacy of the drug.

### *Phase 3 Clinical Trials*

- [119] These trials involve much larger groups of patients, and certain control mechanisms are introduced. Dr. Tozer explained that patients with a single disease site are randomly placed in a group receiving the trial drug of interest, or in a group that is receiving the current therapy. Depending on the trial structure, patients may sometimes be placed in a placebo group. The outcomes are then

compared. Dr. Younus explained that if the trial drug produces outcomes that, when compared to the known standard of care for a medical condition, are found to exceed the current standard of care, then that finding stands as a strong evidentiary basis that the trial medicine will be effective against that given condition.

#### *Phase 4 Clinical Trials*

[120] Dr. Tozer explained that phase 4 trials are conducted after drugs are approved and in use. “They are basically post-marketing studies looking to see -- to detect rare side effects that the Phase III trials would have been too small to have picked up.”

#### *Case Reports*

[121] Apart from clinical trials, certain information can be obtained from physician reports of treating patients or cases (also referred to as case reports). Dr. Younus explained that a certain number of patients is required in order to come to a significant clinical conclusion. “If you fall below that level and you only have report of one case, or two patients, or three patients, it is an interesting finding, but that does not make a strong evidence, or a strong scientific rationale to start using that therapy in every single patient.”

#### Background Information on Cancer Treatment

[122] Cancer is treated by a number of methods including therapies to slow or kill cancer cells. Various medications are used by oncologists in an attempt to achieve this. Some of these drugs are referred to as chemotherapy drugs. In addition to their therapeutic effects, many carry a significant risk of side effects and toxicity.

[123] In July 2013, through his practice at Medicor, Dr. Khan began offering a two-medication regimen for the treatment of cancer which was comprised of the conventional drugs carboplatin and mesna. This cancer regimen was called “side

effect free chemotherapy” (SEF), otherwise referred to by its trademark name, SAFE chemotherapy.<sup>3</sup>

[124] Carboplatin is a platinum-based chemotherapy agent commonly used by conventional oncologists to treat various forms of cancer including melanoma, breast cancer, ovarian and lung cancer.

[125] Mesna is a conventional medication used to protect the bladder from inflammation and the serious bleeding that can occur as a result of the metabolic breakdown of two specific conventional chemotherapy drugs. This type of drug is called a chemoprotectant.

[126] Both carboplatin and mesna are approved by Health Canada. However, their combination is not.

#### *History of the Development of SAFE Chemotherapy*

[127] Dr. Khan’s standard Medicor consent form for SAFE chemotherapy explained that SAFE was developed by Dr. Kenneth Matsumura. The form also stated that Dr. Matsumura developed the world’s first artificial pancreas and liver.

[128] The consent form stated that Dr. Matsumura is a physician. He does not appear to be an oncologist, and during this hearing, no information was provided about his background, training, clinical experience or medical practice.

[129] Dr. Matsumura’s website refers to a company called the Berkeley Institute International. It is unclear where this company is located. However, it appears to be in either California or Mexico.

#### *What Does Dr. Khan Purport that SAFE Chemotherapy Can Do?*

[130] Dr. Khan testified that SAFE chemotherapy can be more effective than conventional chemotherapy in treating cancer, and it can do so with fewer side effects.

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<sup>3</sup> “SAFE” and “SEF” are used interchangeably throughout this decision, depending on the reference document being discussed, and on the witness testifying.

[131] Dr. Khan's standard Medicor SAFE chemotherapy consent form stated that SAFE chemotherapy is a neutrophil-potentiated chemotherapy treatment, and that it has been studied in a phase 2 trial with the following results:

A substantial reduction of side effects of chemo agent carboplatin, in particular, in protecting blood circulating levels of platelets and white blood cell neutrophils (neutrophils are believed to be beneficial during chemotherapy by helping chemo agents eradicate cancers more thoroughly).

[132] The consent form also stated:

It is hoped that SAFE Chemo will cause shrinking of cancer, or remission of cancer...the likelihood of these benefits is still being measured, but early data indicate the likelihood is substantially greater than conventional chemotherapy and with less side effects.

[133] Dr. Khan's Medicor website reports that of the first 20 patients Dr. Khan treated with SAFE chemotherapy, almost all had stage 4 cancers of various types, including rare tumours and those that typically had poor responses to chemotherapy. The website reports an over 80% response rate (using a modified "RECIST" score). His website also states that with some statistical adjustments made to account for the "unique population" being served, the response rate goes up to 90%. This is a two-to-five-time higher response rate than conventional chemotherapy for those types of cancers. On his website, Dr. Khan also refers to SAFE chemotherapy treatment as "life-saving."

[134] "RECIST" stands for Response Evaluation Criteria in Solid Tumours. Dr. Johnston explained that RECIST is a measuring system or guideline to standardize the evaluation of tumour response to therapy across various studies. Since its introduction, many investigators, cooperative groups, industry and government authorities have adopted these criteria in the assessment of treatment outcomes.

[135] Dr. Khan did not specify how he modified RECIST in coming to his conclusions. This is discussed below, in the section dealing with Dr. Khan's dataset.

[136] In his testimony, Dr. Khan explained that chemotherapy medications preferentially kill rapidly dividing cells, such as cancer cells. However, the body also has some other healthy, rapidly dividing cells, and "those do get killed off by chemotherapy as well. That is in fact the main limitation of chemotherapy." He went on to explain

that in the marrow, the white cells, the platelets, the red blood cells and the cells lining the gastrointestinal tract are also rapidly dividing. These systems are therefore vulnerable to the effects of chemotherapy drugs.

[137] Dr. Khan's SAFE chemotherapy form stated that the mesna will protect healthy cells by preventing or reducing side effects from cytotoxic chemotherapy drugs such as carboplatin.

*What are the Known Side Effects and Toxicities of Carboplatin?*

[138] Dr. Khan's SAFE consent form stated that "the usual side effects from carboplatin chemotherapy alone (without the protective drug MESNA) include" (emphasis in original):

1. bone marrow toxicity – 81%
2. nausea and vomiting – 93%
3. diarrhea and other gastro-intestinal side effects – 50%
4. hair loss – 2%
5. abnormal salt balance in the blood
6. nerve injury – 6%
7. allergic reaction – 2%
8. temporarily increased liver enzymes seen on blood testing – 17%
9. kidney injury – 5%
10. hearing impairment – 15%
11. other rare serious side effects

*According to Dr. Khan, How is SAFE Chemotherapy Different From Conventional Carboplatin?*

[139] Dr. Khan explained that the main side effects limiting the dose of carboplatin, referred to as dose-limiting side effects, are nausea, vomiting and bone marrow

suppression. However, he claims that if one uses the SAFE chemotherapy regimen of carboplatin and mesna, the side effects are dramatically reduced compared to using the carboplatin on its own, without the mesna.

[140] Dr. Khan confirmed that without the antidotal effect of the mesna, the use of carboplatin would simply be like treating patients with the conventional chemotherapy, carboplatin.

#### *How Does SAFE Chemotherapy Achieve Its Purported Benefits?*

##### *Claim that Mesna is a Nanoparticle*

[141] Dr. Khan testified that the formulation of mesna in SAFE chemotherapy is different than the standard, commonly used formulation of mesna. He said that the formulation acts as an antidote to the conventional chemotherapy carboplatin, because the mesna is delivered directly to the bone marrow and gastrointestinal cells.

[142] According to Dr. Khan, Dr. Matsumura told him that he had formulated the conventional drug mesna into a nanoparticle. Dr. Khan explained that “a nanoparticle formulation means that the drug mesna is encapsulated into very, very small particles...and by designing these nanoparticles in a specific way, the drugs can be targeted at specific cells in the body.” Dr. Khan claims that the nanoparticle formulation of mesna in SAFE chemotherapy is targeted “...specifically at the bone marrow, at the white blood cells and the platelets and also at the lining of the GI tract.”

##### *Claim that SAFE Chemotherapy is an Immunotherapy*

[143] Dr. Khan explained that the mesna in SAFE chemotherapy gives it cytoprotective effects which, in combination with carboplatin, make SAFE chemotherapy unique, and that SAFE chemotherapy works on cancer because it is an immunotherapy.

##### *What is Immunotherapy?*

[144] Dr. Kerbel, Dr. Khan's expert, conducts research in immunotherapy. He explained that immunotherapy utilizes a class of drugs called immune checkpoint antibodies that target an interaction/binding event that occurs between a cancer and the immune system. The immune system has natural regulatory mechanisms that

allow it to be induced, modulated and shut down. Although the immune system is typically triggered by the presence of a foreign protein, there are a number of homeostatic mechanisms that have evolved over millions of years that mediate its response. The immune system ramps up when exposed to a virus or bacteria, and in response the body's homeostatic mechanisms act as a "brake" to ensure that the immune system does not go into overdrive.

[145] T cells are important in the human immune response. Our immune system has the potential to recognize certain foreign proteins that are expressed by tumour cells, especially if those proteins are found on the cell surface. However, there is evidence that most cancers, through their ability to bind with a T cell receptor called PD-1, can prevent the body's endogenous immune system from effectively ramping up against cancer cells.

[146] Some current immunotherapies specifically target the PD-1 receptor and the corresponding PD-1 binding ligand in the cancer PD-L1 which is found on most cancers' cell surfaces. The goal of immunotherapy is to disrupt the interaction between the T cell PD-1 receptor and the PD-L1 cancer binding ligand because that interaction is what prevents the ramping up of the immune system. Disrupting this interaction will release the "brake" and unleash the immune system so that it can be more active against the cancer.

*Dr. Khan's Claim of How SAFE Chemotherapy Works as an Immunotherapy*

[147] Dr. Khan explained that:

The conventional chemotherapy, the plain carboplatin causes damage to the immune system or to the white blood cells, and so they are not able to attack the cancer. The difference with the SEF Chemo is with the mesna being now in a nanoparticle being targeted at the neutrophils and the white blood cells and the mesna being an antidote to carboplatin, now if you bring the antidote within the cells that you are trying to protect, now when the carboplatin gets in, the antidote is already there. It inactivates the carboplatin. So, what you have is protection of the white blood cells, and then they are now able to attack the cancer alongside the chemotherapy drug. So that is what makes it immune therapy.

[148] Although Dr. Khan testified that SAFE chemotherapy is an immunotherapy, he did not present publications, literature or science supporting his claim. We noted that Dr. Khan's explanation of immunotherapy, which appears to focus on the

protection of white blood cells from carboplatin though mesna's alleged ability to penetrate to the inside of targeted tissues, is not consistent with that of his expert Dr. Kerbel. We accepted Dr. Kerbel's explanation of immunotherapy, which was based on his expertise and extensive experience and knowledge in the field of cancer research. Based on Dr. Kerbel's testimony, we were satisfied that SAFE chemotherapy is not an immunotherapy.

*What Other Information About SAFE Chemotherapy Did Dr. Matsumura Provide to Dr. Khan?*

[149] Dr. Khan testified that he met Dr. Matsumura in June 2013. He began using SAFE chemotherapy for patients in his own practice one month later, in July 2013.

[150] Dr. Khan stated that he was provided with the following information which he considered before he began to treat his patients with SAFE chemotherapy:

1. a SEF [SAFE] chemotherapy booklet (booklet);
2. verbal information from Dr. Matsumura about data/results for four patients treated with SAFE chemotherapy;
3. data results which consisted of information about the types and stages of patients with different cancers, bloodwork results for white blood cells, neutrophils and platelet counts; and
4. information from Dr. Matsumura about his unpublished FDA approved phase 2 study on the efficacy of SAFE chemotherapy, which was based on the blood work results described above.

[151] Dr. Khan requested a ban on disclosure of the booklet, on the basis that his possession of it was subject to a non-disclosure agreement (NDA). He also sought the exclusion of the public from those parts of the hearing in which there were questions about the booklet. The order was made on consent, but on the stipulation that at the conclusion of the hearing, the College would be at liberty to renew its request that the booklet and the questioning on the booklet be made part of the public record. The College did renew its request, and for the reasons set out below, we decided to rescind the ban on publication. We therefore will be

referring in these reasons to the booklet and to evidence that was heard during *in camera* sessions of the hearing.

*What Claims Did Dr. Matsumura Make About SAFE Chemotherapy?*

[152] Dr. Matsumura's website and his booklet make the following statements and claims about SAFE chemotherapy:

- SAFE chemotherapy is a "cancer cure" and a "powerful drug that cures."
- SAFE chemotherapy will change cancer into a "treatable outpatient disease."
- With SAFE chemotherapy, 90% of oncologists will no longer be needed as "there is no need for oncologists with years of training to decide what drugs to use for different cancers."
- There are data "conclusively showing ( $p < 0.001$ )" that SAFE chemotherapy "substantially reduces the dosage-limiting toxicity to the bone marrow by carboplatin, one of the most powerful anti-cancer drugs ever developed."
- Contrary to conventional chemotherapy, with SAFE chemotherapy "we find tumours quickly shrinking over weeks..."
- "[I]n our first Phase II clinical trial with DTRA-Mesna, all four consecutive patients with hopeless cancers of the lung, breast, and blood got well and went onto long term remissions, the longest survivors now living over seven years without cancer."
- Experienced FDA examiners "broke all records" and approved the application for a clinical trial in four days.
- The "first four terminal patients all responded and went into long-term complete remissions." Such a thing can happen by chance "only once in a trillion cases, according to statistical analysis."
- Dr. Matsumura's "personal story is like a John Grisham novel."

[153] Dr. Matsumura's website also states that the United States FDA "rushed" through the approval of his first clinical trial on SAFE chemotherapy in 1992.

[154] Other claims include a letter to Dr. Khan dated April 12, 2014, in which Dr. Matsumura explains that he did not want to have to respond to “days of front page news coverage bringing [hordes] of patients and their relatives demanding treatment for their mothers, wives, or a precious child” as “without proper resources” to implement the therapy on a larger scale, this would be a “challenge.”

[155] Dr. Khan confirmed that since 1992, when Dr. Matsumura began working on SAFE chemotherapy, none of his findings have ever been published, nor is there any information available on any patients he treated since his first four patients in 1992.

*The Booklet on SAFE chemotherapy and the Dataset from Dr. Matsumura)*

[156] On September 23, 2020 (during the hearing), Dr. Khan received an email from Dr. Matsumura containing the “Neutrophil-potentiated, Dose Intense Carboplatin Immuno-Chemotherapy (SEFChemo) Unpublished trial data.” Dr. Khan testified that he had only recently received a waiver of the NDA he had with Dr. Matsumura, which allowed him to share the information in it.

[157] The data pertained to the outcome of Dr. Matsumura’s first four patients, who had four different types of cancer that were all treated with SAFE chemotherapy:

- Patient 1: stage 4 breast cancer with metastatic disease to the liver, treated with SAFE chemotherapy alternating weekly cycles with gemcitabine;
- Patient 2: myelogenous leukemia in the terminal stage, received low dose SAFE chemotherapy for three weeks;
- Patient 3: Non-small cell lung cancer, stage 3B, received SAFE chemotherapy and gemcitabine;
- Patient 4: Non-small cell lung cancer, stage 3B.

[158] These patients were all described as being cancer free or as having extensive remission after the use of SAFE chemotherapy.

The College Expert's Opinion Regarding the Contents of the Information on SAFE Chemotherapy

[159] Dr. Tozer testified that:

- The booklet did not outline the results of a phase 1 clinical trial, which would have established dosage safety.
- He disagreed that the booklet demonstrated whether the treated patients had suffered from myelosuppression (bone marrow suppression) or not, as it was impossible to say from the information provided.
- The patient dataset discussed in the booklet did not disclose whether or not the patients were receiving other medications or agents.
- Neither the booklet nor the patient dataset outlined the results of a phase 2 clinical trial (as described in Dr. Khan's SAFE chemotherapy consent form) and would not meet the requirements for a phase 2 trial. A phase 2 clinical trial typically involves approximately 20 patients with one cancer type while the four-patient dataset had a mix of cancer types. A phase 2 trial would also need to have patients with good performance status and measurable disease. There were also no efficacy data in the document, nor were there enough patients to claim efficacy.
- The frequency of the administration of the carboplatin in the dataset was not clear.
- The patent application for SAFE chemotherapy is only a summary of various compounds and techniques.

*Is There Published Literature to Support the Claims Made About SAFE Chemotherapy?*

[160] Dr. Tozer testified that:

- He works with mesna as a bladder protectant for cyclophosphamide and ifosfamide, and all his "literature searches found no evidence that mesna does anything other than that." Further, the toxicity of carboplatin's side effects are not mitigated by mesna.

- A literature search to find papers which looked at mesna in combination with carboplatin revealed that published literature on pharmacokinetic data demonstrates that mesna does not affect the pharmacokinetics of carboplatin.
- He found no evidence to support the use of SAFE chemotherapy, nor that mesna has special antidotal properties to carboplatin. He testified that mesna does not have antidotal properties to carboplatin.
- After conducting an extensive search looking for literature about mesna and myelosuppression he could find nothing.
- He was unable to find any literature or data comparing SAFE chemotherapy with conventional chemotherapy.

[161] Dr. Khan did not call any expert evidence as to the validity of mesna as an antidote to the potential side effects of carboplatin, or to demonstrate that the use of SAFE chemotherapy is informed by evidence and science or is an effective agent to treat cancer or generally to counter any of Dr. Tozer's expert evidence on the subject.

#### Did Dr. Khan Do an Independent Assessment to Verify Dr. Matsumura's Claims?

##### *Independent Review*

[162] Counsel for the College asked Dr. Khan if, before starting to treat patients in July 2013, he had conducted any independent assessment of the validity of what Dr. Matsumura had told him about SAFE chemotherapy. Dr. Khan answered, "not in July 2013. No."

[163] When College counsel put to Dr. Khan that he had made no independent investigations of the accuracy or reliability of Matsumura's claims (about the data on his four SAFE chemotherapy patients), Dr. Khan responded "correct, I trust him."

##### *Research, Literature Search and Peer Review*

[164] Dr. Khan confirmed that he did not do further research or look for literature or supportive science on SAFE chemotherapy, nor did he obtain a peer review of the

information Dr. Matsumura provided to him from any physicians, apart from his wife.

- [165] College counsel asked if, without peer review by others in the field to approve the methodology of a study, the reported results (such as Dr. Matsumura's) were "nothing other than claims of results." Dr. Khan responded:

Of course it is a claim. But that is what every journal article submission consists of. Any manuscript that any doctor or any research institute submits to a journal is nothing but claims. That's all it is. The peer review is just read the documents. The peer reviewers don't call the patients to verify the results. They don't visit the institution. They don't speak to the doctors. Typically they might have some email correspondence, but there is no...there is no other independent verification other than reviewing the documents. So it is no different than me reviewing the documents myself.

*Dr. Khan's Opinion on the Contents of the Booklet*

- [166] Dr. Khan conceded that the booklet consisted only of blood cell counts and contained "no clinical data."
- [167] Although he testified that "there is independent literature that confirms that mesna is in fact an antidote to carboplatin" and that this is "published and out there for anyone to look at," Dr. Khan did not present any such publications. Further, Dr. Khan acknowledged that he has never seen the pre-clinical data that Dr. Matsumura claimed support the use of mesna as an antidote to the toxic side effects of carboplatin. Dr. Khan also acknowledged that to his knowledge, none of the pre-clinical data or clinical data to which Dr. Matsumura referred had ever been published.

*Is There an FDA-Approved Phase 2 Clinical Trial to Demonstrate the Efficacy of SAFE Chemotherapy?*

- [168] For several years, the College had been requesting that Dr. Khan provide evidence supporting the use of SAFE chemotherapy, and a copy of Dr. Matsumura's phase 2 clinical trial that he alleged can support the efficacy of SAFE chemotherapy. Through his then counsel, Dr. Khan responded that a copy of the phase 2 clinical trial could not be provided because if any portion of it became public, it could affect Dr. Matsumura's ability to publish the trial in future.

Later, counsel advised the College that although Dr. Khan had reviewed the data from the phase 2 trial, he did not have a copy of it. The data are the property of Dr. Matsumura who allowed Dr. Khan to review it pursuant to an NDA.

[169] A phase 2 clinical trial into these matters exists according to:

- Dr. Khan who testified that Dr. Matsumura told him about the trial;
- Dr. Khan's letters to other physicians who were also caring for his patients;
- Dr. Khan's Medicor standard SAFE chemotherapy consent form;
- Dr. Matsumura's website; and
- Dr. Matsumura's booklet on SAFE chemotherapy viewed by Dr. Khan in June 2013.

[170] In cross-examination at this hearing, Dr. Khan disclosed for the first time the existence of the booklet, which had been in his possession since 2013. It refers to "patient data" but Dr. Khan described it as containing "safety data" and "very limited data, which is blood cell counts," but no clinical data. He testified that the real patient data were in the document that he received only on September 23, 2020. However, he also admitted that the document contains information about the supposed phase 2 trial requested by the College.

[171] In any event, neither document appears to include the results of a phase 2 clinical trial. No other information about this supposed trial was presented to support Dr. Khan's oral testimony and written references (above) that the trial exists.

*What Evidence and Science Informed Dr. Khan's Decision to Begin Using SAFE Chemotherapy on Patients?*

[172] An oncologist made a complaint to the College about Dr. Khan in 2014. Dr. Khan then wrote to Dr. Matsumura. This email exchange, beginning on March 29, 2014, strongly suggests that in fact, all Dr. Khan possessed to inform his decision to use SAFE chemotherapy was Dr. Matsumura's word:

The biggest issue is lack of adequate supporting data, especially for colon cancer and carbo (which is the exact nature of the

complaint). I understand the therapy is not carbo alone, but carbo + mesna, but the College won't care. They will need [sic] some hard data to support the therapy...I urgently need your help with this, because we have a limited time to make an initial submission...What I need is the patient data from the Phase 2 trial (cancer types, details of therapy, response from each patient), and any other relevant information like trial ID #, or FDA documents to support its validity...

[173] Dr. Matsumura's email response referred to an FDA trial for a different medication, vinblastine, and told Dr. Khan that he needs to "buy time" and that "you have the Northeast territory, which initially will not have many other centers and desperate patients will seek your care."

[174] In another email the same day, Dr. Khan again requested that Dr. Matsumura provide him with "hard data":

At least if we have data, they won't be able to refute it because no-one has done a clinical trial with carbo and colon cancer that showed it does not work...Can you please collect up some data of colon cancer cases for me to present who have been treated successfully with carbo + mesna?

[175] In the same email, Dr. Khan asked Dr. Matsumura whether the phase 2 Clinical trial was for vinblastine rather than SAFE chemotherapy:

It is going to be bad for me if the trial was vinblastine, because we make reference to the trial and Carbo in our documents. Is it correct that the trial started in 2005 and finished in 2010 (five year mark to indicate cure)?

[176] Dr. Matsumura responded that Dr. Khan should "buy 6 months" so data could be prepared.

[177] These March 2014 emails were sent eight months after Dr. Khan had begun to treat patients with SAFE chemotherapy (in July 2013). Despite not having data to support his claims about SAFE chemotherapy, Dr. Khan did not change any of the claims he made on his SAFE chemotherapy forms or website, and he continued using SAFE chemotherapy on his patients.

[178] On April 3, 2014, Dr. Khan emailed Dr. Matsumura again:

Right now I have nothing to give them [the College] that shows there is a reasonable likelihood of mesna enhancing and working

with carbo, except your word (of course I believe your word 100% but I need something in writing to show the College). That is why I need something from you to summarize your research into mesna and your clinical experience over the last several years...You can give as much or as little as you wish, but I need to show that you are credible...and that you have some data, and that it shows favourable results.

[179] Dr. Khan confirmed that the clinical trial data he was seeking from Dr. Matsumura in his email, was the same FDA-approved phase 2 clinical trial that he had been referring to in his Medicor SAFE chemotherapy form for at least the previous eight months.

*Further Data on SAFE Chemotherapy - Dr. Khan's Dataset*

[180] After Dr. Khan began using SAFE chemotherapy on his patients, he began to track his results. Dr. Khan presented his dataset, which he updated in April 2017, based on his own experience with 17 cancer patients on whom he used SAFE chemotherapy. 10 of the patients in the dataset are subjects of this hearing. Dr. Khan's dataset included the following:

- cancer type and stage;
- use of previous chemotherapy (yes or no), without details on which therapy may have been used;
- treatment initiation dates;
- reason for stopping SAFE chemotherapy;
- number of cycles of SAFE chemotherapy given;
- response to SAFE chemotherapy categorized as partial response, complete response or progression and upon which modality of testing or clinical information the determination of response was based;
- was the patient alive (yes or no); and
- brief notes on the presence or absence of grade 3 or 4 side effects;

[181] According to his categorizations of complete or partial response, Dr. Khan calculated that the response rate to SAFE chemotherapy for the patients in his dataset was 81% after the modification of RECIST criteria. He pointed out that with some statistical adjustments, the response rate rose to 90%. This is a two-to-five times higher rate than conventional chemotherapy for those types of cancers.

[182] At this hearing Dr. Khan testified that he did not adhere to the RECIST criteria in his dataset on SAFE chemotherapy because SAFE chemotherapy is an immunotherapy.

*Dr. Khan's Response to the Allegations Regarding SAFE Chemotherapy*

[183] In responding to the College's allegations about the efficacy of SAFE chemotherapy, Dr. Khan took the position that:

- The College permits physicians to offer CAM.
- It is a patient's right to use CAM.
- The College policy on CAM does not define the amount of required evidence, clinical trial evidence and science that is needed to use a CAM therapy.
- Evidence and science can include clinical experience and judgment.
- Alternative therapies are not the standard of care therapies offered to patients, and so the evidence supporting their efficacy will not, and cannot be the same as that underlying the standard of care therapies.
- If "[the patient chooses] a complementary therapy that has limited data over an established protocol that has extensive data, but the data is poor, then that is the patient's choice."
- His patients were either terminal patients, with months to live, or were well-versed and educated consumers of alternative medicine.
- The use of SAFE chemotherapy can be justified as off label use of the conventional chemotherapy carboplatin.

## Finding

[184] By treating patients with SAFE chemotherapy, Dr. Khan failed to maintain the standard of practice of the profession.

## Analysis

### *SAFE Chemotherapy Did Not Meet the Requirements Set Out in the College's CAM Policy*

[185] We find that with respect to the requirements of the College's CAM policy, and Dr. Khan's use of SAFE chemotherapy to treat cancer in humans:

- There was insufficient evidence and science to support Dr. Khan's claims about SAFE chemotherapy as required by the CAM policy.
- There was insufficient evidence that SAFE chemotherapy possesses a favourable risk/benefit ratio as required by the CAM policy.
- There was insufficient evidence and science to suggest that SAFE chemotherapy gives patients a reasonable expectation of remedying or alleviating their health condition or symptoms as required by the CAM policy.

### *The Evidence Does Not Support Dr. Matsumura's Claims*

[186] Based on Dr. Tozer's testimony, we find that Dr. Matsumura's booklet of information about SAFE chemotherapy and the lab work of four terminal patients with four different cancers who had been given SAFE chemotherapy did not support the claimed benefits of SAFE chemotherapy. The booklet and Dr. Matsumura's conclusions based on his four patients' data did not represent a phase 2, or even a phase 1 trial. It was not possible to draw conclusions about the efficacy of SAFE chemotherapy from the information contained in these documents. Serious issues included, but were not limited to:

- There were too few patients (only four) to obtain sufficient power to detect efficacy.
- Control of the cancer types necessary (different types instead of one type) was also lacking.

[187] We did not accept the four-patient dataset of bloodwork, nor the booklet as evidence that SAFE chemotherapy lives up to Dr. Khan's (or Dr. Matsumura's) claims about its efficacy, its safety or its superiority to conventional chemotherapy.

#### *Phase 2 Clinical Trial*

[188] Additionally, there was no evidence presented to confirm the existence of a phase 2 clinical trial showing the efficacy of SAFE chemotherapy. Nevertheless Dr. Khan referred to this purported trial in his communications with his patients and with other physicians, and he referred to it on his Medicor website and on his SAFE chemotherapy consent forms. He also referred to it throughout this hearing. These references appear to be untruthful, and we found them highly concerning.

[189] Ultimately, with no FDA trial in hand, Dr. Khan admitted that the evidence he was referring to (when discussing the FDA trial on SAFE chemotherapy) was the dataset described in the booklet and the patient bloodwork in the unpublished trial data. However as set out above, Dr. Tozer explained that this information and the data in these exhibits would not qualify as a phase 2 study. More importantly, this data was insufficient to draw any conclusions about the efficacy of SAFE chemotherapy.

#### *Dr. Khan Did Not Have Proof that SAFE Chemotherapy Could Achieve Its Purported Claims*

[190] Nine months into using SAFE chemotherapy on his patients, Dr. Khan was still seeking proof of its efficacy, and asking for phase 2 trial data from Dr. Matsumura. He should not have had to search for proof of efficacy for SAFE chemotherapy when the College asked for it. Rather, he should have had evidence that SAFE chemotherapy was safe and effective before he offered the treatment and used it on his patients.

[191] We also found it odd that Dr. Khan, when presented with Dr. Matsumura's extraordinary claims, which were all based on four patients in 1992, simply accepted them without any further verification and started treating patients with SAFE chemotherapy. Dr. Matsumura claimed that SAFE chemotherapy was significantly superior to conventional chemotherapies, worked on almost all cancers, even at advanced stages, with substantially fewer side effects and

toxicities. He provided no information on patients treated with SAFE chemotherapy since 1992. It is worrisome that Dr. Khan, who is a trained physician, and who stated during this hearing that he is a scientist, did not appear to have been driven by any of his professional obligations, nor by a natural curiosity to scrutinize the information presented.

[192] Dr. Khan admitted that he did not look for evidence to verify Dr. Matsumura's claims. His starting premise appears to have been that SAFE chemotherapy works as Dr. Matsumura claimed. One might fairly characterize Dr. Matsumura's claims as too good to be true. That Dr. Khan did not verify the validity of those claims before offering treatment to his patients, based on the fact that he trusted Dr. Matsumura, is surprising and unacceptable.

[193] Physicians are trained to review evidence to ensure that there is sufficient scientific rigour in methodology such that the conclusions and claims made can be trusted. Before offering any treatment to patients, especially one that can expose patients to the risks of side effects and toxicities, it is a physician's duty to ensure there is a reasonable chance that the patient will benefit from treatment in the manner claimed. In the case of SAFE chemotherapy, there was insufficient science and evidence to support the conclusion that SAFE chemotherapy works, or that it can help people in the way that Dr. Khan claims it can, and he should not have used it.

[194] What Dr. Khan was actually doing was providing the conventional chemotherapy carboplatin under the rebranded name SAFE chemotherapy (in combination with mesna) and using it to treat people who he agreed could be considered "desperate."

*SAFE Chemotherapy and Mesna as a Nanoparticle and SAFE Chemotherapy as an Immunotherapy*

[195] Dr. Tozer did an extensive search and found no supporting literature for the efficacy of SAFE chemotherapy, nor any evidence of the antidotal effects of mesna when paired with carboplatin. Rather, the literature showed that mesna has no special properties other than being a bladder protectant. We accepted Dr. Tozer's evidence on this issue.

[196] Dr. Khan testified that the mesna in SAFE chemotherapy has a special nanoparticle formulation that confers antidotal effects, but he provided no further information. Dr. Khan's explanation amounted to nothing more than a claim, which does not constitute evidence for the use of SAFE chemotherapy in the treatment of cancer.

[197] As noted above, we accepted Dr. Kerbel's definition of immunotherapy, not Dr. Khan's, and found that SAFE chemotherapy is not an immunotherapy agent.

*Dr. Khan's Dataset on His Use of SAFE Chemotherapy*

[198] There are several problems with Dr. Khan's use of his own dataset as evidence for the efficacy of SAFE chemotherapy, which will be discussed with reference to specific patients. However, in summary:

- The dataset did not exist in July of 2013 when Dr. Khan began using SAFE chemotherapy. It therefore could not have served as evidence for the use of SAFE chemotherapy at the time Dr. Khan began using it on his patients.
- Dr. Khan's dataset demonstrates his confirmation bias.
- Dr. Khan's patient response conclusions on his use of SAFE chemotherapy rely on experimental unapproved and unvalidated tests (CTC, to be discussed) and Dr. Khan's own interpretation of radiology results over the interpretation, and at times in conflict with, radiology experts.
- Dr. Khan's interpretation of the clinical status of some of the patients in his dataset was at odds with other health care professionals' views.
- Apart from "yes" or "no," there was no detail provided as to the type or the timeline of any previous chemotherapy the patients received.

[199] In coming to conclusions about the cancer response in his patients, Dr. Khan modified the RECIST criteria and did not provide details on how he did so, i.e. which criteria were changed or by how much. Without details on his specific modifications of the RECIST criteria and the evidence and science to support his modifications, it would not be possible to understand or interpret Dr. Khan's

evaluation of his own results with SAFE chemotherapy within the broader context of other chemotherapies.

- [200] Additionally, for a number of his dataset conclusions, Dr. Khan used ultrasound results. RECIST criteria require the exclusion of ultrasound in formulating conclusion about treatment outcomes. A publication in the European Journal of Cancer explained that:

Ultrasound is not useful in assessment of lesion size and should not be used as a method of measurement. Ultrasound examinations cannot be reproduced in their entirety for independent review at a later date and, because they are operator dependent, it cannot be guaranteed that the same technique and measurements will be taken from one assessment to the next.

- [201] Frequently, Dr. Khan inappropriately compared study modalities such as CT, MRI and ultrasound to each other.

- [202] Further, as will be discussed, with rare exceptions, most of Dr. Khan's data showed only conclusions that supported his narrative of SAFE chemotherapy's efficacy. In his dataset conclusions, Dr. Khan disregarded glaring clinical and radiologic evidence that demonstrated that his patients' disease had progressed.

- [203] Regarding Dr. Khan's claim that SAFE chemotherapy has fewer side effects than carboplatin, for the 10 patients discussed at this hearing who were treated with SAFE chemotherapy, it appears that the majority of them experienced side effects that Dr. Khan recorded. Yet Dr. Khan did not appear to tabulate percentages of side effects formally, nor does it appear that he disclosed this information on his website or to his patients. He only communicated findings that cast SAFE chemotherapy as a successful and superior treatment option. Of significant concern is that Dr. Khan showed this dataset to patients as evidence of the efficacy of SAFE chemotherapy.

- [204] Overall, Dr. Khan's dataset conclusions reflected his opinions on his patients' responses, rather than an accurate monitoring of their cancer progress and response. His results are unverifiable, invalid and demonstrate confirmation bias. His dataset cannot serve as evidence supporting SAFE chemotherapy's efficacy on cancer, and as a person who describes himself as a scientist, Dr. Khan should

have known this. In short, we did not accept Dr. Khan's dataset as evidence of the efficacy or safety of SAFE chemotherapy.

*Dr. Khan's Use of Carboplatin as an Off-Label Therapy for Cancer*

[205] Dr. Khan defended his use of SAFE chemotherapy in part by referring to it as "off label" use of mesna and the conventional chemotherapy carboplatin, and that he could use his experience and judgment to treat patients with this combination.

[206] Dr. Khan's experience and judgment do not obviate the CAM policy's "evidence and science" requirement. To the extent that Dr. Khan's own experience and judgment were relevant to his decision to treat patients with these two drugs in an "off-label" manner, we note that:

- a) Dr. Khan did not have experience prescribing these two off-label drugs for treating cancer when he began treating patients; and
- b) Dr. Khan's subsequent experience and judgment were marred by confirmation bias and inappropriate assessments of patients' responses, as demonstrated in his SAFE chemotherapy dataset, and in his decisions to use carboplatin even when it should not have been used for an individual patient's needs.

[207] Dr. Khan's use of carboplatin as an off-label treatment for cancer is discussed below with respect to individual patients. Even if carboplatin is considered as a stand-alone, off-label medication, Dr. Khan did not appear to know how to use it, nor when carboplatin should or should not be used on various patients. He did not seem to consider how carboplatin could impact each patient individually, or how its use could expose them to the risk of harm from the known side effects and toxicities of this drug. It would seem that Dr. Khan was learning to use carboplatin on the fly while treating patients with it, and more alarming, he did not seem to learn or was ignoring evidence that SAFE chemotherapy was failing, or possibly harming his patients. Ultimately, Dr. Khan used carboplatin on patients even if it was the wrong drug to use, and further, he did so even where there were reasons to avoid doing so. Dr. Khan's use of carboplatin in the wrong manner and when it should not have been used, is not justified by calling its use "off-label."

*Dr. Khan's Argument that His Patients Were Terminal or Sophisticated Consumers of CAM*

- [208] Dr. Khan's argument that his patients were terminal or were sophisticated consumers of CAM therapies does not make sense to us. These characteristics do nothing to alter the expectation that SAFE chemotherapy should do what Dr. Khan communicated to patients it would do, and these patients did not deserve any less information than any other patient. All of Dr. Khan's patients who were on SAFE chemotherapy were taking this medication based on Dr. Khan's claims and the information he provided, and this information was clearly not based on sufficient evidence and science.
- [209] Also, the fact that a patient is a sophisticated consumer of CAM does not alleviate Dr. Khan's duties regarding informing patients of the efficacy of the treatment he was offering.
- [210] Further, as will be discussed, the fact a patient is terminal does not obviate the expectation that the patient will receive optimal treatments that are informed by evidence and science.

Summary

- [211] It is not in dispute that the College's CAM policy does not articulate how much research, trial evidence, general evidence or science must exist to support the use of a CAM therapy. However in the case of SAFE chemotherapy, it appears that the entirety of the evidence that supports it rests on the word of one man who has never published data of any kind to verify his claims.
- [212] The publicly available information presented appeared to be advertising, rather than evidentiary support for SAFE chemotherapy. Neither Dr. Khan's testimony, letters of communication between Dr. Khan and Dr. Matsumura, nor Dr. Khan's and Dr. Matsumura's websites contained any data, supportive literature or evidence regarding SAFE chemotherapy as an effective treatment for cancer. Dr. Khan and Dr. Matsumura also referred to a phase 2 FDA-approved trial that does not seem to exist.

[213] We found it frankly shocking that Dr. Khan began treating patients with SAFE chemotherapy based on what appeared to be nothing more than Dr. Matsumura's word.

[214] In response to the expert evidence tendered by the College, we had before us only Dr. Khan's personal beliefs, along with his limited and what appeared to be biased personal observations of the patients he treated with SAFE chemotherapy, to support his claims of efficacy. Dr. Matsumura's and Dr. Khan's claims or beliefs do not constitute evidence or science to support the use of SAFE chemotherapy as an effective cancer treatment that offers patients a favourable risk/benefit profile.

[215] There was no evidence before us that SAFE chemotherapy offers patients a favourable risk/benefit ratio or that it has a reasonable expectation of remedying or alleviating a patient's health condition, as is required by the College's CAM policy. Dr. Khan should not have treated his patients' cancers with SAFE chemotherapy. In his decision to do so, he repeatedly breached the CAM policy and he failed to maintain the standard of practice of the profession.

[216] Dr. Khan presented letters of gratitude he received from two patients, one of whom gave a positive review of SAFE chemotherapy. While it is heartening for a physician to receive words of praise from a patient, patient satisfaction is not a measure of treatment outcome and is not sufficient to establish the efficacy of a medication. Patient satisfaction does not obviate the requirement for scientific evidence as verification that a treatment lives up to its purported claims.

#### **Dr. Khan's Request for a Publication Ban**

[217] As noted briefly above, an issue arose during the hearing about whether Dr. Matsumura's booklet about SAFE chemotherapy should be protected from public disclosure due to its alleged confidentiality.

[218] In 2013, Dr. Khan signed a non-disclosure agreement with Dr. Matsumura, which covered allegedly proprietary information about SAFE chemotherapy.

[219] The College had been requesting information about SAFE chemotherapy from Dr. Khan since 2016. Dr. Khan testified that he had received a waiver, for the purposes of this hearing, to discuss the information in the booklet. The waiver

permitted the sharing of certain pages of the document on the basis of confidentiality.

[220] In order to allow the hearing to proceed without interruption, counsel agreed that the booklet (a redacted version of which became Exhibit 149) would not be publicly disclosed and would be discussed *in camera* (meaning that the live feed to the public would be paused). This agreement further stipulated that during closing submissions, the College could renew its argument that the booklet and the *in camera* testimony should be made available to the public. We accepted this, and made an order dated October 9, 2020:

[P]ursuant to s. 45(2) and (3) of the Code, that the public be excluded from the portion of the hearing in which there are questions about Exhibit 149, and that Exhibit 149 be prohibited from disclosure. This is without prejudice to the College being at liberty, at the close of the hearing, to renew its submission that Exhibit 149, and the questioning of witnesses about Exhibit 149, should be made part of the public record.

[221] During closing submissions, the College renewed its position that the booklet and the *in camera* session discussions pertaining to it should be made public. Dr. Khan submitted in response that the ban on disclosure should remain in place.

### Finding

[222] We conclude that the booklet and the *in camera* testimony should be made available to the public.

### Analysis

[223] Section 45 of the Code provides, in relevant part:

45 (1) A hearing shall, subject to subsection (2), be open to the public.

(2) The panel may make an order that the public be excluded from a hearing or any part of it if the panel is satisfied that, [...]

(b) financial or personal or other matters may be disclosed at the hearing of such a nature that the harm created by disclosure would outweigh the desirability of adhering to the principle that hearings be open to the public [...]

(3) In situations in which the panel may make an order that the public be excluded from a hearing, it may make orders it considers

necessary to prevent the public disclosure of matters disclosed at the hearing, including orders banning the publication or broadcasting of those matters.

- [224] Under subsection 45 (8) of the Code, the panel may “reconsider an order made under subsection (2) or (3) at the request of any person or on its own motion.”
- [225] Section 45 incorporates the open court principle into proceedings before the Tribunal. This principle requires that the public be able to access a tribunal’s proceedings and records. As stated in *Southam Inc. v. Minister of Employment and Immigration*, [1987] 3 FC 329 at para. 9 and *Toronto Star v. AG Ontario*, 2018 ONSC 2586 at para. 55, “[t]he legitimacy of such tribunals’ authority requires that confidence in their integrity and understanding of their operations be maintained, and this can be effected only if their proceedings are open to the public.”
- [226] As was stated by the Supreme Court of Canada in *R. v. Mentuck*, 2001 SCC 76 at para. 39, the presumption that the hearing should be open and its proceedings uncensored is “so strong and so valued in our society that the judge must have a convincing evidentiary basis” for making the order [to censor]. In *Canadian Broadcasting Corp. v. New Brunswick (Attorney General)*, 1996 CanLII 184 at para. 71 (SCC), the court said that the “burden of displacing the general rule of openness lies on the party making the application.” Since it is Dr. Khan who seeks to impose the ban in this case, it is Dr. Khan who bears the onus.
- [227] Publication bans made under s. 45(3) require a weighing of “harm” with the “desirability of adhering to the principle that hearings be open to the public.” This analysis should be informed by the common law test for publication bans set out by the Supreme Court in *Mentuck* and modified in *Sierra Club of Canada v. Canada (Minister of Finance)*, 2002 SCC 41. In the latter decision, the Court held that the test for making confidentiality orders was a two-stage test:
- **Necessity Stage:** At this stage, the tribunal should consider whether such an order is necessary in order to prevent a serious risk to an important interest, including a commercial interest, in the context of litigation because reasonably alternative measures will not prevent the risk; and
  - **Proportionality Stage:** At this stage, the tribunal should consider whether the salutary effects of the confidentiality order, including the effects on the right of

civil litigants to a fair trial, outweigh its deleterious effects, including the effects on the right to free expression, which in this context includes the public interest in open and accessible court proceedings.

#### a) Necessity Stage

[228] Dr. Khan did not present convincing evidence that adverse consequences would be suffered by himself or Dr. Matsumura if the booklet or the *in camera* testimony became public. We find therefore that a publication ban is not necessary.

#### *Analysis*

[229] The booklet, including Table A consisting of blood cell counts from five patients on SAFE chemotherapy, does not contain information that is specific or technical, or could be used by competitors. The document is already redacted and most of the remaining information is already public on Dr. Khan's SAFE chemotherapy webpage or is found in the various exhibits and the patient charts already made exhibits in this hearing (for example, information on dosing is contained in Dr. Khan's patient charts). Review of relevant *in camera* testimony provided no additional information that could pose a serious risk to Dr. Matsumura or Dr. Khan.

#### b) Proportionality Stage

[230] We find that the deleterious effects of granting a publication ban outweigh the salutary effects.

#### *Analysis*

[231] The salutary effects of granting a publication ban appear to be minimal, and any benefits appear to be limited to Dr. Matsumura and Dr. Khan. The deleterious effect of the Tribunal's withholding relevant information from the public, the families of Dr. Khan's deceased patients and the patients who are currently alive (who had been on SAFE chemotherapy) significantly outweighs any salutary effects of keeping this information confidential.

[232] We agree with the following excerpt from the College's written submissions in this case:

A publication ban would seriously curtail freedom of the press as it would prevent the media from examining an issue which may warrant widespread public debate on the use of, and bases for, CAM therapies. In other words, the Canadian public deserves to understand the scientific basis on which Dr. Khan was treating its members.

[233] The “evidence and science” forming the basis of SAFE chemotherapy is an issue of central importance in this hearing. We are concerned that our written reasons for decision will not be comprehensible if the reader does not have access to our findings as they refer to the booklet or Dr. Khan’s *in camera* testimony, all of which form part of our decision regarding Dr. Khan’s use of SAFE chemotherapy.

[234] Additionally, when a physician’s standard of practice is brought into question, failing to disclose all relevant information on which a decision is based would undermine the public’s confidence that this Tribunal is able to adequately scrutinize physician care. Such confidence requires not only that we inform the public about what conclusions we came to, but also demonstrate how we did so, which requires the disclosure of relevant information upon which we based our decision.

[235] A publication ban would also have the deleterious effect of depriving Dr. Khan’s patients whom he treated with SAFE chemotherapy, and their families, of all the relevant information that entered into our findings with regard to the allegations made about Dr. Khan’s care of them. Without access to all the relevant information, they may be left with unanswered questions, which may cause them to worry or feel distress about these matters.

[236] The College submitted that granting the order to ban this information would conflict with the objective of ensuring that patients give informed consent. Giving effect to a confidentiality agreement which shields the basis of a medical therapy from the public (i.e., consumers of health care) would privilege physicians’ commercial interests over the right of patients to fully understand the basis of the therapy they are receiving or that is being offered to them by a physician.

[237] Dr. Khan disagreed, stating that “the College’s concerns about the deleterious effects of granting a publication ban have been significantly exaggerated.” Counsel submitted that Dr. Khan no longer offers SAFE chemotherapy, and while patients have a right to fully understand the basis of the therapy they are

receiving, Dr. Khan does not currently have any patients on SAFE chemotherapy. Informed consent does not apply retroactively, and “the [Tribunal’s] decision to grant a publication ban can cause no harm to non-existent patients.”

[238] We agree with the College’s submission on this point. First, the booklet and its relevance to the consent process is a live issue in this hearing and does not constitute a retroactive application of informed consent. It is necessary that the evidence and science upon which Dr. Khan obtained his consents be not only analyzed fully, but also that the analysis be understood by those who read the reasons. Second, Dr. Khan’s submission on this issue misses the point. The issue is the implication for future patients, not just patients of Dr. Khan but of any physician, if the physician could, through a confidentiality agreement, withhold information from the patient about the basis of treatment. We agree that this is a valid concern and would be an additional deleterious effect of ordering the publication ban Dr. Khan seeks.

[239] Dr. Khan also asserted that clinical trials are run by pharmaceutical companies with an interest in protecting their intellectual property, and that patients are not entitled to these companies’ sensitive commercial information, nor are they entitled to the clinical trial data on each patient treated with a particular novel therapy.

[240] We were not persuaded by this argument. As noted above, we are satisfied that the booklet and the *in camera* testimony did not contain sensitive commercial information or intellectual property. Furthermore, we were provided with no evidence that there actually was a clinical trial of SAFE chemotherapy.

### *Conclusion*

[241] The open court principle applies to hearings before this Tribunal. The burden to demonstrate that a publication ban is necessary is on Dr. Khan. He failed to do so. Further, the numerous deleterious effects of granting a publication ban greatly outweigh any salutary effects of doing so.

## Standard of Practice of the Profession - Dr. Khan's Use of Dichloroacetate (DCA)

[242] DCA is a medication that Dr. Khan provided to his adult patients as a cancer treatment, and to the pediatric patient A, who had a brain cancer called medulloblastoma.

### *What is DCA?*

[243] Dr. Kerbel testified that DCA is a drug that can be taken orally. It has been used to treat acquired and congenital forms of mitochondrial diseases, including acidosis and lactic acidosis, in children. DCA is known to interfere with some of the major pathways that are involved in the generation of energy from glucose molecules. It has been studied for a long time and has been used in humans for diseases other than cancer, and now more recently for cancer itself.

### *What Does DCA Do?*

[244] DCA impacts cellular metabolism of glucose. Dr. Kerbel explained that cells derive their energy by the metabolism, or breakdown, of glucose molecules into adenosine triphosphate molecules (ATP). There are two major pathways by which this occurs: 1. oxidative phosphorylation and 2. glycolysis (glycolytic pathway).

[245] Oxidative phosphorylation occurs within intracellular organelles called mitochondria. This pathway is dependent on oxygen supply, which makes it an aerobic pathway. It is a highly efficient process and is normally used by cells.

[246] By contrast, glycolysis is a less efficient process. It is thought to be an adaptive pathway that breaks down glucose when there is a relative lack of oxygen, and it is therefore an anaerobic pathway. This process takes place in the cytoplasm (within the liquid of cells).

[247] Cells are able to switch between these two pathways depending on the availability of oxygen. Although the end product of both pathways is ATP,<sup>4</sup> the preferential

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<sup>4</sup> The metabolism of 1 molecule of glucose via the oxidative phosphorylation pathway yields 36 APT molecules. The metabolism of 1 molecule of glucose via the glycolytic pathway yields 2 (sometimes 4) ATP molecules.

pathway of healthy cells is the oxygen-dependent and highly efficient oxidative phosphorylation.

[248] DCA appears to shift cellular metabolism towards the oxidative phosphorylation pathway.

*What is the Implication of DCA in Cancer Therapy?*

[249] In his 2020 report, Dr. Kerbel stated that although DCA has been studied and used clinically for decades in metabolic disease, with respect to cancer, he referred to DCA as a prototype of a new class of drugs called “metabolic inhibitors” used to shift cellular metabolism.

[250] Cancer cells also break down glucose for their high energy demands. However, despite being highly proliferative, motile and active, which would lead one to suspect that cancer cells would use the most efficient method to break down glucose, cancer cells (unlike healthy normal cells) typically use the less efficient oxygen-sparing glycolytic pathway,<sup>5</sup> even in the presence of abundant oxygen.

[251] There is significant research focused on establishing why cancer cells prefer the glycolytic pathway. One theory suggests that lactic acid, the by-product of this pathway, causes a more acidic environment in which cancer cells may become more locally invasive and metastatic. Additionally, it is thought that this acidity confers resistance to many kinds of therapies.

[252] Theoretically, if a drug could make cancer cells switch from the acid-producing glycolytic pathway to the oxygen-dependent oxidative phosphorylation pathway, one could possibly decrease the cancer’s malignant aggressiveness and increase therapeutic responsiveness. It was thought that DCA could possibly induce this pathway shift to oxidative phosphorylation in cancer cells.

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<sup>5</sup> Dr. Otto Warburg won a Nobel Prize for this discovery.

### *What Does the Research Show?*

[253] For the purposes of this section, research discussions will be focused on studies presented at this hearing or those in Dr. Khan's oral or written communications to patients.

### *Pre-Clinical Research*

[254] In 2007, a group of researchers in Alberta published a paper in a medical journal called *Science Translational Medicine*. They demonstrated the metabolic shift from the glycolytic pathway to the oxidative phosphorylation pathway for the first time in mouse tumour cell tissue *in vitro*.

[255] This study showed increased cell death in DCA-treated tumour cells. The study authors considered a number of mechanisms to explain this.

[256] Other pre-clinical research, consisting mostly of mouse tumour therapy trials and the aforementioned study, also showed promising potential benefits for treating cancer with DCA, particularly in conjunction with other therapies.

[257] Dr. Kerbel explained that in cancer, there is a theory that within a tumour mass there is a minority sub-population of cells, referred to as cancer stem cells, that have properties that make them highly resistant to most anti-cancer therapies. While treatments can kill the bulk of the cancer, thereby causing tumour shrinkage, what is left behind is a tumour with an enriched population of cancer stem cells that are resistant to therapy. These cells can quickly regenerate the tumour mass. There has been interest in finding properties of cancer stem cells that can make them vulnerable to therapies. In his 2020 report, Dr. Kerbel referenced a 2017 study<sup>6</sup> that demonstrated that DCA increased the sensitivity of medulloblastoma stem-like cells to radiation and that it altered other stem cell characteristics that contributed to metastatic disease.

[258] However, the authors of this study stated, "it has been pointed out that cancer cell metabolism is different between *in vivo* tumors and *in vitro* cell lines."

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<sup>6</sup> Metabolic analysis of radioresistant medulloblastoma stem-like clones and potential therapeutic targets.

[259] In her testimony, Dr. Johnston stated that this study did not provide evidence and science for the use of DCA as a monotherapy for the treatment of a pediatric patient with medulloblastoma.

[260] In his review of the pre-clinical research into DCA, which mostly consisted of mice tumour therapy studies, Dr. Kerbel stated that one could draw three conclusions about DCA therapy in cancer:

DCA monotherapy has a therapeutic benefit in most of the pre-clinical models that have been published; [...]

combining it with another therapeutic, either a standard of care chemotherapy drug or a targeted therapy resulted in a benefit that was greater than either drug alone; [...]

in a number of cases, the DCA treatment control, monotherapy control was as good or better than the standard of care.

[261] Dr. Kerbel clarified that this was a preliminary “somewhat speculative” conclusion. To show that DCA therapy was in fact better than standard of care therapy or an investigational agent, one would need to do further research. However, he stated that there was a trend that showed that DCA monotherapy did have an anti-tumour effect at the doses and schedules used in the studies.

[262] On cross-examination, Dr. Kerbel agreed that one of the challenges with cancer research is that many promising therapies that show anti-cancer activity (or lack of toxicity in terms of side effects) in pre-clinical stage trials, or in animals, do not successfully demonstrate drug efficacy, or non-toxicity, in human trials. Dr. Kerbel described some of the various reasons for this. They include:

- There is discordance in toxicities between mice and human patients, such that toxicities and adverse events that were minor or not present in mice, are found to be severe in humans. This can in part be explained by the fact that certain elements (such as changes in bloodwork, suggesting myelosuppression and weight loss) may be relatively easy to detect in mice; however, other elements such as fatigue, headache, hearing loss and others are difficult to detect in a mouse.

- Additionally, results using the mouse model in which mice with primary cancers are the test subjects may not translate into humans with metastatic cancers.

[263] In his 2016 report, Dr. Kerbel noted that overall, randomized clinical trials have a high failure rate even when the background science seems strong.

[264] Additionally, Dr. Kerbel explained that clinical research is enormously expensive. He opined that with a drug such as DCA, unless pharmaceutical or biotech companies can be assured of rights over intellectual property, they would likely not undertake the expense of clinical trial research.

[265] The College's expert Dr. Tozer had similar views on DCA. He stated that DCA was like some other drugs that showed potential as effective anti-cancer medication at the pre-clinical phase and in some animal models, but that the potential was not realized. Dr. Tozer was unable to find studies that demonstrated that DCA had anti-cancer effects in humans. He testified that DCA could lead to peripheral neuropathy and numbness and tingling in fingers and toes.

### *Clinical Research*

[266] There have been two phase 2 clinical trials and one phase 2 clinical trial of DCA, along with a small number of case studies.

[267] To examine potential efficacy in treating cancer in humans, in 2010, the Alberta team conducted a limited pilot clinical trial<sup>7</sup> in which they administered DCA to five adult patients with glioblastoma, a brain cancer which is almost universally lethal in its later stages. These patients had been initially treated with standard therapy including surgery, radiation and a medication called temozolomide, an agent that is able to cross the blood-brain barrier. The authors noted some tumour regression based on RECIST criteria and interpreted this as possibly being an argument to undertake further studies on the use of DCA for treating glioblastoma.

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<sup>7</sup> Metabolic Modulation of Glioblastoma with Dichloroacetate

- [268] However, both the Alberta authors themselves and Dr. Kerbel offered the caveat that the effects observed in the study could also have been explained by the other treatments the patients had received (temozolomide and radiation). The authors stated, “[w]ith the small number of treated patients in our study, no firm conclusions regarding DCA as a therapy for GBM [glioblastoma] can be made.” Dr. Johnston, who also reviewed this study, concluded that the study did not provide conclusions on tumour response.
- [269] In a phase 1 study,<sup>8</sup> Dr. Chu and colleagues looked at DCA tolerance and safety in adults. DCA was given to 23 adults who had confirmed treatment-refractory advanced solid tumours of different cancers, none of which included brain cancers. Unlike A, a young boy whose treatment was a subject of this hearing, all the adults were considered to be heavily pre-treated with other therapies for their diseases. None of the 23 patients had RECIST-defined responses to DCA, but eight of 23 were noted to have stable disease. In their analysis, the authors concluded, “it is unlikely DCA will show efficacy as a single agent and, if clinical development continues, combination regimens, utilizing the research from recently published mechanistic studies, should be evaluated in dose-finding and toxicity studies.”
- [270] Dr. Johnston pointed out that most of the patients in this study had progressive disease, and for the group that had a brief stabilization of disease (an average of six weeks), it would be difficult to conclude whether the stabilization that was documented could be attributed to DCA, or to the prior therapy that these patients had received.
- [271] In another phase 1 study<sup>9</sup> by Dr. Dunbar and colleagues published in 2015, DCA was given to 15 patients with brain cancers, all of whom, unlike A, were adults and had been pre-treated with radiation and/or chemotherapy. The authors found that, although the trial could not “provide definitive information on efficacy,” DCA was safe, well-tolerated and feasible for use in adults with recurrent malignant

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<sup>8</sup> A phase 1 open-labeled, single-arm, dose-escalation, study of dichloroacetate (DCA) in patients with advanced solid tumours

<sup>9</sup> Phase 1 trial of dichloroacetate (DCA) in adults with recurrent malignant brain tumors”

brain tumours. Additionally, they noted that there was disease stabilization in all eight evaluable patients, and that these results were consistent with early data in glioblastoma patients and experimental evidence for a metabolic modulation and selective killing of central nervous system (CNS) cancers.

[272] Dr. Johnston agreed with the authors that the study could not prove efficacy for DCA, and she commented again that any stabilization effect noted could be attributed to prior treatments received by the patients.

[273] In a small phase 2 clinical trial<sup>10</sup> by Dr. Garon, Dr. Slamon and colleagues, DCA was given to seven patients with refractory lung and breast cancer. All the patients had been pre-treated with other therapies. The authors stated, “our study demonstrated no clinical improvement in seven subjects with advanced stage cancers treated with DCA.”

#### *Current Understanding of DCA Efficacy on Cancer*

[274] Dr. Kerbel confirmed that at this point, the clinical evidence regarding DCA efficacy is quite limited, although he added that “[b]y definition, if you have a small number of trials with a small number of patients, that would be the case.”

[275] He also confirmed that he could not find any clinical evidence regarding the use of DCA in a pediatric patient with medulloblastoma.

#### *Is DCA an Immune Therapy Checkpoint Inhibiting Drug or Immunotherapy?*

[276] Dr. Khan testified that “there is new literature that shows that DCA in fact does cause [inflammation] and causes immune response against cancer.”

[277] However, Dr. Khan did not place this literature into evidence, and neither Dr. Kerbel nor Dr. Johnston concluded that DCA is an immunotherapy (Dr. Kerbel postulated that some of the effects of DCA may be mediated through an effect on boosting or elevating the efficacy of the immune system to recognize cancer

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<sup>10</sup> “Dichloroacetate should be considered with platinum-based chemotherapy in hypoxic tumors rather than a single agent in advanced non-small cell lung cancer.”

cells). As set out above, Dr. Kerbel referred to DCA as a prototype of a relatively new class of drug called a “metabolic inhibitor.”

*What Did Dr. Khan Claim DCA Can Do?*

[278] In his handout to patients providing information concerning DCA frequently asked questions (FAQ), Dr. Khan referred to the same 2010 Alberta study discussed above. The handout stated “DCA research has accelerated in the last few years. The latest research shows the DCA kills many types of cancer cells...the first formal human cancer research using DCA was published in May 2010. This small study confirmed that DCA is an effective anti-cancer drug for treating glioblastoma patients.” As set out above, this is not what the authors concluded. The authors’ statement that “no firm conclusions regarding DCA as a therapy for GBM [glioblastoma] can be made” stands in direct opposition to the claims Dr. Khan made in his handout.

[279] Dr. Khan’s FAQ section went on to discuss what types of cancers DCA works on, and stated:

Several publications demonstrate that DCA works in a variety of cancers. These include human studies, case reports and lab studies (rat and *in vitro*). The cancer types studied so far are: colon, breast, prostate, ovarian, gastric, brain (neuroblastoma), brain (glioblastoma), lung (carcinoid), uterus (cervix), uterus (cervix), uterus (endometrial), melanoma (including BRAF V600E mutation), lymphoma (non-Hodgkin’s), sarcoma, multiple myeloma and cancer of unknown primary. In our experience, DCA may work on any cancer type, including various rare tumours.

[280] Dr. Johnston testified that based on her review of the literature, this statement is not accurate, and that there is no evidence that DCA may work on any cancer type.

[281] In his testimony, Dr. Kerbel agreed that “cancer cells have [a] tremendous heterogeneity.” He acknowledged that it is “almost universally true” that new cancer therapies will work with some types of cancer but not all.” Avastin and Taxol are two examples of such drugs. He said “[y]ou can take almost any drug” with properties that in principle should work on all cancer cells (due to certain common elements between them), but they do not prove to do so.

[282] In the same information handout, Dr. Khan referred to two of his own publications on the use of DCA to treat cancer, one of which he claimed shows that “DCA can enhance radiation to achieve remarkable results in stage 4 cancer.” Dr. Johnston testified that these were case studies looking at melanoma and colon cancer, and that “on reading the papers, it became evident that they did not appear to be of high-quality calibre, and I questioned how they made it through peer review.” She noted that both journals in which Dr. Khan published his case studies were predatory journals, meaning one pays a fee to have their articles published. However, Dr. Kerbel expressed the opinion that the papers were “actually quite good. They were very thorough.” Dr. Kerbel also stated that the journal that published Dr. Khan’s articles is, in his opinion, one that abides by accepted peer review and publishing standards. He noted that even high quality, well-respected journals charge large sums of money for publication.

[283] Although Dr. Khan’s DCA FAQ sheet states, “we are focusing our efforts on publishing our findings in reputable peer-reviewed medical journals,” he placed no evidence before us that he had done so.

#### *Use of DCA in Pediatric Patients with Medulloblastoma*

[284] Dr. Khan provided A’s parents with the information from his FAQ fact sheet, after which he recommended and prescribed DCA for their child. A had been diagnosed with group 4 medulloblastoma which was considered to be high-risk due to metastatic spread to the spinal cord.

[285] Dr. Johnston testified that, apart from the single common element that both are in the brain, glioblastoma and medulloblastoma are different cancers, which are treated differently from each other. She further testified that Dr. Khan’s therapeutic recommendation to treat a pediatric patient with medulloblastoma with DCA was not informed by evidence and science.

[286] On the same topic, Dr. Kerbel testified that he was unaware of any clinical evidence regarding the efficacy of DCA with a pediatric patient suffering from a medulloblastoma. He also agreed that there is not enough data or clinical evidence to show that, for a specific pediatric patient suffering from medulloblastoma, DCA would have a reasonable expectation of remedying or alleviating that patient’s health conditions or symptoms.

[287] Dr. Khan led some evidence about the use of DCA at the OICC (the clinic in Ottawa that the naturopathic doctor Dr. Seely runs, with whom Dr. Johnston regularly collaborates). We accepted Mr. Dunlop's testimony that the OICC clinic documents he obtained and the OICC website, establish that OICC offers DCA therapy. However, the patient age range and clinical conditions for which DCA would be considered by the practitioners at this clinic were not established, and we gave no weight to these specifics on the use of DCA at OICC.

[288] Overall, we found the evidence about the use of DCA at the OICC to be of minimal assistance in the matter before us and we gave it little weight. It did not serve to establish any scientific bases for the use of DCA in cancer treatment, nor for which conditions, cancers and patient populations it may be efficacious.

### *Finding*

[289] Although it appears that published science does not yet support Dr. Khan's recommendation of the use of DCA for the treatment of cancer patients, there is a body of research and experience that may support consideration of its use in some cancers. We do not find that Dr. Khan failed to maintain the standard of practice by using DCA on his adult patients based solely on the evidence and science informing the use of DCA in cancer cases. We will make our findings on Dr. Khan's use of DCA during his care of adult patients within the context of individual patients.

[290] We find that evidence and science are not sufficient to support the use of DCA to treat pediatric medulloblastoma, and that Dr. Khan failed to maintain the standard of practice of the profession when he used DCA to treat A's condition. This will be discussed in the section on A.

### *Analysis*

[291] Dr. Johnston and Dr. Kerbel agree that there is no clinical evidence that there would be a reasonable expectation that DCA would remedy or alleviate a pediatric medulloblastoma patient's health conditions or symptoms.

[292] Most of the published literature on DCA has been conducted at the pre-clinical stage. When studied in petri dishes, test tubes and on mice, some of the pre-clinical research has shown promising results, suggesting that DCA may have

anti-cancer properties when used as a monotherapy or in combination with other cancer therapies. However, further research is necessary to establish if these properties will translate into effective treatments for people suffering from cancer.

[293] For numerous reasons, many of which were discussed by Dr. Khan's own expert witness Dr. Kerbel, few medications with strong efficacy potential demonstrated at the pre-clinical stage go on to become effective anti-cancer treatments in humans. Further, there has been little clinical research on the efficacy of DCA to treat cancer in humans. As set out above, the phase 1 and phase 2 clinical studies reviewed during this hearing did not clearly demonstrate anti-cancer effects that could be attributed to DCA.

[294] The evidence did not demonstrate that DCA could work on pediatric medulloblastoma, particularly of the type diagnosed in A. Again, this will be discussed in more detail below, in the section of the reasons dealing with Dr. Khan's care and treatment of A.

### **c) Standard of Practice - Informed Consent**

[295] In this section of the reasons, we address whether Dr. Khan failed to maintain the standard of practice of the profession by failing to obtain informed consent from his patients.

[296] As stated in the CAM policy, patients have a right to make their own health care decisions, including the decision to pursue complementary/alternative medicine. These rights are also clearly articulated in the Consent to Treatment policy, which states that "[p]atient autonomy and respect for personal dignity are central to the provision of ethically sound care. In order to exercise their autonomy, patients have the moral and legal right to make decisions regarding their treatment..."

[297] The CAM policy directs that, among other things, physicians must:

- respect patient autonomy with respect to health care goals and treatment decisions; and
- communicate effectively and openly with patients and others involved in the provision of health care.

- [298] The CAM policy states as a specific expectation for physician conduct that physicians must always have a valid informed consent to authorize therapeutic intervention, in accordance with the legal and policy requirements set out in the *Health Care Consent Act, 1996*, SO 1996, c. 2, Schedule A and the Consent to Treatment policy.
- [299] Both the informed consent provisions of the CAM policy and the provisions of the Consent to Treatment policy, were set out above in the “Background Information” section of these reasons, and they need not be repeated here.
- [300] We do not question the decisions or autonomy of Dr. Khan’s patients. The issue is whether Dr. Khan provided his patients with the information necessary for them to make informed choices about which therapies they wished to accept or decline.
- [301] When addressing this question, we consider the quality, in terms of both adequacy and accuracy, of the information Dr. Khan communicated to his patients.

i) Did Dr. Khan Obtain Informed Consent from His Patients?

*Information Provided to Patients*

- [302] Dr. Khan provided patients with information about his treatments through both written (including websites and consent forms) and oral communications. He directed patients towards his Medicor website, and for patients considering SAFE chemotherapy, to Dr. Matsumura’s website, the contents of which were laid out in the SAFE chemotherapy section of these reasons. Through these means, patients learned about the purported benefits of Dr. Khan’s therapies.
- [303] With regard to SAFE chemotherapy, Dr. Khan provided written information including:
- Dr. Khan’s website which:
    - referred to SAFE chemotherapy as “life-saving therapy” and stated that “complete remission is possible” even with stage 4 cancers;
    - referred to Dr. Matsumura’s alleged up to 90% response rate for his first four patients;

- stated that “For our first 20 patients (almost all stage 4 cancers, various types including rare tumours and those that typically respond poorly to chemo), our overall response rate was over 80% using modified RECIST definitions.” He explained that this increased to 90% with statistical adjustment;
- referred to Dr. Khan’s own dataset, describing the results of his SAFE chemotherapy patients with a response rate of 81%.<sup>11</sup> As discussed in the SAFE chemotherapy section above, Dr. Khan’s dataset was not found to constitute evidence or science for the use of SAFE chemotherapy;
- explained that “since the data is preliminary (small patient numbers), direct comparison to published chemo response rates, as determined by large clinical trials, is not entirely fair”;
- stated that SAFE chemotherapy is “not just ‘chemotherapy,’ rather it is ‘chemo-immunotherapy,’ with the patient’s own immune system contributing a large percentage of cancer cell kill”;
- stated that “most oncologists have never used any therapy that is similar to SEF chemotherapy, and therefore are not in a good position to make adverse judgments against this therapy.” The site went on to tell patients what to ask their oncologist if they were skeptical of SAFE chemotherapy;
- referred to Dr. Matsumura’s clinical trial, which he stated the FDA-approved after a “record review time”; and
- addressed oncologists’ skepticism due to a lack of published data by explaining that Dr. Matsumura decided not to publish his data and that the reasons are too long to go into in detail.

[304] Dr. Khan’s SAFE chemotherapy consent form, which included:

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<sup>11</sup> Dr. Khan’s SAFE Dataset was prepared for the College in 2017, but was created earlier.

- that with regard to SAFE chemotherapy's chances of causing cancer remission, early data indicate that "the likelihood is substantially greater than conventional chemotherapy and with less side effects";
- that mesna will protect the patient's healthy cells from the chemotherapy to prevent or reduce side effects; and
- that the results of the phase 2 clinical trial of SAFE chemotherapy showed substantial reduction in the side effects of chemo agent carboplatin.

#### *Dr. Matsumura's Website*

[305] Dr. Khan also testified that he directed patients to Dr. Matsumura's website. In addition to what we referred to in the SAFE chemotherapy section of these reasons, Dr. Matsumura also estimated on his website that with SAFE chemotherapy, 90% of oncologists will no longer be needed, and that he "could cure advanced animal cancers with just two high dose chemo injections, used in combination with my breakthrough antidote to protect normal cells in the gut and the marrow."

#### *Oral Communications to Patients*

[306] Dr. Khan testified that in his general discussion with patients about SAFE chemotherapy, he told them:

...[T]his is a promising novel therapy, it is an off-label therapy, unapproved...the evidence for it is based on limited human data as well as lab research, and it is using drugs that are approved by Health Canada but in an off-label manner. We discussed the safety of it, the idea of the—how the mesna works to protect the body against the side effects...the expected benefits, which is quality of life, reduction of the cancer, up to and including remission, which is uncommon but possible, and reduction of symptoms.

[307] Dr. Khan testified that he understood his obligation was to ensure that patients had "a realistic understanding of their illness and a realistic understanding of what the treatments can do," and that it was his obligation to "give [patients] facts," but that he did not want to take away their hope.

[308] Dr. Khan confirmed in his testimony that he communicated the information he had received from Dr. Matsumura to his SAFE chemotherapy patients, and that this

would have included the claim that long-term remission had been achieved in Dr. Matsumura's first four consecutive patients receiving the treatment.

[309] Dr. Khan explained that although he did not tell patients that "cure" was possible, he told them that SAFE chemotherapy was "life-saving" and that it could obtain remission.

[310] As laid out in the SAFE chemotherapy section of these reasons, the messaging that the data indicated a patient's likelihood of "shrinking of cancer, or remission" using SAFE chemotherapy was "1. substantially greater than conventional chemotherapy and 2. with less side effects," was not supported by evidence and science. SAFE chemotherapy had not been shown to do what Dr. Khan claimed, and the mesna in SAFE chemotherapy had not been shown to protect patients from the known side effects and toxicities of the carboplatin. There was also no evidence to support the claim that SAFE chemotherapy was a "chemo-immunotherapy" which allowed patients' own immune system to contribute to a large portion of the cancer kill. Communicating to patients that SAFE chemotherapy could accomplish such results was not only inaccurate but was also an exaggeration of its potential.

[311] Some patients came to Dr. Khan specifically because they wished to avoid conventional chemotherapies for various reasons such as their side effects or toxicity profiles, or because (after conventional chemotherapy had failed) they asked him for therapy that was more aggressive than conventional chemotherapy. Yet Dr. Khan simply gave these patients the conventional chemotherapy, carboplatin, along with the bladder protectant mesna, without telling them that there was no evidence to support his claims that carboplatin and mesna in combination as SAFE chemotherapy had a better side effect profile than conventional chemotherapy or was any more aggressive.

#### Palliative Care, Indications of Patient Understanding, and Communication with Other Physicians

[312] The College alleges that Dr. Khan was leading patients to believe he was providing them with aggressive treatment to bring about remission of their cancer and communicated this to them. However, Dr. Khan contends he was providing palliative care and that his patients understood this.

- [313] Dr. Khan's patient records do not contain any notes suggesting that he told his patients they were palliative, nor any documentation of discussions with his patients about prognosis or end of life care and planning. This was also observed by Dr. Tozer.
- [314] In his testimony, Dr. Khan defined palliative care as "anything that is not curative," and "not associated with any prognosis." He also said that "remission still falls within the definition of palliative because remission is not a cure."
- [315] Dr. Khan testified that cure was "a very difficult definition." He acknowledged that "even though some people might define 'cure' as remission beyond five years, there are plenty of patients that recur at six or seven years. So I don't necessarily agree with that definition...For me, a cure would be that the patient has to be long-term remission and off therapy for a long term, and even then, it could still recur." Dr. Khan did not say what he meant by long term.
- [316] It is unclear to us what Dr. Khan means when he uses the word "remission," which therapeutic endpoints in a patient's clinical status Dr. Khan uses to define "remission" or for how long this clinical status must endure to be called "remission." According to Dr. Khan's personal definition, cure is long-term remission, and yet remission falls within his definition of palliative (or palliation), thereby allowing palliation to overlap with cure.
- [317] The definitions used by Dr. Khan are broad enough to allow him to shift from one meaning to another, depending on his audience and their level of scrutiny of his statements. Dr. Khan's definitions of palliative care, remission and cure are so broad, in fact, that they render the words almost meaningless.
- [318] OHIP defines palliative care as "care provided to a terminally ill patient in the final year of life where the decision has been made that there will be no aggressive treatment of the underlying disease and care is to be directed to maintaining the comfort of the patient until death occurs."
- [319] By Dr. Khan's personal definition of palliative care, treating a patient with an aggressive chemotherapy to obtain remission would be palliative care, but this is not consistent with the OHIP definition of palliative care. Nor is it consistent with palliative care as described by Dr. Tozer, which is about trying to provide relief

from pain and various symptoms and improving quality of life. We accepted OHIP's and Dr. Tozer's definitions of palliative care.

- [320] Dr. Khan's communications with various physicians, patients and families show what his real goals of care were for his patients. It is evident that in a number of cases, his goals of care were not palliative and were in fact either focused on remission or cure.
- [321] Regarding Patient C, in a letter dated July 3, 2014, to her physician Dr. Sandhu, Dr. Khan objected to treating Ms. C as purely palliative because "this wonderful lady was headed for remission."
- [322] In a letter dated January 15, 2014, to Patient B's physician Dr. Stewart, Dr. Khan described SAFE chemotherapy as having a "good chance of leading to remission of stage 3 and stage 4 cancers of all types."
- [323] In a letter dated June 13, 2014, to Dr. Kis, Patient I's neurosurgeon, Dr. Khan referred to SAFE chemotherapy as a "potentially curative therapy" and stated that "[i]t has good potential to induce remission or even cure in stage 3 and stage 4 cancers."
- [324] Dr. Khan testified that when he was speaking with his patients, he did not use the same terminology as he used when communicating with other physicians because a doctor "would understand the difference between patients that are potentially curable and other patients that are not based on disease and other factors whereas a patient could easily misconstrue that." He denied that he told patients he could cure them. However, Patient D's physician, Dr. Trinkaus reported that Ms. D told her that the response rate for SAFE chemotherapy would be as high as 80%, whereas the conventional treatment Dr. Trinkaus was providing was "not for cure." Although Dr. Khan denied telling D that SAFE chemotherapy was curative, his December 20, 2013, email to Dr. Matsumura discussing a billing inquiry by the family states "she needs to show more respect to your team, who is giving her mother a chance of cure."
- [325] Dr. Khan's definitions appear to conflict with each other. When not under scrutiny, in his own practice and interactions with his patients and their physicians, Dr. Khan did not voluntarily disclose which definition he was using. He used one

meaning while his audience or stakeholder could reasonably assume another. It would seem that Dr. Khan told patients that remission is possible. A patient would have no way of knowing that Dr. Khan was using non-standard definitions of these terms. None of the communications such as Dr. Khan's website, consent forms or his discussions with patients clarify the matter.

[326] One would expect that a patient, and more specifically, a dying person, would reasonably understand the word remission to mean that SAFE chemotherapy could reverse their terminal condition and save their life. Dr. Khan confirmed this notion by telling them that indeed, SAFE chemotherapy was a "life-saving" therapy that put people, even with advanced cancers, into long-term remission.

[327] By contrast, at this hearing when Dr. Khan was challenged on using a treatment that had not been shown to provide the benefits he claimed, Dr. Khan shifted to another definition and testified that putting a patient into remission is a form of palliation.

[328] We do not consider this to be an open and honest way to communicate with patients, physicians nor with us. Dr. Khan should have discussed his treatments in the context of established definitions, and more importantly, Dr. Khan had a duty to ensure that his patients understood their goals of care and the potential limitations of his treatments based on reasonable definitions, not Dr. Khan's personal views and definitions. Dr. Khan failed in this duty.

[329] Dr. Khan's Medicor consent form for SAFE chemotherapy explicitly required that his patients acknowledge that:

I understand that instead of SAFE Chemo®, I have a choice to receive no treatment for my cancer, and that I have the option of receiving only comfort care (palliative care).

[330] By acknowledging that patients had this choice, Dr. Khan's consent form thus indicated that SAFE chemotherapy was something different from palliative care. According to Dr. Khan's own documentation, when patients consented to SAFE chemotherapy, they were actively declining palliative care.

[331] In summary, we find that in providing SAFE chemotherapy to patients, Dr. Khan was not providing palliative care. Moreover, we do not believe that Dr. Khan

communicated differently with physicians as compared to his patients as he claimed to do, nor do we believe that he told his patients, when he was proposing that they use SAFE chemotherapy, that he would be providing them with palliative care. We find that despite his testimony to the contrary, Dr. Khan 1. was attempting to induce remission or cure in his patients, and 2. communicated to patients, their families and their physicians, that with the use of SAFE chemotherapy, patients' lives could be saved. Whether he used the word "cure" or not, he failed to ensure that his patients understood the limitations of the therapy he was offering or that they were being palliated.

- [332] For patients who had previously been told by their conventional physicians that they had only conventional palliative options, Dr. Khan's narrative likely resembled a lifeline that SAFE chemotherapy was superior to the conventional therapies their other doctors offered them and was distinctly different than palliative options, so they needed to acknowledge that he was not providing them palliative care to receive it.

#### ii) Dr. Khan's Evidence about Consent Discussions

- [333] Any clarifications of the merits and limitations of the medications he prescribed would have to have been provided by Dr. Khan to patients during a robust consent discussion. To obtain informed consent for therapy, physicians practising alternative or complementary medicine are required by the CAM policy, as set out above, to provide key information to the patient and to document the discussion in the patient record.
- [334] Dr. Khan testified that he had a consent discussion with each of his patients that included a discussion of conventional treatment options. He stated that he gave patients the facts and ensured they had a clear understanding of what was an expected benefit. He ensured that they understood the limitations of the therapy he was offering. He testified that consent conversations included the percentages of the outcomes of various therapies and how they compared to each other.
- [335] Dr. Khan testified that he was able to make the comparison between standard therapies and SAFE chemotherapy based on the data he had, even in the absence of phase 3 clinical trial information about SAFE chemotherapy. He explained that under the CAM policy, he did not need to have a clinical trial to

make the comparison, and that if he had phase 3 clinical trial information for SAFE chemotherapy, it would no longer be an alternative treatment but by definition would become a conventional treatment.

- [336] On this latter point, we observe that under the CAM policy, Dr. Khan's treatments had to be informed by evidence and science, meaning that there had to be a scientific basis for the therapies and evidence of their efficacy. Further, the evidence and science had to be sufficient to support all the other determinations he was required to make under the CAM policy.

#### Dr. Khan's Checkboxes as Evidence for the Required Discussions with Patients

- [337] Dr. Khan's notes show checked boxes beside the typed statement "Review of R + B [risks and benefits] of change(s) in treatment plans." He pointed to these checked boxes as documentation of his having had the requisite consent discussions with his patients.
- [338] However, the notes do not show any documentation of discussions with patients comparing the risks and benefits of conventional chemotherapy to those of SAFE chemotherapy, DCA, LDN or the other treatments he was offering, nor of how conventional therapy compared to his treatments. His documentation only shows claims about the benefits of his treatments. Dr. Khan did not record in his notes which conventional chemotherapies that could treat the patients' cancer were discussed, or the risks or benefits or the potential of these risks or benefits occurring with conventional chemotherapies as compared to the therapies he was offering his patients. Although Dr. Khan's consent forms for both DCA and SAFE chemotherapy contained lists of risks and benefits, what is written on a consent form is not an adequate substitute for a robust risk vs. benefits discussion with the patient, in which the physician can confirm that the patient fully understands what they are being told.
- [339] We are not satisfied that Dr. Khan's checkmark was adequate proof of the required discussion with patients, and we do not accept Dr. Khan's evidence that he had such discussions. Had such discussions taken place, we would have expected there to be a more detailed account in the records of what was said.

## *Patient Autonomy*

[340] The College's CAM policy states that patients have the right to make health care decisions that accord with their own values, wishes and preferences and that this includes decisions to pursue complementary/alternative medicine.

[341] Dr. Khan made several points about his patients' right to use CAM, and his patients' understanding based on informed consent around the use and goals of therapy.

[342] Dr. Khan submitted that his patients were either terminal, were educated consumers of CAM, had experience with conventional therapy or specifically did not want conventional therapy. There are several issues with this line of argument:

- The fact a patient may be "educated" does not relieve the physician from the obligation to conduct a rigorous consent discussion with the patient. Even an "educated" patient cannot be expected to assess the quality of information that they may have independently obtained.
- The fact a patient wants the therapy does not alleviate Dr. Khan from his duty of providing only those therapies that met the requirements of the CAM policy. SAFE chemotherapy did not meet these requirements, and Dr. Khan did not inform his patients of this.
- Physicians are required to provide all patients with accurate information about proposed therapies. Patients in the terminal stages of their illnesses are no exception and it is unclear to us why this group of patients would be singled out or how a patient's terminal status would justify Dr. Khan's failure to provide accurate information about his proposed therapy.
- Prior conventional treatment does not ensure that a patient is well-informed about the treatments they have received, nor how the prior treatments would compare to future treatments being proposed. Clinical conditions can change, necessitating an alteration of the indicated therapies. Furthermore, the information provided by previous physicians may be forgotten by patients.

- [343] None of these situations diminishes a physician's duty to provide accurate, unexaggerated and thorough information to a patient. Only by providing accurate information themselves, and ensuring that it is understood, can a physician be confident that key information a patient will use to make decisions has been properly communicated. A patient's mindset, their experience with CAM or conventional therapies, their terminal state and their wishes to receive or not receive various forms of therapy should not be expected to alter the physician's role in the provision of quality information for their patient's decision-making. Dr. Khan's arguments shift the burden of information acquisition and analysis from the physician to the patient and imply that the rights of a dying person to access the best information and health care possible can be dismissed because they are going to die regardless.
- [344] Dr. Khan also submitted that patient autonomy extends to a patient's right to choose extreme treatments that may cause them harm despite the lack of evidence of active disease. Examples provided included women who on the basis only of positive genetic tests for the potential of cancer, with no evidence of active disease, take on harm by having physicians remove their breasts in a double mastectomy, or their ovaries in an oophorectomy. Another example was patients who choose to use medical assistance in dying (MAID). Dr. Khan submitted that a physician who performed these services would not fall below the standard of practice by doing so.
- [345] This line of reasoning shows a serious lack of understanding of the underlying principles of the goals of therapy, patient autonomy and informed consent. The goal of both MAID and prophylactic cancer surgeries such as mastectomy and oophorectomy is to diminish a patient's potential exposure to greater harm, in the form of active suffering in the case of MAID and future life-threatening cancers in the case of the surgeries. These patient decisions are based on evidence provided by their physicians that weighs the risks and harms of the interventions with their benefits, and on honest discussions about the evidence surrounding the patient's clinical circumstances as well as the patient's wishes. For example, as Dr. Younus testified, prescribing tamoxifen and raloxifene to lower breast cancer risk as a preventive measure should not breach the standard of care, but that is because "[i]t has been proven in randomized clinical trials that it is effective. So, it

can be used.” It has to be a combined decision between patient and physician, “we weigh the pros and cons about each of the techniques...based on the treatment or based on the risk of developing the cancer.” With regard to a patient’s choice to obtain a preventive mastectomy, Dr. Younus testified:

You will have to also equate the efficacy...By that, I mean that the treatment used has more chances of treating this condition to bring a cure, or a long-term control, or whatever may be the outcome that they are looking for. That will essentially determine a less intrusive versus a highly intrusive, and then that becomes a pros and cons for the treatment strategy...The intended therapy has to be efficacious against the given indication.

[346] When Dr. Khan provided SAFE chemotherapy, patients undertook risk without their knowledge that there was a lack of evidence for the treatment claims Dr. Khan made to them, including his claims of efficacy and his claims that mesna ensures patients are protected from the side effects and toxicities of carboplatin. Dr. Khan was required to engage in a comprehensive consent discussion with his patients, outlining the risks and benefits of the options at hand, which he failed to do. The very autonomy for patients for which Dr. Khan advocates is undermined when patients make decisions based on inadequate or inaccurate information.

[347] In conclusion, the implication that Dr. Khan is being unfairly held to a higher standard than the surgeons who perform prophylactic surgeries or those who provide MAID has no merit.

### iii) Analysis of Data and Information by Patients

[348] Dr. Khan submitted that patients who opted to take SAFE chemotherapy, DCA and LDN were “well informed of the limits of the supporting evidence,” and that his website “clearly indicated the exact basis for his data, including whether it was observational and how many patients he or Dr. Matsumura had looked at.” He submitted that all of his patients knew that the treatments Dr. Khan offered were unproven, had less evidence supporting their efficacy than conventional treatments and that the treatments were not approved by the College. We do not accept these submissions.

[349] First, patients did not have available to them “the exact basis for [Dr. Khan’s] data” upon which the claims of SAFE chemotherapy were based. These claims

were based on data from Dr. Matsumura's first four SAFE chemotherapy patients which was never published. Not only was this data unavailable to patients, Dr. Khan himself did not receive the data on these four patients until this hearing was already underway. What the patients had was not the data upon which SAFE chemotherapy's claims were based, but only the claims themselves.

[350] Further, this argument constituted a shift in the burden of information and data analysis from Dr. Khan to his patients. Without a physician to inform them about it, most patients would not be familiar with the available evidence for conventional treatments to use as a comparison to Dr. Khan's therapy. Moreover, most patients would not have special training to evaluate the quality of evidence, nor the amount of evidence necessary to support the claims of efficacy or remission that they would read about on Dr. Khan's website and on his Medicor consent forms for SAFE chemotherapy. Physicians are responsible for ensuring that the data and science underlying their proposed treatments are verified before they offer them to patients. A patient is not expected to perform this analysis.

[351] It is very reasonable that a patient would consider their physician's communications concerning a proposed treatment as being sufficient for them to believe that the treatment does what the physician claims it will do. It was Dr. Khan's duty to analyze the limitations of the data upon which he based his claims, and he did not do so. The implication that patients should have done so themselves is unreasonable.

[352] Furthermore, we find it hypocritical that Dr. Khan would expect his patients, who do not have special training, to evaluate and understand the implications of limited or preliminary data, or that they should be able to distinguish limited data from no data, when Dr. Khan failed to do so himself by accepting only the unverified word of one person before he began using SAFE chemotherapy in his practice.

[353] We accept Dr. Khan's submission, which is supported by the testimony of the College's expert witnesses Dr. Younus and Dr. Tozer, that patients are entitled to pursue a course of treatment that is not proven or approved by the College, so long as they are told that it is unproven. It is not for us to second-guess these personal patient decisions. But it was Dr. Khan's responsibility to provide the

necessary information upon which his patients made their decision. He did not do so.

#### Finding: Failure to Obtain Informed Consent

[354] Patient autonomy in decision-making is dependent upon the physician fulfilling their duty to provide accurate and sufficient information about the treatments he is providing and how the treatments compare with other therapies. It is also the physician's duty to ensure that the information provided is understood by their patients.

[355] We find that Dr. Khan provided inaccurate information and exaggerated the benefits of the treatments he provided. He failed to provide clear definitions of terms he was using in his communications with his patients. He also failed to ensure that his patients understood the limitations of his treatments. The information Dr. Khan provided fell short of the requirements set out in both the College's CAM and consent policies. Consequently, Dr. Khan did not provide his patients with the necessary information for them to make decisions and give informed consent for their treatments with SAFE chemotherapy, DCA, LDN and other therapies discussed at this hearing. Because he failed to obtain informed consent, Dr. Khan failed to maintain the standard of practice of the profession.

#### **d) Standard of Practice – Dr. Khan's Care of 12 Patients**

##### Dr. Khan's Care of Patient A

[356] In relation to his care and treatment of A, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose A to the risk of harm or injury?

##### *Overview of Relevant Information*

##### *History and Conventional Treatment Overview*

[357] In May 2017, at the age of six, A suddenly experienced a severe headache associated with vomiting. His parents took him to their local ER which sent him to a pediatrician who reassured them that there was no significant concern. His parents insisted on an MRI, but the pediatrician was reluctant to arrange one, and told them that even if one was arranged, there would be a long delay before the

actual study. His parents remained concerned and decided to take him to the Hospital for Sick Children (HSC) in Toronto, where a May 16, 2017, CT<sup>12</sup> scan and May 17, 2017, MRI<sup>13</sup> of the head showed the presence of a large posterior fossa mass with characteristics suggestive of a medulloblastoma which was causing obstructive hydrocephalus<sup>14</sup> and herniation of the cerebellar tonsils<sup>15</sup>. The MRI images also suggested that there were metastatic deposits to A's spinal cord.

### **What is Medulloblastoma?**

[358] Medulloblastoma is a malignant brain tumour/cancer which is the second most common brain tumour seen in children. It occurs in males more often than females and its peak age of occurrence is four to seven years of age. It can occur in adults, but rarely. Medulloblastoma always occurs in the cerebellum or infratentorial region of the brain. The cerebellum is important in the proper functioning of balance and coordination. Disturbance of the cerebellar functions can lead to a condition called ataxia, which can cause difficulty with balance and walking.

### *Grade and Stage of Medulloblastoma*

[359] Medulloblastoma is assigned a grade based on the examination of tissue performed by a pathologist. The majority of medulloblastomas are grade IV. With regard to stage, Dr. Johnston testified that while some cancers are staged from stage 1 to stage 4, medulloblastomas are based on a standard or high-risk classification. While one can still stage within the standard or high-risk categories,

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<sup>12</sup> A CT scan is comprised of x-ray images performed in slices.

<sup>13</sup> An MRI scan: magnetic resonance gives an extremely detailed picture of whatever it is imaging, but within the brain, it shows you, and will delineate everything within the brain. Its imaging of the brain is superior to that of a CT scan.

<sup>14</sup> Hydrocephalus: a build-up of fluid above the tumour caused in A's case by the presence of a tumour in the fourth ventricle which is blocking the flow of fluid [cerebrospinal fluid "CSF"]

<sup>15</sup> The cerebellar tonsils are the areas at the bottom of the cerebellum, and these are herniating, "pushed down through the vertebrae"

treatment decisions are driven by the patient's age and whether the tumour is considered standard or high-risk.

[360] Dr. Johnston also clarified that:

[A] standard risk medulloblastoma is one that is either...completely resected, or...less than 1.5 cm remains post-resection. A high risk is one that has either more than that residual left or there is disease somewhere else in either the brain or along the spinal cord; or there's malignant cells, tumour cells, in the spinal fluid when you do a spinal tap to check; or, this type of tumour is one of the only brain tumours that can actually spread outside of the CNS. It's extremely rare, but it can spread.

#### *Conventional Treatment of Medulloblastoma*

[361] The first line of treatment for medulloblastoma is surgical resection of the tumour. However, evidence shows that even when surgery achieves a complete resection, the tumour will recur unless adjuvant therapy is used in addition to surgery. Adjuvant therapy refers to treatment given after the primary therapy, which in this case would be surgery.

[362] When a standard risk tumour occurs in a child who is over three years old, they would receive radiation therapy to the brain and spinal cord and nine cycles of chemotherapy. A child in the same age group who has a high-risk tumour would also receive radiation therapy, but at a higher dose (than a standard risk tumour patient), and would have two chemotherapy options, each of which has similar outcomes. The first option is to give six cycles of chemotherapy every 28 days over six months. The second option involves four cycles of high dose chemotherapy with stem cell rescue. With this approach, a child's bone marrow (the location of the stem cells) is collected, preserved during chemotherapy and then returned to the child after completion.

[363] In children under age three, radiation is not used due to its known toxicity to the developing brain. Dr. Johnston explained that these children "are treated with just the high-dose chemotherapy stem cell rescue, and then they go on a maintenance type of low-dose chemotherapy for approximately a year."

### *Long-Term<sup>16</sup> Side Effects and Risks of Radiation in Children*

[364] Dr. Johnston testified that radiation has many side effects, including an impact on neurocognitive functions such as thinking and processing speed. It can also affect memory and intelligence, and children who have received radiation may have a decline in their school performance. Additionally, radiation can affect endocrine glands in the brain which control growth, the thyroid and other endocrine functions. Typically, there are medications that can replace hormones if there is endocrine dysfunction from radiation.

[365] There are three agents used to specifically treat medulloblastoma in children: cyclophosphamide, etoposide and cisplatin. Each of these has its own side effects. Cyclophosphamide can cause kidney dysfunction (typically not to the point of requiring dialysis). If given in high doses, it can also potentially cause infertility. Etoposide can cause allergic reactions, and rarely it can cause another form of cancer called leukemia. The third agent, cisplatin, can also cause kidney dysfunction, but of significant concern is its ability to potentially cause hearing loss that needs hearing aids.

### *Survival and Impact on Quality of Life*

[366] Studies show that the survival rate for children who have needed and received these treatments is approximately 69.2%, after which survival generally plateaus and leads to a slightly lower survival at 10 years post-treatment.

[367] Regarding quality of life, there is significant variance as to the level of toxicity that children experience from the different treatments. Some will attend university with good grades, while others may have significant cognitive decline that requires special accommodation at school. Dr. Johnston testified that it is difficult to define what comprises a good quality of life. She believes that this latter group of children find a role in society and can have an enjoyable life, but it may be filled with challenges, although she added that it is how they deal with those challenges that defines quality of life.

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<sup>16</sup> Dr. Johnston explained that these are long term side effects, which differ from short term side effects.

### *A's Initial Conventional Treatment and Diagnosis Confirmation*

- [368] Dr. Johnston testified that based on A's CT and MRI imaging, he likely had a medulloblastoma. Because the imaging suggested that it had already spread to the spinal cord, his tumour would be classified as high-risk.
- [369] A underwent brain surgery on May 17, 2017, at which time his neurosurgeon Dr. Drake was able to remove almost all the tumour apart from a "tiny" portion attached to the brainstem<sup>17</sup> and the metastatic seeding on A's spine,<sup>18</sup> the removal of which is never attempted surgically because it is not safe to do so. The tissue pathology showed group 4 medulloblastoma, and due to the metastatic spread to the spine, it was considered high risk. Group 4 medulloblastoma is part of a further subgrouping of this disease and is a relatively new group.
- [370] Post-operatively, A developed severe posterior fossa syndrome (PFS, also referred to as cerebellar mutism) and was unable to speak. This condition is due to brain swelling and can lead to difficulty walking as well. Dr. Johnston explained that almost all children recover from the condition, but it may require intensive rehabilitation.

### *Prognosis and Conventional Treatment Options*

- [371] Given A's confirmed diagnosis of group 4 medulloblastoma, his postoperative conventional treatment options included radiation followed by one of two potential chemotherapy protocols, one of which would involve stem cell rescue. These were explained to A's parents on June 1, 2017. Both protocols would have given A a 60-70%<sup>19</sup> overall chance of cure.
- [372] On June 13, 2017, A's parents met with his HSC team to discuss his plan of care. This team consisted of A's social worker, nurse co-ordinator, neuro-oncology fellow and staff neuro-oncologist, Dr. Bouffet. Dr. Johnston knows Dr. Bouffet through clinical and research work and described him as one of the world's "pre-eminent neuro-oncologists." She stated that when physicians reach out to the

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<sup>17</sup> Hospital for Sick Children MRI May 18, 2018

<sup>18</sup> Hospital for Sick Children MRI June 7, 2018

<sup>19</sup> The standard of care protocol could give a 60-70% chance of cure.

world's neuro-oncologists with particularly challenging cases, Dr. Bouffet is one of the experts who would be contacted.

[373] At the meeting, A's parents expressed their wish to delay the start of chemotherapy by one month. They felt that it would be psychologically difficult for A to undergo this treatment, as he was still suffering from the effects of PFS. His physicians explained that there were residual tumour and spinal lesions which, being medulloblastoma, were malignant and would continue to grow if treatment was delayed. They recommended starting chemotherapy the next day.

[374] Additionally, citing concerns about its future impacts on neurodevelopment, A's parents refused radiation therapy for A. The HSC team offered to instead treat A with the SickKids Infant Medulloblastoma Protocol (CCG 99703) (for infants below three years of age). This was a chemotherapy-only protocol with no radiation involved but with a much lower chance of survival. A's parents explained that they were not ready to start this protocol either, as they were concerned about A's quality of life. The HSC team emphasized that delay in treatment could compromise A's chance to control his tumour, and that they had never known of a single patient with medulloblastoma who had survived without receiving radiation and/or chemotherapy.

[375] In an attempt to keep the tumour from continuing to grow, the team then offered another milder oral etoposide chemotherapy protocol during the month A's parents wished to delay the standard regimen. His parents stated that they wanted to think about this option. At the end of the meeting, all further treatments were put on hold in accordance with A's parents' wishes. Approximately one week later, A was transferred to Bloorview for rehabilitation therapy and an MRI was scheduled to take place in one month's time.

#### *A's Parents' Experience and Considerations*

[376] Both of A's parents testified that they would have made the same decisions again. His father testified that they had "protected [A's] dignity" and "his outlook on life."

[377] The therapeutic decisions made by A's parents are not in question. It was evident that in order to make the best decision they could for their son, A's parents spent a great deal of time and effort becoming as educated as possible about his

condition, treatment options and potential consequences. There was no question that they were parents who loved their child and were attempting to make decisions that they believed would be in their son's best interests.

[378] His father testified that he and A's mother were devastated that A had cancer. They were not against conventional medicine in principle, and A's younger sibling had health issues that required numerous courses of antibiotics and a surgical procedure. However, A's parents were concerned about how the numerous side effects from radiation and chemotherapy would impact their son. They considered side effects such as potential severe mental disability, growth and hormonal issues, infertility, hearing damage and potentially permanent hair loss.

[379] The parents testified that their son had suffered already, but that they "could spare him some [more] suffering." They stated that they wanted to choose the best treatment option for their son, but they had numerous concerns about giving A radiation and chemotherapy. Apart from the side effects and potential long-term impacts of the therapies, they were very concerned that due to their son's PFS and consequential inability to speak, they would not be able to communicate with him about the chemotherapy, nor would he be able to ask questions.

#### *Potential Impact of Chemotherapy and Radiation Therapy on A*

[380] We learned from A's parent's testimonies that A was home schooled. His mother described the "blessing of being a stay-at-home mom to [A] and also homeschooling him."

[381] His mother described A as a "very funny, kind-hearted, compassionate boy" who was "deeply sensitive, deeply caring, [and] smart as anything." His father described his son as a dignified boy of a cerebral nature who would remember everything taught to him. A played chess and was very advanced with math and reading. His parents stated that he was "definitely not a rough and tumble type of kid." He played with his sibling on the playground but was cautious, and enjoyed asking his parents questions and describing his ideas.

[382] Ultimately, A's parents decided that chemotherapy and radiation therapy were not in the best interest of their son. His father stated that "there was no way that A would have wanted that...it would be like killing him while he was still

alive...especially the mental aspect...it would be a betrayal of trust to [A] for me to allow that to happen...we have had horrifying experiences with [A] going through his death and the memories that we struggle with and all kinds of struggles, but we do not struggle with that issue. We know that that was wrong for him.”

#### *Relationship Between A’s Parents and HSC*

[383] As they were moving through their decision process, A’s parents described a deteriorating relationship with HSC, although his father felt that they had maintained a “great” relationship with A’s neurosurgeon, Dr. Drake. They felt that some team members were exasperated with them for delaying treatment and asking numerous questions. His father testified that they felt pressured by the HSC team to consent to more treatment for A and found one of their HSC physicians to be sarcastic at times.

[384] A consultation note on July 27, 2017 stated that, more than one month after surgery, A was still unable to talk but was beginning to communicate with thumbs up and thumbs down signs. Over the course of the month, several meetings occurred between A’s parents and the HSC team, during which various treatment options and potential outcomes (especially the risk of disease recurrence and dissemination) were discussed. A’s parents continued to reject any treatments until A showed significant recovery from his PFS and mutism. The note indicated that the HSC team was not considering further discussions with A’s parents regarding treatment options, as they felt that they had explored all possible treatment options with them.

[385] His father became worried that the team would attempt to administer treatment regardless of his opinion, and so he and his spouse sought the advice of a lawyer. He was “alarmed” when the lawyer stated that children can be apprehended and taken away from their parents so that treatments can be administered contrary to their parents’ wishes.

[386] His father stated that they were religious people and had been praying for their son but were advised by the lawyer to speak to A’s medical team in a medical and scientific manner only. They were also advised that they had to make sure they had some sort of treatment plan in place for A, which ideally would be administered by a doctor.

[387] The father acted on this advice, and by mid-June 2017 he had emailed numerous places about possible treatment options for A. One of these places was Dr. Khan's clinic.

*Dr. Khan's Involvement with A*

[388] A's parents emailed Dr. Khan with details about their son in June of 2017. Dr. Khan replied stating, "[w]e have used DCA with various brain tumours with good results...We can come up with a suitable combination of therapy for [A]. All of these medicines are gentle and scientifically valid as brain tumour therapies."

[389] In July 2017 A's parents brought A to be assessed at Medicor. Dr. Khan's assessment note states that A had a "poor prognosis with therapy or without."

[390] Dr. Johnston did not agree with this statement and testified that the poor prognosis was without therapy, not with therapy.

[391] Regarding whether he had a discussion with A's parents of the risks and benefits of conventional treatments versus those he was proposing, Dr. Khan pointed to the checked box titled "R + B of change(s) in treatment plan" in A's Medicor treatment record. He testified that he only did a minimal review of conventional treatment options with A's parents because they had already decided to decline this course of treatment.

[392] In July 2017, A's father reviewed the document provided by Dr. Khan containing "frequently asked questions" about DCA. The document stated that DCA may work on any cancer type including "various rare tumours." It also stated that the first formal human cancer research using DCA was published in May 2010, and it said that DCA is "an effective anti-cancer drug for treating glioblastoma patients."

[393] A's mother signed the Medicor DCA consent form, which as noted above stated that she understood DCA had been "shown to effectively treat an aggressive brain cancer called glioblastoma in human research." Subsequently, A began taking liquid DCA, along with other supplements.

[394] As set out above, neither Dr. Kerbel (Dr. Khan's expert), Dr. Johnston nor the authors of the 2010 glioblastoma study concluded that DCA was an effective anti-cancer drug for treating glioblastoma patients. To the contrary, the authors of that

study stated that “no firm conclusions regarding DCA as a therapy for GBM [glioblastoma] can be made,” and that the observed effects in the study could also have been explained by other treatments the patients had received.

[395] Dr. Johnston testified that while conventional therapy gave A a high likelihood of cure, DCA did not. She stated that “there is no literature to support that it is effective in pediatric medulloblastoma,” the use of DCA is “not connected to the diagnosis” and that “[i]t doesn’t have [a] reasonable expectation of alleviating the patient’s condition.” She also stated that Dr. Khan did not discuss conventional therapeutic options with the family.

[396] Not long after, at the request of A’s parents, Dr. Khan became A’s primary physician and he informed HSC that he was taking over his care.

[397] HSC contacted the Children’s Aid Society (CAS), which followed up with A’s parents seeking information about his care. On July 28, 2017, Dr. Khan wrote to the CAS stating, “[A] is receiving medical treatment with a drug called dichloroacetate, among other things. Dichloroacetate was discovered to be an effective cancer therapy by the University of Alberta in 2007. Now there is a large body of medical literature that supports its use as a treatment of cancer (any type), including brain tumors.”

[398] A CAS representative met with A’s parents but ultimately did not take A into protective custody and dropped the case. The CAS representative told them that A was not a child in need of protection.

#### *A’s Investigations and Dr. Khan’s Communications with the Family*

[399] In September 2017, A had a follow-up MRI in Buffalo. Dr. Johnston testified that this study, compared with A’s June 7 MRI at HSC, demonstrated that the “tiny” residual tumour on his brain had become a “significant mass,” and that there was “progression of disease in his spine.”

[400] In reference to this MRI, Dr. Khan emailed the family on September 23 and stated that if A was feeling well and had no clinical findings on examination, then “the MRI is wrong.” By this time A had recovered from PFS. A’s father informed Dr. Khan that A was feeling well and was “dancing” and “climbing hand over hand on the monkey bars which he wasn’t able to do a month ago.” Dr. Khan responded

that the MRI “almost certainly” showed “pseudoproggression” and wrote, “wow I got a scare when [I] read the report, but the scan has to be wrong. It says there is tumour within the spinal cord. Depending on the extent, [A] should be paralyzed.” Dr. Khan went on to state that “we should be giving thanks for a miracle,” and that they should publish A’s case (along with the case of another patient).

[401] In another email to the family on October 19, 2017, Dr. Khan sent the family a journal article and again told the family that “false growth on MRI (‘pseudoproggression’) is common with pediatric brain tumours.” He then wrote that “the latest MRI...suggests significant growth of the cancer all over the spinal cord. If this was real growth, at the very least [A] would have pain in the neck and back. He would also likely have areas of numbness or weakness in the body. When I examined him, he had none of these findings.” He continued, “The false growth is caused by an immune response against the cancer...We have seen other deadly brain tumours also appear to be cured with simple drugs like DCA or LDN.”

[402] One week later, in an October 26 response to a video of A sent by his parents, Dr. Khan wrote, “[t]his is further confirmation that the new MRI is showing pseudoproggression, and [A’s] current therapy is actually working very well!” Dr. Khan’s email went on to state, “[i]t is very unfortunate that ‘world renowned’ pediatric centers like Sick Kids don’t prescribe the therapies that we prescribe, like DCA or LDN. They could save children with serious cancers without gravely harming them using so-called ‘approved’ therapies.”

#### *What is Pseudoproggression?*

[403] Dr. Johnston explained that pseudoproggression is a phenomenon in which changes on MRIs that appear to show disease progression are not in fact progression, but rather are the results of swelling caused by cancer cell death from radiation (or, as some case studies suggest, from immune therapy). The appearance will eventually regress on its own.

[404] Dr. Johnston explained that since A had never received radiation or immunotherapy, it was not possible that the changes on his September 2017 MRI were pseudoproggression. She stated that DCA is not immunotherapy.

[405] At this hearing, Dr. Khan himself testified (with regard to another patient) that “DCA typically does not cause pseudoprogression...it is an uncommon phenomenon”.

[406] With respect to A’s apparently asymptomatic appearance in September 2017, Dr. Johnston explained that even with the progression shown on the MRI, it was possible for A to be asymptomatic because the tumour would only cause symptoms if it was impinging on normal structures in the body. A’s tumour had grown throughout his spinal cord but was not obstructing normal structures.

[407] Dr. Kerbel explained that immunotherapies, which activate the immune system to fight a cancer, take time to begin working and the evidence that they are working can be delayed. He described pseudoprogression as the tumour growth that occurs during the time it takes for an immunotherapy to start working and before it begins shrinking a tumour. With regard to DCA being an immunotherapy, Dr. Kerbel testified that it would be “speculative” to suggest that the logic of immunotherapy applies to DCA.

#### *Dr. Khan’s Communications with Others*

[408] In October 2017, Dr. Khan wrote to the Make-A-Wish Foundation of Canada in which he identified A’s diagnosis as stage 4 medulloblastoma. Dr. Johnston testified that A had group 4 medulloblastoma, not stage 4. Stage 4 medulloblastoma is disease outside the CNS, which A did not have.

#### *A’s Clinical Status and Outcome*

[409] In December 2017, A began to have pain in his head, and other symptoms including neuropathy. His parents wondered about disease progression.

[410] A follow-up MRI showed that the disease had spread “significantly.” A’s mother testified that she recalled that by this time, Dr. Khan had acknowledged that there was disease progression. However, Dr. Khan’s clinic notes from January 15, 2018 state, “possible tumors inflammation versus growth since not progressive (immune attack on cancer cells),” which suggests that he was not convinced that the disease had progressed.

[411] During his testimony, however, Dr. Khan pointed out that in his note from January 15 he stated that the plan was to treat it as “slight growth.” He explained that he currently believes that there was growth occurring simultaneously with inflammation or pseudoprogession, “especially now because there is new literature that shows that DCA in fact does cause [inflammation] and causes immune response against cancer.”

[412] As noted above, the College’s expert Dr. Johnston testified that DCA is not an immunotherapy and Dr. Khan’s expert testified that it would be “speculative” to suggest that the logic of immunotherapy applies to DCA. At this hearing, Dr. Khan did not submit any literature or publications into evidence to support his claim that it is an immunotherapy.

[413] In March 2018, wanting to ensure the best control possible for A’s pain, his parents moved him into a hospice facility. His disease progressed quickly and management was focused on nutrition and pain control. Once A was in hospice care, his parents decided not to continue with the DCA. A died in November 2018.

#### *Expert Review of DCA for the Use of Medulloblastoma*

[414] Discussion on the use of DCA as a treatment for cancer is found earlier in these reasons under the heading “Standard of practice of the profession – Dr. Khan’s use of Dichloroacetate (‘DCA’).” The discussion below pertains specifically to Dr. Johnston’s review of the use of DCA in the treatment of medulloblastoma.

[415] Dr. Johnston conducted a literature search on DCA and found that it is being researched as a potential therapy for cancer. She commented that this could be said of “many, many compounds.” She noted that while there is extensive research occurring *in vitro*, in test tubes and in cell lines, there is limited data on DCA use in humans. She found two clinical trials where DCA was used to treat cancer in humans, and these showed that DCA was ineffective.

[416] With regard to pediatric medulloblastoma, Dr. Johnston found two articles. One,<sup>20</sup> which was a pre-clinical study, looked at the impact of DCA on cell growth in a

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<sup>20</sup> DiMagno et al. Cell Cycle 2014

type of medulloblastoma called Sonic Hedgehog, which A did not have. The other article looked at DCA's impact on response to radiation (which A did not receive) in medulloblastoma cells in a petri dish.

[417] Based on the studies she reviewed, Dr. Johnston concluded that the use of DCA to treat pediatric medulloblastoma is not informed by evidence and science.

*Dr. Khan's Own Understanding of the Use of DCA for Medulloblastoma*

[418] In September 2017, Dr. Khan replied to a question posed to him on his website by a member of the public. This person asked, "Dr. Khan, do you believe dca [DCA] can work against medulloblastoma? What is your experience working with brain cancers?"

[419] The next day, Dr. Khan responded, stating "we don't have any convincing data yet for medulloblastoma. We have 1 patient currently on DCA and he is doing well for now. We will know more in 2 or 3 months." By this time, A had been on DCA for two months.

[420] In cross-examination, Dr. Khan admitted that he "may have treated one or two [medulloblastoma patients] before, but that is just not enough data for me to make a public comment on that."

*Summary of Dr. Johnston's Opinion of A's Care by Dr. Khan*

[421] Dr. Johnston opined that, having regard to the CAM policy, Dr. Khan's care of A did not meet the standard of practice of the profession when he:

- relied on the report of A's father during his initial assessment;
- failed to reach a conventional diagnosis when he diagnosed A with pseudoprogression instead of true progression of his tumour; and
- recommended the therapy DCA, which was not informed by evidence and science and did not have a reasonable expectation of alleviating A's condition.

*Knowledge, Skill and Judgment*

[422] Dr. Johnston testified that Dr. Khan displayed a lack of judgment and a "big lack of knowledge" in misdiagnosing A with pseudoprogression. She explained that this

is a big concern because if there is progression, a discussion about therapy needed to occur and it did not. Dr. Khan also told the family that pseudoprogression was a favourable sign and gave them false hope for their child.

[423] Dr. Johnston also opined that Dr. Khan displayed a lack of knowledge in repeatedly referring to stage 4 medulloblastoma which A did not have; he had group 4 medulloblastoma. Dr. Johnston's opinion is that Dr. Khan's use of DCA as a first line therapy for medulloblastoma demonstrated a lack of skill and judgment.

#### *Exposure to Risk of Harm or Injury*

[424] In Dr. Johnston's opinion, Dr. Khan's care exposed A to risk of harm or injury because A did not receive a therapy that gave him a high likelihood of cure.

#### *Finding*

[425] We considered the written and oral evidence before us and find that, in his care and treatment of A, Dr. Khan failed to maintain the standard of practice of the profession when he:

- a) made a diagnosis which was not a conventional diagnosis and did not satisfy the requirements of the CAM policy;
- b) failed to obtain informed consent to use DCA;
- c) treated a patient's cancer using a medication (DCA) that was not informed by evidence and science, did not possess a favourable risk/benefit ratio and did not have a reasonable expectation of remedying or alleviating the patient's health condition (CAM Policy – Therapeutic Options); and
- d) failed to provide accurate and objective information, substantiated by fact and sound clinical judgment, to the parents about therapeutic options, A's diagnosis and the progress of his cancer. (CAM Policy, Section B(1)(iii): "Specific Expectations for Physician Conduct- Treating the Patient: Therapeutic Options and Informed Consent.")

## *Analysis*

### *a) Analysis - Failing to Reach a Diagnosis which Satisfied the CAM Policy*

[426] Dr. Khan diagnosed A with pseudoprogression even though A had not received any treatments that could have caused it, namely radiation or immunotherapy. We accept Dr. Johnston's evidence that DCA is not an immunotherapy that can cause pseudoprogression.

[427] The September 2017 MRI showed actual and significant progression of both the tumour remnant in the posterior fossa and in A's spine. In diagnosing A with pseudoprogression instead of actual progression of the cancer, Dr. Khan did not make a conventional diagnosis and failed to maintain the standard of practice of the profession.

### *b) Analysis - Failure to Obtain Informed Consent to Use DCA*

#### *i) Dr. Khan's Discussion and Documentation*

[428] A's father testified that they did not go to Dr. Khan expecting a cure, and that Dr. Khan made it clear that DCA would not provide a cure for their son. The box "reviewed standard chemo" appears checked off in Dr. Khan's Medicor chart notes on A. However, A's medical record does not have written documentation of which standard chemotherapeutic treatment options were discussed with his parents, nor how their risks and benefits compared with DCA. As previously discussed under the "Consent and Communication" section above, we do not find credible Dr. Khan's testimony that he always had this conversation with patients. Additionally, Dr. Khan conceded that his provision of information about conventional therapies to A's parents was limited because they had already declined conventional therapies, had been informed about them by their HSC team and had conducted their own research into DCA and conventional therapies. (A's mother had prior experience in conducting research.)

[429] As previously discussed, none of these factors diminished Dr. Khan's duty to provide the relevant information as set out in the CAM policy. This line of reasoning also erroneously shifts the burden from the provision of information by the physician to the acquisition of information by the patient (or in this case, the patient's family).

[430] Consequently, in the absence of written documentation to show otherwise, we do not believe that Dr. Khan had an adequate consent discussion with A's parents.

*ii) Information Presented to the Family*

[431] The information Dr. Khan presented to A's family in his DCA FAQ and consent form consisted of claims that were not proven. Neither Dr. Johnston nor Dr. Kerbel would confirm Dr. Khan's claims, and Dr. Khan did not provide any objective evidence to substantiate his claims that:

- DCA may work on any cancer type, including "various rare tumours";
- the first formal human cancer research using DCA, which was published in May 2010, confirmed that DCA is "an effective anti-cancer drug for treating glioblastoma patients"; and
- DCA has been "shown to effectively treat an aggressive brain cancer called glioblastoma."

[432] Although the family had conducted its own research into DCA, and wanted to use it partly to satisfy their wish to present a therapy to the CAS, this did not relieve Dr. Khan of his duty to provide A's parents with accurate and truthful information about the treatment he was proposing. A consent can only be informed if the information provided by a physician is accurate. Regardless of A's family's belief as to whether or not DCA could cure their son, Dr. Khan did not provide the family with accurate information about DCA.

[433] For these reasons, we find that Dr. Khan did not obtain informed consent to use DCA on A, and consequently he failed to maintain the standard of practice of the profession.

*c) Analysis - Treating a Patient's Cancer Using a Medication, DCA, which was Not Informed by Evidence and Science*

[434] There is insufficient evidence and science to demonstrate that DCA is an effective treatment for pediatric medulloblastoma.

[435] Dr. Johnston and Dr. Kerbel agreed that there is no clinical evidence that DCA would have a reasonable expectation of remedying or alleviating a pediatric

medulloblastoma patient's health conditions or symptoms. Dr. Khan failed to meet the standard of practice of the profession when he used it to treat A's medulloblastoma.

[436] Even if one were to set aside the need for clinical research in humans and consider treating A's cancer based on the two studies looking at pediatric medulloblastoma, these were not applicable to A. He did not have the type of medulloblastoma being researched in the first study (Sonic Hedgehog), nor would DCA's petri dish impact on radiation susceptibility of cancer cells in the second study bring an expectation of alleviating A's symptoms, as he was not receiving radiation.

[437] Dr. Khan should not have used DCA to treat A's medulloblastoma, and in doing so, Dr. Khan failed to meet the requirements of the CAM policy and failed to maintain the standard of practice of the profession.

*d) Analysis - Failure to Provide Accurate and Objective Information about Therapeutic Options, Diagnosis and Cancer Progress (Section B(1)(iii) of the CAM Policy)*

[438] The information about DCA that Dr. Khan provided to A's parents was comprised of unproven claims, which made it inaccurate. Further, the claims of efficacy on Dr. Khan's DCA FAQ form and his DCA consent form were overinflated and exaggerated. This is also a breach of the CAM policy. The conclusions of the authors of the 2010 glioblastoma and DCA study contradicted the statements Dr. Khan made on his forms about the results of this study. We find Dr. Khan's discourse about this study misleading.

[439] Further, in September of 2017, two months after A had started DCA, Dr. Khan himself acknowledged to a public user on his website that there is no convincing data for the use of DCA in medulloblastoma. This is in sharp contrast to his own DCA FAQ handout in which he stated that DCA may work on any type of cancer. Upon being presented with that statement during cross-examination at this hearing, Dr. Khan admitted that he "may have treated one or two [medulloblastoma patients] before, but that is just not enough data for me to make a public comment on that."

- [440] Further, Dr. Khan lamented to A's parents in an email that DCA and LDN should be more widely available to "save children with serious cancers."
- [441] Whether in private or public, patients should be able to count on accurate information during communications with a physician about potential therapies. Dr. Khan's communications about his therapies should be consistent regardless of his audience. Yet, Dr. Khan's communications about DCA's efficacy on cancer to his various audiences not only differed, but were contrary to one another.
- [442] By providing inaccurate information to A's parents, Dr. Khan breached the CAM policy and failed to maintain the standard of practice.
- [443] By September 2017, A had significant progression of his disease as evidenced on his MRI. Dr. Khan should have communicated this to A's parents instead of telling them that the MRI was wrong and that A had pseudoprogression. He also referred to A's September 2017 MRI and clinical condition as "a miracle." All of these statement to A's parents reflected Dr. Khan's opinion and directly contradicted the findings of the MRI and of the radiologist who read it. Further, we find Dr. Khan's statement about "a miracle" to be not only overly optimistic, but also unscientific.
- [444] In her closing submissions, counsel for Dr. Khan stated that Dr. Khan did not promise A's parents a "miracle cure." While Dr. Khan may not have described DCA to the family as a miracle cure during the consent process, in his reference to A's clinical picture as "a miracle," he seemed to have suggested that he had, nevertheless, through his treatment, delivered one.
- [445] By making these statements, Dr. Khan provided an overly optimistic view of A's status and overinflated the efficacy of DCA. In doing so, he provided inaccurate information to A's parents, contrary to the CAM policy, and failed to maintain the standard of practice of the profession.
- [446] Not only did Dr. Khan provide A's parents with inaccurate information about the potential benefits of DCA, he also provided them with inaccurate information about the results of treatment. When A's cancer inevitably progressed, as would be expected without effective therapy, Dr. Khan interpreted the results to deny the disease progression and instead attempted to show the therapy he was offering in

a favourable light. This is a pattern and will be discussed within the context of other patients.

#### *Knowledge, Skill and Judgment*

- [447] It is reasonable to expect that a physician who treats cancer, at a “cancer centre” no less, should have a solid understanding of the cancers he is treating. Yet, Dr. Khan’s misdiagnosis of A’s significant disease progression as pseudoprogression demonstrates a serious lack of knowledge.
- [448] It is also reasonable to expect a physician who treats cancer to know how to refer to cancers by their correct and standard accepted nomenclature. Dr. Khan’s referral to A’s disease as stage 4 medulloblastoma, which he did not have, instead of the correct diagnosis of group 4 medulloblastoma, also demonstrates a lack of knowledge and suggested that he did not understand the significance of this distinction. Dr. Johnston testified that different stages of this disease (including progress) warrant different treatments and different conversations about such treatments. Dr. Khan should have been able to distinguish between stage 4 and group 4.
- [449] Furthermore, a patient’s or guardian’s desire for a medication is not an indication for its use. Physicians do not have a duty to provide ineffective treatments because people want them. On the contrary, it is a physician’s duty to refrain from providing ineffective treatments even when a patient requests them, and even if there is a therapeutic vacuum due to the patient’s reluctance to use a conventional therapy. Therefore, regardless of the wishes of A’s parents, Dr. Khan’s decision to use DCA as a first line treatment for A’s pediatric medulloblastoma shows a lack of skill and judgment, and frankly, a lack of clinical prowess expected of a physician who has taken on care of patients in the field of pediatric neuro-oncology.

#### *Exposure to the Risk of Harm or Injury*

- [450] Dr. Johnston opined that Dr. Khan’s care exposed A to risk of harm or injury because A did not receive a therapy which gave him a high likelihood of cure. However, we did not agree.

- [451] The decision to decline conventional therapy was made by A's parents before they met Dr. Khan and reflected their autonomy as their child's guardians to make decisions with regard to his cancer care. A's parents described their strong feelings against the use of conventional post-surgical therapies for their son and made their decisions accordingly. It was clear to us that they were resolute in their views and convictions that they were doing right by their son.
- [452] Dr. Khan was not a part of these decisions and accordingly, in this regard specifically, we find that Dr. Khan did not expose A to the risk of harm or injury.
- [453] However, regardless of the strong views of A's parents, Dr. Khan provided incorrect and inaccurate diagnostic information about A's disease progression when he told A's parents that A had pseudoprogression and that the September 2017 MRI was wrong. In doing so, he exposed his young patient to the risk of harm or injury.
- [454] When Dr. Khan made the statements, not only did he potentially provide false hope, but his statements pre-empted an accurate re-evaluation of his patient's clinical status and a discussion about what treatment may benefit him at that time. While A's parents held strong views on the matter of therapy when they came to Dr. Khan, their son's disease progress warranted a new discussion on future therapy and care. There is no evidence that Dr. Khan conducted such a discussion with A's parents in September or October 2017.
- [455] Additionally, Dr. Khan emailed the family and stated, "it is very unfortunate that 'world renowned' pediatric centers like Sick Kids don't prescribe the therapies that we prescribe, like DCA or LDN. They could save children with serious cancers without gravely harming them using so-called 'approved' therapies." While Dr. Khan is entitled to his opinion, his statements to the family and the context in which he made them suggested that DCA therapy was superior to approved conventional therapies (for which he had no evidence) and increased the likelihood that other treatment options would not be explored or considered again by A's parents when their son's cancer progressed.
- [456] The disease progression shown on A's September 2017 MRI constituted a milestone which should have triggered the appropriate discussion, as set out

above. Dr. Khan's communications were not only inaccurate, but also pre-empted such a discussion. This exposed A to the risk of harm.

#### *Disregard for Patient Welfare*

[457] Through all of the above conduct, Dr. Khan demonstrated a disregard for A's welfare.

#### *Conclusion*

[458] We considered the written and oral evidence before us, and conclude that in his care of A, Dr. Khan failed to maintain the standard of practice of the profession, demonstrated a lack of knowledge, skill and judgment, exposed A to the risk of harm or injury and demonstrated a disregard for his welfare.

#### Dr. Khan's Care of Patient B

[459] In relation to his care and treatment of Ms. B, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose Ms. B to the risk of harm or injury?

#### *History and Conventional Treatment Overview*

[460] Ms. B is a woman who began her interactions with Medicor staff in the summer of 2017; at that time she was 59 years old. During her testimony, she confirmed that she had an extensive health history and had experience with alternative medicine.

[461] Ms. B had learned about Medicor when she did a Google search looking for LDN after hearing it mentioned on a Facebook group for chronic fatigue syndrome. When she went to the Medicor website, she learned about a test called ONCOblot.

[462] On her June 28, 2017 Medicor questionnaire, Ms. B provided the clinic with her past medical and social history, medications and allergies, a list of her other physicians and other information pertaining to her functional status. Ms. B wrote that she had been experiencing various health issues for many years which among other conditions, included fibromyalgia, chronic fatigue syndrome, multiple chemical sensitivities, chronic adrenal exhaustion and migraines.

[463] Ms. B came to Medicor on June 27, 2017, and was initially seen by Dr. Andrews, who is a naturopath. He documented that Ms. B had been experiencing weight loss, fatigue, decreased appetite and loss of muscle mass. Dr. Andrews' examination also revealed a breast lump on Ms. B's right side, and a one-centimeter nodule on the right side of her neck. Dr. Andrews' note also stated that Ms. B wished to rule out a diagnosis of cancer. The section of the note titled "Plan" shows that Dr. Andrews was planning to order a test called an ONCOblot test.

*What is an ONCOblot Test?*

[464] Dr. Younus described an ONCOblot test as follows:

...[T]his is a blood test, which is just a peripheral blood sample, which is then processed to find out a particular set of proteins that can, according to the test, be interpreted as positive or negative to show the presence of any cancer cells in the body, and the organ from which it may have arisen.

[465] The ONCOblot test is designed to look for ENOX2 proteins, which the developers say are specific to the surface of cancer cells. The founders and makers of the test who patented it, MorNuCo, claim that based on the isoelectric point of the proteins, they can determine the presence of cancer and the tissue of origin.

[466] Dr. Younus explained the determination as follows:

...[L]et's suppose that they tested 100 patients with breast cancer, they almost always found one particular type of the protein with one specific molecular weight, and one specific isoelectric point. So, that's how they were sure that this belongs to breast cancer whenever it is detected. Similarly, non-small cell lung cancer was different than breast cancer, and so on, and so forth. That's how the tissue of origin is determined.

[467] The patients to whom Dr. Younus was referring would have already had a diagnosis of breast cancer or lung cancer established by another method, after which time an ONCOblot test was administered. This situation is different from the case of Ms. B who had not had a diagnosis of cancer established through conventional medical investigations. Dr. Khan's expert witness, Dr. Rosenberg, testified that although a positive ONCOblot suggests the presence of cancer cells, the test, which is no longer available, was not in use long enough to determine if a

person with a positive ONCOblot test would actually go on to develop a malignancy, nor when.

[468] Dr. Khan's consent form for ONCOblot testing stated that the test can pick up early stages of cancer including stage 0 and stage 1 cancers. Dr. Younus opined that while some cancers may be defined as existing at stage 0,<sup>21</sup> blood cancers may not exist in this stage. Additionally, to reach even a stage 0 diagnosis, one would need to have confirmatory investigations by other techniques, such as radiology.

[469] Dr. Younus reviewed the data and literature available on ONCOblot. His report noted that "although reasonable published data exists regarding the basis of this [ONCOblot] test, the clinical applicability and the use of this test has not been established or approved in North America. This test is not used by oncologists in Canada."

[470] Dr. Younus testified that the ONCOblot test could be seen as a marker - there are a number of markers that conventional medicine uses in the prognostic field - and to follow patients. One example of such a marker is the carcinoembryonic antigen (CEA) that is shed by certain cancers, but there are very specific indications to use this marker. He explained that every single time there is a fluctuation in the marker, one would need a confirmatory test to prove what is happening. Dr. Younus clarified that, "you don't treat the markers. You actually treat the disease."

[471] However, Dr. Younus did not think that Dr. Khan fell below the standard of practice in having Ms. B take the ONCOblot test.

#### *Ms. B's Consent to ONCOblot Testing*

[472] Ms. B signed a Medicor consent form for ONCOblot testing at her June 27, 2017 visit. During this hearing, Ms. B explained that since she assumed it was a "standard consent form," she did not read the form when she signed it and was thus unaware that the test was not within the usual practice of medicine or was

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<sup>21</sup> Dr. Younus stated that an example of stage zero cancer would be a "breast cancer that has not gone through the basement membrane, which is just at the layer of the first layer of cells...it is still a ductal carcinoma in situ...would probably be called a stage 0."

not approved by the College. Ms. B testified, “I was told that it was a test [that] will tell me definitely whether there was cancer in my body, usually the source of the cancer...and it’s accurate” and that “I really had the test done because I thought it was going to come back negative and I’d have peace of mind to continue, you know, not worrying about this being cancer.”

[473] Dr. Khan testified that he met and spoke with Ms. B about the test after the blood sample was taken, but before the test was sent. However, there is no record showing that such a meeting and conversation took place, and Ms. B denies that she ever met with Dr. Khan until after her ONCOblot test results had come back. In the absence of any record of such a meeting and discussion, we accept Ms. B’s testimony that this meeting did not take place.

[474] Ms. B’s June 27, 2017 Medicor patient record with Dr. Khan’s naturopath, Dr. Andrews, also does not show that at this appointment (during which Ms. B agreed to have an ONCOblot test), she was informed of the key points to consider when taking this test.

#### *Ms. B’s Cancer Diagnosis by Dr. Khan*

[475] Ms. B’s ONCOblot test results came back to Medicor, and were time stamped as having been reviewed by Dr. Khan on Saturday, July 22, at 6:17 am. The results indicated that the ENOX2 protein had been identified and that the tissue of origin was “blood cell.” Based on these results, Dr. Khan diagnosed Ms. B with acute leukemia.

[476] Dr. Younus opined that Dr. Khan did not reach a conventional diagnosis when he diagnosed Ms. B with acute leukemia. He also expressed concerns about Dr. Khan having made his diagnosis based on the ONCOblot test, without conducting the investigations that are necessary to establish the correct diagnosis (of which blood cancer is present).

#### *Did Ms. B Have Acute Leukemia?*

[477] Dr. Younus testified that isolating the tissue of origin for blood cancer using ONCOblot is complicated in this case because there could be three major categories of diagnoses which arise from blood cells: leukemia, lymphoma or multiple myeloma. He explained that these conditions are treated completely

differently from each other. He also stated that if acute leukemia was present, the treatment would have to be completely different and “on an acute level.”

[478] Along with the results, the ONCOblot laboratory report contained a caveat that the “utility for ENOX2 detection in the general population for cancer has not been determined. The ONCOblot test results are provided to medical professionals for interpretation and are not intended to replace current standards of care.”

[479] Dr. Rosenberg confirmed this, and explained that the test would provide a basis on which one could refer their patient to an expert (hematologist) for diagnosis. In his jurisdiction (Florida), the standard would require a tissue sample (biopsy) to make a diagnosis of cancer. Similarly, Dr. Younus stated that peripheral blood tests may be one clue for leukemia, but the definitive diagnosis for leukemia is through bone marrow biopsy, followed by confirmatory antibody testing and marker tests (known as “flow cytometry”).

[480] In contrast to both his own expert Dr. Rosenberg and the College’s expert, Dr. Younus, Dr. Khan testified that the disclosure statement on the lab test results was untrue, and nothing more than a legal disclaimer.

#### *Dr. Khan’s Disclosure of a Cancer Diagnosis to Ms. B*

[481] On Saturday July 22, at 6:31 am, 14 minutes after he had received the results, and not yet having met Ms. B, Dr. Khan emailed her and told her:

Thank you for having the ONCOblot test done with us. Here is your ONCOblot test result. It is positive for leukemia.

[482] In his email he also told Ms. B that:

There is about a 4% chance that the origin of the cancer is another organ (not the blood), but there is < [less than] 1% chance that the test is wrong about diagnosing the presence of cancer.

[483] The email advised Ms. B to make an appointment at the clinic to plan further diagnostics and treatments.

#### *Ms. B’s Initial Reaction to a Diagnosis of Leukemia*

[484] Ms. B described the results as “devastating” to her and as causing a “commotion” in her house. She said that she “didn’t know what to do” and “just sat there.” After

five hours of “heart aching” she emailed Medicor to ask for the earliest appointment possible. Ms. B stated that she initially delayed responding to Dr. Khan’s email because she was worried that if she responded to the email, she would be charged a fee. Ms. B followed up with a call to the clinic on Monday.

*Further Evaluation of Ms. B’s Cancer Diagnosis by Dr. Khan*

[485] Ms. B and her family met with Dr. Khan on Thursday July 27, 2017. His Medicor note from this date documented Ms. B as having a “new diagnosis of leukemia per ONCOblot.”

[486] Ms. B testified that she recalled asking Dr. Khan to refer her to an “oncologist...a hematologist...cancer doctor” because she wanted to do both conventional and alternative therapies for her leukemia. She described herself as being “shocked” to find out that she needed a biopsy and was “terrified” of doing so, but it was “part of the process, so I had no choice.”

[487] Dr. Khan testified that he remembered discussing the accuracy of the test, and that the cancer may be small and difficult to detect by conventional means. His chart, however, does not show documentation of such a discussion.

[488] Dr. Khan’s treatment plan for that appointment shows that he wanted to start LDN and HonoPure, increase Ms. B’s dose of vitamin D, refer Ms. B to a hematologist/oncologist at Sunnybrook for a lymph node or bone marrow biopsy and seek a review of conventional therapy options by Sunnybrook’s team.

[489] In his written report, Dr. Younus expressed concern that:

Dr. Khan had mentioned weight loss but no details appear about how much was the weight loss and over what interval of time. Similarly, factors that could potentially contribute to such a weight loss also are not mentioned. The notes from Dr. Andrews pointed [to] a breast lump and possible problems with lymph nodes and some lesion/lymph node in the neck. Dr. Khan also mentioned lymph node enlargement and wanted to get a biopsy...

[490] Dr. Younus also noted that Dr. Krieger, a physician who later saw and examined Ms. B, did not find palpable lymph nodes (i.e., that he could feel on examination). Dr. Younus opined that Dr. Khan appeared to have a concern and wanted to

confirm the diagnosis by conventional methods. However, he started treatment without such confirmation.

*Dr. Khan's Treatments of Ms. B: HonoPure and LDN*

*What is HonoPure, and What is the Evidence for Using it to Treat Ms. B's Presumed Diagnosis of Leukemia?*

- [491] HonoPure (also known as honokiol) is a biological extract from magnolia bark. Dr. Khan testified that it “does a few things” and has anti-inflammatory properties.
- [492] Dr. Younus was asked about an *in vitro* study by Dr. Shigemura and seven others published by the American Cancer Society in its journal, *Cancer*, in 2007. The study looked at the use of honokiol in bone metastatic growth in human prostate cancer cells. This article referred to a different 2005 study conducted by Dr. Battle that looked at exposure of B Cell chronic lymphocytic leukemia, B-CLL cells to honokiol, which was noted to cause apoptosis (known as “cell death”).
- [493] When he was asked whether the study provided some information that honokiol is used for, or can have an impact on, lymphocytic leukemia, Dr. Younus said “no, this is still describing what it can do to chronic lymphocytic leukemia cells in a petri dish...it is not referring to its efficacy and the ultimate impact that it may exert when it is used in a human being.”
- [494] Dr. Younus was also asked about a 2015 study by Dr. Bi, which looked at whether honokiol inhibits leukemia cells. Dr. Younus again pointed out that the study only looked at what happened in a petri dish.
- [495] In a 2018 article, “The Safety and Toxicology of Magnolol and Honokiol”, the author, Dr. Sarrica, suggested that the substance was relatively non-toxic in humans. Dr. Younus agreed that few side effects may have been found in the study, but pointed out that the study had a relatively small number of subjects.
- [496] Dr. Younus stated that HonoPure “has no obvious efficacy in cancer except perhaps in the lab conditions.” His opinion was that the use of HonoPure to treat leukemia in humans was not informed by evidence and science, as there is only limited petri dish-based science with no information about efficacy and impact in humans.

*What is Low Dose Naltrexone (LDN)?*

[497] Dr. Younus explained that naltrexone is an opioid antagonist that is used to reverse the effects of an opioid overdose. It can also be used in patients with alcohol addiction with a standard dose of 50 mg per day. By comparison, Dr. Khan testified that he uses LDN in the 2-4.5 mg range. At Medicor, he uses LDN to treat cancer, autoimmune diseases, symptoms of fibromyalgia and chronic fatigue syndrome.

[498] The main side effect of LDN is insomnia and vivid dreams. Other side effects include withdrawal and liver toxicity.

*What is the Evidence and Science Supporting the Use of LDN to Treat Cancer and Ms. B's Presumed Diagnosis of Leukemia?*

[499] Dr. Younus reviewed the data and literature available on LDN and reported that "there is no conclusive evidence in the published literature for low dose naltrexone to be an effective anti-cancer therapy. I could not find a prospectively conducted clinical trial with published results on low dose naltrexone in patients with cancer." He testified that while "no one can claim that they have read all the papers in the world...I also did not find any paper about naltrexone referring to a human case series to treat the blood cancers or acute leukemias."

[500] Dr. Younus explained that any treatment that is investigated at the level of an *in vivo* and *in vitro* experiment forms the basis or the scientific reasoning for further testing in human clinical trials but is still, at that level, not recommended to be used in patients as a definitive treatment.

[501] Dr. Younus also reviewed the studies on LDN sent to him by Dr. Khan for review and found that none of them showed that LDN was supported by evidence and science as an appropriate treatment for cancer, including leukemia. However, he agreed that one could say "[a]t the basic science level" the articles suggest that there is some connection to treatment with low-dose naltrexone and various types of cancer.

[502] One of the articles that Dr. Younus was asked about was published in 2011 on the use of naltrexone and cell proliferation by the Society of Experimental Biology and Medicine (the article was not shown to us). The article indicated that LDN had

been found to be non-toxic and efficacious in the treatment of patients with advanced pancreatic cancer. When he was asked if this to him constituted a scientific basis to believe that LDN “may exist [*sic*] in cancer,” Dr. Younus replied, “it provides a very minute level of biological evidence that this [LDN] should be tested further...Whether it is going to be efficacious in the treatment for whatever dose, and for whatever indication, is not clear from this article.” When it was put to him that the article appeared to provide some scientific information that there is a connection between LDN and certain types of cancers, Dr. Younus said “relating that connection to come from the *in vitro* studies that we are discussing...is really insufficient. The science and evidence may belong to the petri dishes in this case, but not to any human studies.”

[503] Another article that was discussed with Dr. Younus was a single 2009 case report by Dr. Berkson looking at LDN in humans with pancreatic cancer. Dr. Younus stated that benefit could not be attributed to LDN and that it was almost impossible to dissect its potential impact because LDN was just one of a number of therapies the study patients were receiving.

[504] The same study by Dr. Berkson refers to a set of data compiled by Dr. Bahari in which he used LDN in 450 patients with refractory cancer. Dr. Bahari presented his work in 2005 at the first annual Low Dose Naltrexone Conference, and reported that his patients had decreased tumour bulk, were in remission or were close to remission. Dr. Bahari never published any related study. While Dr. Khan cited Dr. Bahari as having pioneered LDN use in cancer therapy, Dr. Younus stated that without publication to provide relevant information on how the study was conducted, the validity of Dr. Bahari’s data could not be ascertained or verified.

[505] In his testimony, Dr. Khan also brought up cell-based research conducted at Penn State University. Dr. Khan explained how LDN fools the body into thinking that it does not have enough endorphins and thereby boosts endorphin production, and that some natural endorphins could stop cancer growth or kill cancer cells. However, Dr. Younus commented about the perils of relying on petri dish research and their application to humans, describing the petri dish system as “artificial.” The cancer cells are “grown under very strict laboratory circumstances. That does not really apply or mimic exactly the human system, which is significantly more

complicated and intricate.” He also testified that chemotherapy drugs that work for one type of cancer may not work for another.

[506] Dr. Younus concluded that in using LDN on Ms. B to treat a presumed diagnosis of leukemia, Dr. Khan treated her with a therapy that had no quantifiable benefit and was not informed by evidence and science.

[507] Dr. Khan’s expert witness, Dr. Rosenberg, was asked to review the file on Ms. B. He was asked whether Dr. Khan met the standard of practice for diagnosing cancer and providing treatment in his use of the ONCOblot test, and then sending her for a biopsy and providing LDN. He answered, “of course what he did was not standard of practice.” However, he thought that Dr. Khan’s use of the test and referring the patient to an expert to confirm the diagnosis was “very reasonable.” In his opinion, Dr. Khan adhered to the standard of an integrative cancer physician or integrative physician in letting Ms. B know that through the ONCOblot she was found to have the protein associated with cancer, and that she needed to be referred to a hematologist who could confirm this through biopsy.

[508] However, in testifying about LDN, Dr. Rosenberg said that he uses LDN only as an adjunct to hopefully augment more powerful substances, but “certainly not” as a primary treatment. He does not regard LDN as a “power player,” and stated that it could not alter the progress of a person with cancer by itself.

#### *Monitoring the Effects of LDN on Cancer*

[509] Dr. Younus opined that it was unknown how long a patient would have to continue LDN therapy, and that since there were no abnormal test results, there was no apparent method to evaluate the efficacy of ongoing treatment. He testified that, in Ms. B’s case particularly, although one could theoretically do repeated ONCOblot testing to see if the ENOX2 protein disappears, there would be no objective method by which one could monitor treatment response because there was no established diagnosis of cancer through conventional methods. He explained that:

...[A]s it applies to this particular case, it will be very hard to see the impact. He could keep on repeating the ONCOblot test to see if there is any change, and if the ENOX2 protein goes away. But that, in a strict sense of science and evidence, does not really prove,

because the presence of the disease was not documented [by] any other means, which means that in any conventional method of follow up, there is really no disease activity that you could measure objectively, and then follow it to be counted as a response to the treatment.

[510] We understood this to mean that there was no way to know through a reliable monitoring method, whether the treatment was having an impact on Ms. B, or when treatment was complete, and therefore when she should stop taking LDN.

Ms. B's Consent to Start LDN

[511] At her July 27, 2017 meeting, Ms. B signed a Medicor LDN treatment consent form. The first line of the form stated "I hereby confirm that I have been diagnosed with Cancer. I further confirm that I have elected to have Medicor Cancer Centres Inc. ("Medicor") treat my cancer with low dose naltrexone ("LDN")." Dr. Younus testified that at this point, Ms. B had not received a conventional diagnosis of cancer, and there was no indication on the consent documentation that Ms. B had been informed that by conventional standards she did not have a cancer diagnosis at all.

[512] The form went on to require that the patient confirm that she belonged to one of three described categories (A, B, C), none of which described Ms. B's circumstances.

[513] Category A stated:

I am not currently being offered medical treatment of my cancer, either because all standard medical treatments have failed, or because my oncologist (or other specialist) has determined that there are no proven treatment options for me. I understand that instead of LDN, I have a choice to receive no treatment for my cancer, and that I have the option of receiving only comfort care (palliative care).

[514] Dr. Younus stated that this category did not apply to Ms. B because:

- by this time, she had not even seen a medical oncologist/hematologist to have a meaningful discussion about whether there was even a need for treatment, or what the treatment would be if she needed it; and

- with regard to the statement “I have a choice to receive no treatment for my cancer,” Dr. Younus opined that “I think the patient does not have all the information to really make that decision yet.”

[515] Category B stated:

I am currently receiving generally accepted medical treatment for my cancer which is not working optimally or has a poor chance of success, and I would like to combine it with LDN.

[516] Dr. Younus testified that this section did not apply to Ms. B “because she hasn’t even seen the medical oncologist yet.”

[517] Category C stated:

I have been offered generally accepted medical treatments for my cancer. After reviewing the risks and benefits of those treatments with my specialists I voluntarily choose not to receive them. This time I would like to be treated with LDN.

[518] Dr. Younus testified that this section was also not applicable to Ms. B “because none of the accepted medical treatments have ever been discussed by this time.”

[519] There was also no documentation in Ms. B’s Medicor patient records to show that Dr. Khan provided Ms. B with information about conventional therapy for leukemia and compared it with the risks and benefits of his own therapies.

### *Confirming a Diagnosis of Leukemia*

[520] It would prove to be difficult to find a conventional oncologist who would see Ms. B for further work up and treatment of leukemia. Dr. Khan’s first two referrals were declined, and Sunnybrook reported that Ms. B’s blood test results<sup>22</sup> were normal. Dr. Khan’s plan was to refer Ms. B to Scarborough General Hospital, after which, if they refused, he would refer her to Dr. Rupert, a physician in the United States.

[521] After Sunnybrook declined to see Ms. B, Dr. Khan emailed her on September 14, 2017, and told her, “I am sorry the doctors at Sunnybrook are judging your illness without even seeing you first to discuss your symptoms, examine you and review

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<sup>22</sup> Specifically, her CBC.

the test results in the proper context.” Ms. B testified that she could not understand what the problem was and why other patients with leukemia were being seen, but not her. She described herself as losing faith and specified, “I didn’t understand why no one was going to see me, and I was...I had cancer. And I just didn’t understand.”

[522] Dr. Khan’s referral to Scarborough General Hospital was successful. Dr. Krieger, a hematologist-oncologist, agreed to see her for further evaluation despite her normal CBC blood test, and even though her blood work demonstrated an absence of immature cells. Dr. Younus testified that immature cells are the hallmark of leukemia, and one would not expect a person with no immature cells to have leukemia. Dr. Younus was of the opinion that Dr. Khan’s referral of Ms. B to a hematologist/oncologist was “absolutely” the most appropriate step that one could take.

[523] Dr. Krieger saw Ms. B on September 25, 2017. In addition to the ONCOblot test itself, Dr. Krieger had another indication to proceed with a bone marrow biopsy, which was Ms. B’s concern over her diagnosis of leukemia. Ms. B testified that even had Dr. Krieger told her she did not need a biopsy, she would still have done it.

[524] In his consultation note to Dr. Khan, Dr. Krieger wrote that Ms. B was worried about her diagnosis of acute leukemia, and that to rule it out he would perform a bone marrow biopsy and send it for flow cytometry.<sup>23</sup> In a subsequent note to Dr. Khan on October 6, he stated that he did not believe Ms. B had acute leukemia but he was awaiting flow cytometry.

[525] On October 18, 2017, Dr. Krieger wrote to Dr. Khan to tell him that Ms. B’s bone marrow aspirate and biopsy were normal. Her flow cytometry test did not show any evidence of acute leukemia and her CBC was also normal. He told Dr. Khan,

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<sup>23</sup> Dr. Younus stated: “Flow cytometry is essentially a laboratory technique that sends a number of cells in quick succession to undergo a variety of tests in a very short manner of time, in order to diagnose the characteristics of a cell. So, if the cell is abnormal, if the cell is cancerous, if there are leukemias or lymphomas, there are certain changes that will be picked up by these tests.”

"I do not think that there is any evidence at present of acute leukemia. I have reassured the patient in the office today."

[526] Ms. B testified that she had come to Dr. Krieger's office prepared to discuss a file she had brought with her that contained therapies she had looked up online to treat her cancer. Instead, Dr. Krieger told her, "your results...You do not have leukemia. You do not have cancer. You've never had cancer. Go home and enjoy your life." She testified that although she knows she should have been happy, she found the experience "overwhelming" and "didn't know what to think." During her testimony at this hearing, Ms. B became tearful when she recounted this experience.

#### *Dr. Khan's Ongoing Diagnosis of Leukemia*

[527] After receiving Dr. Krieger's letter stating that Ms. B did not have leukemia and that he had reassured her of this, Dr. Khan wrote to Dr. Krieger on October 24, 2017 to ask if Ms. B could have a very early low grade chronic lymphocytic leukemia. Dr. Younus testified that the tests administered by Dr. Krieger are meant to provide the diagnostic basis for all the chronic leukemias as well as acute leukemia, and that "having [a] completely negative bone marrow aspirate and biopsy and flow cytometry, essentially, at least rules out the possibility of even CLL [chronic lymphocytic leukemia] at this point."

[528] Despite this being the case, Dr. Khan began a series of communications with Ms. B in which he challenged Dr. Krieger's diagnosis that she was cancer-free. In his October 25, 2017 email to her, Dr. Khan explained that while the ONCOblot test could be wrong, the chance of this occurring was 0.07%. He told Ms. B that Dr. Krieger's bone marrow test was not sensitive enough to find a low number of cancer cells. He provided her with a lengthy technical explanation of why this could be the case, along with a medical paper discussing the number of cancer cells that marrow testing can find among normal cells. Dr. Khan's conclusion to Ms. B was that the most likely correct diagnosis was that she did indeed have leukemia, but that it was very early-stage chronic lymphocytic leukemia which was so mild that it was not making her ill. He recommended that she continue the LDN "which should keep this under control."

[529] In her testimony, Ms. B stated that a lot of Dr. Khan's October 25 email meant nothing to her as she is not a doctor. She felt that the email was written to justify the test, and she did not know what to believe.

*Ms. B's Ongoing Care from Dr. Khan*

[530] Even after Dr. Krieger had ruled out leukemia as a diagnosis for Ms. B, Dr. Khan did not alter his diagnosis. His November 16, 2017 Medicor note continued to say that Ms. B had leukemia for which she was receiving LDN. Ms. B's LDN prescriptions from Dr. Khan continued to state that she had a diagnosis of blood cancer.

[531] Dr. Khan testified that he was using LDN for cancer prevention and to treat Ms. B's chronic fatigue, fibromyalgia and lymphocytic colitis. Ms. B in her testimony confirmed that she continued taking LDN until June 2018 because it helped with some of her other clinical issues. However, the LDN consent form did not make any reference to cancer prevention. The consent form made it clear that LDN was being provided for treatment of an established cancer diagnosis.

*The Impact of a Leukemia Diagnosis on Ms. B's Life*

[532] During her testimony, Ms. B became noticeably tearful and distraught when she described her experience of being diagnosed and treated for leukemia. She described emotions such as feeling devastated when Dr. Khan emailed her that she had leukemia. She was shocked and terrified when she learned she would need a bone marrow biopsy, confused as to why oncologists were seeing other cancer patients but not her, overwhelmed when she learned from Dr. Krieger that she did not have cancer and further confused when Dr. Khan told her (after her cancer free diagnosis from Dr. Krieger) that she did in fact have cancer.

[533] Ms. B testified that in addition to making personal financial arrangements when she learned she had cancer, her diagnosis had other impacts. In the spring of 2017, Ms. B and her husband had sold their house in Ajax so that they could retire to Guelph to be closer to their son. When she received her cancer diagnosis, they stopped looking for a new home in Guelph and tried to have the sale of their home reversed. They considered renting in Ajax, but were worried about commuting to the hospitals, especially during the winter, and ultimately

decided to rent a house in Toronto as Ms. B wanted to be close to the hospitals. Ms. B stated that she was not working, and her husband was on long-term disability. Their total monthly income was not much more than the cost of Toronto rent. To stay in Toronto so that she could be close to the hospitals, Ms. B had to use a good portion of her equity. She used up so much of the equity that by the time she felt that she could leave Toronto, she could no longer afford a house in Guelph as had been the original plan. She ultimately purchased a smaller home in another town where she is currently living.

#### *Ms. B's Outcome*

[534] Ms. B continued to be a patient of Dr. Khan's until January 2019. She explained that there was no prescription cost if she went in for an appointment to receive it. She continues to take LDN for another condition, which is prescribed to her by another doctor.

[535] On November 3, 2019, Ms. B received a letter from Dr. Khan's clinic reminding her that she has cancer. She did not open the letter until March 2, 2021, the day before her testimony at this hearing. The letter stated, "NOTICE TO MEDICOR PATIENTS WITH A DIAGNOSIS OF CANCER" and went on to tell patients that because Dr. Khan's cancer therapy consists of "complementary treatments which are not generally accepted in Ontario" and "not considered medically necessary," OHIP would no longer be paying for the doctor's fees. The letter contained an outline of the fees that Medicor would be billing patients directly going forward.

[536] Ms. B stated, "I didn't read it till yesterday. Am I surprised? I don't know how I feel about it. I'm totally overwhelmed. I guess I'm still considered a patient with cancer."

#### *Summary of Expert Witness Opinion of Ms. B's Care by Dr. Khan*

[537] Dr. Younus's opinion was that Dr. Khan met the standard of practice of the profession when:

- he used the ONCOblot test on Ms. B; and,

- he referred Ms. B to a hematologist/oncologist to further evaluate her. Dr. Younus stated that this was “absolutely” the most appropriate step that one could take.

[538] In Dr. Younus’s opinion, Dr. Khan failed to maintain the standard of practice of the profession in the following:

- he did not reach a conventional diagnosis when he diagnosed Ms. B with leukemia;
- he failed to obtain informed consent to use LDN;
- in using LDN on Ms. B to treat what he presumed to be leukemia, he treated her with a therapy that had no quantifiable benefit and was not informed by evidence and science; and
- in using HonoPure on Ms. B to treat what he presumed to be leukemia, he treated her with a therapy that was not informed by evidence and science.

#### *Lack of Knowledge and Judgment*

[539] Dr. Younus expressed the opinion that in his care and treatment of Ms. B, Dr. Khan displayed:

- a lack of knowledge by treating Ms. B for the presumed diagnosis of acute leukemia with LDN and Honopure, without the data based on science and evidence that would support the treatment; and
- a lack of judgment by pre-selecting a diagnosis and continuing with a plan of treatment despite negative test results from bone marrow aspirate and biopsy.

#### *Exposure to the Risk of Harm or Injury*

[540] Dr. Younus also expressed the opinion that Dr. Khan exposed Ms. B to the risk of harm by labelling her with the “grim diagnosis” of cancer without it being properly established and embarking on a treatment plan without a clear pathway in front of it, thus putting the patient into significant mental stress, anxiety and tension. He also exposed Ms. B to the potential harm or risk of the investigations or treatments that followed.

## *Finding*

[541] We considered the written and oral evidence before us and find that in his care and treatment of Ms. B, Dr. Khan failed to maintain the standard of practice of the profession by:

- a) making a diagnosis which was not a conventional diagnosis, thus failing to comply with the requirements of the CAM policy;
- b) failing to obtain the patient's informed consent to the use of LDN and HonoPure; and
- c) treating a patient's presumed cancer using medications, LDN and HonoPure, which were not informed by evidence and science, did not possess a favourable risk/benefit ratio, did not have a reasonable expectation of remedying or alleviating his patient's health condition (CAM Policy – Therapeutic Options) and were not the appropriate treatment for this patient's presumed cancer.

## *Analysis*

### *a) Analysis - Failing to Reach a Diagnosis that Satisfied the CAM Policy*

[542] The CAM policy is clear in its requirement that physicians providing CAM must reach a conventional diagnosis, and that their patient assessments and diagnoses must be consistent with the standards of conventional medicine and informed by evidence and science.

[543] Currently, it is unknown if a person with a positive ONCOblot test will go on to develop a malignancy. ONCOblot testing is not considered conventional, nor sufficient as a stand-alone diagnostic tool for the diagnosis of cancer.

[544] While Dr. Khan did not fail to meet the standard of practice by choosing to use the ONCOblot test on Ms. B, the result of this test was insufficient to make a diagnosis of leukemia. This test does not conclusively prove the presence of clinically significant blood cancer, nor which form of blood cell cancer (of which there are several) may be present. Dr. Khan failed to maintain the standard of practice when he diagnosed Ms. B with acute leukemia based on the ONCOblot

test, and in the absence of confirmatory testing through conventional investigations.

- [545] Further, highly sensitive conventional investigations, conducted by her hematologist-oncologist Dr. Krieger, demonstrated that Ms. B did not have leukemia, and she was informed of this by Dr. Krieger. Dr. Khan challenged the integrity of these tests and proclaimed that a different type of leukemia was present, even though the investigations administered by Dr. Krieger would have diagnosed chronic lymphocytic leukemia if Ms. B had this disease. We were frankly shocked that instead of reassuring Ms. B that her ordeal of worrying that she had leukemia could come to a close, Dr. Khan insisted to Ms. B that indeed, she did still have leukemia and urged her to keep taking LDN “to keep this under control.”
- [546] In this instance, not only did Dr. Khan fail to come to a conventional diagnosis, he also disregarded established diagnostic methods, in favour of an unestablished method (ONCOblot).
- [547] Dr. Khan also appeared to have shifted the burden of the analysis of tests and literature to Ms. B. After Dr. Krieger told Ms. B that she did not have cancer, Dr. Khan emailed her with technical explanations about diagnostic testing and medical literature, which she testified she did not understand. It was Dr. Khan’s job to make sense of this information, not Ms. B’s. What is clear is that through all of this, Dr. Khan’s messaging to Ms. B was that he had correctly diagnosed her with cancer, she continued to have cancer (albeit of a different kind), and she needed ongoing treatment with LDN if she did not want it to get worse.
- [548] In their closing oral submissions, counsel for Dr. Khan stated that “the most important evidence that emerged from both [Ms. B] and Dr. Khan was after the positive ONCOblot test, Dr. Khan went through extensive efforts to get her a conventional diagnosis. Again, not the type of behavior you would expect from a person who is trying to sell snake oil.”
- [549] Dr. Khan did go through extensive efforts to get Ms. B a conventional diagnosis, but he then proceeded to ignore it. The conventional test results and Dr. Krieger’s diagnosis showed that Ms. B did not have cancer, but Dr. Khan insisted that she did. He persisted in selling Ms. B on more LDN on the premise that she did indeed

still have leukemia but simply a different type than the one he initially diagnosed her with. He told Ms. B that she should keep taking LDN to keep the cancer “under control.” We find, and the CAM policy demands, that Dr. Khan should have accepted the conventional diagnosis, and should have stopped prescribing LDN to Ms. B to treat cancer.

[550] Ms. B described herself as feeling shocked and terrified that she would need to undergo a bone marrow biopsy. It is unfortunate, to say the least, that despite putting herself through this testing, it was all for naught because Dr. Khan essentially ignored the results, which cleared her of cancer.

[551] In short, Dr. Khan gave Ms. B a diagnosis that she did not have, for which he sold her a remedy that she did not need, which - as per evidence and science - turned out to be no remedy at all. We find that with regard to Dr. Khan’s treatment of Ms. B, this was the most important evidence to have emerged.

[552] When Dr. Krieger’s tests showed that Ms. B did not have blood cancer of any kind, Dr. Khan should have confirmed this for her rather than making a new, second diagnosis of a different type of leukemia (chronic lymphocytic).

*b) Analysis - Failure to Obtain Informed Consent to Perform ONCOblot Testing, and Treat Ms. B with LDN and HonoPure*

[553] It is not in dispute that, as Dr. Khan’s counsel pointed out, Ms. B was a sophisticated consumer of CAM who spent time doing her own research on various medical conditions and therapies. However, as previously discussed in the section of these reasons dealing with informed consent, this does not discharge a physician of their duty to provide their patients with high quality and pertinent information so that patients are able to make fully informed health decisions.

[554] With all patients, it is important that a physician presents a thorough, well-balanced and relevant discussion comparing the conventional treatment options with the therapies they are proposing, including alternative and complementary options. This conversation is particularly important when a patient is more likely to engage with therapies and tests that may not have met a high bar for efficacy and scientific rigour.

[555] It is a physician's duty to discuss key information with their patient, answer their questions and assure themselves that their patient truly understands all the key information that must be considered before their patient makes a decision regarding a therapy or a test. While written information provided to patients may be helpful in some circumstances, it is not a substitute for a proper discussion between a physician and their patient.

[556] Dr. Khan told Ms. B that she had leukemia and proposed to treat it, but his Medicor chart notes do not show documentation of which standard chemotherapeutic treatment options for leukemia were discussed with her, nor how their risks and benefits compared to those of the LDN and the HonoPure treatments he was offering. As previously discussed, we did not find credible Dr. Khan's word that he always had this conversation with patients and had done so with Ms. B. Informed consent for treatment is contingent upon such conversations, and in failing to have these with Ms. B before treating her with LDN and HonoPure, Dr. Khan failed to obtain informed consent for these treatments and failed to meet the standard of practice of the profession.

[557] Additionally, Ms. B did not fall into any of the three categories (A, B, C) outlined on Medicor's LDN consent form. It would seem that even by the standards laid out on that form, Ms. B did not qualify for LDN treatment. Yet he treated her with it anyway.

*c) Analysis - The Use of LDN in the Treatment of a Presumed Leukemia Diagnosis*

[558] We find that Dr. Khan's treatment of Ms. B with LDN and HonoPure was not informed by evidence or science. Neither LDN nor HonoPure showed favourable risk/benefit profiles as cancer therapies, nor were they effective and appropriate treatments for a patient with presumed leukemia or to prevent blood cancer, as Dr. Khan later claimed. In using these medications to treat Ms. B's presumed cancer, he failed to maintain the standard of practice.

[559] Dr. Khan submitted that Dr. Younus's opinion that he failed to meet the standard of the profession by starting to treat Ms. B before her ONCOblot test results were confirmed with conventional investigations completely ignored the context of Ms. B's medical history and the risk profile of LDN, which counsel described as "relatively low." We disagree.

[560] Dr. Younus's analysis reflected the use of LDN and HonoPure to treat cancer, specifically leukemia. The use of LDN (and HonoPure) to treat conditions other than cancer is not the subject of this hearing. That Ms. B and Dr. Khan may have hoped that LDN could also help Ms. B's other conditions if she used it, and the after-the-fact observation that it did possibly help one of those conditions, does not act as a factor to support the use of LDN to treat Ms. B's presumed cancer to begin with and is not relevant to our analysis. The evidence shows that LDN was instigated, and continued by Dr Khan for "anti-cancer" effect, which is the subject of this hearing, and the focus of Dr. Younus's analysis. Any benefit that Ms. B may have derived from using LDN and continuing to use LDN for her various non-cancer medical issues does not alter the analysis regarding Dr. Khan's inappropriate use of LDN as a cancer treatment for leukemia, and his failure to confirm the presence of cancer in Ms. B before he started treatment.

[561] Finally, given that a cancer diagnosis is, as Ms. B described, "devastating" and as Dr. Younus described, "potentially fatal," physicians should make every effort to give such news in the most supportive environment possible. While we did not make a finding on this matter, we were disturbed to learn that Ms. B was told that she had cancer via email. Dr. Khan, a physician whom Ms. B had never met, should not have emailed Ms. B with this life-altering information in the early hours of the morning of a Saturday. He should have given her this news in person or directly via telephone or video so that at the very least there could have been two-way communication. Instead, Dr. Khan dropped this news in her lap. This is an extremely unsupportive, bordering on callous, way to give a person a diagnosis of cancer.

#### *Analysis - Knowledge, Skill and Judgment*

[562] We find that Dr. Khan showed considerable lack of judgment when he diagnosed Ms. B with cancer before he had confirmed the condition through conventional investigations, as he was required to do by the CAM policy. Additionally, Dr. Khan either did not know or did not understand the limitations of the test he was administering. He made a presumptive diagnosis of leukemia even though the test could not provide that level of diagnostic detail. He either ignored, or did not know, that blood cancer could signify three groups of completely different blood-based cancers that required completely different treatments.

[563] Based on his interpretations, Dr. Khan not only started treating Ms. B before confirming that she did indeed have cancer, he then treated her with a medication, LDN, that did not have quantifiable benefit for the cancer that he was presumably treating. This shows considerable lack of judgment on his part. This also applies to Dr. Khan's use of HonoPure to treat cancer.

[564] Additionally, Dr. Khan did not appear to understand the diagnostic relevance of the conventional test results (bone marrow aspirate and biopsy) provided by Dr. Krieger. These tests ruled out not only acute leukemia, but chronic lymphocytic leukemia as well, yet Dr. Khan continued telling Ms. B that she had cancer and recommended that she should keep taking LDN to keep it under control. We find this to be a highly concerning display of Dr. Khan's lack of knowledge and judgment.

*Exposure to the Risk of Harm or Injury and Disregard for His Patient's Welfare*

[565] Dr. Khan used LDN to treat Ms. B's presumed cancer and exposed Ms. B to the risks of side effects and toxicities from this medication despite the absence of its efficacy against cancer in humans. That Ms. B did not experience significant harm from the drug does not alter her exposure to the risk of harm.

[566] Ms. B was worried that the numerous health problems and various symptoms she was experiencing were due to cancer, and she came to Dr. Khan hoping to rule out this possibility. Instead, Dr. Khan gave Ms. B a cancer diagnosis that would change the course of her life, her emotional wellbeing and her financial stability, and which ultimately impacted her ability to retire in the location and in the way she had planned.

[567] As suggested by Dr. Younus, the diagnosis of cancer is grim and potentially fatal, and not only exposes a patient to the risk of harm, but in Ms. B's case caused significant mental stress, anxiety and tension. This was heightened by the uncertainty she experienced when she was cleared of a cancer diagnosis by Dr. Krieger, only to be informed by Dr. Khan that she still had cancer.

[568] This put Ms. B in an impossible predicament. With no conventional diagnosis, and no conventional medical doctor offering her therapy, Ms. B's only option was to either ignore Dr. Khan's diagnosis of chronic leukemia or take the only cancer

treatment being offered to keep her cancer “under control.” Yet, there would be no objective method by which to monitor her cancer and its response to therapy, as discussed by Dr. Younus, and therefore, no way to provide this patient with – at a minimum – information that would allow her to understand her clinical progress or response to treatment.

[569] That Ms. B suffered as a result of her experience with the diagnosis of leukemia was clear. This was evident to us not only from her testimony, but from her demeanour and tearfulness when she recounted her experience. Even when keeping in mind the very limited weight that should be given to a witness’s demeanour in evaluating their credibility, it was evident that Ms. B was experiencing genuine grief during certain periods of her testimony. Further, Ms. B did all the rational things one would expect a person would do when they believed that their life was in danger from cancer. She made personal arrangements and put her life on hold to move into the city to receive therapy.

[570] Dr. Khan’s conduct in diagnosing Ms. B with, and treating her for a cancer she did not have, ignoring conventional testing that conclusively showed she did not have cancer, continuing to tell her she had cancer that needed treatment with LDN to keep it “under control” and treating her presumed cancer with agents, LDN and HonoPure, that were not informed by evidence and science and did not offer her a beneficial risk/benefit ratio and could not reasonably be expected to alleviate her presumed cancer, without Ms. B’s informed consent, demonstrated a disregard for Ms. B’s welfare.

### *Conclusion*

[571] We considered the written and oral evidence before us, and conclude that in his care of Ms. B, Dr. Khan failed to maintain the standard of practice of the profession, demonstrated a lack of knowledge and judgment, exposed Ms. B to the risk of harm or injury and disregarded her welfare.

### Dr. Khan’s Financial Ties with the Makers of ONCOblot

[572] During this hearing, Dr. Khan confirmed that Medicor had an agreement with the company MorNuCo, the maker of ONCOblot, to be its Canadian distributor, and that this agreement was in place when he was providing care to Ms. B. Dr. Khan

testified that he disclosed the distribution agreement between Medicor and MorNuCo to patients, and submitted that evidence of this disclosure was present in the following words on the second page of his Medicor ONCOblot test consent form: "I understand that Medicor is owned by a family member of the Medical Director." We disagree. This statement pertained to the owners of Medicor, not to a distribution agreement between Medicor and MorNuCo. It did not disclose the financial relationship between Dr. Khan and MorNuCo. Dr. Khan should have disclosed this to patients.

#### Dr. Khan's Care of 10 Patients with SAFE Chemotherapy

##### Dr. Khan's Care of Patient C

[573] In relation to his care and treatment of Ms. C, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose Ms. C to the risk of harm or injury?

#### *Overview of Relevant Information*

##### *History and Conventional Treatment Overview*

[574] Ms. C was a 65-year-old woman who had been diagnosed with pancreatic cancer in the summer of 2012. She underwent a Whipple's procedure which was followed by six months of adjuvant chemotherapy with gemcitabine, a conventional chemotherapy.

[575] A Whipple's procedure is a complicated surgery that plays a key role in the surgical treatment of pancreatic cancers. Dr. Tozer explained that although it is an aggressive surgery that is performed with curative intent, the cancer can come back.

[576] This was the case with Ms. C. Despite the Whipple's surgery and the gemcitabine chemotherapy, Ms. C developed metastatic disease to the liver. Dr. Tozer testified that "now that she's developed metastatic disease, she is no longer in a position where cure by conventional means is an option...treatments would be with palliative intent and...the patient has a very, very low probability of surviving a year."

### *Conventional Treatment Options*

[577] Dr. Tozer testified that once she was diagnosed with pancreatic cancer metastases to the liver after her surgery, Ms. C's conventional therapeutic options would have been:

- palliative and best supportive care with no anticancer therapy; or
- gemcitabine; or
- FOLFIRINOX, which is the most aggressive palliation approach.

[578] Dr. Tozer testified that:

FOLFIRINOX is a rather complex chemotherapy regimen, consisting of 5FU, leucovorin, oxaliplatin and irinotecan... gemcitabine was one of the first drugs that actually got approval where there [were] no improvements in survival, however there was improvement in quality of life. So, patients who were on gemcitabine did better with respect to pain control and other symptoms. FOLFIRINOX is then compared to gemcitabine, and what FOLFIRINOX demonstrated was actually a survival benefit. So, the purpose here is to improve quality of life and to attempt to prolong life. But, again, it is not a cure.

[579] Oxaliplatin is the "sister drug" to carboplatin, which, as previously discussed, is the main chemotherapeutic component of SAFE chemotherapy. The key similarity is that both medications contain platinum.

[580] According to a consultation note from Ms. C's physician Dr. Sandhu, Dr. Welch, Ms. C's oncologist at the time of her metastatic liver disease diagnosis, planned on using FOLFIRINOX. However, Ms. C declined further chemotherapy and decided to pursue treatment with Dr. Khan after her sister, who was a naturopath, referred her to him.

### *Relevant Information on Care and Treatment by Dr. Khan and Other Physicians*

[581] Ms. C met with Dr. Khan on October 11, 2012. His Medicor clinic note from that day states that Ms. C "needs info on other therapies. Given a poor prognosis from oncologist." Dr. Khan's note documents that in addition to some other medications, Ms. C was also on gemcitabine. This same note suggests that Dr. Khan was considering various treatments including LDN, DCA and HonoPure.

- [582] A chart note on November 11, 2013, stated that Dr. Khan had begun treating Ms. C with DCA, two cycles of which she had already completed at a dose of 500 mg orally, twice daily, although Dr. Khan was considering increasing the dose.
- [583] Dr. Khan was measuring Ms. C's liver enzymes and his chart notes from that same day state they were decreasing, while CA19-9 (a cancer/tumour marker) was pending. (CA19-9 is a protein secreted into the blood that is identified as a marker for pancreatic cancer.) The "Plan" section of the chart note stated that Dr. Khan was considering SAFE chemotherapy if DCA proved to be "futile."
- [584] Dr. Khan's records show that Ms. C signed a standard Medicor Consent and Direction for SAFE Chemotherapy form on January 21, 2014. In answering the question of whether Dr. Khan had reviewed conventional chemotherapy options with Ms. C, Dr. Tozer stated, "I was not able to determine that. It was not recorded."
- [585] Apart from previously described checkboxes showing "R + B [risks and benefits] in changes of therapy discussed," Dr. Khan's charts for Ms. C showed no documentation of a discussion comparing the risks and benefits among conventional treatments, SAFE chemotherapy and DCA therapy.
- [586] Dr. Khan treated Ms. C with six cycles of SAFE chemotherapy between January and June 2014.

*Cancer Progression with Respect to Clinical Status and Laboratory Investigations*

- [587] By June 2014, five months after starting SAFE chemotherapy, Ms. C was experiencing weakness, distended abdomen, stroke, hepatic encephalopathy and rising tumour markers.
- [588] Dr. Khan's chart notes from June 12, 2014 stated that Ms. C was feeling weak in her legs, "especially getting up from chair" and was "experiencing shortness of breath on exertion." When he performed a physical examination of Ms. C, Dr. Khan became concerned about anemia, and he noticed that she had a distended abdomen.
- [589] A June 16, 2014 note by Dr. Young, another physician caring for Ms. C, stated that by then Ms. C had experienced a stroke. In his testimony, Dr. Tozer stated

that this was possibly due to a blood clot as a result of the increased risk of blood clots brought on by pancreatic cancer. In the same note, Dr. Young stated that he was also suspicious that Ms. C had a metabolic encephalopathy. Dr. Tozer assumed that this was due to hepatic (liver) impairment. He explained that if the liver, due to dysfunction, is unable to metabolize (break down) various products or toxins in the blood, this can lead to severe confusion, and ultimately death.

[590] Dr. Sandhu's June 17, 2014 consultation note also referenced tumour markers ordered by Dr. Khan which showed that Ms. C's CA19-9 had increased from 86,564 on April 14, 2014, to 120,000 on May 6, 2014. Dr. Tozer testified that this suggested that Ms. C's "tumour burden," or the amount of pancreatic cancer in her body had increased. However in his July 3, 2014 letter to Dr. Sandhu, Dr. Khan stated that CA19-9 is an unreliable indicator when a patient is on SAFE chemotherapy treatment.

[591] In the same June 17 consultation note, Dr. Sandhu stated that Dr. Khan believed that the increasing CA19-9 level was due to tumour necrosis rather than progression of cancer. Dr. Sandhu noted that this was contradicted by evidence of liver metastases and ascites (the accumulation of fluid in the abdomen) seen on a recent ultrasound of Ms. C's liver.

[592] Dr. Tozer testified that Ms. C's symptoms and findings were consistent with "the usual pattern of disease progression we see in somebody with pancreatic cancer."

[593] Dr. Khan had a different view, and in his letter to Dr. Sandhu of July 3, 2014, he stated:

I'm also concerned with your note, in which you did not accept my explanation about [Ms. C's] excellent response to the special chemotherapy regimen she has been receiving. Rather, you have indicated to the family that she has deteriorated while on therapy as a result of disease progression.

[594] In his testimony, Dr. Tozer described Ms. C's SAFE chemotherapy treatment as "a conventional chemotherapy being given in a cancer which has not been shown to work." He disagreed that Ms. C had an "excellent response" to the "special chemotherapy regimen" she was receiving.

[595] In the same letter, Dr. Khan told Dr. Sandhu that SAFE chemotherapy was not a conventional chemotherapy, and that data from an approved phase 2 trial of SAFE chemotherapy showed that “4 of 6 stage 3 and 4 patients with (various cancers) achieved remission greater than 5 years with no recurrence.”

[596] Dr. Tozer testified that he could not find literature, evidence or science to support the use of carboplatin for pancreatic cancer, used either alone or in conjunction with mesna. He also stated that carboplatin is not listed by the FDA for off-label use in pancreatic cancer.

#### *Cancer Progression with Reference to Imaging Investigations*

[597] On March 6, 2014, the radiologist’s impression of Ms. C’s abdomen/pelvis ultrasound was “metastatic disease in the liver.”

[598] On April 23, 2014, the radiologist’s doppler ultrasound impression stated that Ms. C had five hepatic metastases. The radiologist went on to state that the “largest in the left lobe of the liver appears partially viable medially...possible necrotic tissue laterally with no flow [on doppler]...the four in the right lobe of the liver would appear necrotic and no flow identified.”

[599] Dr. Tozer testified that there were two issues with the April 23, 2014 ultrasound, the first being that it was not compared to a previous ultrasound: “So, the issue here is actually what does this mean?” The second is that one could not determine whether the necrosis of the tumours represented response to treatment or progression of disease “because as metastases get bigger and bigger in size, they outgrow their blood supply. The internal part ends up dying off or liquefying anyway.”

[600] Dr. Tozer stated that one would have to interpret the ultrasound in conjunction with blood work and the patient being assessed. If one looked at Ms. C’s worsening liver function tests, elevation of CA19-9, the development of ascites and her increasing weakness, one would not conclude that she was getting better. Dr. Tozer concluded, “I would say clinically she’s progressing.”

[601] Dr. Khan’s view is that tumours which outgrow their own blood supply would show blood flow around the periphery, but the tumours in the ultrasound did not show

such flow. He believed that these images represented a response to SAFE chemotherapy and not the natural metastatic outgrowth of blood supply.

- [602] On June 5, 2014, an ultrasound with a doppler was compared to the April 2014 ultrasound. The radiologist noted the following: a partially necrotic lesion in the left lobe of the liver which had not significantly changed in size, a new lesion in the left lobe of the liver with flow and a completely cystic and likely necrotic lesion in the right lobe of the liver, which also was noted to be “superiorly” increased in size compared to the previous ultrasound. Apart from the small nodule that may have been new in the left lobe of the liver, there did not appear to be any progression of the patient’s metastatic disease of the liver and the lesions remained necrotic or partially necrotic.
- [603] On June 17, 2014, the radiologist compared a CT scan of the chest, abdomen and pelvis to a previous CT scan. The radiologist stated that there was “[i]nterval marked increase in size of a hypodense mass centered in segment 4 of the liver,” and his opinion was that there was progression of hepatic metastatic disease, thrombus [blood clot] in the hepatic vein extending into the inferior vena cava, new moderate ascites, likely pulmonary [lung] metastatic disease, metastases in the spleen and possibly omental metastatic disease.
- [604] In reference to the CT scan on June 17, 2014, Dr. Tozer stated that one of the lesions was “markedly bigger” and that “they’re actually seeing more evidence of disease. They are now seeing a clot in the hepatic vein. Remember I said that cancer of the pancreas does make one more predisposed to blood clots. So, that’s what’s happened.” Dr. Tozer also noted two more metastases in the spleen, as well as metastases in the lungs, and omentum (“the lining in your abdomen”), which he stated could contribute to the ascites. Overall, he concluded that the CT scan “is really, very strongly, suggestive of progression.”
- [605] On June 17, 2014, the radiologist read a CT scan of the head as having “[f]indings suggestive of brain metastases.”
- [606] On June 27, 2014, a guided aspiration ultrasound of the posterior right lobe of the liver was performed to exclude the presence of an abscess [collection of pus]. The results showed that “[n]o pus could be withdrawn” and that “the fluid was probably necrotic metastasis rather than abscess.”

[607] In Dr. Khan's July 3, 2014 letter to Dr. Sandhu, referencing Ms. C's April and June 2014 ultrasounds and her June 2014 CT scan, he wrote that "there is conclusive proof of dramatic success of the chemo." He continued:

...[A]fter only four cycles of carboplatin AUC5, plus mesna as a cytoprotective...complete necrosis of four or of five large liver mets, and partial necrosis of the fifth liver met, while no new tumours appearing during that time.

[608] Dr. Tozer explained that AUC is "...the rather unique way that carboplatin is dosed...it's a combination of the glomerular filtration rate, GFR, which is a measure of how quickly things are passing through the kidney, and basically weight/height. So, it basically takes into account excretion, and it's a way of dosing that's really only used for carboplatin."

[609] It was put to Dr. Khan on cross-examination that, consistent with Dr. Tozer's evidence, the June 17 CT scan suggested that disease had continued to progress throughout the period he was treating Ms. C with SAFE chemotherapy. Dr. Khan responded by stating that College counsel was attempting to mislead the panel because the CT scan was done "much later." He stated that Ms. C was off SAFE chemotherapy by the time of this scan, "and of course there was going to be growth." (For reference, SAFE chemotherapy had been discontinued in May 2014, a short time before the June 17 CT scan.)

[610] On re-examination, Dr. Khan explained that the June 6 ultrasound was what he had been referring to when he concluded that Ms. C had shown at least a partial response to SAFE chemotherapy. It showed that there was a cystic appearance of liver lesions/tumours. He understood this to mean that "the tumours had dissolved away...and that there was no tumour left." He also pointed out that the June 27, 2014 aspiration of the lesion in the right lobe of the liver also showed necrotic metastatic fluid.

*Did Dr. Khan Treat Ms. C with Palliative Intent?*

[611] In Dr. Khan's letter to Dr. Sandhu of July 3, 2014, he also stated:

I have attached the post-chemo April 2014 ultrasound report for you to review. So, perhaps you may come to the only reasonable conclusion that this wonderful lady was headed for remission.

[612] Dr. Tozer's opinion was that there was no evidence that this patient was headed for remission.

[613] In the same letter, Dr. Khan went on to hypothesize that Ms. C could have a bowel leak due to the necroses of omental metastases. He requested an urgent surgical consultation to determine if a surgeon could determine if "something more aggressive can be attempted, since the prognosis without definitive intervention is grave." He asked if Dr. Sandhu "would be so kind as to treat [Ms. C's] life as precious (as all patients) and give her a fighting chance, by not writing her off as a palliative case."

[614] Dr. Tozer opined that by this time, Ms. C "was obviously progressing," and that Dr. Khan was "pushing for...an urgent surgical intervention in somebody who has clearly got ascites, poor performance status..." Dr. Tozer felt it was not clear that Ms. C could survive the surgery as she was "very much in a way of pure palliation."

*Dr. Khan's Updated 2017 "SAFE" Chemotherapy Medicor Patient Data Compilation*

[615] On his dataset of patients whom he had treated with SAFE chemotherapy, Dr. Khan listed Ms. C as having stage 4 pancreatic cancer. In the response column, he wrote that she had a "partial response" of her cancer as per "imaging 4.5 of 5 masses dead after 4 cycles." He gave as the reason for stopping her SAFE chemotherapy "fever/infection." The "Gr 3 of Gr 4 Side Effects?" column stated that Ms. C had "serosal mets/bowel perf" which Dr. Khan documented as "most likely due to rapid chemo action".

[616] It was put to Dr. Khan on cross-examination that based on RECIST criteria, a CT scan would be preferred over an ultrasound. Dr. Khan responded that the RECIST criteria apply to conventional therapy, but not to SAFE chemotherapy because it is an immunotherapy.

[617] As set out above in the SAFE chemotherapy section of these reasons, the evidence and science do not demonstrate that SAFE chemotherapy possesses the properties claimed by Dr. Khan, that SAFE chemotherapy is an immunotherapy or that SAFE chemotherapy is anything other than the

conventional chemotherapy, carboplatin plus the bladder protectant medication, mesna.

[618] In coming to the conclusions in his dataset on Ms. C's response to SAFE chemotherapy, Dr. Khan relied on unfounded claims. Instead of using the superior radiological method (which would have been CT) to ascertain treatment response, he used ultrasound, which is not in keeping with the expectation of RECIST recommendations. Dr. Khan's scientific method was flawed, which brings into question the veracity of his dataset conclusion that Ms. C had a response to SAFE chemotherapy.

*Summary of Expert Witness Opinion on Dr. Khan's Care of Ms. C*

[619] Dr. Tozer opined, with respect to the CAM policy, that the treatment of Ms. C with SAFE chemotherapy was not informed by evidence and science because there was insufficient clinical trial evidence to support its use.

[620] He further opined that Dr. Khan's care did not meet the standard of practice because:

- Dr. Khan was using a conventional chemotherapy in an unconventional setting;
- carboplatin was not a good choice of chemotherapeutic agent for this patient; and
- although Dr. Khan did make a conventional diagnosis with respect to pancreatic cancer, he appeared to be unable to recognize the progression of disease in the patient as indicated by declining functional status, laboratory analysis and radiological imaging.

[621] In Dr. Tozer's opinion, Dr. Khan showed a lack of knowledge around the treatment of specific cancers, particularly with respect to the efficacy or lack of efficacy of some chemotherapeutic drugs in different disease settings. He did not appear to have the skill to determine that a patient's pancreatic cancer was progressing based on summation of the patient's symptoms and laboratory and radiologic investigations, and he "seemed to be incapable of accepting any alternative explanation for the patient's findings other than response to [his] treatment."

[622] Dr. Tozer also opined that Dr. Khan showed a lack of judgment in the choice of treatment he offered, and in being “overly optimistic about the patient responding to treatment in the clear face that the patient was declining.” His plan for the patient just a week before her hospitalization included further chemotherapy, despite a poor performance status and lack of clearly demonstrated benefit. Dr. Khan demonstrated a “serious lack of judgment by imploring the physicians in Owen Sound to follow an aggressive surgical course to determine the source of sepsis and not acknowledge that the patient was palliative.”

[623] Dr. Tozer also expressed the opinion that, based on Dr. Khan’s treatment of Ms. C, his clinical practice, behaviour or conduct exposed or was likely to expose his patients to harm or injury. His “overly optimistic interpretation of imaging and laboratory values could prevent patients from seeking more appropriate treatment and particularly palliative care.” Also, the surgery that Dr. Khan was pushing for in his July 3, 2014 letter would have “had a much higher than expected likelihood of surgical complications, including death,” and it appeared Dr. Khan was “quite willing to administer more chemotherapy despite the patient’s poor performance status, which could have hastened her death.”

### *Finding*

[624] We considered the written and oral evidence before us and find that in his care and treatment of Ms. C, Dr. Khan failed to maintain the standard of practice of the profession when he:

- a) treated Ms. C’s cancer using SAFE chemotherapy, which was not informed by evidence and science, did not possess a favourable risk/benefit ratio and did not have a reasonable expectation of remedying or alleviating the patient’s health condition or symptoms;
- b) failed to obtain informed consent to the use of SAFE chemotherapy; and
- c) failed to recognize the progression of his patient’s cancer.

## *Analysis*

### *a) Analysis - the Use of SAFE Chemotherapy*

[625] For the reasons stated above in the SAFE Chemotherapy section of these reasons, we find that in his use of SAFE chemotherapy in his treatment of cancer patients, including Ms. C, Dr. Khan failed to maintain the standard of practice of the profession.

[626] Even if one were to set aside concerns about SAFE chemotherapy and consider carboplatin as a stand-alone, off-label treatment for Ms. C's cancer, as Dr. Tozer testified, Dr. Khan was using a conventional chemotherapy in an unconventional setting, and carboplatin was not a good choice of chemotherapeutic agent for this patient. By offering Ms. C a conventional chemotherapy that did not show a favourable risk/benefit profile, Dr. Khan failed to maintain the standard of practice of the profession.

### *b) Analysis - Failure to Obtain Informed Consent*

[627] The box "review of R + B of change(s) in treatment plan" is checked in Ms. C's chart notes. We were not satisfied that this checkbox proves that Dr. Khan provided Ms. C with the information necessary for her to make an informed decision on the use of SAFE chemotherapy. The words "reviewed std chemo, pt declined" appear in Dr. Khan's November 11, 2013 chart notes on Ms. C, yet there is no mention in the chart of which standard chemotherapeutic drugs Dr. Khan reviewed and with what level of detail.

[628] For the reasons set out earlier, we did not find credible Dr. Khan's testimony that he reviewed conventional options with his patients in detail, including possible response rates and side effects of both conventional chemotherapeutic options and the therapy he was offering, and how these compared with each other.

[629] We find that Dr. Khan failed to maintain the standard of practice by failing to obtain informed consent from Ms. C to treat her with SAFE chemotherapy.

### *c) Analysis - Failure to Recognize Disease Progression*

[630] During Ms. C's care, Dr. Khan ordered tests to monitor her and referred her to certain specialists, such as a neurologist. However, Dr. Khan did not integrate the

information provided by these tests and specialists to assess her as having cancer progression, even though he was required to do so by the CAM policy.

- [631] At the time Ms. C presented to Dr. Khan in October of 2012, her pancreatic cancer had already metastasized to the liver and her condition was terminal, making her a palliative care patient. Whether he failed to recognize this or refused to do so, Dr. Khan did not acknowledge Ms. C's clinical condition as palliative and, rather than offering her palliative care, he started her on SAFE chemotherapy for active treatment of her cancer. Several months later, Ms. C continued to show clear evidence of disease progress as evidenced by her clinical decline - weakness, fatigue, weight loss, decrease in appetite, and her laboratory findings - rising CA and increasing liver function tests. Dr. Khan did not discuss or acknowledge these symptoms to Ms. C as disease progress.
- [632] Dr. Khan expressed the view at the time that CA19-9 is an unreliable indicator, or that the patient's increasing level of CA19-9 was due to tumour necrosis. This was unsupported by any evidence at this hearing, and was directly contradicted by Dr. Tozer. Dr. Khan's view on CA19-9 and SAFE chemotherapy amounted to nothing more than his opinion. We do not accept Dr. Khan's explanation as a reasonable argument to reject this laboratory test as evidence of Ms. C's disease progression.
- [633] Nor do we accept Dr. Khan's assertion that necrotic lesions on imaging, or liver lesion aspiration showing necrotic metastatic fluid (June 27, 2014) were indications that Ms. C was responding to SAFE chemotherapy, or that Ms. C's liquified necrotic liver lesions were an indication of "dramatic success of the chemo," as Dr. Khan wrote in his July 3, 2014 letter to Dr. Sandhu. We also do not accept Dr. Khan's explanation that on a Doppler ultrasound, "the absence of blood flow around the outer rim of the tumour (as one might expect with central necrosis due to rapid growth)" suggested that there was no tumour growth and that the SAFE chemotherapy in April 2014 was successful. We accept Dr. Tozer's expert evidence that when cancer progresses, metastases can outgrow their own blood supply and die, and these can appear as necrotic metastases on imaging.
- [634] A proper evaluation of these findings should have led Dr. Khan to conclude that Ms. C's disease was likely progressing. Dr. Khan's personal evaluation was not

evidence that he had successfully used SAFE chemotherapy to treat Ms. C's cancer when her clinical, radiological and laboratory tests showed that her cancer had progressed.

[635] It was also unclear why in his July 3, 2014 letter to Dr. Sandhu, Dr. Khan would refer to an April 2014 ultrasound to assert that the only reasonable conclusion to draw was that Ms. C was headed for remission, when he had evidence of disease progress on multiple and more recent (than April) imaging modalities that suggested the opposite conclusion from remission.

[636] Dr. Khan seemed to be focusing on his belief that necrosis of an omental metastasis could be the cause of intra-abdominal sepsis, which he felt required aggressive care. At the same time, he seemed unable or unwilling to comprehend that Ms. C's deterioration in the broader context of ongoing metastatic seeding throughout her body clearly indicated disease progress. He did not appreciate that Ms. C's prognosis was grave, with or without the definitive care he was calling for in the form of surgery.

[637] In his closing submission, Dr. Khan submitted that he was not unrealistic about Ms. C's prognosis. He referred to a "positive partial response - confirmed in three separate test results - in a case with an extremely dire prognosis" as being in his mind when he suggested to Dr. Sandhu in July 2014 that Ms. C undergo surgery. In fact, however, all Ms. C's clinical findings and investigations pointed to disease progression. Dr. Khan testified that for patients with a terrible diagnosis, such as stage 4 pancreatic cancer, "[e]ven small things for them are big victories." However, we do not see any victories in the ongoing clinical decline of Ms. C. Whatever optimistic view Dr. Khan wished to apply to his assessment of her clinical status does not change the fact that Dr. Khan failed to come to the appropriate conclusion of disease progress and failed to communicate to Ms. C that her disease was progressing.

[638] The abundance of information should have clearly led to a diagnosis of a palliative clinical state, yet Dr. Khan would not acknowledge that Ms. C was a patient in need of palliative care, as evidenced by his plea to Dr. Sandhu to refrain from writing off Ms. C as palliative. Dr. Khan should have realized that Ms. C showed disease progress, and he should have treated her with palliative intent, which

would have included end of life planning to prepare Ms. C for her impending death. Instead, Dr. Khan pushed for aggressive therapy in the form of surgery and planned to expose his patient to further SAFE chemotherapy treatments. He thereby failed to maintain the standard of practice.

#### *Knowledge, Skill and Judgment*

- [639] We accept Dr. Tozer's opinion and find that Dr. Khan demonstrated a lack of knowledge regarding the appropriate chemotherapeutic agents for Ms. C's cancer.
- [640] Dr. Khan was unable or refused to utilize his patient's laboratory, radiological and symptomatic information to conclude that Ms. C's pancreatic cancer had progressed. This demonstrated a lack of skill and knowledge.
- [641] Dr. Khan also showed a lack of judgment in his willingness to administer more SAFE chemotherapy and suggest other aggressive treatments, such as surgery, despite Ms. C's deteriorating clinical status.

#### *Exposure to the Risk of Harm or Injury*

- [642] Dr. Khan submitted that since Dr. Tozer did not point to any actual harm to Ms. C, her exposure to risk or harm from SAFE chemotherapy is speculative. This argument obfuscates the fact that actual harm need not occur for there to be exposure to risk of harm or injury. Exposure to the risk of harm is, by its definition, always speculative, otherwise one would be discussing actual harm or injury instead of risk. The goal is to minimize such exposure, which Dr. Khan failed to do. Ms. C may not have suffered actual harm because of SAFE chemotherapy directly. However, this was not due to sound care on the part of Dr. Khan, who exposed her to the risk of harm or injury from the known side effects and toxicities of carboplatin.
- [643] Additionally, Dr. Khan exposed Ms. C to the risk of harm or injury when, despite Ms. C's deteriorating clinical status, he administered more SAFE chemotherapy or was pushing for other aggressive treatments (such as surgery) which could have hastened her death.

### *Dr. Khan's Disregard for His Patient's Welfare*

[644] Dr. Khan treated Ms. C with SAFE chemotherapy, the efficacy of which is not informed by evidence and science. Further, we accept Dr. Tozer's expert opinion that carboplatin was not a good chemotherapeutic agent for Ms. C. His care exposed Ms. C to harm and he failed to provide palliative care to Ms. C at the end of her life. In his care of Ms. C, Dr. Khan displayed a disregard for his patient's welfare.

### *Conclusion*

[645] We considered the written and oral evidence before us, and conclude that in his care of Ms. C, Dr. Khan failed to maintain the standard of practice of the profession, demonstrated a lack of knowledge, skill and judgment, exposed Ms. C to the risk of harm or injury and disregarded her welfare.

### Dr. Khan's Care of Patient D

[646] In relation to his care and treatment of Ms. D, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose Ms. D to the risk of harm or injury?

### *Overview of Relevant Information*

#### *History and Conventional Treatment Overview*

[647] Ms. D was a 70-year-old woman who, in January 2012, was diagnosed with stage 4 colon cancer and metastatic disease to the liver.

[648] Ms. D's oncologist's clinic visit note from February 4, 2014 summarized that Ms. D's conventional cancer treatments included:

- Initial treatment with "pseudoneoadjuvant [*sic*] FOLFOX chemotherapy." Neoadjuvant therapy is given before the primary therapy which in this case was surgical resection. As previously stated, FOLFOX is a chemotherapeutic regimen consisting of 5FU, leucovorin and oxaliplatin. Dr. Tozer testified that Ms. D's treatment regimen was "a very very aggressive approach," the goal of which was to decrease the size of the tumour so it would be more amenable to local treatments like surgery. Dr. Tozer described Ms. D's response to the treatments she received to that point in time, as "very good."

- After treatment with FOLFOX, Ms. D underwent a hepatic arterial embolization for liver metastases. This procedure attempted to block blood flow to liver metastases to starve them of their blood supply.
- What followed was a hepatic metastasectomy in July 2012 at Sunnybrook. This operation was performed in an attempt to remove the tumours that had metastasized to the liver.
- Ms. D was then re-treated with FOLFOX chemotherapy from August to September 2012. This treatment was an attempt to decrease any micrometastatic disease (i.e. metastatic disease that is too small to visualize radiologically).
- Thereafter, in October 2012, Ms. D began chemoradiation therapy for the primary colon cancer.
- In January 2013 Ms. D underwent a surgical resection of the primary colorectal tumour, as well as some lymph nodes. The goal of this surgery was to remove as much of the cancer from the body as possible, ideally all of it, as this would give Ms. D the best chance for remission.
- The pathologist's histopathology report for Ms. D stated that her surgical resection margins were clear (or cancer free), and that none of the 25 sampled lymph nodes showed the presence of cancer. This would have been the best possible outcome for a surgery which aims to remove a cancer from the body.
- After the surgery, in mid-April 2013, Ms. D received another two cycles of FOLFOX chemotherapy.

[649] Despite this aggressive multidisciplinary treatment approach, re-staging CT scans performed on Ms. D four months later in August 2013 showed significant cancer progress with diffuse pulmonary, liver and pelvic sidewall metastases. Ms. D's conventional physicians informed her that due to the spread of the cancer, her treatment options going forward were non-curative.

### *Conventional Treatment Options Available*

[650] Dr. Tozer testified that at the time of her post-operative metastatic disease recurrence in August of 2013, and depending on her kidney function, conventional palliative treatment options for Ms. D could have included cetuximab, FOLFIRI, Avastin or regorafenib. Ms. D's physicians offered to treat her with FOLFIRI and Avastin which she planned to begin after an upcoming family event in September. Ms. D was also informed of the possibility of enrolling in a trial called COMPACT.

[651] Ms. D later decided she was not interested in conventional palliative chemotherapy and wished to pursue a naturopathic approach.

### *Care and Treatment by Dr. Khan and Other Physicians*

[652] Ms. D met with Dr. Khan in October 2013. Dr. Khan's chart notes from October 7, 2013 show that Ms. D had been offered FOLFIRI and Avastin, that she did not wish to pursue these options and that she was interested in SAFE chemotherapy. They also contain a checkmark in the checkbox "review of R + B of change(s) in treatment plan."

[653] Ms. D signed a standard Medicor Consent and Direction for SAFE chemotherapy on November 6, 2013. The form does not contain any comparison of the risks and benefits of SAFE chemotherapy to those of conventional treatments.

[654] Dr. Khan treated Ms. D with six cycles of SAFE chemotherapy between November 2013 and January 2014.

### *Ms. D's understanding of Her Disease and Prognosis*

[655] Ms. D's conventional oncologist was Dr. Trinkaus. Ms. D visited Dr. Trinkaus's clinic on January 10, 2014. Dr. Trinkaus's clinic visit note outlined her concern that Ms. D did not truly understand that her prognosis was terminal. Dr. Trinkaus's records showed that Ms. D told Dr. Trinkaus that she (Ms. D) believed that the conventional therapy offered to her "was not for cure," whereas her response rate to SAFE chemotherapy would be as high as 80%.

[656] Dr. Trinkaus's note stated that when she attempted to clarify to Ms. D that her prognosis was terminal, Ms. D was "dumfounded, bewildered and frankly annoyed." Dr. Trinkaus went on to say that she was concerned Ms. D "does not

have a good understanding of her disease state, nor does she have a good understanding of her potential effective treatment options for her that can palliate her disease and hopefully extend her longevity.” This same clinic note indicated that in addition to her upcoming staging CT, Dr. Trinkaus offered Ms. D irinotecan and EGFR monoclonal antibody treatment, both of which are conventional medications. Ms. D declined. Dr. Trinkaus also noted that Ms. D would “require further counselling with respect to potential beneficial chemotherapeutic options, her further care plan, and prognosis.”

*Dr. Khan’s Lack of Awareness of Evidence and Science for the Use of SAFE Chemotherapy*

- [657] In a January 17, 2014 letter, Dr. Khan told Dr. Trinkaus that SAFE chemotherapy has “...already undergone an FDA-approved phase 2 trial with great success and is considered to be off-label therapy for colon cancer, so is legal in Canada” and that SAFE chemotherapy “...prevents or dramatically reduces the severe marrow toxicity and GI [gastrointestinal] toxicity of the chemo.” As discussed, no evidence or science were presented to support these claims, nor were we presented with an FDA-approved phase 2 clinical trial, or documentation of any phase 2 clinical trial, on SAFE chemotherapy.
- [658] In her February 7, 2014 letter to Dr. Khan, Dr. Trinkaus told Dr. Khan that Ms. D “likely had platinum resistant disease to begin with...[and] now unfortunately has grade 3 myelosuppression and worse functional status.” She stated that augmenting the dose of carboplatin “will only augment toxicity and have no benefit whatsoever in inducing a response...augmenting the dose in this case has no rationale and in fact is dangerous.” She also suggested that Dr. Khan consider a three-day clinical trial program workshop from Queen’s University to improve his “understanding on how to critically appraise data and scientific literature” including the regimen he was offering, and pointed out that the level of evidence for the SAFE chemotherapy regimen was “level 4 at best.”
- [659] Ultimately, Dr. Trinkaus made a complaint to the College about Dr. Khan. It was this complaint that led to the email exchange cited above in the SAFE chemotherapy section of these reasons, in which Dr. Khan asked Dr. Matsumura for “hard data” to back up the efficacy of SAFE chemotherapy.

*Resistance - Treatment with SAFE Chemotherapy After Ms. D Had Received Platinum Containing Chemotherapy*

- [660] In a February 7, 2014 letter to Dr. Khan, Dr. Trinkaus wrote “[s]pecifically, in the case of [Ms. D], it needed to be appreciated that this lady was heavily pre-treated with oxaliplatin and chemotherapy as part of the FOLFOX regimen, and therefore likely had platinum resistant disease to begin with.” As previously discussed, both oxaliplatin and carboplatin are platinum-based chemotherapies.
- [661] In his evidence, Dr. Tozer agreed with what Dr. Trinkaus had written. He testified that since Ms. D had already progressed on a platinum-based regimen, her cancer was very unlikely to respond to a drug of the same class. Dr. Tozer conceded that there may be some variation within the medical community on the definition of platinum resistance, but the general convention is that patients may not be platinum resistant “if they don’t progress within 12 months.” Dr. Tozer further explained that “typically when we talk about platinum resistance, we’re referring to a situation where somebody has responded to platinum and then has progressed. If the progression has happened after 12 months, then we would consider re-challenging them [with more platinum]. If they’ve regressed in less than six months, then we would be less likely to [re-challenge them].”
- [662] In his evidence-in-chief, Dr. Khan was asked to explain his understanding of platinum resistance. He differentiated between what he called the “conventional definition” and the “more technical definition.” The former, which he described as “arbitrary,” is based on data showing the average number of cycles it takes for patients to become resistant. The latter, which he believes is “more rigorous,” is based on the individual: “if a patient has stopped responding to carboplatin while they are receiving it, in other words, while they are on treatment and the treatment stops working...or if they had already tried carboplatin and it just didn’t work, that...is how I would define ‘platinum resistance.’ So it is a...more individual definition whereas the more conventional definition is sort of an average based on a clinical study.”
- [663] There was no documentation in Dr. Khan’s records that he informed Ms. D that conventional practitioners would generally not offer platinum-containing medications to her because her cancer was likely already resistant to them.

[664] Dr. Khan also testified that he does not routinely discuss platinum resistance with his patients because he believes that it is “not actually relevant” for SAFE chemotherapy “because it is a chemo immunotherapy.” As previously noted, we concluded that SAFE chemotherapy is not an immunotherapy.

*Treatment of Ms. D with SAFE Chemotherapy in the Context of Myelosuppression*

[665] On January 10, 2014, Ms. D visited Dr. Trinkaus because she needed a blood transfusion. Dr. Trinkaus wrote a clinic visit note, copied to Dr. Khan, expressing concern that Ms. D had “developed significant myelosuppression with a further decline in her functional status as a result.” Dr. Trinkaus noted that Ms. D acknowledged her own “significant weight loss...and worsening clinical status in general.”

[666] Dr. Tozer explained that “the term myelosuppression refers to the various cell lines that make up blood cells in the bone marrow being impaired. In other words, they’re slow. And so, what that leads to is a drop in the cell counts, particularly the red blood cell count, which is anemia; the platelet count, which is thrombocytopenia; and potentially in the various white blood cells, so neutropenia, leukopenia, et cetera.”

[667] Approximately one month later, in her February 4, 2014 clinic letter, Dr. Trinkaus stated that she believed some of Ms. D’s symptoms were caused by myelosuppression, which she believed was caused by the carboplatin used in the SAFE chemotherapy Ms. D was receiving. In his evidence, Dr. Tozer concurred that Ms. D was “definitely progressing on carboplatin” and that she was experiencing myelosuppression secondary to the carboplatin.

[668] Dr. Khan testified that “[Dr. Trinkaus] is making a mistake in attributing [the symptoms] to the chemotherapy whereas [they] are from disease progression.” He stated that Ms. D had bone marrow toxicity from her previous treatments and therefore she did not have any side effects from the SAFE chemotherapy. “So there may have been a preservation of quality of life.”

[669] Dr. Tozer explained that while myelosuppression can occur due to progression of the cancer in the bone marrow, this is not a common occurrence with colon cancer. He opined that the cause of Ms. D’s myelosuppression was “probably a

consequence of this patient having received a lot of chemotherapy, both the FOLFOX beforehand and the carboplatin now.”

[670] Dr. Trinkaus’s February 4, 2014 clinical note stated that Ms. D had reported that since December 2013 she had “developed symptoms of presyncope [feeling that one is about to faint] and that she ‘can’t breathe,’ with a heavy sensation on her chest.” In this note, Dr. Trinkaus also discussed Ms. D’s investigations. Amongst these, she mentioned that it appeared Ms. D’s liver enzymes seemed relatively stable, her albumin was normal and her LDH seemed to be creeping upwards (these laboratory measurements are used to gauge liver function in patients, and there is significance in mentioning them at this stage, as will be discussed below).

[671] In that note, Dr. Trinkaus went on to state “[i]n summary, this 70-year old woman is presenting with complications related to her recent Carboplatin chemotherapy, with concern that she also is experiencing disease progression from her metastatic colon cancer.”

[672] In her January 10, 2014 note, Dr. Trinkaus wrote that Dr. Khan assured her by phone that he would not offer Ms. D further SAFE chemotherapy. However, in late January, Dr. Khan was still recommending that Ms. D be treated with SAFE chemotherapy, as evidenced by a January 20, 2014 email communication with the family in which Dr. Khan explained that he was in fact considering increasing Ms. D’s SAFE chemotherapy dose.

*Dr. Khan’s Understanding About How to Dose SAFE Chemotherapy*

[673] Exchanges of emails between Dr. Khan and Dr. Matsumura in January and February 2014 show that Dr. Khan was receiving direction from Dr. Matsumura on how to modulate the dose of SAFE chemotherapy for Ms. D.

[674] On January 6, Dr. Khan sent an email in which he noted that a drop in Ms. D’s platelets seemed prolonged, and he asked if Dr. Matsumura thought it was “from carbo or too much SAFE?” On January 7, Dr. Matsumura responded, “[w]hy don’t we try 15, 15, 12 an[d] 10 also. I am in the process of analyzing data, but never in 10 years history have we given more than 13 or 14 B at a time to patients who are ladies and on the small side. 15 plus have [sic] been given only to husky men weighing around 75 to 80 kg. I am not sure how I ended up with a series of

recommendations that resulted in such high numbers, but I am figuring this out.” Dr. Khan responded, “she had 17 today, but I will just carry on with 15/12/10 for this week...she would like to get up to a higher carbo dose.” Dr. Matsumura responded on January 8 with further advice.

[675] On February 6, weeks after Dr. Trinkaus brought concerns about myelosuppression to Dr. Khan’s attention, Dr. Khan told Dr. Matsumura that Ms. D’s family was ignoring her oncologist’s “nonsense” and stated, “I hope that it [SAFE chemotherapy] starts to work better at AUC5.” (This is a dose that had been increased from the early January dosing of AUC3.)

*Dr. Khan’s Communications with Family About Relevant Investigations, Cancer Progression and Cure*

[676] After her appointment with Dr. Trinkaus in January 2014, Ms. D had various investigations, which included:

- Chest x-ray of January 16, 2014: The radiologist reported that, compared to an October 11, 2013 chest x-ray, pulmonary nodules had increased in both size and number.
- Abdominal ultrasound of January 16, 2014: The radiologist reported that, compared to an October 11, 2013 ultrasound, liver metastases were slightly larger than previously, and there was severe right sided hydronephrosis (kidney obstruction). The radiologist was unable to see a tumour obstructing the kidney and suggested a CT scan for further visualization.

[677] In an email titled “new reports” sent on January 20, in reference to the chest x-ray and ultrasound, Dr. Khan told Ms. D’s daughter that her mother’s “largest lung spot is about ½” bigger.” As evidenced above, this same chest x-ray had revealed that in addition to enlarging pulmonary nodules, there were new pulmonary nodules. In his communication with the family, Dr. Khan did not tell them that Ms. D’s chest x-ray showed that she had new pulmonary nodules.

[678] In the same email Dr. Khan said that “the liver tumours are about the same (largest appears 2mm larger now which is within the range of error of the scan).” The radiologist, however, reported them as “slightly larger in comparison to

previous.” Dr. Khan also told the family, “overall it looks like the chemo is stabilizing/slowing down the cancer, but not shrinking it.”

[679] When he was questioned about this narrative to the family, Dr. Khan testified that when he referred to the chemotherapy “not shrinking” the tumour, he meant there was growth. When it was put to him that “the message from the x-ray that we just looked at would actually be concerning that there has been disease progression,” he replied “Right. And that is what I said.”

[680] When it was put to Dr. Khan that based on the disease progression reported in Dr. Trinkaus’s chart note it was impossible to say that Ms. D’s cancer had stabilized, he noted reference in that note to the results of some liver function tests and said there “actually were some signs that even Dr. Trinkaus recognized.” He said he was “just describing two different findings”: he accepted there was disease progression but there was also “some stabilization of part of the cancer in the liver.”

[681] Ms. D’s subsequent radiological studies showed further evidence of cancer. On February 25, 2014, her CT scan showed periureteral masses entrapping the kidney. This meant the cancer was surrounding the kidney and blocking or obstructing key structures.

*Dr. Khan’s Updated 2017 SAFE Chemotherapy Medicor Patient Data Compilation*

[682] In his dataset, Dr. Khan noted Ms. D as having stage 4 colon cancer which he treated with six cycles of SAFE chemotherapy. In the response column of this dataset, Dr. Khan concluded that Ms. D had “progression” of her cancer as per “imaging, clinical” indicators. The reason for stopping SAFE chemotherapy in this patient was noted to be due to “low cell counts.”

[683] We note that while Dr. Khan reported in his dataset that he stopped using SAFE chemotherapy due to Ms. D’s low cell counts, he would not acknowledge that the low cell counts could have been due to the SAFE chemotherapy. Instead, he attributed the low cell count to the platinum chemotherapy Ms. D completed six months before starting the platinum-containing SAFE chemotherapy, and on the progress of Ms. D’s cancer.

[684] It is noteworthy that even though Dr. Khan stated clearly in his dataset that this patient had disease progression, he did not do so in his communications to the family.

#### *Use of DCA*

[685] In March 2014, Dr. Khan began treating Ms. D with DCA. Ms. D signed a standard Medicor Consent and Direction for DCA treatment on March 3, 2014.

#### *Informed Consent for SAFE Chemotherapy*

[686] Apart from previously described checkboxes showing “R/B in changes of therapy discussed,” Dr. Khan’s charts do not show documentation of a discussion between Dr. Khan and this patient comparing the risks and benefits of conventional treatments with those of SAFE chemotherapy.

[687] Dr. Khan testified that he reviewed Ms. D’s conventional options with her in detail, including possible response rates and side effects, and that he did not tell Ms. D that there was a possibility of cure. He testified that the purpose of his therapy was to improve Ms. D’s quality of life.

[688] Dr. Khan submitted that given Ms. D’s extensive treatment history, it was evident that she was well-informed about her prognosis as well as the potential outcomes of her treatment. In fact, Ms. D did not appear to be well-informed about her prognosis or potential outcomes from treatment, judging by Dr. Trinkaus’s January 10, 2014 clinic note that recorded Ms. D telling Dr. Trinkaus that her response rate to SAFE chemotherapy could be “as high as 80%” whereas Dr. Trinkaus’s treatment was “not for cure.” As noted earlier in these reasons, Dr. Khan himself considered that SAFE chemotherapy was potentially curative for Ms. D, writing in an email to Dr. Matsumura that it was giving her “a chance of a cure.”

#### *Expert Witness Conclusions on Dr. Khan’s Care of Ms. D*

[689] Dr. Tozer testified that in his opinion, Dr. Khan failed to maintain the standard of practice because he showed a lack of knowledge in the use of SAFE chemotherapy for Ms. D, for the following reasons:

- Dr. Khan should have understood the ramifications of using carboplatin, a platinum-containing compound, in a patient whose disease had already

progressed on a very aggressive regimen of a similar agent (the oxaliplatin in FOLFIRINOX), suggesting that her cancer was resistant to this class of medications.

- There is a lack of evidence to support the use of carboplatin in colon cancer.
- He should have had the data to support the use of SAFE chemotherapy before using it on his patient, yet he “clearly did not.”

[690] Dr. Tozer also testified that in his opinion, Dr. Khan failed to maintain the standard of practice because he showed a lack of judgment in the use of SAFE chemotherapy for Ms. D for the following reasons:

- Dr. Khan failed to recognize a patient who had evidence of progression of a disease on a particular regimen.
- Dr Khan failed to recognize that his patient was experiencing toxicity from his treatment, specifically in the form of myelosuppression and fatigue.
- Dr. Khan exposed his patient to the risk of harm or injury from the carboplatin’s potential side effects, particularly on the bone marrow.
- Dr. Khan exposed his patient to the risk of harm in that the myelosuppression, likely brought on by SAFE chemotherapy, limited Ms. D’s conventional treatment options if she decided she wanted them.

[691] Dr. Tozer also testified that he was concerned Dr. Khan needed direction from Dr. Matsumura on the dosing of SAFE chemotherapy for this patient, as evidenced by the emails they exchanged in January and February 2014 described above. He commented that “...it comes down to skill...he’s treated enough patients, he himself should know what to do.” Dr. Tozer felt that these communications went beyond the standard second opinions physicians sometimes seek from colleagues.

### *Finding*

[692] We find that Dr. Khan failed to maintain the standard of practice of the profession when he:

- a) treated Ms. D's cancer using medication (SAFE chemotherapy) that was not informed by evidence and science, did not possess a favourable risk/benefit ratio and did not have a reasonable expectation of remedying or alleviating the patient's health condition or symptoms;
- b) used SAFE chemotherapy on Ms. D even though she was likely resistant to it;
- c) used SAFE chemotherapy on Ms. D even though she was myelosuppressed;
- d) failed to obtain informed consent from Ms. D for the use of SAFE chemotherapy; and
- e) failed to provide accurate and objective information, substantiated by fact and sound clinical judgment, to Ms. D and her family about the progress of her cancer.

*a) Analysis - The Use of SAFE Chemotherapy*

[693] For the reasons stated above in the SAFE Chemotherapy sections of these reasons, we find that in his use of SAFE chemotherapy in his treatment of cancer patients, including Ms. D, Dr. Khan failed to maintain the standard of practice of the profession.

[694] Even if one were to set aside concerns about SAFE chemotherapy and consider carboplatin as a standalone off-label treatment for Ms. D's colon cancer, there is a lack of evidence to support the use of carboplatin in colon cancer, as Dr. Tozer testified.

*b) Analysis - Resistance*

[695] Not only was there no indication, informed by evidence and science, to justify the use of SAFE chemotherapy in this patient, there were good reasons to avoid using it to begin with. Dr. Tozer's expert opinion, which was consistent with Dr. Trinkaus's clinical note, was that given Ms. D's treatment history with platinum-based agents, and the fact that her cancer returned four months after completing FOLFOX, her cancer was resistant to platinum-based agents. Based on this, we find that when Dr. Khan began treating Ms. D with SAFE chemotherapy, she was

already resistant to SAFE's main chemotherapeutic agent, the platinum-containing carboplatin.

[696] Given these factors alone, there were good reasons for Dr. Khan to avoid using carboplatin on Ms. D. Carboplatin as an off-label treatment. It did not possess a favourable risk/benefit ratio and could not reasonably be expected to remedy or alleviate Ms. D's health condition or symptoms. In using SAFE chemotherapy to treat Ms. D, Dr. Khan failed to maintain the standard of practice of the profession.

*c) Analysis - Myelosuppression*

[697] It is a reasonable expectation that any physician treating cancer patients with chemotherapy should be able to recognize and diagnose myelosuppression in their patient and make appropriate adjustments in the patient's treatment. In this case, this would have involved stopping Ms. D's SAFE chemotherapy. Instead, Dr. Khan continued to use the carboplatin-containing SAFE chemotherapy at escalating doses.

[698] Furthermore, with no clear indication of efficacy, and in the face of her worsening myelosuppression as diagnosed by Dr. Trinkaus, Dr. Khan not only continued treating Ms. D with SAFE chemotherapy, but also increased the dosage.

[699] It would appear that in his care of Ms. D, Dr. Khan was operating outside of the known dose ranges of his own therapy as communicated to him by Dr. Matsumura, and had administered a SAFE chemotherapy dose the safety of which had not been vetted for Ms. D's weight range. Dr. Khan used a SAFE chemotherapy dose that even Dr. Matsumura had "...never in 10 years history..." used on "patients who are ladies on the small side." We are concerned that Dr. Khan was administering this high a dose to Ms. D, who was exhibiting what Dr. Tozer referred to as "severe marrow toxicity."

[700] Additionally, in his own dataset, Dr. Khan recorded that he discontinued SAFE chemotherapy on Ms. D due to low cell count which, as Dr. Tozer explained, is an indication of myelosuppression. Dr. Khan continued the medication despite this condition.

[701] Dr. Khan should not have continued to use SAFE chemotherapy on Ms. D because he should have known she had myelosuppression, and he failed to maintain the standard of practice of the profession when he did so.

*d) Analysis - Failure to Obtain Informed Consent*

[702] As set out above in the Consent section of these reasons, we find that Dr. Khan did not obtain informed consent from his patients, including Ms. D, for the use of SAFE chemotherapy. In the specific case of Ms. D, for the reasons previously discussed, we did not find credible Dr. Khan's testimony that he reviewed Ms. D's conventional options with her in detail, including possible response rates and side effects and how these compared to the therapies he was offering her.

[703] Furthermore, Dr. Khan did not inform Ms. D that by conventional diagnostic standards, her cancer would be considered resistant to platinum therapy, thereby making it unlikely that a platinum-based chemotherapy like SAFE chemotherapy would be able to effectively treat her cancer. Without this information, Ms. D could not have given informed consent to use SAFE chemotherapy.

[704] We also do not find credible Dr. Khan's statement that he told Ms. D the purpose of his therapy was to improve the quality of her life. Nor do we believe that he "did not tell her that there was a possibility of cure." The SAFE chemotherapy consent form stated that her response rate could be as high as 80%. There is nothing in Dr. Khan's notes to suggest that he disabused Ms. D of this possibility, or that he clarified what the realistic response rate could be for her. Moreover, Dr. Trinkaus's note of January 10, 2014 suggests that Ms. D believed SAFE chemotherapy had a distinctive advantage over conventional therapy, in that it could provide a cure, and Dr. Khan's own words in his December 20, 2013 email to Dr. Matsumura demonstrated that he believed SAFE chemotherapy could cure Ms. D.

[705] Based on the oral and written evidence, we find that Dr. Khan either directly told Ms. D (and her family) that SAFE chemotherapy could cure her, or by way of omission of key information or encouragement, led her to believe that it could. At the very least, Dr. Khan failed in his duty to ensure Ms. D understood there was no possibility that SAFE chemotherapy could cure her and that furthermore, she was likely resistant to it. The common endpoint of these scenarios is that in Dr.

Khan's communications with Ms. D, he failed to convey critical and realistic information about the limitations of SAFE chemotherapy. It was both Dr. Khan's duty and his responsibility to do so and his failure in this regard was a violation of both the CAM policy and the Consent to Treatment policy. This constitutes a failure to maintain the standard of practice of the profession.

*e) Analysis - Failure to Provide Accurate and Objective Information*

[706] We find that Dr. Khan's communications with Ms. D's family about relevant investigations, particularly about Ms. D's January 16, 2014 chest x-ray and abdominal ultrasound, and about her cancer progression, were misleading.

[707] There were two problems with Dr. Khan's communications about these investigations and Ms. D's cancer progress: what he told the family, and what he did not tell the family.

*What Dr. Khan Told the Family*

[708] On cross-examination, Dr. Khan testified that when he told the family that SAFE chemotherapy was "stabilizing/slowing down the cancer," he was actually referring to an improved liver function test of the blood, not her ultrasound, and that he was "just describing two different findings." We did not find his testimony on this point to be credible.

[709] Laboratory work was not the subject of Dr. Khan's email to the family, nor did his email even mention liver function blood test reports. Any reasonable interpretation of this email is that Dr. Khan was telling the family that based on the radiology that he did reference in the email (not the bloodwork that he did not mention), SAFE chemotherapy was stabilizing the cancer. Based on his communication, the family would have reasonably concluded that SAFE chemotherapy was stabilizing and slowing Ms. D's cancer. This was not true.

*What Dr. Khan Did Not Tell the Family*

[710] Furthermore, when communicating with Ms. D's family, Dr. Khan did not accurately relay the full picture of disease progression in the liver and lungs reported by the radiologist: that her ultrasound showed increased growth of her liver metastases. In contrast, Dr. Khan told the family that the liver tumours were

“about the same.” Nor did he tell them that her chest x-ray showed new pulmonary nodules. During his cross examination, Dr. Khan testified that he accepted that there was disease progression, however he did not communicate this to Ms. D’s family in his emails to them.

#### *Summary of Dr. Khan’s Communications with the Family*

- [711] Dr. Khan’s overall messaging to the family was that were it not for the impact of SAFE chemotherapy, the cancer would not have slowed or stabilized, implying that it was a good thing that Ms. D was on SAFE chemotherapy. Dr. Khan’s communications to the family impeded them from having a realistic understanding of the state of Ms. D’s disease progression and its lack of response to SAFE chemotherapy.
- [712] Dr. Khan did not give the family accurate information about the results of Ms. D’s radiological studies and cancer progress. Rather, he gave them an overly optimistic narrative of Ms. D’s clinical scenario which did not reflect her actual clinical status. He misinterpreted or reinterpreted investigations and demonstrated confirmation bias. He thus failed to provide accurate and objective information, substantiated by fact and sound clinical judgment, about the progress of her cancer, in contravention of the CAM policy. In that regard, he failed to maintain the standard of practice of the profession.
- [713] We were also troubled by the fact that in his January 17, 2014 letter to Dr. Trinkaus, he told her that SAFE chemotherapy had undergone an FDA approved phase 2 trial with great success, and that it was approved as an off-label therapy for colon cancer when, in reality, Dr. Khan had never seen, nor was in possession of such a trial.

#### *Dr. Khan’s Knowledge, Skill and Judgment*

- [714] Dr. Khan demonstrated a lack of knowledge, skill, and judgment across numerous areas of Ms. D’s care.
- [715] Since the use of SAFE chemotherapy to treat cancer is not informed by evidence and science, the high likelihood of failure of this medication in treating Ms. D’s cancer should have been predictable to a physician who was knowledgeable

about cancer disease and the treatment of cancer. Dr. Khan did not appear to have this knowledge.

[716] Furthermore, Dr. Khan's inability to recognize and understand the likely futility of using a platinum-based SAFE chemotherapy regimen specifically on a patient whose cancer he should have known was likely already resistant to platinum medications to begin with also demonstrated a lack of knowledge.

[717] Dr. Khan also showed a lack of judgment in continuing to use carboplatin on Ms. D, who was myelosuppressed. His failure to recognize that she was experiencing toxicity from his treatment also demonstrated a lack of knowledge.

[718] Furthermore, even if Dr. Khan did not have the knowledge to recognize that myelosuppression in Ms. D was being exacerbated by the carboplatin he was giving her, his decision to ignore Dr. Trinkaus's concerns about Ms. D's condition and his continuing use of carboplatin treatment shows a lack of judgment. It was particularly concerning that after telling Dr. Trinkaus he would stop Ms. D's SAFE chemotherapy, he continued it.

[719] Dr. Khan seemed to need more help from his colleague, Dr. Matsumura, than would have been required by a physician who was skilled in the use of a particular therapy. A skilled physician would either have already known how to modulate their patient's therapy or would have recognized that they had reached the limitations of their abilities and the limits of safe dosing for their patient. This showed a lack of skill in administering the SAFE chemotherapy he was using to treat Ms. D. We agree with Dr. Tozer that with regard to Dr. Khan's use of the SAFE chemotherapy medication he was administering "he himself should know what to do."

[720] In this regard, Dr. Khan demonstrated both a lack of skill and insight to recognize his own limitations. That he proceeded to treat his patient shows a lack of knowledge and judgment.

[721] Despite a worsening metastatic and clinical picture that showed Ms. D's cancer was progressing, Dr. Khan singled out two laboratory tests and communicated to her family that SAFE chemotherapy was stabilizing and slowing her cancer. Dr. Trinkaus documented, and Dr. Tozer testified, that SAFE chemotherapy was

having no impact on Ms. D's cancer progress. This demonstrates an underlying deficit in Dr. Khan's understanding of cancer and how to evaluate its progress and treatment efficacy based on relevant studies.

#### *Exposure to Risk of Harm or Injury*

[722] Dr. Khan exposed Ms. D to the risk of harm or injury from the side effects and toxicities of SAFE chemotherapy. Further, by using his carboplatin-containing SAFE chemotherapy on Ms. D when she was myelosuppressed, Dr. Khan exposed her to further bone marrow suppression and its clinical consequences.

[723] Also, based on her communications with her oncologist, Dr. Trinkaus, it is evident that Ms. D was motivated to seek therapy that could help her. She believed SAFE chemotherapy to be superior to conventional chemotherapy because she accepted Dr. Khan's claims that it could give her an 80% chance of remission. If Ms. D knew that SAFE chemotherapy would likely not work for her, she may have sought other treatment. Yet, due to the bone marrow suppression perpetuated by the SAFE chemotherapy, Dr. Khan exposed Ms. D to potential harm by limiting her options for conventional treatments had she, at any point, wished to utilize them.

#### *Disregard for Patient Welfare*

[724] Dr. Khan's treatment of Ms. D with SAFE/carboplatin was unlikely to help her. SAFE chemotherapy has not been demonstrated to have efficacy in treating cancer in the way Dr. Khan claims, but further, carboplatin has not been shown to have benefit in colon cancer. Additionally, Ms. D's cancer was likely resistant to it. Without informing Ms. D about these issues, Dr. Khan, having failed to obtain informed consent, treated her with SAFE/carboplatin anyhow. He also endangered Ms. D's health by exposing her to the risk of harm from the toxicities of carboplatin, including myelosuppression, which Ms. D had, and which Dr. Khan perpetuated or exacerbated by treating her with carboplatin. Ms. D's cancer progressed, but Dr. Khan did not tell the family when he should have, and may have diverted her from appropriate palliation, end of life planning, and time to plan for her death.

[725] Ultimately, Dr. Khan treated his patient with a drug that could not help her, and likely harmed her. He told her that his therapy was working, while in fact her cancer was progressing and she was dying. In his care of Ms. D, Dr. Khan displayed a disregard for his patient's welfare.

### *Conclusion*

[726] We considered the written and oral evidence before us and conclude that in his care of Ms. D, Dr. Khan failed to maintain the standard of practice of the profession, demonstrated a lack of knowledge, skill and judgment, exposed Ms. D to the risk of harm and injury and disregarded her welfare.

### Dr. Khan's Care of Patient E

[727] In relation to his care and treatment of Ms. E, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose Ms. E to the risk of harm or injury?

### *Overview of Relevant Information*

#### *History and Conventional Treatment Overview*

[728] Ms. E was in her late 40s when she was diagnosed with locally advanced non-small cell lung cancer (NSCLC). She underwent a right middle lobectomy<sup>24</sup> which showed that cancer was present in seven of the 30 lymph nodes that were sampled. Ms. E received an adjuvant chemotherapy regimen with cisplatin (a platinum medication) and vinorelbine, after which she had chest radiation to the mediastinum.<sup>25</sup> Subsequent imaging showed cancer recurrence in her lymph nodes for which Ms. E received further radiation as well as chemotherapy consisting of cisplatin and etoposide. This was followed by a cisplatin and gemcitabine regimen, which was completed in December 2010.

[729] In September 2011, nine months after completing the cisplatin and gemcitabine chemotherapeutic regimen, an MRI showed that the cancer had metastasized to Ms. E's brain, and she received whole brain radiation. Ms. E also attempted

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<sup>24</sup> lobectomy: surgical resection of a portion of the lung.

<sup>25</sup> mediastinum refers to a specific region of the chest.

experimental treatments including autologous vaccine and dendritic cell therapy. A subsequent MRI of her brain in December 2011 showed regression of the brain masses. Dr. Tozer testified that at that point, Ms. E had "a prognosis of potentially less than six months, depending on how well the brain metastases were controlled."

[730] Ms. E was an experienced consumer of CAM therapies, which she sought out and researched on her own. In addition to conventional medical treatment for her cancer, she received a broad array of alternative medical treatments.

#### *Conventional Treatment Options*

[731] Dr. Tozer testified that all possible treatments for Ms. E would "be entertained with palliative intent" and that her treatment options depended on various factors, including location of recurrence. Brain metastases could potentially be treated with stereotactic radiosurgery, and recurrences elsewhere could be treated with pemetrexed (a conventional chemotherapy)-based options. Depending on the mutation to the cancer, tyrosine kinase inhibitors could also be entertained with palliative intent.

#### *Care and Treatment by Dr. Khan and Other Physicians*

[732] Ms. E was offered pemetrexed in 2012 but declined this treatment. She was also offered nivolumab. This medication is currently in use as a conventional immunotherapy treatment but would have been experimental for NSCLC at the time it was offered to Ms. E.

#### *Ms. E's Progress Between June 2012 and June 2013*

[733] In 2012, Ms. E went to see Dr. Khan. His June 28, 2012 chart note states that at the time, Ms. E had no evidence of disease (NED) or minimal evidence of disease, which he noted would make it difficult to measure response to any therapy. Dr. Khan recommended DCA, TM, HonoPure and monitoring with CTC. The "problem list" section of Dr. Khan's Aug 13, 2012 Medicor clinic note states that Ms. E "wants to continue gentle therapies, not immune suppressing chemo." Dr. Khan started Ms. E on DCA.

- [734] Six months after meeting Dr. Khan, Ms. E's chest x-ray on February 1, 2013 showed "near complete opacification of the right lung."
- [735] By June 5, 2013, one year after coming to Dr. Khan, a CT of Ms. E's chest showed "interval disease progression...increased lymphadenopathy, a pleural effusion, bronchial obstruction and increased tumour in the right lung."
- [736] Dr. Tozer testified that by this time Ms. E's prognosis was "Grim. Months."
- [737] Ms. E's June 17, 2013 MRI brain study (as compared to a September 9, 2012 study) suggested that the metastases in her brain had responded to therapy and that there were no new lesions. That said, Ms. E's December 2011 MRI – prior to her first visit to Dr. Khan – had showed regression of brain lesions, and as noted above she showed no evidence of disease when she first met Dr. Khan.
- [738] Dr. Khan's July 9, 2013 clinic note stated that Ms. E's cancer showed "definite progression, including new liver mets [metastases]" as well as in other parts of the body. This note documented that Ms. E "wants to start new therapy soon" and Dr. Khan wished to review two options, including NaPB<sup>26</sup> and SAFE chemotherapy with a consult with Dr. Matsumura.
- [739] Dr. Khan's records show that Ms. E signed a standard Medicor Consent and Direction for SAFE chemotherapy on July 24, 2013. Dr. Khan started Ms. E on SAFE chemotherapy. Three months later, in October 2013, Ms. E was receiving her fifth and last cycle.
- [740] Dr. Khan confirmed that Ms. E was the first patient he treated with SAFE chemotherapy, and that she was aware of this.
- [741] Dr. Tozer testified that there was an issue of resistance to platinum therapy for Ms. E because she too had shown disease progression despite having received a platinum-based regimen consisting of cisplatin.<sup>27</sup>

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<sup>26</sup> NaPB: Sodium phenylbutyrate is a drug

<sup>27</sup> E completed gemcitabine and the platinum-based Cisplatin nine months before metastatic cancer was diagnosed in her brain.

*Ms. E's Clinical Status Between July 2013 and October 2013*

[742] On July 24, 2013, the same day the SAFE chemotherapy consent form was signed, Dr. Khan wrote a letter to Ms. E's physician Dr. Hess. The letter explained that Ms. E was starting a new chemotherapy, which could result in rapid cancer cell death that could place Ms. E at risk for progress of the small pericardial<sup>28</sup> and pleural effusions<sup>29</sup> she had already developed.

[743] Dr. Khan testified that he believed Ms. E's cancer had spread to her pericardium<sup>30</sup> and was causing a pericardial effusion. He explained that as SAFE chemotherapy is an immune therapy, there could be swelling and an increase in the pericardial effusion when the immune system started attacking the cancer and that this was a recognized phenomenon with immune therapies.

[744] Dr. Tozer explained that some very fast-growing cancers can cause these issues when rapid cancer cell death occurs with exposure to chemotherapy. However, NSCLC is not a fast-growing cancer, so the risk of these types of emergencies occurring due to the start of chemotherapy was very low.

[745] In emails written to Dr. Khan on July 26 and 27, 2013, Ms. E expressed gratitude for Dr. Khan's care, and reported improvement in her shortness of breath. She also reported improvement in emails sent on September 16 and 17. This was reflected in Dr. Khan's Medicor clinic notes on July 26, August 7, 8, 29, September 10, 11, September 16, and September 17, 2013.

[746] During this same period, in addition to SAFE chemotherapy, Ms. E was being treated with numerous medications including morphine,<sup>31</sup> nebulizer medication,<sup>32</sup> antibiotics and prednisone,<sup>33</sup> and she underwent therapeutic interventions in the hospital.

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<sup>28</sup> Pericardial effusion: fluid around the heart. When fluid builds up to such a degree that it negatively impacts the heart's ability to beat, this is called a cardiac tamponade, and this is an oncologic emergency.

<sup>29</sup> Pleural effusion: fluid around the lungs. A significant amount of fluid can collapse the lung.

<sup>30</sup> Pericardium: membrane around the heart

<sup>31</sup> Morphine: morphine would prevent cough in E.

<sup>32</sup> Nebulizer medications: E's nebulizer medications likely consisted of either Ventolin, Atrovent, or both medications, which help deal with restricted airways.

<sup>33</sup> Prednisone is a steroid medication.

[747] After the start of SAFE chemotherapy in late July 2013, Ms. E made two trips to the emergency room (ER) for shortness of breath:

- August 8, 2013: resulting in a two-day admission during which she had a workup of a pericardial effusion; and
- August 14, 2013: resulting in an eight-day admission (with discharge on August 26) during which she underwent pericardiocentesis,<sup>34</sup> had a chest x-ray and a CT of the chest (looking for pulmonary embolus) and consultation with relevant specialists. She also developed atrial fibrillation<sup>35</sup> which was treated with medications.

[748] In his evidence-in-chief, Dr. Khan referred to a CT of the chest on August 12, 2013 (two days before Ms. E's second admission) and a CT pulmonary angiogram of September 6, 2013, which he reported showed decreased vascularity of the tumours. Dr. Khan believed these findings reflected that the tumour was dying.

[749] Dr. Tozer testified that at the time of her ER visits, Ms. E was "symptomatic because of her cancer" and that the right lung was "totally compromised," which he felt was enough to account for Ms. E's shortness of breath.

[750] Ms. E's chest x-ray on September 6, 2013 (as compared to a previous chest x-ray on August 6) showed "extensive right pleural-parenchymal opacity...right upper lobe bronchus obstruction...left lung and pleural space remain clear."

[751] Ms. E's September 10, 2013 abdominal ultrasound showed "multiple liver metastases and a suspected large periportal nodal mass" which were "concerning for disease recurrence."

[752] Dr. Tozer testified that between July and September 2013, while she was on SAFE chemotherapy, Ms. E's cancer spread to the liver and brain. She developed fluid around the heart, a pulmonary embolus and the cancer completely obstructed her right lung. He stated that overall, her condition was getting worse

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<sup>34</sup> Pericardiocentesis: fluid accumulated around the heart is drained with a needle.

<sup>35</sup> Atrial fibrillation: a particular type of irregular heartbeat.

and that “she was dying all along.” Ms. E was admitted to hospital on October 10, 2013 and died on October 13.

[753] Dr. Khan disagreed with Dr. Tozer’s view that Ms. E deteriorated throughout her course of SAFE chemotherapy. His view was that Ms. E achieved significant symptom improvement, which she reported to him.

*Dr. Khan’s Communications*

[754] In September 2013, one month before her death, Ms. E was still receiving SAFE chemotherapy. In a September 20 letter to another medical professional, Dr. Khan explained that Ms. E was on experimental chemotherapy and stated, “last chemo 10d ago, no signify [sic] side effects noted, breathing was steadily improving, repeated CXR [chest x-ray] already has showed ongoing signif [sic] improvements after four cycles.”

[755] In an August 31, 2013 email to Ms. E titled “Daily Update,” Dr. Khan wrote “I think you are doing great. Fatigue is apparently a normal side effect with a large amount of cancer cells are dying.”

[756] Dr. Tozer testified that this was not an accurate statement by Dr. Khan because non-small cell lung cancers do not show a dramatic response to chemotherapy in the form of a “large number of tumour cells dying” as do some other types of cancer. He also stated that Ms. E’s fatigue could be explained by the fact that she was only getting two hours of sleep per night due to coughing, and by the fact she was dying.

[757] In a September 9, 2013 email exchange between Ms. E and Dr. Khan, Ms. E asked Dr. Khan if the latest x-ray “confirms that the therapy is working and shrinking the tumour?” He responded “Yes...X-ray definitely shows improvement. Left lung is now clear (before there were clearly several spots of cancer).”

[758] Dr. Tozer testified that this was not an accurate statement by Dr. Khan because (with respect to the September 6 chest x-ray) the left lung was always clear and the right side certainly “did not sound improved.”

[759] In cross-examination, Dr. Khan testified that based on his review of his files in preparation for this hearing, he realized that his statement that the left lung had

improved and was “now clear” was a mistake, as was his statement in his dataset that the chest x-ray showed “rapid visible improvement.” He stated that in fact, the x-ray showed improvement (not rapid improvement) in the right lung, not the left lung which was “already okay.” He ascribed the error to a “mix-up in the images”: a mislabelling of a pre-SAFE chemotherapy treatment x-ray. Dr. Khan did not identify which specific chest x-ray was mislabelled, nor which chest x-ray he was looking at when he communicated about the September 6 chest x-ray.

*Dr. Khan's Updated 2017 SAFE Chemotherapy Medicor Patient Data Compilation*

- [760] In the response column of his dataset, Dr. Khan noted that Ms. E had “partial response” of her cancer after five cycles of SAFE chemotherapy as per “Imaging - CXR rapid visible improvement on PA films.” The reason for stopping SAFE chemotherapy in this patient was noted to be due to “DVT, pericard [pericardial] effusion.”
- [761] As discussed, Ms. E’s chest x-ray did not show rapid visible improvement. Her left lung had always been clear, and her right lung showed significant cancer progress.
- [762] When questioned by College counsel regarding the inaccuracy of what he had written about the September 6, 2013 chest x-ray, Dr. Khan testified although it was an overstatement and an error to say in his SAFE chemotherapy dataset that there was rapid improvement, or to tell another health care provider that there was significant improvement after four cycles of SAFE chemotherapy, “there was improvement.”
- [763] Dr. Khan’s dataset conclusion based on what appears to be one chest x-ray (even if it was erroneously read due to mislabelling as Dr. Khan later claimed), in the face of clearly progressing cancer, brings into question his dataset conclusions for Ms. E and his overall calculations of the efficacy of SAFE chemotherapy in his patients.

*Summary of Expert Witness Opinion on Dr. Khan's Care of Ms. E*

- [764] Dr. Tozer testified that with reference to the CAM policy, Dr. Khan’s care of Ms. E did not meet the standard of practice because he placed a patient on a platinum

chemotherapy when the patient had already shown decline on this class of medication and was likely resistant to it.

[765] Dr. Tozer testified that Dr. Khan showed knowledge in recognizing the risk of various cancer-related clinical conditions, and managed or referred them appropriately. But he identified “the issue” with Dr. Khan as being “when you have a serious illness conversation, when do you discuss that things aren’t going well, and that it’s time to pull back.”

[766] Dr. Tozer testified that Dr. Khan exposed Ms. E to the risk of harm by putting her on a chemotherapy that exposed her to the risks of its toxicities despite a lack of benefit.

### *Finding*

[767] We considered the written and oral evidence before us and find that in his care and treatment of Ms. E, Dr. Khan did not maintain the standard of practice of the profession when he:

- a) treated a patient’s cancer using medication, SAFE chemotherapy, which was not informed by evidence and science, did not possess a favourable risk/benefit profile and did not have a reasonable expectation of remedying or alleviating the patient’s health condition or symptoms;
- b) failed to obtain informed consent from Ms. E for the use of SAFE chemotherapy and DCA; and
- c) failed to provide accurate and objective information, substantiated by fact and sound clinical judgment, to Ms. E about the progress of her cancer.

### *a) Analysis - The Use of SAFE Chemotherapy*

[768] We do not dispute that Dr. Khan monitored and treated Ms. E’s cancer-associated symptoms, and appropriately referred her to other specialists and the ER when necessary. Dr. Khan maintained the standard of practice in this regard. However, physicians may meet the standard of practice in some areas of their care, while simultaneously failing to do so in others.

- [769] Earlier in these reasons, we set out our finding that in his use of SAFE chemotherapy to treat patients, including Ms. E, Dr. Khan failed to maintain the standard of practice of the profession, as well as the reasons for our finding. The desire of patients, including Ms. E, to receive this medication does not alter our conclusion.
- [770] Even if one were to set aside Dr. Khan's claims about the special effects of SAFE chemotherapy and consider carboplatin as a standalone or off-label treatment for Ms. E's cancer, there was reason to avoid its use. Ms. E was likely already resistant to the carboplatin in SAFE chemotherapy, and it would not offer her a favourable risk/benefit profile, nor could it reasonably be expected to remedy her condition. Dr. Tozer testified that the general convention is that patients may not be platinum resistant "[i]f they don't progress within 12 months." However, Ms. E completed cisplatin and gemcitabine in December 2010, only nine months before her MRI in September 2011 showed that the cancer had spread to her brain.
- [771] That Ms. E reported intermittent improvement of her shortness of breath symptoms while she was on SAFE chemotherapy is not proof of a causative relationship between SAFE chemotherapy and her clinical changes. As Dr. Tozer testified, her intermittent improvements could have been attributed to other changes in her care, such as medications and interventions, which were being implemented over the three-month period that she was receiving SAFE chemotherapy. Further, transient symptomatic improvements do not provide definitive evidence that SAFE chemotherapy lived up to Dr. Khan's claims about its efficacy in treating cancer, particularly since Ms. E's cancer was progressing while she was on SAFE chemotherapy.
- [772] Regarding the issue of diminished vascularity and diminished tumour death brought up by Dr. Khan, Dr. Tozer testified that tumours can outgrow their own blood supply and subsequently necrose. We accepted this evidence, especially in the absence of any other evidence to support the assertion that tumour necrosis seen on imaging was conclusively attributable to SAFE chemotherapy.
- [773] For these reasons, Dr. Khan should not have treated Ms. E with SAFE chemotherapy, and by doing so he failed to maintain the standard of practice of the profession.

*b) Analysis - Failure to Obtain Informed Consent*

- [774] The box “review of R + B of change(s) in treatment plan” was checked off in Dr. Khan’s July 28, 2012 Medicor chart notes on Ms. E (prior to the start of DCA) and on July 9, 2013 (prior to the start of SAFE chemotherapy). However, the notes do not state which standard chemotherapeutic options were reviewed with the patient and with what level of detail. We find that this level of documentation is inadequate to prove that Dr. Khan provided Ms. E with the information necessary for her to make an informed decision on the use of SAFE chemotherapy.
- [775] For the reasons outlined earlier, we did not find credible Dr. Khan’s testimony that he reviewed conventional options with all of his patients in detail, including possible response rates and side effects of both conventional chemotherapeutic options and the therapy he was offering and how the risks and benefits of using these medications compared with each other.
- [776] Additionally, there is no notation in Ms. E’s patient records showing that Dr. Khan told her that because her cancer had already progressed despite her conventional platinum regimen, it was likely resistant to the carboplatin in SAFE chemotherapy. Ms. E would have needed to have this information if she were to make an informed decision about the use of SAFE chemotherapy.
- [777] Ms. E was an experienced consumer of CAM, did her own research on alternative therapies and had partaken in numerous alternative therapies. These facts do not diminish Dr. Khan’s responsibility, nor his ultimate deficiency in providing Ms. E with the information necessary for her to make an informed decision about her care. The quality and reliability of accurate information available to patients can vary significantly based on the source they are using. It is only by providing the information themselves that physicians can be certain that their patient is well informed.
- [778] Finally, Dr. Khan’s August 13, 2012, clinic note under “Problem List” stated: “Patient wants to continue gentle therapies, not immunosuppressing chemo.” As previously discussed in the SAFE chemotherapy section of these reasons, there is insufficient evidence or science to support the claim that the mesna in SAFE chemotherapy will prevent the known side effects of the carboplatin, including immunosuppression. There is no evidence that Dr. Khan explained this to Ms. E.

On the contrary, his SAFE chemotherapy consent form purports that mesna will protect patients from the known side effects of carboplatin. These side effects were a specific concern for this patient, and like all patients, she should have been informed that she would be exposed to the toxic side effects of carboplatin, including immunosuppression.

[779] Dr. Khan failed to provide numerous pieces of key information to Ms. E before starting her on SAFE chemotherapy, and we find that Dr. Khan did not maintain the standard of practice when he failed to obtain informed consent from Ms. E to treat her with SAFE chemotherapy.

*c) Analysis - Failure to Provide Accurate and Objective Information*

[780] Even if one were to set aside Dr. Khan's erroneous statement in his September 2013 email to Ms. E about the state of her left lung, which had always been clear, Ms. E's September 6, 2013 chest x-ray did not demonstrate improvement in the right lung that would have reflected that her treatment was "working." To the contrary, the right side showed "extensive right pleural-parenchymal opacity...right upper lobe bronchus obstruction." His optimistic statement and confirmation to her that the treatment was working were not accurate because her right lung was almost completely compromised. It is evident that by this time, Ms. E's condition was progressing significantly.

[781] Dr. Khan's August 31, 2013 email to Ms. E in which he told her "I think you are doing great. Fatigue is apparently a normal side effect with a large amount of cancer cells are dying" was also overly optimistic and misleading. The symptoms could have been due to lack of sleep from coughing at night, and cancer progress causing impending death. Dr. Khan's statements would lead a reasonable person to conclude that cancer progress was not a possibility to consider in explaining their fatigue because they had been informed that their therapy was working, and they were improving. Dr. Khan should have told Ms. E that cancer progress and impending death were also possible causes of her fatigue.

[782] Overall, the messaging to Ms. E from these emails was that SAFE chemotherapy was having a significant positive impact on her cancer progress and that she was improving, suggesting that it was a good thing that she was on SAFE chemotherapy. Dr. Khan did not accurately relay the full picture of disease

progression to Ms. E and by failing to do so, Dr. Khan may have lessened Ms. E's ability to prepare for her inevitable death.

[783] We find that Dr. Khan's emails to Ms. E failed to provide accurate and objective information substantiated by fact and sound clinical judgment about the progress of her cancer, in contravention of the CAM policy. In that regard, he failed to maintain the standard of practice of the profession.

#### *Knowledge, Skill and Judgment*

[784] Ms. E's cancer progressed nine months after she had completed conventional platinum therapy, suggesting that she was likely resistant to platinum treatments. By placing her on SAFE chemotherapy when she was likely resistant to this class of chemotherapeutic drugs, Dr. Khan demonstrated a lack of judgment.

[785] The September 10 ultrasound report showed clearly that Ms. E's condition was deteriorating. Dr. Khan's statement in his September 20 email communication to another health care professional that Ms. E's chest x-ray had shown ongoing significant improvements after four cycles of SAFE chemotherapy, without any reference to the September 10 ultrasound, did not accurately reflect Ms. E's actual response to SAFE chemotherapy. Nor did his overly optimistic emails to Ms. E cited above. These communications were inaccurate and misleading, and displayed a lack of knowledge and judgment.

#### *Exposure to Risk of Harm or Injury*

[786] By using SAFE chemotherapy on Ms. E, Dr. Khan exposed her to the risk of harm or injury from the side effects and toxicities of carboplatin. Dr. Khan also exposed Ms. E to the risk of harm by using SAFE chemotherapy on her when her cancer was likely resistant to it.

[787] We do not agree with the submission by counsel for Dr. Khan that transient improvements in Ms. E's shortness of breath indicated that Ms. E derived benefit from SAFE chemotherapy (despite having been previously on platinum medication) and that this indicated she was not resistant to SAFE chemotherapy. As articulated above, Ms. E's perceived transient symptomatic improvements cannot be conclusively attributed to SAFE chemotherapy, do not prove that SAFE

chemotherapy was a benefit to HS and do not prove that her cancer responded to this agent.

[788] Furthermore, regardless of whether Ms. E was or was not ultimately resistant to or harmed by SAFE chemotherapy, the risk of harm existed. In placing her on SAFE chemotherapy, Dr. Khan exposed Ms. E to the risks of harm from the toxic side effects associated with carboplatin (the side effects of which have been long established and previously discussed) and ignored reasons to avoid its use because Ms. E was likely resistant. Additionally, her outcome did not alter the fact that the science and evidence to support the use of SAFE chemotherapy was not sufficient to begin with.

#### *Dr. Khan's Disregard of His Patient's Welfare*

[789] Dr. Khan treated Ms. E with a medication (SAFE chemotherapy) which could not reasonably be expected to benefit her, especially as she was likely resistant to it to begin with.

[790] Dr. Khan used therapy on Ms. E that was not informed by evidence and science, did not offer her a favourable risk/benefit profile, did not possess a favourable risk/benefit ratio and did not have a reasonable expectation of remedying or alleviating her health condition or symptoms. Simultaneously, Dr. Khan both exposed Ms. E to the risks of harm from the side effects and toxicities of carboplatin, and disregarded Ms. E's expressed wish to avoid immunosuppressing medication. Further, Dr. Khan did not provide Ms. E with accurate communications about her cancer state and its response to SAFE chemotherapy. This care on the part of Dr. Khan demonstrated a disregard of his patient's welfare.

#### *Conclusion*

[791] We considered the written and oral evidence before us, and conclude that in his care of Ms. E, Dr. Khan failed to maintain the standard of practice of the profession, demonstrated a lack of knowledge and judgment, exposed Ms. E to the risk of harm or injury and disregarded her welfare.

## Dr. Khan's Care of Patient F

[792] In relation to his care and treatment of Ms. F, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose Ms. F to the risk of harm or injury?

### *Overview of Relevant Information*

#### *History and Conventional Treatment Overview*

[793] Ms. F was diagnosed with right-sided breast cancer in 2010. Dr. Khan's Medicor clinic note from January 14, 2013 stated that Ms. F had been treated with a lumpectomy and an axillary node dissection, which showed the presence of cancer in a number of the lymph nodes. This was followed by another surgery for re-excision. Because Ms. F had triple negative<sup>36</sup> breast cancer, hormonal therapy and targeted therapy could not treat her cancer, which left chemotherapy as her only treatment option. Dr. Khan's records did not list which conventional chemotherapeutic agent was used on her. Dr. Tozer commented that Ms. F would likely have received an anthracycline taxane-containing regimen,<sup>37</sup> followed by radiation to her breast and lymph nodes.

[794] After these treatments, Ms. F had a recurrence of cancer and underwent a completion mastectomy (breast removal). The cancer then recurred in the chest wall, over the mastectomy site. This is considered stage 4 disease. Dr. Tozer described the condition as tragic, explaining that over time the cancer could begin to ulcerate, rot and smell. This situation for the patient can be socially isolating, and eventually painful as the cancer infiltrates nerves.

#### *Conventional Treatment Options*

[795] Dr. Tozer testified that Ms. F's cancer had "the least treatment options." He said it was "bad" that she had not responded to the cisplatin (conventional chemotherapy) she received. Dr. Tozer explained that at the stage when the cancer recurred in the chest, Ms. F's conventional treatment options would

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<sup>36</sup> Triple negative breast cancer means that the cancer does not express the estrogen, progesterone or HER2 new receptors.

<sup>37</sup> Dr. Tozer stated that this would have been a standard regimen at the time when F had her cancer.

include palliative chemotherapy and a review of radiation fields to see if any further radiation could be given.

#### *Care and Treatment by Dr. Khan*

- [796] Ms. F met Dr. Khan on January 14, 2013. His note stated that Ms. F was “looking for new options to improve therapy given. Limited conventional options.” Dr. Khan testified that because of her previous experience with chemotherapy, Ms. F was particularly concerned about side effects of chemotherapy, which attracted her to SAFE chemotherapy. The “plan” section of Dr. Khan’s chart stated “consider combination of DCA with chemo. Potential synergy with cisplatin. Considering low-dose Naltrexone with chemo. Considering ChemoFit testing.”
- [797] A standard Medicor DCA consent form appeared in the chart dated January 30, 2013, and Ms. F began taking DCA along with numerous other compounds such as vitamin C, lipoid acid and vitamin B.
- [798] Dr. Khan’s January 21, 2014 note (almost a year later) stated that Ms. F had “previous marrow injury” and had failed on chemotherapy in March 2013. The note did not state which chemotherapy had failed. Dr. Tozer opined that at that time Ms. F would have been given a standard palliative regimen for a triple negative breast cancer which would have consisted of cisplatin and gemcitabine. A March 6, 2013 letter by a naturopath, Dr. Tina Konstantinou, stated that Ms. F told her that she had completed 4½ cycles of a gemcitabine and cisplatin regimen. Dr. Tozer testified that this confirms that Ms. F was platinum resistant. Nevertheless, Dr. Khan’s January 2014 note stated that he was planning to use the platinum-containing SAFE chemotherapy.

#### *Conventional Treatment Options in January 2014*

- [799] Dr. Tozer testified that in January 2014, conventional treatment options for Ms. F could have included capecitabine, eribulin, vinorelbine and metronomic chemotherapy with cyclophosphamide. She never received any of these.
- [800] Dr. Tozer found no indication from Ms. F’s chart that Dr. Khan discussed conventional treatment options with her.

### *Monitoring Ms. F's Cancer*

[801] Dr. Khan treated Ms. F with SAFE chemotherapy and gemcitabine between May and July 2014. Due to the absence of metastatic disease in Ms. F's organs, he monitored her response to SAFE chemotherapy using serial photography of her chest wall and by tracking any symptom she could observe. Dr. Khan presented a January 21, 2014 and an April 9, 2014 photograph of Ms. F's chest wall and testified that there was intermittent improvement in the form of drying and crusting over in previously wet and oozing portions of her chest wall.

### *Dr. Khan's Use of SAFE Chemotherapy and Gemcitabine on Ms. F - Resistance*

[802] Dr. Tozer opined that re-treating Ms. F with the platinum-containing SAFE chemotherapy and gemcitabine was basically treating her with the same regimen on which she had previously shown disease progress. He further testified that no matter how platinum resistance was defined, Ms. F met the definition because she "hasn't responded to a platinum at all."

[803] Dr. Tozer agreed that if a patient received a second platinum-based therapy it would not necessarily result in harm, "only that it won't work." He also agreed that a patient who was told that a previous round of platinum-based therapy did not work could choose to try it again so long as they were told it was unlikely to be successful.

[804] However, Ms. F's patient records do not contain documentation that Dr. Khan had a discussion with her in which he informed her that SAFE chemotherapy, like her previous platinum-based chemotherapy, was not likely to work. As previously discussed, Dr. Khan testified that he does not routinely discuss the possibility of resistance with his patients because it is not relevant to SAFE chemotherapy, which is a "chemo immunotherapy." Furthermore, as previously discussed, Dr. Tozer testified to carboplatin having a well-known history of toxic side effects. So whether or not harm would "necessarily" result, by putting patients such as Ms. F through a second round of platinum-based therapy, Dr. Khan was exposing them to a risk of harm.

*Dr. Khan's Updated 2017 SAFE Chemotherapy Medicor Patient Data Compilation*

[805] In his dataset, Dr. Khan recorded Ms. F as having stage 3 (rather than stage 4) breast cancer, which he treated with 24 cycles of SAFE chemotherapy. In the response column of this dataset, he documented Ms. F as having a "partial response" of her cancer as per "visual - skin mets only." The reason for stopping SAFE chemotherapy in this patient was noted to be due to "decreased response."

[806] In his written report, Dr. Tozer commented that cutaneous/chest wall metastases are "notoriously difficult to assess in terms of treatment response." This calls into question Dr. Khan's dataset conclusion that Ms. F had a response to SAFE chemotherapy.

*Summary of Expert Witness Opinion on Dr Khan's care of Ms. F*

[807] Dr. Tozer opined that with respect to the CAM policy:

- Dr. Khan's care of Ms. F did not meet the standard of practice of the profession because he should not have treated her with a platinum regimen to which she was already resistant. He should have used a different agent.
- He displayed a lack of skill, knowledge or judgment by not realizing that Ms. F had already received and progressed on a platinum-containing regimen.
- He exposed Ms. F to harm or injury by continuing with a platinum regimen which could have irreparably damaged her bone marrow and led to other side effects of caboplatinum [*sic*]. The use of gemcitabine gave her no potential for response benefit and exposed her to hemolytic/uremic syndrome.

*Finding*

[808] We considered the written and oral evidence before us and find that in his care and treatment of Ms. F, Dr. Khan did not maintain the standard of practice of the profession when he:

- a) treated her cancer using SAFE chemotherapy, which was not informed by evidence and science, did not possess a favourable risk/benefit ratio and did not have a reasonable expectation of remedying or alleviating the patient's health condition or symptoms; and

b) failed to obtain informed consent for the use of SAFE chemotherapy.

## *Analysis*

### *a) Analysis - The Use of SAFE Chemotherapy*

[809] Even if one were to set aside concerns about SAFE chemotherapy generally, and one were to consider carboplatin as a standalone, off-label treatment for Ms. F's cancer, there were reasons not to use it on Ms. F because she was likely resistant to platinum-based therapies. Dr. Khan's use of carboplatin exposed Ms. F to side effects such as the risk of bone marrow suppression, which she had already experienced when previous conventional chemotherapy caused bone marrow damage.

[810] Carboplatin did not offer Ms. F a favourable risk/benefit profile, nor could it reasonably be expected to alleviate her condition. By using it on this patient, Dr. Khan failed to maintain the standard of practice of the profession.

### *b) Analysis - Failure to Obtain informed Consent*

[811] Although the box "reviewed standard chemo" appears checked off in the Medicor chart notes on Ms. F, there was no documentation in Dr. Khan's chart on Ms. F of which standard chemotherapeutic treatment options he discussed with her Ms. F, nor how their risks and benefits compared with the treatments Dr. Khan was offering including SAFE chemotherapy and gemcitabine. As previously discussed, we did not accept as credible Dr. Khan's word that he always had this conversation with patients and did so with Ms. F. There were also no notes showing that Dr. Khan told Ms. F that by conventional oncologic definitions, she was resistant to the SAFE chemotherapy and gemcitabine regimen he was proposing. Dr. Khan pointed out a checkmark in the checkbox "review of R + B [risks and benefits] of change(s) in the treatment plan" of his notes. However, as previously noted, we were not satisfied that Dr. Khan's checkmark was adequate proof of the required discussion with patients, and we did not accept Dr. Khan's evidence that he had such discussions.

[812] Furthermore, Ms. F did not wish to receive conventional chemotherapy due to the side effects she had experienced while on such drugs previously. Dr. Khan presented to Ms. F that SAFE chemotherapy was not a conventional therapy and

could achieve response and remission that conventional chemotherapies could not (and with fewer side effects). However, there was no evidence that SAFE chemotherapy would give Ms. F the better chance of avoiding the side effects of conventional chemotherapy she was seeking. Additionally, Dr. Khan's chart on Ms. F did not show that he told her the SAFE chemotherapy and gemcitabine regimen would likely not work for her because her cancer had already progressed on an almost identical regimen. As previously noted, Dr. Khan testified that he does not routinely discuss resistance with his patients because he believes that SAFE chemotherapy is an immunotherapy.

[813] Despite presenting the foregoing to Ms. F, Dr. Khan submitted in justification of his use of carboplatin on Ms. F, that SAFE chemotherapy (and gemcitabine) was almost equivalent to a conventional palliative chemotherapy regimen and this suggested there was therefore sufficient evidence and science to support Dr. Khan's treatment.

[814] SAFE chemotherapy cannot be both significantly different from conventional chemotherapy in terms of improved efficacy and decreased side effects, and yet be almost equivalent to it. Those two notions contradict each other. What is key is that Dr. Khan's presentation of SAFE chemotherapy to Ms. F did not include accurate information about the lack of evidence and science supporting his claims, or that it would likely not work on Ms. F specifically because she was resistant to it.

[815] This, coupled with the absence of the requisite risk/benefit discussion comparing conventional treatments with SAFE chemotherapy, strongly suggests that Dr. Khan did not provide Ms. F with adequate information on which to base her decision to use SAFE chemotherapy. Dr. Khan breached the CAM policy by failing to obtain informed consent from Ms. F to use SAFE chemotherapy. Consequently Dr. Khan failed to maintain the standard of practice of the profession.

#### *Knowledge, Skill and Judgment*

[816] Dr. Khan showed a lack of knowledge and judgment in using a SAFE chemotherapy/gemcitabine regimen, which was unlikely to benefit Ms. F, while it simultaneously exposed her to the risk of side effects and toxicities.

### *Exposure to the Risk of Harm*

[817] Dr. Khan exposed Ms. F to the risk of harm from the side effects and toxicities of both gemcitabine and carboplatin in the form of, respectively, hemolytic/uremic syndrome and irreparable damage to bone marrow.

### *Disregard of Patient Welfare*

[818] Dr. Khan used therapy on Ms. F, SAFE chemotherapy, that was not informed by evidence and science, did not offer her a favourable risk/benefit profile and did not have a reasonable expectation of remedying or alleviating her health condition or symptoms. Dr. Khan exposed Ms. F to the risks of harm from the side effects and toxicities of SAFE chemotherapy. Dr. Khan's care of Ms. F demonstrated a disregard of his patient's welfare.

### *Conclusion*

[819] We considered the written and oral evidence before us, and conclude that in his care of Ms. F, Dr. Khan failed to maintain the standard of practice of the profession, demonstrated a lack of knowledge and judgment, exposed Ms. F to the risk of harm or injury and disregarded her welfare.

### Dr. Khan's Care of Patient G

[820] In relation to his care and treatment of Ms. G, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose Ms. G to the risk of harm or injury?

### *History and Conventional Treatment Overview*

[821] Ms. G was a 52-year-old woman who had been diagnosed with NSCLC in 2012. Her disease was in both lungs, and was metastatic to the brain, lymph nodes and liver. Although initially she had a good response to whole brain radiation, lung radiation and five rounds of conventional chemotherapy, her metastatic disease recurred.

### *Conventional Treatment Options*

[822] Dr. Tozer testified that at the time of her recurrence in 2012, and depending on her EGFR (kidney function) and tumour status, conventional treatment options for

Ms. G would have included second and third-line chemotherapy, and possibly tyrosine kinase inhibitors. Immunotherapy was not being used in 2012 so was not an available treatment option for Ms. G.

*Relevant Information on Care and Treatment by Dr. Khan*

[823] Dr. Khan's Medicor patient records show that he was involved with Ms. G's care by April 4, 2013. Records show that Ms. G's lung cancer was an adenocarcinoma. She was in the midst of receiving her second of six rounds of conventional chemotherapy consisting of paclitaxel and carboplatin, which Dr. Tozer stated was a standard doublet regimen (meaning two different chemotherapy drugs).

[824] Dr. Khan's treatment plan at this visit showed that he was considering Metformin, LDN, DCA, low dose-vitamin D and a scan in three months' time. He started Ms. G on metformin and LDN.

*Investigations, Cancer Progress and Communications*

[825] A CT scan on April 25, 2013 showed that compared to her December 22, 2012 CT scan, Ms. G's numerous lung nodules had "almost completely resolved." However, the radiologist also noted that there were new sclerotic lesions in Ms. G's pelvic bones, left femur and spine, which could "potentially represent skeletal metastatic disease."

[826] Four months later, on July 15, 2013, the radiologist read Ms. G's CT scan (as compared to the April CT scan) as "unfortunately both lungs now show multiple pulmonary nodules, ranging in size to 0.9 cm left lung base. Many of these nodules are new and are consistent with increased metastatic burden." The radiologist also noted, "subtle heterogeneity to the liver, suspicious for barely visualized metastatic deposits."

[827] Dr. Tozer testified that this July CT scan indicated that Ms. G's cancer was progressing.

[828] Two weeks later, on July 29, 2013, Ms. G saw Dr. Khan. His note says that after completing her chemotherapy in May, Ms. G did not receive any other chemotherapy. He also documented that Ms. G's July CT scan showed recurrence in the lungs, and that Ms. G now wanted to "proceed with more aggressive

treatment.” The plan section of Dr. Khan’s note indicated that he provided Ms. G with information on DCA and SAFE chemotherapy and wished to arrange an urgent MRI of her brain “to see if SAFE chemo can be done.”

- [829] An August 8, 2013 MRI of Ms. G’s brain reported brain lesions that had an appearance “consistent with treatment response.” Dr. Tozer testified that the response seen on the MRI imaging showed that Ms. G seemed to be responding to the radiation she had received.

### *Resistance*

- [830] Ms. G had been off chemotherapy and, specifically, platinum-based chemotherapy for only three months when Dr. Khan started her on SAFE chemotherapy. As previously noted, Dr. Tozer testified, with respect to resistance, that in oncology the minimum interval that is used when considering re-challenging a patient with a chemotherapy that they received previously is one year.
- [831] Dr. Tozer testified that Ms. G “was basically being re-challenged fairly soon after progression with one of the two drugs that she received beforehand. Normally, in this situation, we would consider changing to another chemotherapy altogether.”
- [832] Dr. Khan agreed that “by the more traditional definition of ‘platinum resistance,’ [...] based on counting a number of cycles of platinum that a patient had before, she [Ms. G] would probably fall under platinum resistance.”
- [833] Nevertheless, Dr. Khan proceeded to treat Ms. G with SAFE chemotherapy starting in late August 2013, two weeks after her MRI. Dr. Khan had only started using SAFE chemotherapy on patients in July 2013, so Ms. G was also one of Dr. Khan’s first SAFE chemotherapy patients.

### *SAFE and the Blood Brain Barrier*

- [834] Prior to starting Ms. G on SAFE chemotherapy, Dr. Khan sought a consultation from a neurosurgeon, Dr. Kis. In his consultation letter, Dr. Khan noted that “since the carboplatin penetrates the BBB [blood-brain barrier], there is a concern about tumour necrosis and edema.” In commenting about this statement, Dr. Tozer testified that carboplatin does not cross the blood-brain barrier in any meaningful way.

[835] In his testimony, Dr. Khan stated that his understanding was that carboplatin “absolutely does cross the blood-brain barrier.” He pointed to a monograph from Cancer Care Ontario (CCO) in support of this statement. The monograph said, in answer to the question “Cross blood brain barrier,” “Yes; Low concentrations,” which Dr. Khan indicated meant “it crosses, but maybe it doesn’t cross fully.” The monograph also noted that carboplatin is used for the treatment of brain tumours.

[836] In his closing submissions, Dr. Khan stated that Ms. G’s imaging results support the conclusion that carboplatin as administered in SAFE chemotherapy crossed the blood-brain barrier and had an observable, clinical effect.

*Immediate Effect and Symptom Resolution by SAFE Chemotherapy.*

[837] Dr. Khan’s clinic notes documented that Ms. G reported that while receiving SAFE chemotherapy infusions or shortly afterwards, she would feel symptom improvements such as decrease of her shortness of breath and rapid heart rate, and she noticed an increase in her energy levels. Dr. Khan attributed Ms. G’s changes to the effects of SAFE chemotherapy.

[838] In his testimony, Dr. Tozer acknowledged that Ms. G had reported these observations to Dr. Khan, but Dr. Tozer did not acknowledge that the symptom improvement was the result of the SAFE chemotherapy.

*Ms. G’s Ongoing Cancer and Clinical Status, Imaging and Respective Communications*

[839] Two and a half months after starting SAFE chemotherapy, Ms. G’s November 5, 2013 abdominal ultrasound was read by the radiologist as demonstrating:

[M]ultiple target lesions throughout both lobes of the liver. Some are dense and relatively avascular, others have a low density circumference which is a typical appearance of an active metastasis. Most are too small for an accurate assessment by color doppler.

...

CONCLUSION:

Multiple liver metastases. Most show a classic target appearance of a vascular metastasis, some are dense and are likely affected by chemotherapy...

[840] Three weeks later, on November 26, 2013, Ms. G was admitted to North York General Hospital (NYGH) for dyspnea (shortness of breath), which she described to the hospital physicians as progressing over the previous month.

[841] Ms. G's admitting physician considered numerous potential causes for Ms. G's shortness of breath, including pulmonary embolus (blood clot in the large blood vessels of the lung), rare infections such as rare fungal infections due to an immunocompromised state, radiation pneumonitis, deconditioning and bronchogenic spread of her cancer.

[842] Ms. G's admission studies included a CT scan performed on November 26. The radiologist stated that the study showed "diffuse pulmonary findings in keeping with pulmonary metastatic disease...hepatic metastases, as well as skeletal metastases." Her admitting physician noted that Ms. G's November 26 chest x-ray showed "bilateral pulmonary nodules with mild elevation of the right hemidiaphragm."

[843] Dr. Tozer opined that "the most likely cause of [Ms. G's] shortness of breath is progression of her disease in the lungs. And the raised right hemidiaphragm that was they commented about [seen on her chest x-ray] is most likely due to the disease on the liver."

*Dr. Khan's Communications with Ms. G*

[844] Dr. Khan's records for Ms. G do not contain any documentation that he informed Ms. G about conventional treatment options, that he described the risks and benefits of such options or how they compared to the risks and benefits of the treatment options he was offering to Ms. G.

[845] There were also no notes showing that Dr. Khan told Ms. G that by conventional oncologic definitions, she was resistant to carboplatin.

[846] The radiologist's report on Ms. G's November 5 ultrasound (described above) showed the presence of multiple lesions throughout her liver, which had the typical appearance of active liver metastases. On November 11, 2013, five days after the radiologist's report, Dr. Khan sent an email to Ms. G in which he reported that "of course the ultrasound confirmed the liver spots are dying."

*Ms. G's Outcome*

[847] Ms. G died in January 2014, shortly after her treatment with SAFE chemotherapy had ended.

*Dr. Khan's Updated 2017 SAFE Chemotherapy Medicor Patient Data Compilation*

[848] Dr. Khan's dataset stated that Ms. G had stage 4 NSCLC, which he treated with eight rounds of SAFE chemotherapy. In the response column of this dataset, he documented Ms. G as having a "partial response" as per "clinical - rapid decr [decreased] SOB [shortness of breath], imaging - U/S [ultrasound]." The reason for stopping SAFE chemotherapy in this patient was noted to be due to "[l]ow cell counts, progression."

[849] For this entry in his dataset, Dr. Khan relied in part on an email from the patient dated November 28, 2013, indicating that immediately after a single SAFE chemotherapy treatment, her cough had subsided to almost nothing and her heart had stopped feeling like it "was beating out of my chest."

[850] Dr. Khan claimed to remember witnessing this "dramatic improvement" and testified, "I recall even her sitting in the chair receiving the infusion, towards the end of the infusion telling me how much better her breathing was." Nevertheless, around the same time Ms. G was experiencing breathing difficulties, which prompted her admission to NYGH on November 26. She told physicians at NYGH that she had experienced progressive shortness of breath for "the past month." This is evidence that Ms. G's overall breathing status was worsening.

[851] We do not believe that a brief episode of subjective symptomatic improvement, in the context of a worsening overall clinical picture, suggested that Ms. G had a partial response to SAFE chemotherapy.

[852] As noted above, and in contrast to Dr. Khan's observation of "partial response," her November 6 ultrasound three months after starting SAFE chemotherapy showed multiple metastatic lesions throughout her body, including "active" lesions in her liver.

[853] On cross-examination, Dr. Khan based his conclusion of partial response on the radiologist's ultrasound report that some of the liver metastases "are dense and

are likely affected by chemotherapy” and that some were vascular and live, and some were necrotic. In our view, this was a rationalization that could not be supported on any objective view of the report or of the other evidence that showed the progress of Ms. G’s disease.

[854] Relevant radiology showed that Ms. G’s cancer was progressing throughout her course of SAFE chemotherapy, yet Dr. Khan concluded that Ms. G had a partial response to SAFE chemotherapy without evidence. His dataset conclusion also ignored RECIST requirements and the active metastases in her liver. For his dataset, Dr. Khan used his own overly optimistic personal opinion of Ms. G’s study results, rather than the actual study results, which showed that the cancer was progressing.

#### *Summary of Expert Witness Opinion of Dr. Khan’s Care of Ms. G*

[855] In Dr. Tozer’s written report, he stated that “[t]here is a paucity of information” about Ms. G. Dr. Tozer conceded on cross-examination that in preparing his written report, he had initially not seen or reviewed a significant part of Ms. G’s charts. After being taken through numerous additional records by counsel for Dr. Khan, Dr. Tozer agreed that there was no “paucity” of patient information, and that the material he did not see may have informed his opinion. We noted however that Dr. Tozer’s opinions and conclusions about Dr. Khan’s care of Ms. G were not altered after counsel for Dr. Khan took him through the sections of the records he had missed. Given this, and given Dr. Tozer’s expertise in cancer and its care, we are satisfied that we can attribute significant weight to Dr. Tozer’s testimony and conclusions about Dr. Khan’s care of Ms. G.

[856] Dr. Tozer opined that Dr. Khan’s care of Ms. G did not meet the standard of practice because he chose to use a single agent chemotherapy that the patient had already progressed on, and which “had already biologically demonstrated that it was ineffective.”

#### *Knowledge, Skill and Judgment:*

[857] Dr. Tozer opined that Dr. Khan showed a lack of skill and judgment because he did not realize “that cancers become resistant to chemotherapy drugs,” and that “early progression of disease, after having received a drug, would indicate that

the disease is resistant to that drug, and therefore, you need to consider another option”; and also because “[t]here’s no evidence that carboplatin crosses the blood brain barrier to any amount to have any effect on brain metastases.”

#### *Exposure to Risk of Harm or Injury*

[858] When asked if he had formed an opinion about whether Dr. Khan’s care of Ms. G exposed her to risk of harm or injury, Dr. Tozer opined that Ms. G was exposed to “unnecessary exposure to carboplatin, again, with all the side effects and toxicities [sic] that it could have” in addition to a “lack of access to alternate conventional treatment modalities.”

#### *Finding*

[859] We considered the written and oral evidence before us and find that in his care and treatment of Ms. G, Dr. Khan failed to maintain the standard of practice of the profession when he:

- a) treated a patient’s cancer using SAFE chemotherapy, which was not informed by evidence and science, did not possess a favourable risk/benefit ratio and did not have a reasonable expectation of remedying or alleviating the patient’s health condition or symptoms;
- b) failed to obtain informed consent for the use of SAFE chemotherapy; and
- c) failed to provide accurate and objective information, substantiated by fact and sound clinical judgment, to Ms. G about the progress of her cancer.

#### *Analysis*

##### *a) Analysis - The Use of SAFE Chemotherapy*

[860] As we noted in the SAFE chemotherapy section of these reasons, in using SAFE chemotherapy to treat cancer in patients, including Ms. G, Dr. Khan failed to maintain the standard of practice of the profession.

[861] By November 2013, Ms. G’s cancer had returned. This was three months after she completed her conventional chemotherapy consisting of the platinum agent carboplatin and paclitaxel. We accepted Dr. Tozer’s opinion that by conventional definitions, Ms. G was resistant to platinum agents, including carboplatin. Dr.

Khan failed to recognize Ms. G's resistance to platinum therapy and proceeded to place her on the platinum-containing carboplatin in SAFE chemotherapy. In doing so, Dr. Khan failed to maintain the standard of practice of the profession.

[862] There is insufficient evidence to support Dr. Khan's assertion that carboplatin crosses the blood-brain barrier and is effective in treating brain metastases. Although the CCO monograph referred to above notes that carboplatin is used in the treatment of brain cancer, it gives no information about the drug's efficacy, nor does it clarify the extent to which it crosses the blood-brain barrier. The practice of medicine and the treatment of cancer require more than identifying the name of a drug on a list before using it. Expert knowledge is necessary to understand the level of evidence underlying listed medication, and expert experience and judgment must underline decisions around which drug should actually be used in a clinical setting. We placed significant weight on Dr. Tozer's testimony that few chemotherapies work on brain metastases, and that carboplatin does not cross the blood-brain barrier in any meaningful amount. We place little to no weight on Dr. Khan's belief that it does, given his lack of formal training in oncology and the fact he failed to present any expert testimony or literature to support it.

[863] We do not accept that the response to treatment seen on Ms. G's August 8, 2013 MRI was due to the effects of carboplatin, or that the MRI evidenced that SAFE chemotherapy had crossed Ms. G's blood-brain barrier to have observable, clinical effect. Although Ms. G had been on carboplatin as part of her conventional regimen, we accepted the testimony of Dr. Tozer that the response effect seen on Ms. G's MRI was likely due to the radiation therapy she had previously received.

#### *b) Analysis - Failure to Obtain Informed Consent*

##### *Dr. Khan's Documentation*

[864] Although the box "reviewed standard chemo" appeared as checked off in Medicor chart notes on Ms. G, there was no written documentation of which standard chemotherapeutic treatment options were discussed with Ms. G, nor how their risks and benefits compared with the SAFE chemotherapy Dr. Khan was offering. As previously discussed in the Consent and Communications section of these reasons, we did not accept as credible Dr. Khan's word that he always had this conversation with patients. Consequently, in the absence of written

documentation to show otherwise, we did not believe that Dr. Khan had an adequate consent discussion with Ms. G. Dr. Khan did not maintain the standard of practice of the profession when he failed to obtain informed consent for the use of SAFE chemotherapy.

[865] Furthermore, Ms. G was likely resistant to platinum-based chemotherapy, and Dr. Khan did not inform her about this. Without knowing this, Ms. G could not have given informed consent to the use of SAFE chemotherapy.

[866] Also of significance is that Ms. G informed Dr. Khan that she wanted to “proceed with more aggressive treatment.” Yet without informing her, Dr. Khan simply treated her with the very same medication, carboplatin, that had failed to treat Ms. G’s cancer three months earlier. Certainly, SAFE chemotherapy was no more aggressive than the treatments she had already received and in failing to inform her of this, Dr. Khan disrespected Ms. G’s wishes.

[867] Not only did we find that Dr. Khan failed to obtain informed consent from Ms. G, but with respect to SAFE chemotherapy, we find that he misled her.

*c) Analysis - Failure to Provide Accurate and Objective Information*

[868] Dr. Khan’s email to Ms. G informing her that her November 5, 2013 ultrasound showed that “the liver spots are dying” misrepresented the radiologist’s conclusions, in which he stated that Ms. G’s liver lesions were “active.” When Dr. Khan communicated with Ms. G, he should have given her the actual study results as read by the radiologist, not his personal opinion and embellishment of the results. When Dr. Khan failed to provide Ms. G with her accurate test results, he failed to provide accurate and objective information substantiated by fact and sound clinical judgment about the progress of her cancer, in contravention of the CAM policy. In that regard, he failed to maintain the standard of practice of the profession.

*Knowledge, Skill and Judgment*

[869] In failing to recognize that Ms. G was resistant to platinum agents, Dr. Khan showed a lack of knowledge. By placing her on the platinum-containing carboplatin, Dr. Khan showed a lack of judgment. By failing to properly interpret

the evidence and science, and thus failing to recognize that SAFE chemotherapy would not overcome platinum resistance, Dr. Khan demonstrated a lack of skill.

[870] Dr. Khan also showed lack of knowledge by failing to recognize that there was no evidence that carboplatin (even with the addition of special formula mesna) could cross the blood-brain barrier in any appreciable amounts, such that it could be effective in treating cancer metastases to the brain.

#### *Exposure to Risk of Harm or Injury*

[871] Dr. Khan unnecessarily exposed Ms. G to the risk of harm from the known side effects and toxicity of carboplatin. Further, Dr. Khan exposed Ms. G to these risks without providing her with the “more aggressive therapy” she had requested.

#### *Disregard of Patient Welfare*

[872] Dr. Khan’s care for Ms. G displayed a disregard of his patient’s welfare. Not only did Dr. Khan treat Ms. G with SAFE chemotherapy, the efficacy of which is not informed by evidence and science, he used this medication even though Ms. G’s cancer was resistant to platinum medications. Further, after Ms. G had requested “more aggressive” therapy, Dr. Khan treated her with not only a platinum class medication, but with the exact same medication, carboplatin, through which her cancer had progressed.

#### *Conclusion*

[873] We considered the written and oral evidence before us, and conclude that in his care of Ms. G, Dr. Khan failed to maintain the standard of practice of the profession, displayed a lack of knowledge, skill and judgment, exposed Ms. G to risks of harm and disregarded her welfare.

#### Dr. Khan’s Care of Patient H

[874] In relation to his care and treatment of Mr. H, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose Mr. H to the risk of harm or injury?

### *History and Conventional Treatment Overview*

[875] Mr. H was a 54-year-old man from Alberta who had pancreatic cancer encasing his celiac axis<sup>38</sup> and a number of important vascular structures in his abdomen. The cancer was unresectable. A September 24, 2013 MRI showed that there was a likelihood of metastatic disease to the liver. Dr. Khan confirmed this during the hearing.

### *Conventional Treatment Options*

[876] Dr. Tozer testified that these findings meant that Mr. H's prognosis was that he had less than a year to live, and his treatments needed to focus on supportive care, pain control and symptom management. Mr. H's conventional treatment options included gemcitabine for quality of life improvement, but not survival improvement, FOLFIRINOX<sup>39</sup> which would have more toxicities but could prolong life, and a clinical trial.

### *Care and Treatment by Dr. Khan*

[877] Mr. H came to Dr. Khan hoping to receive gentle treatment that could improve his quality of life as well as extend his life. Mr. H had rejected FOLFIRINOX and gemcitabine because he and his family were particularly concerned about the side effects of these medications, including those that were life-threatening. Mr. H saw Dr. Khan on October 29, 2013. Dr. Khan's patient record for this visit shows that Mr. H was experiencing neuropathic pain, and that according to Dr. Khan he was a good candidate for SAFE chemotherapy, which Dr. Khan planned to initiate within a week.

[878] Dr. Tozer testified that the use of carboplatin and mesna for Mr. H's pancreatic cancer was not informed by evidence and science.

### *Dr. Khan's Communications with Mr. H*

[879] Dr. Khan testified that he made sure Mr. H understood his conventional options. He discussed these options with Mr. H "without repeating everything" since he

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<sup>38</sup> Celiac axis: an important exit point for nerves

<sup>39</sup> FOLFIRINOX: a conventional 4 drug regimen including 5FU, leucovorin, irinotecan, and oxaliplatin

had received documentation that Mr. H had discussed conventional treatments with his own conventional oncologists, such that he was already well informed about his palliative and conventional options. Dr. Tozer confirmed that based on this documentation, Mr. H had been informed by his previous doctors about his conventional and palliative options, including gemcitabine and FOLFIRINOX.

[880] Although the box “reviewed standard chemo” appears checked off in Dr. Khan’s Medicor chart notes on Mr. H, the notes do not contain any documentation showing that he discussed conventional treatment options with Mr. H, nor that he described the risks and benefits of those options or how they compared to the risks and benefits of the treatment options he was offering.

[881] Dr. Khan acknowledged that he told Mr. H that Dr. Matsumura’s experience had been that four consecutive patients who had been on SAFE chemotherapy had lengthy periods of remission, lasting up to seven years. Dr. Khan testified that he was sure Mr. H understood the limits of SAFE chemotherapy and the limited evidentiary basis for it. He also explained that “if they [the patient] choose a complementary therapy that has limited data over an established protocol, conventional protocol that has extensive data, but the data is poor, then that is the patient’s choice.”

[882] We do not accept that, in the absence of clarification and an adequate risk and benefit discussion with Dr. Khan, Mr. H would have had sufficient knowledge and experience to be able to assess the value or the weight to be given to the “limited evidentiary basis” for SAFE chemotherapy, such that he could make an informed decision to use it.

### *SAFE Chemotherapy Treatment*

[883] Mr. H signed a Medicor SAFE chemotherapy consent form on November 6, 2013. Subsequently Dr. Khan treated him with six cycles of SAFE chemotherapy, which continued until at least mid-February 2014, around which time Mr. H was admitted to hospital.

### *Investigations, Cancer Progress, and Further Communications*

[884] On February 24, 2014, approximately three months after starting SAFE chemotherapy, Mr. H had an ultrasound that showed the thickness in the

pancreatic lesion decreasing from 3 cm (as seen on a January 13, 2014 ultrasound) to 2.7 cm. The radiologist described this as “a slight decrease in the size of the mass involving the tail of the pancreas.” Dr. Tozer explained that the decrease was “slight” and that there were difficulties in the use of ultrasonography to image the pancreas:

[N]umber one, the ultrasounds definitely have a difficult time imaging the pancreas...what you're going through, because of where the colon is, because of air in the colon. So it's not the best way to image it...the typical way of imaging the pancreas would be CT in this sort of situation. The other problem is it's very, very operator dependent. It depends on where the person puts the probe, how much pressure they're applying...[I]t can change from person-to-person. So, a slight decrease is...almost like an experimental error.

[885] Dr. Tozer illustrated the issues with using ultrasound for visualizing pancreatic cancer by pointing out that on Mr. H's October 31, 2013 ultrasound the pancreatic lesion could not be seen at all, even though it was clearly present on previous radiological studies, including an MRI and a September 2013 CT scan, which showed that the mass had replaced the entire tail of the pancreas.

[886] Overall, Dr. Tozer described Mr. H's cancer as not progressing nor responding rapidly, stating that it was “stable” over a four-week period.

[887] After receiving the results of the February 2014 ultrasound, Dr. Khan emailed various people including Mr. H's daughter, informing them that “there is further shrinkage of the pancreatic tumour!” Dr. Tozer opined that this statement was “a bit overplayed.”

[888] Dr. Khan testified that the reduction in tumour size on ultrasound imaging meant that “...the treatment is working.”

#### *Mr. H's Clinical Progress and Outcome*

[889] Within one month of starting SAFE chemotherapy, Mr. H was having significant issues. Dr. Tozer commented that “the patient did not appear to tolerate treatment very well with intractable nausea and vomiting and was described as being dehydrated on a number of occasions.”

[890] The vomiting and diarrhea that Mr. H was experiencing were serious enough that he required a visit to the ER. Dr. Khan's December 7, 2013 letter to the ER attending physician stated that Mr. H was on an "experimental combination of carboplatin and mesna...the combination with mesna is supposed to prevent GI toxicity, however he has been vomiting since December 5<sup>th</sup>."

[891] In February 2014 Mr. H was admitted to the hospital for cachexia.<sup>40</sup> Dr. Khan acknowledged that Mr. H had been weakening while on SAFE chemotherapy, but he felt that this was not necessarily due to the SAFE chemotherapy. He explained that Mr. H could have been weakening from his disease. Mr. H died in March 2014, approximately one month after his admission to the hospital.

*Dr. Khan's Updated 2017 SAFE Chemotherapy Medicor Patient Data Compilation*

[892] Dr. Khan's dataset listed Mr. H as having stage 4 pancreatic cancer which he treated with six cycles of SAFE chemotherapy. In the response column of this dataset, Dr. Khan documented Mr. H as having had a "partial response" of his cancer as per "(pre-CT 6.4 x 3.4 x 4 cm, post ULTRASOUND 3.1 x 3.6 cm)." The reason for stopping SAFE chemotherapy in this patient was noted to be due to "cachexia."

[893] Dr. Khan reached his "partial response" conclusion for Mr. H by comparing two different imaging modalities. One of these modalities, ultrasound, is rejected by the RECIST recommendations for tumour measurement due to its lack of reliability.

[894] In his testimony, Dr. Khan acknowledged that it is not scientifically valid to compare a CT scan to an ultrasound "[i]f it was a small difference," "[b]ut because it is such a dramatic difference, then I believe it has some meaning."

*Summary of Expert Witness Opinion of Dr. Khan's Care of Mr. H*

[895] Dr. Tozer acknowledged that he had initially not seen nor reviewed a significant part of Mr. H's charts. After being taken through numerous additional records by Dr. Khan's counsel, Dr. Tozer agreed that in his written report, his statement that

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<sup>40</sup> Cachexia: wasting of the body

"[i]t is not clear that the patient ever had metastatic pancreatic cancer given no pathology, confirmatory imaging or an elevation in CA [CA19.9]" was not correct. We noted this when considering Dr. Tozer's opinions and conclusions. Nevertheless Dr. Tozer's expertise in cancer, cancer care and his testimony and report regarding the science and evidence for using SAFE chemotherapy on this patient were not altered after Dr. Khan's counsel took him through the sections of records he had missed. We felt it was reasonable to attribute significant weight to Dr. Tozer's testimony and conclusions on Dr. Khan's care of Mr. H.

#### *Standard of Practice of the Profession*

[896] Dr. Tozer opined that Dr. Khan's care of Mr. H did not meet the standard of practice of the profession because he used a conventional chemotherapy on a cancer in which "it has no activity [and] would not be appropriate." The use of carboplatin and mesna for Mr. H, who was suffering from pancreatic cancer, was not informed by evidence and science.

#### *Knowledge, Skill and Judgment*

[897] Dr. Tozer discussed the financial aspects of treating a patient with self-paid costly medications but did not present an opinion on whether Dr. Khan's care of Mr. H demonstrated a lack of knowledge, skill or judgment.

#### *Exposure to Risk of Harm or Injury*

[898] Dr. Tozer expressed concern over the toxicity to a patient with a life-threatening illness making multiple trips from Alberta and wondered if this time could have been better spent. However, he did not provide an opinion on whether Dr. Khan's clinical care exposed Mr. H to the risk of harm or injury, stating that Mr. H would have died regardless.

#### *Finding*

[899] We considered the written and oral evidence before us and find that in his care and treatment of Mr. H, Dr. Khan failed to maintain the standard of practice of the profession when he:

- a) treated a patient's cancer using a medication, SAFE chemotherapy, which was not informed by evidence and science, did not possess a favourable

risk/benefit ratio and did not have a reasonable expectation of remedying or alleviating the patient's health condition or symptoms;

- b) failed to obtain informed consent to the use of SAFE chemotherapy; and
- c) failed to provide accurate and objective information, substantiated by fact and sound clinical judgment, to Mr. H's family and others about the progress of his cancer.

### *Analysis*

#### *a) Analysis - The Use of SAFE Chemotherapy*

[900] For the reasons stated in the "SAFE Chemotherapy" section of these reasons, we find that Dr. Khan should not have used SAFE chemotherapy on his patients, including Mr. H, and in doing so, he failed to maintain the standard of practice of the profession. Even if one were to consider the use of carboplatin as a conventional stand-alone, or off-label therapy for Mr. H, its use was inappropriate because, as stated by Dr. Tozer, it would have no activity on pancreatic cancer.

#### *b) Analysis - Failure to Obtain Informed Consent*

[901] Even if documentation obtained from previous physicians suggests that they provided information to a patient, the treating physician cannot rely on such previous discussions, and must not use them as a substitute for the information that he is obliged to present to his patient as part of the consent process. This is clear from the CAM policy.

[902] This makes sense because a physician cannot know exactly how well the information was presented by another physician, how much the patient understood, how much information a patient remembers from previous conversations or if the patient has any new questions. Additionally, a patient's clinical status and cancer progress can change, requiring a re-evaluation and a new discussion of potential therapies. Only by presenting the information themselves can physicians be confident that all relevant information has been accurately presented to the patient.

[903] Furthermore, a physician offering CAM treatments is expected to compare the risks and benefits of conventional medications with the treatments they are

proposing, and the quality of the discussion depends on a robust discussion of all the medications and their comparison to each other. Mr. H's previous physicians would not have had a conversation with Mr. H comparing conventional options with SAFE chemotherapy. That was Dr. Khan's duty. Therefore, Dr. Khan should have discussed all the relevant medications, and such a conversation could not depend on what Mr. H might know or remember from previous conversations with other physicians. Therefore, a risk/benefit discussion, even if one did occur as Dr. Khan claims, would have to have included a review of Dr. Khan's proposed treatments, and conventional treatments – in full. Anything less is insufficient to obtain informed consent.

[904] In the absence of written documentation to show that he had this discussion with Mr. H, we do not find credible Dr. Khan's claim that he had an adequate consent discussion with Mr. H, or that Mr. H told Dr. Khan he understood the limits of SAFE chemotherapy. Consequently, Dr. Khan did not maintain the standard of practice of the profession when he failed to obtain informed consent to treat Mr. H with SAFE chemotherapy.

[905] There is no evidence that SAFE chemotherapy is anything but the conventional chemotherapy carboplatin, with all its established side effects and toxicity; nor is there evidence that SAFE chemotherapy could have fulfilled Mr. H's requests and wish for life extension. When he treated Mr. H with SAFE chemotherapy, Dr. Khan did not inform Mr. H of any of this. By presenting SAFE chemotherapy to Mr. H as a treatment that could fulfil his requests when it could not, and by giving him conventional chemotherapy when he wanted to avoid it, not only did Dr. Khan fail to obtain informed consent from Mr. H and fail to meet the standard of care of the profession, he disregarded Mr. H's wishes.

[906] In an October 20, 2013 letter to Mr. H, Dr. Khan described SAFE chemotherapy as having "much higher potential for remission than conventional chemotherapy based on limited initial data (including long-term remission lasting for years)." As set out above, these claims were not supported by evidence and science.

[907] In the same letter, Dr. Khan told Mr. H, "if cost is not prohibitive, we recommend consideration of SAFE chemo (instead of FOLFIRINOX)." When questioned about this statement, Dr. Khan would not acknowledge that he was recommending

SAFE chemotherapy over FOLFIRINOX. He emphasized that he said “‘consideration of.’ I didn’t recommend it over FOLFIRINOX.” This came across to us as an intentional sidestepping of the question.

- [908] It is a given that all treatment information presented to patients is only for their consideration. However, a patient’s consideration relies on the quality of information provided by the physician proposing the therapy. When Dr. Khan communicated to Mr. H that he “recommend[ed] consideration” of one drug (SAFE chemotherapy) “instead of” another (FOLFIRINOX), that was a clear statement as to which therapy Dr. Khan thought Mr. H should take.
- [909] We find that Dr. Khan’s statements to Mr. H in this letter constituted advice that he should choose SAFE chemotherapy (a medication with no evidentiary support for its efficacy) over FOLFIRINOX (a medication that Dr. Tozer testified could prolong life in this patient). The clear message was that SAFE chemotherapy had a much higher potential to put Mr. H into long term remission than did conventional chemotherapy. This, in addition to the inadequate risk/benefit discussion as set out above, virtually obliterated the possibility that Dr. Khan presented Mr. H with a balanced discussion upon which to base his decisions around his treatment options.
- [910] Dr. Tozer opined that in this letter, Dr. Khan “doesn’t really give a real rationale as to why he’s choosing SEF [SAFE] over FOLFIRINOX...he’s making it sound like...FOLFIRINOX is only good for you if you don’t have enough money to pay for SEF [SAFE].”
- [911] Dr. Khan also testified that should a patient “choose a complementary therapy that has limited data over an established protocol, conventional protocol that has extensive data but the data is poor, then that is the patient’s choice.” In saying that, he failed to acknowledge his role and duty as a physician and his impact on the choices patients make.
- [912] Patients have a right to make choices about their health care. However, a physician has duties about the types of therapies that he should offer and how these therapies are presented to patients. Dr. Khan had a duty to offer Mr. H only a therapy that would give him a favourable risk/benefit profile and a reasonable chance at providing the benefits he claimed. Instead, Dr. Khan made a number of

unproven claims about SAFE chemotherapy, suggested that Mr. H go and read about more unproven claims on Dr. Matsumura's website and told Mr. H that he should consider SAFE chemotherapy over conventional therapy.

[913] It was Mr. H's right to choose a therapy with limited data to support it. But it was also Mr. H's right to be given accurate information upon which to base his decision so that he could give informed consent. By failing to provide accurate information, Dr. Khan undermined his patient's autonomy.

#### *Summary of Informed Consent for Mr. H*

[914] Dr. Khan provided Mr. H with inaccurate and inadequate information about the potential efficacy and safety of SAFE chemotherapy, recommended that it be considered over established therapies and did so in the absence of a risk and benefit discussion comparing conventional chemotherapy with SAFE chemotherapy. The consent Mr. H gave was not informed, and in failing to obtain informed consent from Mr. H to use SAFE chemotherapy, Dr. Khan failed to maintain the standard of practice of the profession.

#### *c) Analysis - Failure to Provide Accurate and Objective Information*

[915] We accept Dr. Tozer's testimony that the change in tumour thickness seen on the February 24, 2014 ultrasound compared to the January 13, 2014 ultrasound was closer to an experimental error, such that the tumour was stable (and not significantly decreased) over the interval period between the two scans.

[916] We find that Dr. Khan's email to various people including Mr. H's about this ultrasound<sup>41</sup> informing them that "there is further shrinkage of the pancreatic tumour!" would mislead them into believing that there was true and significant shrinkage of the mass.

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<sup>41</sup> The February 24 ultrasound is not specifically referenced anywhere in the subject line or body of Dr. Khan's February 27, 2014 email to H's family and CS. However, in his written closing submission, Dr. Khan confirmed that is what he was referring to in the email.

[917] This was Dr. Khan's personal opinion, which neglected to take into account the importance of study technique, ultrasound operator or other important factors that radiologists consider when interpreting an ultrasound, and instead drew conclusions based only on the measurements rendered by the ultrasound technologist. Dr. Khan's statement was overly optimistic and "overplayed" compared to the real-life implications that a 3 mm change in tumour thickness, which Dr. Tozer described as an "experimental error," would have on Mr. H's prognosis. In making the statement, Dr. Khan failed to provide accurate and objective information substantiated by fact and sound clinical judgment about the progress of his cancer, in contravention of the CAM policy. In that regard, he failed to maintain the standard of practice of the profession.

#### *Knowledge, Skill and Judgment*

[918] As set out above, the use of SAFE chemotherapy was not appropriate for Mr. H because it would have no impact on his pancreatic cancer. As detailed in other sections of these reasons, we accepted that SAFE chemotherapy fails to offer patients a favourable risk/benefit profile as required by the CAM policy, while simultaneously exposing patients to the risk of harm from the side effects and toxicity of carboplatin. By using it on Mr. H, Dr. Khan demonstrated a lack of judgment. Additionally, Dr. Khan should have known that carboplatin, even as an off-label therapy, is not effective in pancreatic cancer. Dr. Khan demonstrated a lack of knowledge in using it on Mr. H.

#### *Exposure to Risk of Harm or Injury*

[919] In our view, the fact that a patient is terminal and has no prospect of survival, regardless of the therapy used, does not mean that the patient cannot experience harm or injury from the known side effects and toxicity of medications. They may potentially suffer, or worse, die earlier as a result of the clinical consequences of such side effects and toxicity.

[920] As set out elsewhere in these reasons, Dr. Tozer confirmed in his testimony that using SAFE chemotherapy exposes patients to a risk of injury from the side effects of carboplatin. There is insufficient evidence to show that the use of mesna protects patients from the toxic side effects of carboplatin. Thus, whether

or not Mr. H was terminal, by placing him on SAFE chemotherapy, Dr. Khan exposed him to a risk of harm.

[921] Indeed, as Dr. Tozer's written report pointed out, Mr. H did not appear to tolerate SAFE chemotherapy. He needed rehydration in the emergency department as a result of intractable nausea and vomiting. In his dataset, Dr. Khan confirmed that Mr. H experienced side effects from SAFE chemotherapy: "[weight] loss, Gr 3-4 vomiting (req IV fluid bolus in office)."

#### *Exposure to Risk of Harm - Opportunity Cost*

[922] While it was Mr. H's right to make choices about his health care, he did so based on the inadequate and inaccurate information about SAFE chemotherapy that Dr. Khan presented to him. There was no reasonable expectation that Mr. H would derive the benefits or efficacy that Dr. Khan presented to him, and there was no reasonable expectation that he would experience fewer side effects and toxicity than the conventional chemotherapies he told Dr. Khan he was trying to avoid. Dr. Khan exposed Mr. H to the risk of harm from the opportunity cost of leaving his home and family, and possibly preparing for his death, to travel across the country, likely repeatedly, for ineffective treatment when he had little time to live.

#### *Disregard for Patient Welfare*

[923] Mr. H wanted a gentle cancer therapy that could spare him from the side effects of conventional chemotherapy. Without evidence to support its use in cancer, or that its side effects were mitigated by mesna, Dr. Khan told Mr. H that cost permitting, he should consider SAFE chemotherapy over the conventional chemotherapy FOLFIRINOX. He used SAFE chemotherapy on Mr. H without obtaining his informed consent and continued it even though Mr. H developed symptoms that could have been due to carboplatin. He also provided his own overly optimistic personal opinion of Mr. H's radiological study, instead of the radiologist's findings or conclusions. Ultimately, even though Mr. H travelled across the country to obtain the efficacy and treatment safety that Dr. Khan described to him, Dr. Khan gave Mr. H exactly what he wanted to avoid, a conventional chemotherapy with established side effects and toxicity, in the last months of his life. In his care of Mr. H, Dr. Khan displayed a disregard for his patient's welfare.

## *Conclusion*

[924] We considered the written and oral evidence before us, and conclude that in his care of Mr. H, Dr. Khan failed to maintain the standard of practice of the profession, demonstrated a lack of knowledge and judgment, exposed Mr. H to the risk of harm or injury and displayed a disregard for his welfare.

## Dr. Khan's Care of Patient I

[925] In relation to his care and treatment of Mr. I, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose Mr. I to the risk of harm or injury?

## *History and Conventional Treatment Overview*

[926] Mr. I was a man in his 60s who had a CT scan demonstrating the likely presence of metastatic lung cancer with enlarged lymph nodes. He was told by a specialist that there was roughly a 90% chance that the CT findings were lung cancer. Mr. I also exhibited symptoms of recurrent laryngeal [nerve] compression,<sup>42</sup> which according to Dr. Tozer likely rendered the presumed cancer inoperable. Mr. I was offered a bronchoscopy and a biopsy but declined these and started natural therapies on his own.

[927] A May 13, 2013 CT scan of Mr. I's chest and abdomen showed the following key findings: mass occluding the left upper lobe bronchus at its origin, two enlarged lymph nodes with low density centres suggesting central necrosis and no concerns for cancer in the abdomen or bones.

[928] Dr. Tozer testified that Mr. I likely had NSCLC, the treatment for which had significantly expanded over the last decade. A tissue sample would have been very important in guiding which therapy would best treat Mr. I's cancer.

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<sup>42</sup> Recurrent laryngeal nerve passes into the middle of the chest (the mediastinum). It controls the larynx (or voice box). Cancers affecting the mediastinum can damage this nerve and cause hoarseness.

### *Conventional Treatment Options*

[929] Dr. Tozer testified that without a biopsy, it would be difficult to say what Mr. I's conventional options were. However, they would probably involve chemotherapy, the goal of which would be palliative. Dr. Tozer also testified that lung cancers are typically treated with doublets, meaning two different chemotherapy drugs.

### *Care and Treatment by Dr. Khan*

[930] Mr. I met Dr. Khan after a naturopath referred him for DCA treatment. Dr. Khan described Mr. I as a knowledgeable consumer of CAM who had done his own research about DCA therapy. Dr. Khan's July 16, 2013 Medicor note stated that Mr. I wanted "natural therapies only" and had declined bronchoscopy and biopsy. Dr. Khan testified that he tried to convince Mr. I to have a biopsy and to consider bronchoscopy.

[931] Dr. Khan's notes from this July 2013 meeting state that Mr. I was "interested in DCA." Dr. Khan was planning to try "DCA now, [and] SAFE chemotherapy as backup." Dr. Khan's medical record does not contain any documentation showing that he reviewed conventional treatment options with Mr. I. Mr. I signed a DCA consent form at this July 16 visit and Dr. Khan commenced DCA therapy.

[932] Two months later, Dr. Khan began treating Mr. I with SAFE chemotherapy. Dr. Khan's notes show that Mr. I started his first cycle in September 2013 and received a total of 19 cycles.

[933] Dr. Khan did not start Mr. I on a second agent until February 25, 2014, at which time he added gemcitabine, a conventional drug, to Mr. I's regimen.

[934] With regard to the evidence and science supporting the use of SAFE chemotherapy on Mr. I, Dr. Tozer stated, "[w]e have no clinical trial evidence that [it] is effective in this patient. If this patient was to come to me and ask me what the response rates were, I wouldn't be able to tell them. And, if the patient was going to say, 'Will this drug meaningfully prolong my life?' I can't answer that question either because I don't have a comparative."

[935] It was put to Dr. Khan that having treated his first SAFE chemotherapy patient only in late July 2013, at the time Mr. I came to see him he would not have had a

lot of time to “develop a track record.” He responded that he was not sure “what difference that makes how much data there is. There is scientifically valid data.” He added that he was not aware of anything in the CAM policy specifying that he had to have “‘x’ number of patient experience or ‘x’ amount of data.” This comment came across to us as evasive. It seemed that Dr. Khan was attempting to justify his use of SAFE chemotherapy on Mr. I by pointing out how little data he needed in order to use it.

*Dr. Khan’s Care of Mr. I and Mr. I’s Clinical Condition from February 2014 Onwards*

- [936] Six months after starting SAFE chemotherapy, Mr. I’s February 18, 2014 chest x-ray showed further increase of the left-sided tumour mass, further decrease in left lung volume, an early shift of mediastinal structures to the left and his right lung was clear.
- [937] Dr. Khan’s February 25, 2014 note about the chest x-ray stated, “increased [arrow up symbol] mass and necrotic tissue expected after each chemo cycle.” However, Dr. Tozer stated that “the chemotherapy isn’t working” and that the increase in tumour size on this chest x-ray represented the chemotherapy’s “lack of efficacy.”
- [938] Mr. I’s February 24, 2014 PET/CT scan of his whole body showed: a metabolically active large infiltrating left “suprshilar” [sic] mass with central necrosis in keeping with malignancy, metabolically active intrathoracic and left supraclavicular adenopathy compatible with nodal metastases and metabolically active, morphologically indeterminate right adrenal nodule, which “must be considered metastatic until proved otherwise.”
- [939] By March 2014, seven months after starting SAFE chemotherapy, Mr. I was experiencing light-headedness, headache, reduced memory and reduced coordination in his right arm. Dr. Khan started him on prednisone for presumed metastases to the brain and sent him for an MRI of his head on March 25.
- [940] The MRI showed that Mr. I had metastatic disease in his brain, with vasogenic edema [swelling] causing mass effect and compression of the lateral ventricle.
- [941] Immediately after the MRI, on March 26, 2014 Dr. Khan requested an urgent radiation oncology consultation for Mr. I. He also planned to start Mr. I on a new drug called Tarceva, continue carboplatin and continue the gemcitabine.

[942] Dr. Tozer opined that Dr. Khan's urgent referral to radiation oncology and the initiation of prednisone were appropriate actions. However, Tarceva<sup>43</sup> gemcitabine and more carboplatin would not play a role in the treatment of brain metastases. He explained that Tarceva, a conventional chemotherapy, is used for cancers with a specific receptor. With no biopsy for Mr. I, the use of this drug for him was "hoping." Regarding the carboplatin plus gemcitabine, Dr. Tozer explained that, apart from some notable exceptions,<sup>44</sup> chemotherapy typically does not penetrate the blood-brain barrier and would not help treat Mr. I's metastases to the brain (particularly since Mr. I's metastases occurred while he was on chemotherapy). Thus, radiation was the key treatment for Mr. I's metastatic brain disease.

[943] Mr. I had a good response to the prednisone. with a reduction of his brain metastases-related symptoms. This indicated that radiation therapy would likely help him. Dr. Tozer explained that radiation treatment to the brain could potentially give Mr. I long-term benefits such as being able to reduce or stop the prednisone (a medication that has long-term side effects) and possibly prolonging his survival.

[944] Dr. Khan's March 28, 2014 clinic notes show that he accompanied Mr. I and his wife for Mr. I's radiation oncology consultation at Sunnybrook. Mr. I declined the brain radiation because of side effects and stated that he did not want brain radiation unless "absolutely necessary." Dr. Tozer explained that a physician's obligation in this circumstance was to explain the benefits of radiation to the patient. Dr. Tozer agreed that Dr. Khan did have an ongoing discussion with Mr. I about radiation as a conventional treatment for brain metastases.

[945] In the March 28 note, Dr. Khan wrote that Mr. I "likely [had] a rapid response to chemo once Gemzar [gemcitabine] [was] added." Dr. Tozer stated that he did not see anything in the chart to indicate there had been a rapid response with the addition of this medication. Dr. Khan disagreed and testified that although Dr.

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<sup>43</sup> Tarceva: a conventional chemotherapy in the use of lung cancer which is used when there is evidence of a mutated epidermal growth factors receptor. Biopsy is required to determine the presence of this receptor. It is not clear from the evidence whether Dr. Khan ever started Mr. I on Tarceva.

<sup>44</sup> Dr. Tozer listed which chemotherapy agents may cross the blood-brain barrier. Dr. Khan was not using any of these medications to treat Mr. I.

Tozer did not accept that the mesna in SAFE chemotherapy had any activity, he believed that Mr. I's immediate development of signs and symptoms of brain edema were due to the addition of gemcitabine, suggesting that it was "now more effective." Dr. Khan believed that this was consistent with the finding from Mr. I's MRI of necrotic metastases.

#### *Investigations and Dr. Khan's Communications*

[946] On June 13, 2014, Dr. Khan wrote a letter to Dr. Kis (a neurosurgeon) asking for an urgent consult and aggressive therapy for Mr. I after his scheduled MRI. In this letter, Dr. Khan stated:

- that Mr. I was on a "unique neutrophil potentiated chemotherapy" which had "good potential to induce remission or even cure in stage 3 and stage 4 cancers";
- "[s]ince this is a potentially curative therapy, we are looking for any aggressive management that you think may help"; and
- that he was using a "higher dose than what oncologists normally prescribe" regarding the carboplatin and mesna regimen.

[947] Further, Dr. Khan:

- described Mr. I's follow-up MRI as showing pseudoprogression of brain metastases and that "PET confirmed they were largely necrotic"; and
- disputed a radiologist's conclusion that Mr. I's CT had shown disease progression, instead stating that "there is a very good chance this is again pseudo-progression resulting from the powerful anti-cancer immunity."

[948] Dr. Tozer testified that there was no evidence Mr. I had pseudoprogression. Apart from his own opinion, Dr. Khan did not lead any evidence to counter Dr. Tozer's opinion. Dr. Tozer also testified that at the time of Dr. Khan's June 2014 letter to Dr. Kis, there was no prospect that Mr. I could be cured of his cancer. Dr. Khan confirmed that it was "very unlikely" that in June 2014 SAFE chemotherapy could potentially cure Mr. I.

- [949] Although he wrote to Dr. Kis about cure, Dr. Khan denied that he told Mr. I the SAFE chemotherapy was potentially curative. When asked by College counsel why he would give Dr. Kis, but not his patient, important information about prognosis and the possibilities of treatment, Dr. Khan responded that his letter to Dr. Kis had nothing to do with Mr. I's prognosis, that he was explaining the therapy to Dr. Kis. We do not accept this; on its plain wording the letter spoke about Mr. I being potentially cured. Dr. Khan's denial under cross-examination that he was referencing Mr. I's prognosis seemed like a deflection and undermined the credibility of his testimony.
- [950] Furthermore, it was only during his cross-examination that Dr. Khan acknowledged that SAFE chemotherapy was very unlikely to cure Mr. I. There is no evidence that Dr. Khan held this view at the time he was caring for Mr. I. There is nothing in his chart for Mr. I, or in his communications to Mr. I or his family or to other physicians, to suggest that he did. To the contrary, as discussed above, in the letter to Dr. Kis which includes a description of the same highly optimistic curative potential of SAFE chemotherapy seen in Dr. Khan's other written documentation, Dr. Khan asked Dr. Kis to provide aggressive treatment for Mr. I since SAFE chemotherapy was potentially curative. We were presented with no evidence, or any good reason to cause us to believe, that Dr. Khan would communicate one thing to his medical colleague and another to his patient.
- [951] All of this leads us not to believe Dr. Khan's denial that he told Mr. I the SAFE chemotherapy was potentially curative. We conclude that Dr. Khan did not provide Mr. I with a realistic picture of what SAFE chemotherapy could or could not do for him, even later in his therapy when there was evidence his cancer was progressing.
- [952] Dr. Khan testified that when he called and spoke directly to the radiologist who read the MRI referred to in his letter to Dr. Kis, the radiologist told him he thought the brain metastases were necrotic. Dr. Khan suggested that Dr. Tozer may have missed this information when he made his assessment that Mr. I did not respond to SAFE chemotherapy. However, Dr. Tozer gave evidence (with reference to another patient) that tumour necrosis may simply indicate that a tumour has outgrown its own blood supply.

[953] Dr. Kis recommended surgical debulking to help decrease the mass effect of one of the lesions and lower the steroid dosing, as well as stereotactic radiosurgery for another lesion. Dr. Khan's August 3 note shows that Mr. I underwent neurosurgery, during which some of his brain metastases were excised.

[954] After surgery, Mr. I was again offered whole brain radiation for his remaining brain metastases. Dr. Khan testified that he went to Mr. I's radiation appointment with him because he knew that Mr. I was going to refuse the treatment, so he wanted to be there with him and his wife when they saw the doctor to help convince Mr. I to take the radiation.

[955] Mr. I died in the summer of 2014. Two days before his death, he dictated a letter to his wife for Dr. Khan, greatly praising Dr. Khan and deeply thanking him for his care.

*Dr. Khan's View on SAFE Chemotherapy and CTC Testing for Mr. I*

[956] Dr. Khan's view as expressed in his August 3, 2014 note was that "SAFE chemo [was] highly effective —> brain mets" for Mr. I. He testified that "initially, there was definitely response" from SAFE chemotherapy, as shown by what Dr. Khan said were more reliable studies such as PET scan and circulating tumour cell (CTC) counts, and symptom improvement.

[957] On cross-examination, when asked if Mr. I "was getting worse at the same time that the circulating tumour cell counts were actually decreasing," Dr. Khan referred to Mr. I's February 2014 PET scan as showing that tumours were dying and that there was "necrosis" when the CTC count was decreasing. Dr. Khan did not address the fact that Mr. I's May 6, 2014 PET/CT scan of his whole body, as compared to the February PET scan, showed increasing pericardial effusion and progressive collapse of the entire left lung, a new metabolically active paratracheal lymph node, possible new metastasis in the liver and three brain metastases with rim metabolism. In May 2014, Mr. I's CTC count was zero.

*What is a CTC Count?*

[958] Dr. Tozer testified that CTC (also referred to as Maintrac) refers to "circulating tumour cells," which are "tumour cells that have basically gone from the tumour --

invaded the blood stream and are basically in the circulation.” Dr. Tozer explained:

[W]e know, for example, in renal cell carcinoma [kidney cancer]...you can actually measure billions of circulating tumour cells prior to nephrectomy [surgical removal of the kidney]. The interesting thing is, whether you see them or not, it has very little impact on a patient’s outcome. In other words, just because you have tumour cells circulating in your blood stream, doesn’t mean that they’re actually going to be able to attach to a blood vessel, get into the surrounding parenchyma [the tissue surrounding a blood], set up new blood vessels...it doesn’t necessarily predict that you’re going to develop metastatic disease.

[959] Dr. Tozer testified that Dr. Khan “almost uses it [CTC] as a tumour marker [in his patients]...in other words, seeing tumour cells going up is bad, seeing the number of tumour cells going down is good.”

[960] Dr. Tozer stated that “this is not a way that we follow cancer,” and that for the kinds of diagnosis and treatment occurring at his institution, circulating tumour cells are not used as a method of monitoring a patient’s progress or status. Dr. Tozer’s opinion is that CTC was experimental and not the standard of care in Ontario or Canada.

#### *Dr. Khan’s Updated 2017 SAFE Chemotherapy Medicor Patient Data Compilation*

[961] Dr. Khan’s dataset lists Mr. I as having stage 4 NSCLC for which he was treated with 19 cycles of SAFE chemotherapy. In the “Response” column of this dataset, Dr. Khan noted that Mr. I had a “Partial response” of his cancer as per “clinical, CTC from 14,250->0, PET/CT.” The reason for stopping SAFE chemotherapy in Mr. I was noted to be “Patient request.”

#### *Summary of Expert Witness Opinion on Dr. Khan’s Care of Mr. I*

[962] Dr. Tozer testified that Dr. Khan met the standard of practice when he recognized Mr. I’s brain metastases, started him on steroids and arranged a second neurosurgical appointment for him. However, regarding Dr. Khan’s use of medications, Dr. Tozer commented:

- until late in Mr. I’s therapy, Dr. Khan used a single agent, carboplatin, to treat lung cancer when he should have used a combination of agents;

- Tarceva, if started, should have been used as a single agent chemotherapy because it interferes with the other medications; and
- dosing with carboplatin with mesna without the addition of gemcitabine would not be an evidence-based regime.

[963] Dr. Tozer testified that Dr. Khan showed a lack of knowledge, skill and judgment by not using the right chemotherapy regimen on Mr. I.

[964] With regard to exposing Mr. I to the risk of harm or injury, Dr. Tozer stated:

In this case, I think the patient exposed himself to harm or injury ...by not allowing a biopsy...[and] he put off [treatment]...So, I think a lot of the harm in this case is actually attributable to the patient's decision making.

### *Finding*

[965] We considered the written and oral evidence before us and find that in his care and treatment of Mr. I, Dr. Khan did not maintain the standard of practice of the profession when he:

- a) treated a patient's cancer using medications (SAFE chemotherapy) that were not informed by evidence and science, did not possess a favourable risk/benefit profile and did not have a reasonable expectation of remedying or alleviating the patient's health condition or symptoms; and
- b) failed to obtain informed consent for the use of SAFE chemotherapy.

### *Analysis*

#### *a) Analysis - The Use of SAFE Chemotherapy*

[966] For the reasons stated in the "SAFE Chemotherapy" section of these reasons, we find that Dr. Khan should not have used SAFE chemotherapy on his patients, including Mr. I, and in doing so, he failed to maintain the standard of practice of the profession.

[967] As previously discussed, the fact that patients such as Mr. I may do their own research on treatments and may be sophisticated and experienced consumers of CAM therapy does not eliminate the physician's obligation to conduct the

appropriate conversations with their patients, and to offer them only therapies that have a favourable risk/benefit profile which could reasonably be expected to alleviate their health condition, as demonstrated by evidence and science. The physician's obligations do not change even when a patient does not want conventional therapy and favours CAM treatments.

*b) Analysis - Failure to Obtain Informed Consent*

*i) Written Evidence*

[968] As previously discussed, checking the box "Review of R + B of change(s) in treatment plan" in Mr. I's SAFE chemotherapy treatment record is not sufficient to indicate that Dr. Khan conducted a discussion sufficient to obtain informed consent. In Dr. Khan's chart on Mr. I, there was no mention of which standard chemotherapeutic options Dr. Khan described to Mr. I or with what level of detail. We do not find that this level of documentation is adequate to prove that Dr. Khan provided Mr. I with the information necessary to make an informed decision on the use of SAFE chemotherapy.

*ii) Oral Evidence*

[969] We find that Dr. Khan tried to explain the benefits of radiation and attempted to convince Mr. I to undergo this therapy when Mr. I was diagnosed with brain metastases in March 2014.

[970] As a treatment for Mr. I's presumed lung cancer, Dr. Khan started Mr. I on-SAFE chemotherapy six months before the diagnosis of brain metastases. For the reasons outlined in the "Consent and Communications" section of these reasons, we do not find credible Dr. Khan's testimony that he reviewed conventional therapy options with all his patients in detail, including possible response rates and side effects of both conventional chemotherapeutic options and the therapy he was offering, and how the risks and benefits of using these medications compared with each other. While Dr. Khan did discuss radiation with Mr. I in March 2014, he did not have an adequate risk/benefit discussion with Mr. I in the fall of 2013 when he started treating him with SAFE chemotherapy.

[971] The treatment for Mr. I's presumed NSCLC should have consisted of doublet chemotherapy. While it was Mr. I's right to refuse all standard chemotherapy, it

remained Dr. Khan's duty to inform him of it. There was no documentation in Mr. I's chart suggesting that Dr. Khan did so. Dr. Khan did not add Mr. I's second chemotherapy, gemcitabine, until much later in his treatment course. We do not accept that Dr. Khan gave this information to Mr. I and believe that Mr. I did not have the critical information necessary to give informed consent to use SAFE chemotherapy.

[972] Additionally, as Dr. Tozer noted, there was no clinical trial evidence that this therapy would be effective for this patient, nor could Dr. Khan have said whether it would meaningfully prolong this patient's life. Within the context of obtaining informed consent, this would have been critical information to provide to a patient about a proposed therapy. As such, informed consent was not possible here.

[973] When considering all the above, we find that Dr. Khan did not obtain informed consent from Mr. I to treat him with SAFE chemotherapy, and in that regard he failed to maintain the standard of practice of the profession.

#### *Knowledge, Skill and Judgment*

[974] Dr. Khan showed a lack of judgment in using SAFE chemotherapy to treat Mr. I, which exposed him to the known risks and side effects of carboplatin, even though it was unlikely to treat his presumed cancer. Dr. Khan did not have any published literature or robust scientific evidence demonstrating the efficacy of SAFE chemotherapy, and since he had only recently started using SAFE chemotherapy in his own practice, Dr. Khan also had little in the way of personal experience or data to validate its use on Mr. I.

[975] At the time of his June 2014 letter to Dr. Kis, there was evidence from reliable imaging such as MRI and PET scans that Mr. I's cancer had already spread to multiple locations outside of the lung and brain, and that the spread had occurred while Mr. I was on SAFE chemotherapy. Dr. Khan showed a lack of knowledge in failing to recognize the significance of the various radiological studies that evidenced cancer progress in his patient. Dr. Khan's misdiagnosis of Mr. I's disease progress in his brain as pseudoprogression also demonstrates a lack of knowledge.

[976] We accept Dr. Tozer's evidence that CTC count is experimental and not an approved medical test in Canada as a reliable method for monitoring cancer. Dr. Khan did not lead any evidence supporting the use of CTC counts to monitor cancer, or showing that a falling CTC count has clinical implications for cancer response to therapy. Consequently, we reject Dr. Khan's claim that a falling CTC count meant that Mr. I was having a partial response to therapy, rather than that he was having cancer progress as shown by conventional and accepted methods for monitoring cancer.

[977] As seen with other patients, Dr. Khan's descriptions highlighted non-standard experimental testing such as CTC counts and downplayed or disputed the evidence of cancer progress described by the radiological experts reading Mr. I's imaging.

#### *Exposure to Risk of Harm or Injury*

[978] We accept Dr. Tozer's opinion that in not allowing a biopsy and in putting off treatment in declining conventional chemotherapy, Mr. I exposed himself to the risk of harm or injury (from his cancer).

[979] However, even though Mr. I specifically wanted to avoid the side effects of conventional chemotherapies, which he turned down for that reason, Dr. Khan nevertheless treated him with the conventional chemotherapy carboplatin and exposed Mr. I to the risk of harm or injury from the well-established side effects and toxicities of this medication.

#### *Conclusion*

[980] We considered the written and oral evidence before us, and conclude that in his care of Mr. I, Dr. Khan failed to maintain the standard of practice of the profession, demonstrated a lack of knowledge and judgment and exposed Mr. I to the risk of harm or injury.

[981] We recognize that, with regard to radiation therapy specifically, Dr. Khan directed Mr. I on various occasions to conventional treatment that could have helped him. Additionally, it is evident to us that Dr. Khan diagnosed, monitored and treated (with prednisone) Mr. I's symptoms of metastatic brain disease appropriately, and

referred him to other specialists when necessary. Dr. Khan maintained the standard of practice in this regard.

[982] However, the fact that Dr. Khan maintained the standard of practice in some aspects of his care of Mr. I does not alter our finding that he failed to maintain the standard of practice in other aspects of his care.

#### Dr. Khan's Care of Patient J

[983] In relation to his care and treatment of Ms. J, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose Ms. J to the risk of harm or injury?

#### *History and Conventional Treatment Overview*

[984] Ms. J was in her early 20s when she was being cared for by Dr. Khan for stage 4 melanoma with brain metastases. She had been initially diagnosed with melanoma in 2008 when she was a teenager. Ms. J had BRAF mutation positive metastatic melanoma which had progressed to involve her brain and liver. Ms. J was being cared for by a multi-disciplinary team of physicians, including a team at Sunnybrook that supervised the numerous treatments she had received over the years since her diagnosis. These included: surgery, interferon alfa, vemurafenib and ipilimumab, which was one of the first immunotherapy drugs used successfully with melanoma. For her brain metastases, she had received whole brain radiation and then stereotactic radiation and the chemotherapy drug temozolomide, which Dr. Tozer testified is one of the few chemotherapies that crosses the blood-brain barrier.

[985] Despite these treatments, a July 20, 2012 staging CT showed two new liver metastases since Ms. J's previous staging CT. The lesions measured 1 cm and 8.9 cm respectively.

#### *Conventional Treatment Options*

[986] Dr. Tozer testified that Ms. J's disease was progressing and that her conventional treatment options included re-challenging her with ipilimumab, a conventional therapy that would give her a 20% response rate, and chemotherapies that would give her a maximum response rate of 5% with no chance of cure.

### *Care and Treatment by Dr. Khan*

[987] Dr. Khan's Medicor patient records show that he was involved with Ms. J's care by April 7, 2011. He testified that the goal of treatment with Ms. J was palliative care, but given her young age he was hoping for significant life extension with good quality of life.

[988] His notes from April 7, 2011 show that Ms. J was receiving a conventional therapy named temozolomide and was due to have another stereotactic radiosurgery. Dr. Khan's plan was to add other agents including vitamin D, TM<sup>45</sup> and DCA to Ms. J's treatments. Records show that he started Ms. J on DCA.

[989] Dr. Khan explained that "DCA actually does penetrate the brain, and so that would have been a good choice for her because she did have brain metastasis. So she wanted treatment...for all the cancer in the body basically. DCA was...that was one of the reasons to choose that for her."

[990] Dr. Tozer testified that there was no evidence and science to support the recommendation of DCA for Ms. J. Melanoma behaves "very very different[ly] from other cancers...this is a cancer that is intrinsically chemotherapy resistant." He did not find any evidence and science to support the use of DCA in treating melanoma.

[991] In 2013, Ms. J was taking high-dose DCA, but had become frustrated with taking medication, and was considering taking a break from all therapies.

[992] Dr. Khan believed that DCA likely contributed to Ms. J's survival, but that it was difficult to know because she was also on other medications.

### *Ms. J's Fertility*

[993] By February 2014, Ms. J was having right lower quadrant pain. Dr. Khan arranged for a PET scan, which showed that the melanoma was present in Ms. J's ovaries

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<sup>45</sup> TM stands for tetrachloride molybdenite which is compound thought to be antiangiogenic.

and right axilla. Dr. Khan testified that Ms. J had been told by her Sunnybrook team that she would need to have a bilateral oophorectomy (removal of her ovaries) to treat the metastatic spread of the cancer to her ovaries. Dr. Khan's chart note indicates that he discussed the possibility with Ms. J of preserving her fertility by resecting the right ovary only.

[994] Dr. Tozer testified that a discussion about fertility assumed that Ms. J would be cured, while in actuality her prognosis at the time would have been less than one year. If she could get pregnant, it was unlikely that she would be able to carry the child to term. Another issue with pregnancy in Ms. J's circumstances is that melanoma is able to cross the placenta and implant in the fetus, thereby putting it at risk of death from metastatic melanoma.

[995] Dr. Khan testified that it was Ms. J herself who brought up concerns about her fertility after her team at Sunnybrook had told her she needed to have her ovaries removed.

#### *SAFE Chemotherapy*

[996] Records show that Dr. Khan started Ms. J on SAFE chemotherapy in April 2014. Dr. Tozer testified that there was no evidence or science to support treating Ms. J with SAFE chemotherapy, particularly because melanoma is a chemotherapy-resistant cancer. "If you were going to use a platinum containing compound, the only regimens that have shown any activity, albeit very low, have been in combination with the drug Taxol."

#### *Investigations*

[997] Dr. Khan stated that he started SAFE chemotherapy after the surgical resection of Ms. J's ovaries and arm metastasis. He explained that she had no symptoms from her cancer, so he monitored her with scans of her brain and liver, and via CTC counts. As previously discussed, CTC count is an experimental test that is not approved in Canada.

[998] By May 16, 2014, as indicated in the report of her abdomen/pelvis ultrasound, Ms. J had undergone a resection of both ovaries and a portion of her liver. The radiologist read the ultrasound as showing a "[c]oarse liver with inhomogeneity

and multiple nodules. Uncertain if these represent metastases or liver regeneration.”

[999] 10 days later, on May 26, Dr. Khan sent Ms. J an email titled “[J] May 16, 2014, and us.pdf” in which he stated, “[u]ltrasound looks very good. The masses in the liver seen on the last CT scan appear to be regenerating liver tissue, not tumour.”

[1000] This is not what the radiologist had concluded. He did not rule out that the masses could be metastases - he said it was “uncertain.” When Dr. Tozer was asked if there was a basis to conclude from this ultrasound that the masses in the liver were regenerating liver tissue, he replied, “[w]e can’t determine that.”

#### *Ms. J’s Current Status*

[1001] Despite her very poor prognosis in 2014, Dr. Khan testified that Ms. J is alive and disease-free.

#### *Dr. Khan’s Updated 2017 SAFE Chemotherapy Medicor Patient Data Compilation*

[1002] In the response column of his dataset, Dr. Khan noted that he treated Ms. J with 12 cycles of SAFE chemotherapy, and he documented her as having a “partial response” of her cancer as per “CTC.” The reason for stopping SAFE chemotherapy in this patient was noted to be “Carbo allergy.” Dr. Khan testified that allergy was the reason he stopped SAFE chemotherapy. However, Dr. Khan’s patient records show that Ms. J’s discontinuation of SAFE chemotherapy was due to lack of funds.

[1003] As set out above, CTC is an experimental test that is not approved for use in Canada. Additionally, in the months before patients die, and despite radiology that shows cancer progress, a patient’s CTCs can drop to 0, as shown in the case of Mr. I. The use of CTC was insufficient to reach a conclusion of “partial response” for Ms. J.

#### *Summary of Expert Witness Opinion of Dr. Khan’s care of Ms. J*

[1004] Dr. Tozer conceded in cross-examination that he had not initially reviewed significant parts of Ms. J’s chart (those prior to May 2013) in preparing his written report, and that consequently his report was incorrect in some respects. We noted

this issue when considering Dr. Tozer's opinions and conclusions and ensured that our findings were not reliant on any of Dr. Tozer's erroneous conclusions.

[1005]Dr. Tozer opined that Dr. Khan's care of Ms. J did not meet the standard of practice because "[t]here's no evidence that either of the two principal treatment modalities that he used, either DCA or [carboplatin] alone have any benefit in the setting of metastatic melanoma." He also stated in his written report that there did not appear to be "an honest discussion as to whether Dr. Khan's treatments were working or not."

[1006]With regard to knowledge, skill and judgment, Dr. Tozer stated that fertility discussions come up quite frequently in his own practice, particularly among his breast cancer patients, and he expressed surprise that there was "a discussion around fertility in the setting of a patient with a very, very limited life expectancy." In addition, his written report stated that "Dr. Khan does not have a realistic understanding of the prognosis of metastatic melanoma." He also noted that "diagnoses related to changing symptoms never included the possibility of disease progression."

[1007]Dr. Tozer concluded that Ms. J was exposed to harm from the "side effects and toxicities from an ineffective treatment, especially the carboplatin."

### *Finding*

[1008]We considered the written and oral evidence before us and find that in his care and treatment of Ms. J, Dr. Khan failed to maintain the standard of practice of the profession when he:

- a) treated a patient's cancer using SAFE chemotherapy and DCA, both of which were not informed by evidence and science, did not possess a favourable risk/benefit ratio and did not have a reasonable expectation of remedying or alleviating the patient's health condition or symptoms;
- b) failed to obtain informed consent for the use of SAFE chemotherapy and DCA; and
- c) failed to provide accurate and objective information, substantiated by fact and sound clinical judgment, to Ms. J about the progress of her cancer.

## *Analysis*

### *a) Analysis - The Use of SAFE Chemotherapy and DCA*

[1009]As noted in the SAFE Chemotherapy section of these reasons, we find that in his use of SAFE chemotherapy for treating patients with cancer, Dr. Khan failed to maintain the standard of practice of the profession. There is insufficient evidence and science supporting Dr. Khan's purported claims that it is effective in treating cancer.

[1010]Even if one were to set aside concerns about SAFE chemotherapy and consider carboplatin as a standalone treatment for Ms. J's melanoma, Dr. Khan would have had to use it with Taxol to achieve even a very low effect, which he did not do. Carboplatin did not offer Ms. J a favourable risk/benefit profile and Dr. Khan failed to maintain the standard of practice of the profession when he used it to treat Ms. J's melanoma.

[1011]Furthermore, melanoma behaves differently than other cancers, and there is no literature supporting DCA as effective in treating this cancer. DCA did not offer Ms. J a favourable risk/benefit profile. We accept Dr. Tozer's opinion that Dr. Khan failed to maintain the standard of practice of the profession when he used DCA to treat Ms. J's melanoma.

### *b) Analysis - Failure to Obtain informed Consent*

[1012]Although the box "reviewed standard chemo" appears checked off in the Medicor chart notes on Ms. J, there is no written documentation of which standard chemotherapeutic treatment options were discussed with Ms. J, nor how their risks and benefits compared with the SAFE chemotherapy and DCA treatments Dr. Khan was offering. As previously discussed in the Consent and Communications section of these reasons, we do not find credible Dr. Khan's testimony that he always had this conversation with patients. In the absence of written documentation, we do not believe that Dr. Khan had an adequate consent discussion with Ms. J, and consequently, he did not maintain the standard of practice of the profession when he failed to obtain informed consent for the use of DCA and SAFE chemotherapy treatments on Ms. J.

*c) Analysis - Failure to Provide Accurate and Objective Information*

[1013] In his May 26, 2014 email to Ms. J concerning the May 16 ultrasound, Dr. Khan gave his patient his own optimistic personal opinion of a scan instead of the radiologist's findings and conclusions. Dr. Khan should have told Ms. J what the radiologist concluded, particularly that the nodules could be new metastatic disease. In leaving out the full findings of the radiologist, and in putting his own personal spin on the results, Dr. Khan failed to provide accurate and objective information substantiated by fact and sound clinical judgment about the progress of her cancer, in contravention of the CAM policy. He deprived his patient of critical information that could have helped her to better understand her clinical status. In that regard, he failed to maintain the standard of practice of the profession.

*Knowledge, Skill and Judgment*

*i) Fertility Discussion*

[1014] We do not accept Dr. Tozer's opinion that Dr. Khan's fertility discussion with Ms. J demonstrated a lack of knowledge or necessarily constituted evidence that Dr. Khan did not have a realistic understanding of the prognosis of metastatic melanoma. Dr. Khan's notes do not show who brought up the subject, but he testified that Ms. J had brought up the subject of fertility on her own because her Sunnybrook team was planning for a bilateral oophorectomy. It is plausible that a young woman facing infertility would bring up the subject to her physician, and we believe Dr. Khan's testimony on this point. That the conversation occurred, taken on its own, is not sufficient to show that Dr. Khan was lacking in knowledge, skill or judgment, nor is it sufficient, on its own, to demonstrate that Dr. Khan did not have a realistic understanding of metastatic melanoma.

*ii) Possibility of Disease Progression*

[1015] In his written report, Dr. Tozer noted that "diagnoses related to changing symptoms never included the possibility of disease progression." It is true, as we found in the case of many patients, that Dr. Khan often failed to attribute changing symptoms to disease progress. However, we did not accept the conclusion that Dr. Khan never did so. In the case of Ms. J, based on his Medicor patient record, it appears that Dr. Khan took note of Ms. J's right lower quadrant pain, examined

her and created a differential diagnosis that ranked ovarian metastatic disease to be the most likely cause of her pain. He then arranged for a timely PET scan to confirm his suspicion. Thus, in this specific instance Dr. Khan did attribute his patient's symptoms to the possibility that her cancer was progressing.

*iii. Treatment with DCA and SAFE Chemotherapy*

[1016]Dr. Khan's decision to treat Ms. J with SAFE/carboplatin and DCA, which exposed her to side effects and toxicities of these treatments even though they were unlikely to provide effective treatment for her cancer, demonstrated a lack of judgment on the part of Dr. Khan.

*Exposure to Risk of Harm or Injury*

[1017]Dr. Khan exposed Ms. J to the risk of harm or injury from the known side effects and toxicities of carboplatin and DCA.

[1018]We considered Dr. Khan's submission that Ms. J's conventional treatments also came with significant risks, yet she chose to undergo all of them. This is true, and Ms. J was entitled to exercise her patient autonomy to make these decisions. However, that is not the issue at hand. Ms. J's decisions around conventional treatments and her acceptance of their side effects do not change the fact that when Dr. Khan treated her cancer with DCA and SAFE chemotherapy, he exposed her to potential harm from the side effects and toxicities of those therapies.

[1019]Patient consent and acceptance of risk for some therapies at some point in their treatment are not a blanket agreement that they will consent to, and accept the risk of, all medications and treatments in all cases. Ms. J's consent to take on the risks involved with her prior conventional therapies does not automatically extend to the subsequent therapies, SAFE and DCA, offered by Dr. Khan. Each new therapy proposed by a physician warrants a new and in-depth discussion about key information so that informed consent can be obtained. There is no documentation in Dr. Khan's chart for Ms. J that such discussion occurred when he proposed DCA and SAFE chemotherapy. Further, Dr. Khan claimed that SAFE chemotherapy had fewer side effects and toxicities than conventional carboplatin

without mesna, which is what Ms. J consented to, yet there was no evidence for this claim.

### *Disregard of Patient Welfare*

[1020] Dr. Khan treated Ms. J with medications that could not be expected to help her and exposed her to the associated risks and toxicities of DCA and the carboplatin in SAFE chemotherapy. Thus, Dr. Khan's care demonstrated a disregard for Ms. J's welfare.

### *Conclusion*

[1021] We considered the written and oral evidence before us, and conclude that in his care of Ms. J, Dr. Khan failed to maintain the standard of practice of the profession, demonstrated a lack of judgment, exposed Ms. J to the risk of harm or injury and demonstrated a disregard for her welfare.

### Dr. Khan's Care of Patient K

[1022] In relation to his care and treatment of Mr. K, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose Mr. K to the risk of harm or injury?

### *Overview of Relevant Information*

#### *History and Conventional Treatment Overview*

[1023] Mr. K was diagnosed with small cell lung cancer (SCLC)<sup>46</sup> by fine needle biopsy.

[1024] Dr. Tozer explained that SCLC is a fast-growing cancer that is considered to be metastatic at the time of diagnosis even when there is no evidence of metastatic disease. It is divided into the following categories:

- limited stage: in which the cancer is confined to the lungs, and

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<sup>46</sup> Small cell lung cancer and non-small cell lung cancer are treated very differently.

- extensive stage, in which the cancer is present both within and outside of the lungs.

[1025]Mr. K had limited stage SCLC. This gave him a better prognosis than extensive stage, which is considered to have no chance of cure. The treatment for SCLC has not changed in many years and usually does not involve surgery. Patients are typically treated with a combination of cisplatin, which is a platinum-containing medication, along with another medication called etoposide. After these conventional chemotherapies, patients receive radiation to the relevant area. Mr. K had also received radiation to the brain, in an effort to reduce the chances of metastases to this region. He had a good response to his treatments and was found to have no evidence of disease (NED) after the completion of his conventional chemotherapy and radiation therapy.

#### *Conventional Treatment Options*

[1026]Dr. Tozer testified that having completed his cycles of chemotherapy/radiation and with no evidence of disease, Mr. K's conventional therapy would have been to engage in watchful waiting and follow-up, with no further treatment.

#### *Relevant Information on Care and Treatment by Dr. Khan*

[1027]Mr. K first presented to Dr. Khan in August 2012. Dr. Khan's clinic note dated August 3 noted that Mr. K had NED and recorded that Mr. K was concerned about the high recurrence risk of his cancer. This note also stated that Dr. Khan was considering treating Mr. K with LDN and DCA.<sup>47</sup>

[1028]Mr. K was initially treated with DCA and eventually LDN. He also had various radiological studies, as discussed below.

[1029]Dr. Khan's Medicor clinic note for Mr. K dated September 13, 2013, one year after their initial meeting, indicated that Dr. Khan provided Mr. K with information on SAFE chemotherapy and was planning to refer him to Dr. Matsumura. Dr. Khan's

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<sup>47</sup> Two more words are noted after LDN and DCA in the August 3 treatment plan, however these are illegible.

records show that on October 2, 2013, Mr. K signed a standard Medicor Consent and Direction for SAFE chemotherapy.

[1030]Dr. Khan treated Mr. K with nine cycles of SAFE chemotherapy between October 2013 and February 2014.

[1031]In his testimony, Dr. Khan confirmed that during the three years that he treated him, Mr. K was symptom-free from cancer.

*Dr. Khan's Communications with Mr. K and Informed Consent*

[1032]While a checkmark in the "R/B in changes of therapy discussed" box can be seen in Mr. K's August 3, 2012 and September 13, 2013 notes, Dr. Khan's charts do not document any discussion with Mr. K comparing the risks and benefits of conventional treatments with those of DCA, LDN or SAFE chemotherapy.

[1033]Dr. Tozer testified that in looking at Dr. Khan's initial chart note from August 2012, he could not tell if there had been any discussion with the patient about simply doing nothing.

[1034]Dr. Khan testified that at their initial meeting in August 2012, he spoke to Mr. K about the conventional option of watching only, with no treatment. Mr. K had come to him specifically because he did not want to "do nothing." "So... it was a mandatory part of the discussion."

[1035]On cross-examination by College counsel, Dr. Khan confirmed that his September 13, 2013 chart note for Mr. K said nothing about simply waiting and seeing as a conventional option, but said that is because the patient did not want to do that. He also agreed that the chart note said nothing about the possibility of cure if the patient simply did nothing.

[1036]In an email on January 20, 2014, Dr. Khan asked for confirmation that Mr. K had previously been treated with cisplatin and etoposide. The notation in the chart from the initial consultation note on August 3, 2012, stated that Mr. K had received "chemo/rads." On cross-examination, Dr. Khan confirmed that as of the date of this email he had been treating Mr. K with SAFE chemotherapy for four months without knowing specifically which chemotherapy Mr. K had been on previously.

[1037]Dr. Tozer confirmed that the treatment for SCLC had not changed for decades, but he opined that detailed treatment information should have been collected from the patient and confirmed at the initial consultation.

*The Use of SAFE Chemotherapy on Mr. K*

[1038]Dr. Tozer explained that the carboplatin in SAFE chemotherapy is a conventional chemotherapy, which in this case was being given to a patient who had already received a “sufficient amount of a platinum containing regimen” and had no evidence of disease, so there was no reason to give it. Based on clinical trials looking at maintenance chemotherapy (extending chemotherapy beyond the initial treatment cycles) there was no benefit to prolonged chemotherapy and standard treatment was just follow-up.

[1039]Dr. Tozer went on to add that there was no way to monitor response to the treatment since the patient did not have evidence of disease to begin with, as seen in his two normal liver scans: “So we don’t know what he’s monitoring, unless he’s thinking that his therapy is failing, so he’s looking to see if a new metastatic disease develops.”

[1040]Dr. Tozer acknowledged that although Mr. K had no evidence of disease, he nevertheless had a high risk of recurrence, and that his chance of cure would be approximately 20%.

[1041]Dr. Tozer explained that by placing Mr. K on SAFE chemotherapy, Dr. Khan exposed him to the risks of toxicities of carboplatin, which included short-term issues such as febrile neutropenia, and long-term risks such as peripheral neuropathy and damage to the bone marrow and kidneys. He added that “we have good numbers on harm.” Above these baseline risks of carboplatin exposure, Mr. K had a significant risk of developing renal impairment because of the previous cycles of conventional cisplatin chemotherapy he had received.

[1042]Dr. Tozer explained that another issue for Mr. K was that if a patient was kept on the same drug for a long time and the cancer was to finally recur, it would have a higher likelihood of being resistant to treatments.

### *Cancer Progression with Respect to Laboratory and Imaging Investigations*

[1043]The documentary record shows that between August 2012 and April 2014,<sup>48</sup> Dr. Khan monitored Mr. K by using CTC testing.

[1044]Imaging investigations for this patient showed the following:

- April 3, 2013 CT chest: this study was compared to a February 4, 2013 chest x-ray and a CT of the chest from October 15, 2012. The study showed a “mild progression of opacity in the left pulmonary apex. This is of uncertain significance however progressing malignancy cannot be ruled out.”
- September 9, 2013 CT chest: showed post-surgical changes, and within the left lung apex, the parenchymal opacity with air bronchograms and volume loss appeared stable to previous. Overall, there was no significant interval change compared to a previous CT scan on February 5, 2013.
- September 21, 2013 abdominal ultrasound: showed “no obvious focal liver lesions.”
- January 16, 2014 abdominal ultrasound: showed “no sonographic evidence of metastatic lesions.”
- January 16, 2014 chest x-ray, two views: showed “an area of scarring...in the left upper lobe” and “a 2 mm nodular density is seen projecting in the left lung Apex which could be related to a vessel seen end on...previous surgery...however the possibility of nodule is also to be considered.” The radiologist went on to state that the findings were difficult to interpret because they did not have a previous study for comparison.
- February 18, 2014 abdominal ultrasound: showed no significant interval change from the previous January 16, 2014 abdominal ultrasound.

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<sup>48</sup> CTC Maintrac performed August 28, 2012, December 18, 2012, November 5, 2013, November 26, 2013, January 13, 2014, February 18, 2014, April 11, 2014.

[1045] In Dr. Khan's February 11, 2014 abdominal ultrasound requisition, he stated that the reason for the test was to monitor Mr. K's response to "new experimental neutrophil potentiating chemotherapy."

[1046] Dr. Tozer testified with regard to the April 2013 scan that the radiological findings in Mr. K's left upper lobe "could represent recurrence of progression of his disease or, just as likely, radiation fibrosis, i.e., scarring after the radiation to the area, which would also progress over the same time point." The September 2013 and January 2014 ultrasounds showed no evidence of metastatic disease. The September 9, 2013 CT scan of the chest showed that opacity was still present; Dr. Tozer said it did not look like progression. When it was suggested to him that he could not rule out progression, he said progression was not likely because SCLC grows quickly. Similarly, the February 2014 ultrasound showed that the patient had no evidence of recurrent disease, which was consistent with the fact Mr. K was "NED" when he first saw Dr. Khan in August 2012.

*Dr. Khan's Updated 2017 SAFE Chemotherapy Medicor Patient Data Compilation*

[1047] Dr. Khan's dataset noted that Mr. K had stage 4 SCLC, which he treated with nine cycles of SAFE chemotherapy. In the response column, Dr. Khan noted that Mr. K had a "partial response" of his cancer as per "(NED - CTC reduction only)." The reason for stopping SAFE chemotherapy in this patient was noted to be due to "cost."

[1048] Mr. K showed no evidence of disease before, during or after Dr. Khan treated him with SAFE chemotherapy. Further, there is no evidence that Mr. K's NED status was due to SAFE chemotherapy. Mr. K's initial treatment with conventional chemotherapy rendered him with no apparent disease in the first place and may have cured him.

*Summary of Expert Witness Opinion on Dr. Khan's Care of Mr. K*

[1049] Dr. Tozer opined, with reference to the CAM policy, that Dr. Khan's care of Mr. K did not meet the standard of practice because:

- he used chemotherapy when there was no demonstrated role for it, and when it would not improve survival (following the initial cycles of cisplatin and etoposide);

- he subjected Mr. K to the side effects of prolonged exposure to carboplatin with no evidence of benefit;
- he did not know what conventional treatment Mr. K received prior to treating him; and
- there was no evidence in the chart that watchful waiting was discussed as a treatment option for Mr. K.

[1050]Dr. Tozer also opined that Dr. Khan showed a lack of knowledge in that he should have been aware that trials looking at short vs. long course chemotherapy in SCLC, which used a drug very similar to the one he used, showed no benefit.

[1051]In Dr. Tozer's opinion, Dr. Khan exposed this patient to harm or injury by exposing him to the toxicities of chemotherapy for which there was no role, leading to short-term issues such as febrile neutropenia and long-term risks such as peripheral neuropathy and damage to the bone marrow and kidneys.

#### *Finding*

[1052]We considered the written and oral evidence before us and find that in his care and treatment of Mr. K, Dr. Khan failed to maintain the standard of practice of the profession when he:

- a) treated a patient's cancer using SAFE chemotherapy, which was not informed by evidence and science, did not possess a favourable risk/benefit ratio and did not have a reasonable expectation of remedying or alleviating the patient's health condition or symptoms;
- b) failed to obtain informed consent for the use of SAFE chemotherapy;
- c) failed to provide an adequate clinical assessment; and
- d) failed to come to a conventional diagnosis.

## *Analysis*

### *a) Analysis - The Use of SAFE Chemotherapy*

[1053]As noted earlier in these reasons, we find that the use of SAFE chemotherapy for treating cancer does not meet the standard of practice of the profession.

[1054]Despite Dr. Khan's claims about SAFE chemotherapy, no evidence supports its use in treating patients with cancer, including Mr. K, who may have already been cured by his initial conventional chemotherapy.

[1055]Even if one were to set aside concerns about SAFE chemotherapy, and one considered carboplatin as a standalone off-label treatment for Mr. K's cancer, there were compelling reasons for Mr. K not to use SAFE/carboplatin. As Dr. Tozer noted, Dr. Khan was using a conventional platinum-containing chemotherapy in a patient who had already received sufficient platinum therapy that may have cured him. Also, as Dr. Tozer explained, the literature does not show benefit from extended chemotherapy beyond the initial treatment cycles.

[1056]Not only did SAFE/carboplatin fail to offer Mr. K any known benefit while exposing him to risks from its side effects, it potentially rendered less effective any future treatments he might need in the event his cancer recurred, so there was good reason to avoid using it on this patient.

[1057]Watchful waiting with no further chemotherapy would have been the conventional medical treatment for a patient in Mr. K's clinical circumstance. The fact that Mr. K was fearful regarding his high risk of cancer recurrence, while understandable, does not shift the risk/benefit profile of SAFE chemotherapy such that it becomes an indicated and evidence-based medication for treating cancer. Furthermore, although physicians must always respect patient autonomy, patient demand is not a sufficient reason to provide a medical therapy that is not indicated, or, as in this case, has no evidence supporting its use in cancer or in this specific patient.

[1058]It was Mr. K's right to seek alternative medical treatments, but as previously discussed, it was Dr. Khan's duty to offer his patients only those treatments which had a favourable risk/benefit profile, which SAFE chemotherapy did not have. By treating Mr. K with SAFE chemotherapy, Dr. Khan failed to maintain the standard of practice of the profession.

*b) Analysis - Failure to Obtain Informed Consent*

*Dr. Khan's Documentation*

[1059]For the reasons outlined previously, we did not find credible Dr. Khan's testimony that he reviewed conventional options with all patients in detail, including possible response rates and side effects of both conventional chemotherapeutic options and the therapy he was offering, and how these compared with each other.

[1060]There is an absence of documentation in the patient chart of which standard chemotherapeutic drugs Mr. K received, or of how conventional treatment, which was watchful waiting in his case, would compare with the treatments Dr. Khan was offering.

[1061]There is no evidence in Mr. K's chart that Dr. Khan informed him that if his cancer recurred, using SAFE chemotherapy could potentially render future treatments with chemotherapy less effective in treating that recurrence. Without this vital piece of information, Mr. K could not have given informed consent for the use of SAFE chemotherapy.

[1062]Dr. Khan did not know what chemotherapies Mr. K had received previously. Four months after he placed Mr. K on SAFE chemotherapy, Dr. Khan sent an email asking which chemotherapeutic drugs Mr. K had received.

[1063]While we appreciate that treatment for SCLC was established and unchanged for a significant period of time, there are numerous reasons why a physician should inquire into a patient's previous treatments. Notably, a patient may not have received a standard treatment for a disease. A physician should also know how the patient tolerated their treatments. Without confirmation, any conclusions on the part of a physician regarding which treatments were received by their patient is speculative.

[1064]Additionally, without knowing which medications a patient received to treat their cancer (and the likelihood of cure vs. recurrence after that treatment), a physician would not be able not speak to a patient about the patient's risk of recurrence, nor how that risk may be modified by another chemotherapy like SAFE chemotherapy. It concerns us that Dr. Khan proceeded to treat his patient for almost a year and a

half with various medications, including four months with SAFE chemotherapy, before he requested that Mr. K provide him with these critical details.

[1065]Based on the above, Dr. Khan did not provide Mr. K with key information he needed to provide informed consent. Dr. Khan did not obtain informed consent and in that additional respect, his care of Mr. K failed to maintain the standard of practice of the profession.

*c) Analysis - Failure to Provide Adequate Clinical Assessment*

[1066]During his initial assessment of Mr. K, Dr. Khan did not confirm which conventional chemotherapy regimen Mr. K had previously received. Dr. Khan failed to take an appropriate patient history as is required by the CAM policy, and in this regard, he failed to maintain the standard of practice of the profession.

*d) Analysis – Failure to Come to Conventional Diagnosis*

[1067]Even during this hearing, Dr. Khan persisted in his belief that Mr. K had evidence of microscopic disease. Dr. Khan's belief was not based on conventional and accepted diagnostic methods, but rather on an experimental test that tested CTCs. The CAM policy states that all patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science. Dr. Tozer testified that the use of CTCs as a way of following disease is regarded as experimental, and that this test is not accepted as the standard of care in Ontario or Canada. By diagnosing Mr. K with microscopic disease based on the results of this test instead of accepting the conventional diagnosis of no evidence of disease based on accepted diagnostic methods, Dr. Khan violated the CAM policy and failed to maintain the standard of practice of the profession.

*Knowledge, Skill and Judgment*

[1068]We accept Dr. Tozer's opinion that Dr. Khan demonstrated a lack of knowledge in that he ought to have been aware that trials looking at long-course chemotherapy in SCLC (which used very similar drugs to the carboplatin he used) showed no benefit, with some trials also demonstrating harm.

[1069]Dr. Khan showed a lack of judgment in placing Mr. K on more platinum-containing medication and exposing him to the side effects, toxicities and subsequent risk of harm from being on such medications when there was no added benefit.

[1070]Dr. Khan also showed a lack of judgment by treating Mr. K with chemotherapy for several months before confirming what previous therapy he had received from his conventional oncology team, and by placing Mr. K, who showed no evidence of disease, on a regime that could render his cancer more resistant to future chemotherapeutic agents if it recurred.

*Exposure to The Risk of Harm or Injury*

[1071]The side effects of carboplatin have been long established and previously discussed.

[1072]Additionally, due to his previous cycles of cisplatin, Mr. K was at significant risk of developing renal impairment. By retreating Mr. K with carboplatin, Dr. Khan exposed his patient to the risk of harm from the side effects and toxicities of this medication, and to the risk that if Mr. K's cancer returned, certain chemotherapeutic agents could be less effective.

[1073]Dr. Khan submitted that the SAFE chemotherapy that Mr. K received was far less dangerous than a preventive double mastectomy. However, Dr. Khan was offering Mr. K SAFE chemotherapy without any evidence that it could prevent cancer. In fact, Dr. Khan's use of carboplatin on Mr. K could have decreased the efficacy of cancer treatments if Mr. K's cancer returned. Mr. K knew his cancer could recur. He was seeking a treatment to decrease the chance that it would. SAFE chemotherapy has not been found to decrease the chance of cancer.

[1074]Counsel for Dr. Khan noted that Mr. K did not develop kidney problems from SAFE chemotherapy. This does not alter the fact that Mr. K was exposed to these risks nonetheless. That a patient did not suffer ill effects does not negate the established risk profile of a treatment, nor render concerns about the exposure to such risks merely speculative, as proposed by Dr. Khan's counsel. Harm need not occur for the risk of harm to exist.

### *Disregard of His Patient's Welfare*

[1075] Mr. K knew that his cancer could return and he was specifically seeking treatment to decrease the chances that it would. Yet Dr. Khan's treatments could not be reasonably expected to prevent a recurrence of cancer in Mr. K, and further, by using carboplatin on Mr. K, if his cancer did return, other therapeutic agents would be less likely to work on the cancer. Dr. Khan exposed Mr. K to all these risks in the absence of benefit and may have undermined Mr. K's goal in the process. Dr. Khan's care demonstrated a disregard for Mr. K's welfare.

### *Conclusion*

[1076] We considered the written and oral evidence before us, and conclude that in his care of Mr. K, Dr. Khan failed to maintain the standard of practice of the profession, demonstrated a lack of knowledge and judgment, exposed Mr. K to the risk of harm or injury and disregarded his welfare.

### Dr. Khan's Care of Patient L

[1077] In relation to his care and treatment of Mr. L, did Dr. Khan fail to maintain the standard of practice of the profession, demonstrate a lack of knowledge, skill or judgment or expose Mr. L to the risk of harm or injury?

### *Overview of Relevant Information*

#### *History and Conventional Treatment Overview*

[1078] Mr. L was a man in his early 60s who lived in Eastern Canada. In July 2013, he was diagnosed with esophageal cancer that had metastasized to his liver.

#### *Conventional Treatment Options*

[1079] At the time of his diagnosis, Mr. L's conventional treatment options included radiation to the esophagus with chemotherapy given as a radiation sensitizer,<sup>49</sup> usually with a 5FU epirubicin backbone. Dr. Tozer explained that esophageal

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<sup>49</sup> Giving chemotherapy can sometimes make radiation more effective. Therefore, in a number of situations chemotherapy and radiation are given simultaneously.

obstruction, which can be caused by esophageal cancer, is an alarming situation to patients, and this makes the radiation particularly important as a treatment.

[1080]At the time of Mr. L's diagnosis, his prognosis would have been less than one year, and Dr. Tozer agreed that Mr. L's oncology team on the east coast would have told him that he was palliative and had a short time to live.

#### *Care and Treatment by Dr. Khan*

[1081]Mr. L became Dr. Khan's patient in August 2013. Dr. Khan testified that he recommended that Mr. L take regular chemotherapy, along with some of the other therapies he was proposing such as metformin and IV vitamin C. He further testified that Mr. L declined conventional therapy, including radiation, because he and his family were worried about quality of life and that his "goal was to have safer treatment than the conventional chemo...and he also wanted to hopefully have life extension." Another of Mr. L's goals was the "reduction of the cancer or at least stabilization of the cancer."

[1082]In an August 1, 2013 letter to Mr. L, Dr. Khan outlined various treatments including SAFE chemotherapy, which he described as having a "much higher potential for remission than conventional chemotherapy based on limited initial data (including long-term remission lasting for years)." This letter also referred Mr. L to Dr. Matsumura's website which, as set out above, made several unproven claims about SAFE chemotherapy.

[1083]Dr. Khan started Mr. L on SAFE chemotherapy on August 19, 2013, making Mr. L one of the first patients he treated with SAFE chemotherapy. The only data available to Dr. Khan at that time about the efficacy of the regimen would have been that provided by Dr. Matsumura.

[1084]Dr. Tozer was unable to find patient records demonstrating that Dr. Khan reviewed conventional therapeutic options with Mr. L, or how the risks and benefits of such options compared to those of SAFE chemotherapy. He also testified that the use of SAFE chemotherapy for Mr. L was not informed by evidence or science because "single agent carboplatin in this situation has never been studied" and that in the conventional setting, Mr. L "would receive a combination of two to three drugs." Dr. Tozer also re-emphasized that "radiation

would have been a very important component of [Mr. L's] treatment...to delay the onset of an esophageal obstruction."

[1085]When Dr. Khan was asked by College counsel about the absence of documentation in his record of any discussion that compared the risks and benefits of conventional therapy with the therapies which he was proposing, Dr. Khan pointed out that his August 1, 2013 letter recommended that Mr. L take "metformin and ascorbic acid i.v. with chemo" as proof that he had a discussion with Mr. L around this subject. Dr. Khan also clarified that since Mr. L lived on the east coast, the letter served the same purpose as his typical initial assessment document, but without the examination.

#### *Investigations, Cancer Progress and Further Communications*

[1086]While Dr. Khan was treating Mr. L with SAFE chemotherapy in Toronto, it appears that most of Mr. L's studies were conducted on the east coast where he lived.

[1087]On October 30, 2013, two months after he began seeing Dr. Khan and taking SAFE chemotherapy, Mr. L had a barium swallow study.<sup>50</sup> Dr. Tozer commented that the x-rays showed "a very, very significant obstruction, secondary to the esophageal cancer" and that the persons responsible for administering the x-ray were "concerned that there may be some involvement of the stomach and duodenum"<sup>51</sup> in causing the blockage.

[1088]An abdominal ultrasound was also performed in October 2013. It showed the possibility of further increase in the size of Mr. L's suspected metastatic liver lesions. Dr. Tozer explained that although one could compare Mr. L's August 14, 2013 ultrasound, which showed the largest liver lesion in the right lobe to be 4.3 cm, to his October 16, 2013 ultrasound, which showed the largest lesion (in the right lobe) to be 6.3 cm, one would have to remember that "we're comparing two

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<sup>50</sup> Barium swallow: imaging in which X Rays are taken while the patient is swallowing a radio opaque substance. This allows visualization of whether or not the barium is able to travel easily through the esophagus and into the stomach.

<sup>51</sup> Duodenum: the first portion of the small bowel (as defined by certain specific anatomical landmarks) is referred to as the duodenum.

different ultrasound operators, [and] two different radiologists. But, if this is all you had to go on, you would say it was bigger.”

[1089] In an October 24, 2013 email to Mr. L’s family titled “Ultrasound,” Dr. Khan acknowledged that “the 3 spots in the liver are larger.” However, he went on to explain the size increase to the family by stating, “[a]s I mentioned, there can be swelling which sometimes gives a false impression of growth, even though the tumour is mainly dead.” Dr. Tozer testified that this was not an accurate comment “in the setting of administering cytotoxic chemotherapy.”

[1090] Reporting on an ultrasound conducted two months later, on December 12, 2013, the radiologist stated:

Based on measurements there may be a mixed response to therapy with some of the lesions smaller and others larger than previous. I am concerned however that the measurements especially of the larger lesions are not reproducible and demonstrated significant intraobserver [sic] variation on this study.

[1091] The radiologist went on to say, “if comparisons are required to assess response to therapy I recommend triphasic CT of the liver as a baseline and follow-up.” Dr. Tozer echoed the same concerns about intraobserver variation, stating “...you're using different ultra-sonographers, different radiologists reading different things.”

[1092] In the same December 12, 2013 report, the radiologist stated, “[t]here is some flow relating to the [liver] lesions mainly on the periphery of these lesions. There is a small amount of perihepatic fluid.”

[1093] Just over two weeks later, Dr. Khan requested another ultrasound, noting in the request that Mr. L was on an “experimental treatment” in which “tumours become inflamed/enlarged as they die.” Dr. Khan’s request stated that the reason for the test was to “assess response to treatment” and whether “[metastases] are active vs. necrotic.” Dr. Khan made this request despite having been informed of the issues with using ultrasound to follow liver lesions, and despite having received the radiologist’s recommendation to use triphasic CT of the liver to assess response to treatment.

[1094] Early in 2014, Mr. L went for an endoscopy study under fluoroscopy. The January 10, 2014 visit consultation report by Dr. Schweiger, the physician who performed

the endoscopy, noted that Mr. L had developed a pneumonia, and was experiencing persistent epigastric pain<sup>52</sup> for which he required “a fair amount of morphine.” By this time Mr. L was having difficulty swallowing not only solids, but fluids as well, suggesting that the esophageal obstruction (previously noted on his October 2013 barium swallow) was advancing. In an attempt to improve his ability to eat and drink, his physicians placed a stent<sup>53</sup> into the esophagus.

[1095]Dr. Schweiger’s report also referenced a January 7, 2014 ultrasound and commented that the report found that Mr. L had “advanced metastatic liver disease” and that “it was felt that the liver lesions appeared solid.” This suggested to Dr. Tozer that the liver lesions were not necrotic. Dr. Schweiger’s report also noted that the January 7 ultrasound had found that one of the liver lesions had increased in size, and “there was also mild to moderate ascites present.”

[1096]Dr. Schweiger stated “there is a mass which affects the distal 6-7 cm [of the esophagus] and it extends right to the GE junction.<sup>54</sup> However, it cannot be seen on retroflexion.” Dr. Schweiger concluded that “[t]his patient has a persistent esophageal mass which undoubtedly is residual cancer, although I did not biopsy it. I think overall it does not seem to be worse than the last time I saw it in November. This was stented today, hoping to give him some palliation.”

*Dr. Khan’s Communications with Mr. L, His Family, and Others Involved in His Care*

[1097]On January 12, 2014, two days after Dr. Schweiger’s report on Mr. L’s endoscopy, Dr. Khan wrote to the family stating:

We received the remarkable endoscopy report that the tumour appears to have gotten smaller...[w]e have heard that ultrasonography indicates worsening of the [metastases] in the liver. We are in the process of receiving further clarification since that report is not consistent with the positive picture on the primary tumor, in the esophagus.

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<sup>52</sup> Epigastric: refers to a region approximating the middle of the stomach.

<sup>53</sup> Stent: a hard tube that goes through the tumour which allows liquids and solids to pass through.

<sup>54</sup> GE junctions: The gastroesophageal (GE) junction is the location where the esophagus meets the stomach.

[1098]When he was questioned about the discrepancy between the endoscopy report (which stated that the mass “does not seem to be worse than the last time”) and Dr. Khan’s email<sup>55</sup> telling the family that the tumour appears to have gotten smaller, Dr. Khan insisted that the endoscopy report did say that the tumour had gotten smaller.

[1099]When it was pointed out to Dr. Khan that he was not present at the endoscopy, and that the physician who had performed both endoscopies had not said that the mass had gotten smaller and had specified only that it “does not seem to be worse than the last time I saw it in November,” Dr. Khan stated, “I am just reporting what is in the report.” He added that Dr. Schweiger’s report noted the mass could not be seen on retroflexion, and “the doctor did not say anything contrary to what I’m saying in his report.” In Dr. Khan’s opinion, this indicated the mass had gotten smaller. In our view, this was a selective, overly optimistic interpretation that was simply wrong in light of Dr. Schweiger’s clear conclusion that the mass was not “worse than...last time.”

[1100]Dr. Khan’s statement that “the doctor did not say anything contrary to what I’m saying in his report” came across as using semantics to sidestep the questions in an effort to avoid acknowledging that he gave inaccurate information to Mr. L and his family. During this line of testimony, Dr. Khan came across as evasive and defensive.

[1101]Included in the email thread discussing the January 10 endoscopy study was an email that Mr. L’s wife wrote to Dr. Khan on January 12. In it, she said that when the physician who had performed the endoscopy told the family that Mr. L’s liver had gotten worse, she told the physician that “the last ultrasound with Doppler that was done on Dec 12 indicated life in a few small tumours around the outside edge but that the others were dead.” When questioned about this, Dr. Khan stated “Yes. That is what the Doppler was showing, that there was some necrosis of the tumours.”

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<sup>55</sup> Dr. Khan confirmed that the endoscopy report he referenced his January 12, 2014 email, was the January 10, 2014 endoscopy.

[1102] On January 15, 2014, a few days after the endoscopy study, Dr. Khan wrote to Mr. L's primary care physician, Dr. Stewart, and told him that the SAFE chemotherapy being administered to Mr. L "has a good chance of leading to remission of stage 3 and stage 4 cancers of all types" and that "[Mr. L] has responded very well to the carboplatin chemo."

[1103] Dr. Tozer testified that in contrast to what Dr. Khan wrote to Dr. Stewart, by January 2014, Mr. L was:

... [A]ctually deteriorating. He's becoming more symptomatic of his tumour with increased pain, more difficulty swallowing, requiring a stent, development of ascites, i.e. fluid in the abdomen, and the fact that the liver metastases appear to be getting bigger. So, I would say that his disease is progressing and that his prognosis at this point is very poor.

[1104] On January 21, 2014, at the request of Dr. Stewart, Mr. L was seen in the emergency department by Dr. Searle, a palliative care physician.<sup>56</sup> Dr. Searle's consultation letter stated that Mr. L told her that he was having "10/10 discomfort" and sometimes felt like "he is going to burst." Dr. Searle's letter provided recommendations to manage Mr. L's symptoms, and also stated Mr. L's wife told Dr. Searle that the family had been told Mr. L's liver metastases had "no blood supply and are 'dead.'" The multiple other smaller lesions have reduced blood supply and they are taking this as a positive sign of response to the chemotherapy." Dr. Tozer testified that the ultrasound report in question had made no mention of dead tumours, and only reported the blood flow to some of the tumours. Dr. Tozer stated that Mr. L's wife's comment reflected an over-interpretation of what the radiology report actually stated.

[1105] Dr. Khan testified that Mr. L was seeing Dr. Searle while he was receiving CAM treatment from Dr. Khan. The evidence shows however that Dr. Searle, the palliative care physician, did not become involved with Mr. L's care until late January 2014, almost six months after Dr. Khan became Mr. L's physician and one month before Mr. L's death.

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<sup>56</sup> Dr. Tozer testimony

### *Mr. L's Outcome*

[1106] Mr. L died in February 2014, one month after his January ER visit and consultation with Dr. Searle, and one month after Dr. Khan's letter to Dr. Stewart, in which Dr. Khan reported that Mr. L had responded "very well to the carboplatin chemo."

### *Dr. Khan's Updated 2017 SAFE Chemotherapy Medicor Patient Data Compilation*

[1107] Mr. L was diagnosed with esophageal cancer. However, in his dataset Dr. Khan stated that Mr. L had been diagnosed with stage 4 gastric cancer, which he treated with 10 cycles of SAFE chemotherapy. In the response column, Dr. Khan documented that Mr. L had a "partial response" of his cancer as per "Imaging – Dec [ultrasound] loss of vascularity and decr[eased] size." Dr. Khan noted that he stopped using SAFE chemotherapy in Mr. L due to "progression."

[1108] Contrary to Dr. Khan's conclusions in his dataset, the evidence does not support the statement that Mr. L experienced a partial response to SAFE chemotherapy. Additionally, although he recorded "progression" as the reason for stopping SAFE chemotherapy, he did not inform Mr. L or his family that Mr. L's cancer was progressing. To the contrary, in the month before his death, Dr. Khan told the family that the esophageal mass had gotten smaller, and that there was a positive picture in the primary tumour. Not only did Dr. Khan communicate to the family that SAFE chemotherapy was working for Mr. L, the evidence shows that he was planning to treat him with more SAFE chemotherapy.

### *Summary of Expert Witness Opinion of Dr. Khan's care of Mr. L*

[1109] Dr. Tozer acknowledged that in his written report, some of his criticisms of Dr. Khan's care of Mr. L, specifically those pertaining to home care orders in New Brunswick and his communications about the risk of esophageal obstruction, were not correct. He confirmed that Dr. Khan had appropriately referred Mr. L to physicians who could assist him and who were experts in the area.

[1110] We noted this issue when considering Dr. Tozer's opinions and conclusions with regard to Mr. L. Nevertheless Dr. Tozer's expertise and testimony on cancer, cancer care and on the science and evidence for using therapy, including SAFE chemotherapy, on this patient presented valuable insights on these topics. We

rely on Dr. Tozer's oral testimony with regard to Mr. L, rather than his written report.

### *Standard of Practice*

[1111]Dr. Tozer opined that Dr. Khan's care of Mr. L did not meet the standard of practice of the profession because he used a single agent, carboplatin, to treat Mr. L whereas the standard treatment in Mr. L's situation required the combination of chemotherapy and radiation. He stated that Dr. Khan failed to appreciate the progression of the patient's symptoms, particularly with respect to difficulty swallowing, pain and the development of ascites. He saw no evidence that Dr. Khan had provided accurate information about conventional therapeutic options, as is required by the CAM policy. He also opined that Dr. Khan inappropriately used ultrasounds to follow Mr. L's disease progress, and over-interpreted the ultrasounds.

### *Knowledge, Skill and Judgment*

[1112]Dr. Tozer testified that Dr. Khan displayed a lack of knowledge:

- regarding what the standard treatment should have been for this patient;
- on how patients with esophageal cancer are managed; and
- on how to manage the patient's symptoms.

### *Exposure to the Risk of Harm or Injury*

[1113]Dr. Tozer testified that Dr. Khan exposed Mr. L to the risk of harm or injury because the patient:

- suffered more with the late provision of palliative care than if he had received it earlier;
- was given a treatment that was ineffective;
- was given false hope; and
- had to travel 10 times to Toronto from the east coast.

## *Finding*

[1114]We considered the written and oral evidence before us and find that in his care and treatment of Mr. L, Dr. Khan failed to meet the standard of practice of the profession when he:

- a) treated a patient's cancer using a medication, SAFE chemotherapy, which was not informed by evidence and science, did not possess a favourable risk/benefit ratio, did not have a reasonable expectation of remedying or alleviating the patient's health condition or symptoms and was not the appropriate treatment for this patient's cancer;
- b) failed to obtain informed consent in the use of SAFE chemotherapy;
- c) failed to diagnose Mr. L with disease progress; and
- d) failed to provide accurate and objective information, substantiated by fact and sound clinical judgment, about the progress of Mr. L's cancer.

## *Analysis*

### *a) Use of SAFE Chemotherapy*

[1115]As noted earlier in these reasons, we found that in his use of SAFE chemotherapy for treating his patients with cancer including Mr. L, Dr. Khan failed to maintain the standard of practice of the profession.

[1116]Even if one were to consider the use of carboplatin as a conventional stand-alone or off-label therapy for Mr. L, its use was inappropriate because Mr. L's condition required a combination of chemotherapy (possibly multiple agents) and radiation.

[1117]The use of single agent carboplatin for patients in Mr. L's situation had never been studied and, as he wrote in his January 3, 2014 abdominal ultrasound request, Dr. Khan had put Mr. L on an "experimental treatment." However, this experimental treatment was not informed by evidence and science. Dr. Tozer explained that single agent carboplatin would not be regarded as standard of care. Dr. Khan should not have used carboplatin alone to treat Mr. L. In doing so, he failed to maintain the standard of practice of the profession.

*b) Failure to Obtain Informed Consent*

[1118]Dr. Khan's Medicor chart notes for Mr. L do not show documentation of which standard chemotherapeutic treatment options Dr. Khan discussed with Mr. L, nor how their risks and benefits compared with those of the SAFE chemotherapy treatment Dr. Khan was offering. As previously discussed, we did not accept as credible Dr. Khan's word that he always had this conversation with patients and had done so with Mr. L.

[1119]Additionally, Mr. L specifically wanted to have a "safer treatment" than conventional chemotherapy and did not want to lose quality of life. Dr. Khan's claims about the efficacy and lower side effect profile for SAFE chemotherapy, were not based on evidence and science. Dr. Khan did not inform Mr. L that this was the case, and by treating Mr. L with the conventional chemotherapy carboplatin, Dr. Khan exposed Mr. L to the toxicities and side effects that he had wanted to avoid. Informed consent is impossible if a patient is not apprised of the actual risk of their treatments.

[1120]In failing to obtain informed consent from Mr. L to treat him with SAFE chemotherapy, Dr. Khan failed to maintain the standard of practice of the profession.

*c) Failure to Diagnose Mr. L With Disease Progress*

[1121]Dr. Tozer testified that based on Mr. L's clinical state and the radiological findings in January 2014, Mr. L's disease had progressed. However, Dr. Khan did not diagnose Mr. L with disease progress, which he should have. Dr. Khan ignored clear clinical signs and radiological investigations and persisted in telling the family and other physicians that the treatment was working, which he based on his own personal unfounded opinions of Mr. L's various studies. Dr. Khan failed to appreciate the progression of Mr. L's disease, and consequently in this respect too, Dr. Khan did not maintain the standard of practice of the profession.

*d) Failure to Provide Accurate and Objective Information*

*i) Ultrasound and False Growth*

[1122]The statement in Dr. Khan's October 24, 2013 to Mr. L's family that the increased size in Mr. L's liver lesions could be explained by "swelling which sometimes gives

a false impression of growth, even though the tumour is mainly dead,” was inaccurate. To us it appears that Dr. Khan was positioning SAFE chemotherapy as successfully treating Mr. L’s cancer and he was explaining away the very real possibility that Mr. L’s cancer was progressing and the SAFE chemotherapy was failing. Dr. Khan should not have provided the family with this information.

*ii) Endoscopy and Smaller Tumour and Positive Picture*

[1123]A reasonable person would have taken Dr. Khan’s references in his January 12, 2014 email about the endoscopy report to the smaller tumour size and “positive picture” of the primary tumour to mean that Mr. L was getting better, whereas he was getting worse. As previously discussed, by January 2014 Mr. L was deteriorating. His esophageal obstruction from the cancer had progressed to such a degree that Dr. Schweiger felt he required the stent that he had not required at the time of his previous endoscopy in November 2013. In this context, Dr. Schweiger’s conclusion that the mass was “not worse” could not reasonably be interpreted as meaning that it was getting smaller.

[1124]Cancer assessment requires the integration of multiple findings, including not only imaging, lab work, and direct visualization (when possible), but also a patient’s clinical status.

[1125]Dr. Schweiger clearly stated that the mass was “not worse,” not that it was getting smaller. Dr. Schweiger should not have had to say explicitly that it was “not getting smaller” for Dr. Khan to understand that. Rather than telling the family what the endoscopist did state, Dr. Khan exploited what he did not state, and it appears that he used this as an opening to insert his own opinion and present it as if it were a legitimate finding.

[1126]At this hearing, Dr. Khan maintained that the mass was smaller and he would not concede he was wrong to have told that to the family. This demonstrates a lack of insight into the limitations of his own knowledge. On this issue of Mr. L’s endoscopy, Dr. Khan was intransigent. We find that Dr. Khan gave the family an inaccurate report.

### *Summary on Dr. Khan's Communications to the Family*

[1127] Apart from his own opinions on the matter, Dr. Khan did not present any acceptable justification for telling the family the esophageal mass was smaller, and that there was a positive picture in the primary tumour. This, in combination with his insistence that Mr. L's ultrasound had "false impression of growth" (instead of real growth) and that Mr. L's liver metastases were dead, gave us the impression that Dr. Khan would not concede on any point that might bring into question his claims about the efficacy of SAFE chemotherapy.

[1128] Dr. Khan made statements to the family that were inaccurate, contradicted the scoping physician's report – who was arguably the only person in a position to give an accurate report on Mr. L's mass – and, of significant concern, misled Mr. L and his family by failing to provide them with an accurate picture of Mr. L's true clinical status. In doing so, he failed to provide accurate and objective information substantiated by fact and sound clinical judgment about the progress of Mr. L's cancer, in contravention of the CAM policy. In that regard, he failed to maintain the standard of practice of the profession.

### *Knowledge, Skill and Judgment*

[1129] Dr. Khan demonstrated a lack of judgment when he treated Mr. L with SAFE chemotherapy, which did not have a likelihood of remedying his cancer but exposed him to the risk of harm from the side effects and toxicities of carboplatin.

[1130] Dr. Khan demonstrated a lack of knowledge in terms of the standard treatment and management of Mr. L's esophageal cancer. Even in the face of Mr. L's rejection of radiation therapy, Dr. Khan should have discussed what conventional agents were available to Mr. L apart from carboplatin. However, we find that he did manage Mr. L's progressing esophageal obstruction by referring him appropriately.

[1131] While the statement in Dr. Khan's January 15, 2014 letter to Dr. Stewart that Mr. L had "responded very well to the carboplatin chemo" may have reflected Dr. Khan's opinion, that opinion was unreasonable in light of Mr. L's radiological studies and clinical status, which showed that Mr. L was deteriorating, becoming more

symptomatic and requiring interventions such as stenting. This also shows a lack of knowledge and judgment.

*Exposure to Risk of Harm or Injury*

[1132]Dr. Khan exposed Mr. L to the risk of harm from the side effects and toxicities of carboplatin.

*Exposure to Risk of Harm from False Hope*

[1133]We agreed with Dr. Tozer's opinion that Dr. Khan exposed Mr. L to the risk of harm by giving him and his family false hope.

[1134]Physicians offering treatment must ensure that they provide their patients with accurate information upon which to base their decisions and their hopes. When information is accurate, patients will be empowered to exercise their autonomy in making decisions about their health, life and death.

[1135]When a therapy does not have a reasonable expectation of curing or treating a person's cancer, or if a therapy is failing and a patient's cancer is progressing, a patient has a right to know that is the case regardless of how difficult it is for a physician to tell them and how devastating it may be for a patient to hear the information. It is a physician's duty to ensure that a patient has this critical information so that they can understand their options.

[1136]When a physician fails to provide robust and accurate information, patients are disempowered, patient autonomy is undermined and hope may become false hope.

[1137]False hope may expose a patient to the risk of harm in a number of ways. It may cause a patient to believe that they are doing better than they really are, or that they have more options for effective therapy than they really do. Patients may be devastated and experience great mental anguish when the truth of their condition finally does come to light and when they learn that they are sicker and possibly closer to death than they had previously understood themselves to be.

[1138]False hope may delay a patient's and their family's acceptance of impending death and potentially rob them of the opportunity to put their affairs in order, say

goodbye to each other and in some cases, false hope may preclude a peaceful death.

[1139]Mr. L told Dr. Khan he was hoping that treatment could give him life extension. By January 2014, after 10 rounds of SAFE chemotherapy, Mr. L was deteriorating and becoming more symptomatic from his cancer. Yet that same month, one month before his death, Dr. Khan was telling Mr. L's family that the endoscopy showed that the esophageal mass was smaller and that there was a "positive picture" of the primary mass. The picture that Dr. Khan was painting was that Mr. L was responding to therapy, and he planned to treat Mr. L with more rounds of SAFE chemotherapy to be administered in Toronto.

[1140]In reality, Dr. Khan's SAFE chemotherapy treatment of Mr. L was failing, the cancer was progressing; and Mr. L was dying and would be dead in a month.

[1141]Mr. L might have chosen to spend his time differently if he knew SAFE chemotherapy was failing to work. Had Dr. Khan told Mr. L that his cancer was progressing, he might not have chosen to repeatedly fly to another province for treatment. Instead, he might have chosen to spend this time with his family. We cannot know what Mr. L would have done, but by inflating and exaggerating Mr. L's response to SAFE chemotherapy, Dr. Khan undermined Mr. L's ability to make decisions based on his true clinical status and its implications. Dr. Khan gave Mr. L and his family false hope, and in doing so, not only did he expose Mr. L to harm from the consequences of false hope as set out above, he undermined Mr. L's patient autonomy and may have robbed him of the opportunity to spend more time with his family, put his affairs in order and prepare as best he could for a peaceful death.

#### *Disregard for Patient Welfare*

[1142]Mr. L's goal was to avoid the side effects of chemotherapy and he was also hoping for life extension. Despite these wishes, Dr. Khan treated Mr. L with carboplatin and exposed him to all of its associated side effects and toxicities, without providing him with the benefit of appropriate cancer therapy. Dr. Khan failed to provide an accurate picture of Mr. L's clinical status and cancer progress. In all these respects, Dr. Khan showed a disregard for his patient's welfare.

## *Conclusion*

[1143]We considered the written and oral evidence before us, and conclude that in his care of Mr. L, Dr. Khan failed to maintain the standard of practice of the profession, demonstrated a lack of judgment and knowledge, exposed Mr. L to the risk of harm or injury and demonstrated a disregard for his welfare.

### *Summary: Dr. Khan's Use of SAFE Chemotherapy to Treat His Patients' Cancers*

[1144]Dr. Khan used SAFE/carboplatin indiscriminately, as a one size fits all cancer therapy that he claimed could treat almost all types of cancers at even advanced stages, regardless of his patients' specific clinical status and needs. For all 10 patients discussed at this hearing on whom Dr. Khan used SAFE/carboplatin, he used it inappropriately or in a manner that was not indicated and could not reasonably be expected to treat their specific cancer.

[1145]Further, Dr. Khan used SAFE/carboplatin on his patients even if there were specific reasons to avoid its use such as resistance or myelosuppression.

[1146]Additionally, many of Dr. Khan's patients stated that they specifically wished to avoid conventional chemotherapies and their side effects while others wished for different or more aggressive treatment than conventional chemotherapy. Despite his patients' wishes, Dr. Khan used the conventional chemotherapy carboplatin in the form of SAFE chemotherapy. In doing so, Dr. Khan failed to act in the best interests of his patients, failed to address the pertinent specific clinical circumstances of his patients, ignored their wishes and treated them with a regimen that could not reasonably be expected to alleviate their illness and he did so without obtaining informed consent.

[1147]Dr. Khan either did not understand or chose to disregard the important studies suggesting that his patients' cancers were progressing and that his treatments were failing or, worse, were causing actual toxicity and harm. Not only did Dr. Khan appear incapable of admitting to himself when his treatments were not working, he also failed to disclose evidence of failure to his patients. Instead, Dr. Khan engaged in a pattern of conduct in which he provided patients and their families with inaccurate, overly positive and optimistic communications in which he substituted his views for the true findings reported by radiologists and other

physicians. In evaluating SAFE chemotherapy's efficacy in his patients' cancers, with rare exceptions Dr. Khan appeared to be incapable of accepting as valid evidence that did not put it in a favourable light or support his narrative.

[1148]Dr. Khan testified that where he showed enthusiasm about patient progress, it was because any response at all in such seriously ill patients was surprising, and he wanted to recognize these "small victories." We find this assertion to be disingenuous given the claims Dr. Khan had made to patients about the benefits they could obtain from SAFE chemotherapy.

[1149]There is no evidence that Dr. Khan told any of the 10 SAFE chemotherapy patients discussed at this hearing that SAFE chemotherapy should be stopped because it was not working. Almost without exception, Dr. Khan stopped the therapy only when his patients could not take it any longer because they could no longer afford it, their condition had deteriorated to such a degree that they could not tolerate it, they were so ill that they were admitted to hospital or they died.

[1150]We also note that Dr. Khan's documentation through his website and consent forms for SAFE chemotherapy resembled elaborate advertisements with accompanying disclaimers. Dr. Khan did not use his medical training and experience to validate the data he was presenting to the patients who trusted him, nor did he demonstrate that he mitigated or explained the very low likelihood that patients could realistically realize the benefits he was advertising.

#### *Final Comments on the Professional Misconduct*

[1151]Dr. Khan's counsel submitted that Dr. Khan was not offering "snake oil" or "witches' brew." Yet, it would appear that Dr. Khan treated people who he admits were likely "desperate" for anything that might help them, with therapies (SAFE, DCA, LDN) about which he made extraordinary and enticing claims that were not informed by evidence or science, he had not evaluated or verified, did not have a favourable risk/benefit ratio and could not reasonably be expected to alleviate or remedy his patients' conditions. Whether it was "snake oil," "witches' brew" or otherwise, whatever it was that Dr. Khan was offering his patients, it was not what he claimed. In doing so, Dr. Khan set aside his obligations as a physician to uphold the College's CAM and consent policies, and in doing so, he failed his patients.

[1152] Physicians who practise in the area of cancer care must know how to evaluate the evidence and science behind the myriad of drugs and therapies in cancer care, and must have the knowledge, skill and judgment to decide when, and when not, to offer medications based on each patient's very specific clinical scenario. They must be able to monitor their patients' cancer progress and evaluate the impact of therapy. When therapies are failing, they must be willing to instigate a re-evaluation of other treatment options or goals of care.

[1153] Dr. Khan took on the responsibility of actively treating patients with cancer, and at advanced stages, and referred to his clinic as a "Cancer Centre." In taking on this responsibility, Dr. Khan was required to have the necessary knowledge, skill and judgment to safely treat his cancer patients. In his care and treatment of the 10 patients whom he treated with SAFE chemotherapy whose care was at issue in this hearing, as well as in his care and treatment of A and Ms. B, it is clear to us that he did not.

[1154] It is deeply disturbing that the trust patients placed in Dr. Khan could not have resulted in the benefits he claimed. In all 12 cases, these people, in the absence of their informed consent, received ineffective treatments and care that did not meet the standard of practice of the profession.

### **Incompetence**

[1155] As set out above, we are satisfied that in his professional care of all 12 patients who were the subject of this hearing, Dr. Khan failed to maintain the standard of practice of the profession, displayed a lack of knowledge, skill or judgment and exposed his patients to the risk of harm or injury.

[1156] The College also alleges that Dr. Khan is incompetent as defined by subsection 52(1) of the Code, which reads:

A panel shall find a member to be incompetent if the member's professional care of a patient displayed a lack of knowledge, skill or judgment of a nature or to an extent that demonstrates that the member is unfit to continue to practise or that the member's practice should be restricted.

[1157] As was stated in *College of Physician and Surgeons of Ontario v. Depass*, 2009 ONCPSD 27:

Thus, to make out an allegation of incompetence, the College must establish that:

- (i) the alleged incompetence relates to the member's professional care of a patient;
- (ii) in his professional care of a patient, the member displayed a lack of knowledge, skill or judgment [or a disregard for a patient's welfare];<sup>57</sup> and
- (iii) the lack of knowledge, skill or judgment [or disregard for the patient's welfare] was of a nature or to an extent that demonstrates that the member is unfit to practise or that the member's practice should be restricted.

[1158] Incompetence differs from professional misconduct in that a finding of professional misconduct will be based purely on events that occurred in the past. Incompetence is assessed based on the member's care of patients in the past, but the Tribunal must be satisfied that the member is presently incompetent in order to make a finding of incompetence.

[1159] There is no evidence before us that since he treated the patients whose care was at issue in this hearing, Dr. Khan has acquired any of the knowledge, skill or judgment that he lacked at the time he treated them. Moreover, Dr. Khan made various statements during his testimony at this hearing that demonstrate that he continues to have little insight into his failings.

[1160] In the case of A, the young boy who was diagnosed with medulloblastoma that had metastasized to his spine, Dr. Khan continued to maintain that A had pseudoprogression. He stated:

This is what scientifically makes the most sense to me at this time and at that time and especially now because there is new literature that shows that DCA in fact does cause [inflammation] and causes immune response against cancer. So there is actually new publications that confirm this.

[1161] In the case of Ms. B, the patient whom Dr. Khan diagnosed with early-stage chronic leukemia based on the results of the ONCOblot test, Dr. Khan continued

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<sup>57</sup> Disregard for a patient's welfare is no longer part of the definition of incompetence under subsection 52(1) of the Code.

to maintain, in his testimony, that chronic leukemia was the most likely correct diagnosis, even though conventional test results and Dr. Krieger's diagnosis demonstrated that she did not have cancer.

[1162] In his testimony, Dr. Khan continued to maintain that SAFE chemotherapy is an immunotherapy. He continues to believe that carboplatin in SAFE chemotherapy will not cause the known side effects and toxicities of platinum-containing chemotherapeutic medications, including myelosuppression, and that mesna in SAFE chemotherapy diminishes the known side effects and toxicities of carboplatin. He testified that his belief, based on Dr. Matsumura's initial data, that SAFE chemotherapy has "good potential to induce remission" in stage 3 and stage 4 cancers "actually turned out to be true based on our data." He testified that Dr. Tozer may not understand or recognize the phenomenon of pseudoprogression with a chemotherapy drug simply because he does not accept that mesna has any activity.

[1163] We were also struck by the fact that Dr. Khan did not appear to understand that his communications to patients' families and other practitioners about investigations as interpreted by the medical experts were wholly unacceptable and misleading on numerous occasions.

[1164] We are therefore satisfied that the lack of knowledge, skill and judgment that Dr. Khan displayed in his care of all 12 of the patients whose care was at issue in this hearing continues to this day. This lack of knowledge, skill and judgment was so serious, and the consequences or potential consequences of such deficiencies were so grave, as to demonstrate that Dr. Khan is unfit to continue to practise or that his practice should be restricted. Accordingly, we find Dr. Khan to be incompetent.

## **Part C - Disgraceful, Dishonourable or Unprofessional Conduct**

### **Dr. Khan's Submission of Palliative Care Billing Codes to OHIP**

#### *The Allegation*

[1165] The College alleges that Dr. Khan used palliative care codes to bill OHIP for his care of SAFE chemotherapy patients when he was presenting his treatment as potentially curative, or when he was not providing the patients with palliative care.

The College says that in contrast to palliative care, Dr. Khan was providing patients with an aggressive chemotherapy regimen with the goal of tumour shrinkage, remission or cure, that this was inconsistent with the information he conveyed to patients about his use of SAFE chemotherapy and in some cases was inconsistent with the patients' clinical status. It submits that this constitutes disgraceful, dishonourable or unprofessional conduct.

#### *Disgraceful, Dishonourable or Unprofessional Conduct*

[1166] It is an act of professional misconduct for a physician to engage in an act or omission relevant to the practice of medicine that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional. The determination of whether conduct is disgraceful, dishonourable or unprofessional must be made on the basis of the evidence before the Tribunal and its assessment as to whether members of the profession would reasonably regard that conduct as disgraceful, dishonourable or unprofessional: *Cartier v. College of Nurses of Ontario*, 2019 ONSC 2289.

#### *Palliative Care Terminology*

[1167] The OHIP Schedule of Benefits defines palliative care as:

[C]are provided to a terminally ill patient in the final year of life where the decision has been made that there will be no aggressive treatment of the underlying disease and care is to be directed to maintaining the comfort of the patient until death occurs.

[1168] As noted earlier in these reasons, Dr. Khan uses his own definition of palliative care ("anything that is not curative," and "not associated with any prognosis") and says that "remission still falls within the definition of palliative because remission is not a cure."

[1169] In his testimony, Dr. Khan denied that SAFE chemotherapy was aggressive or powerful therapy intended for cure. He stated that it was a "very gentle treatment." Dr. Khan also uses his own definition of aggressive: "My definition of 'aggressive' is that it is a powerful treatment with a lot of side effects for intended to cure."

[1170]As previously discussed, we do not accept Dr. Khan's definition of "palliative care" over that established by OHIP, to which Dr. Khan submitted claims. We also do not accept his definition of "aggressive."

[1171]If Dr. Khan did not provide the service that OHIP remunerates, then Dr. Khan should not have billed OHIP using the billing code in question. He was not entitled to substitute his own language and definitions for those provided in the Schedule of Benefits, particularly when those definitions contradict each other.

[1172]Although he defines palliative care differently than does OHIP, Dr. Khan repeatedly billed OHIP for services using the K023A and G512A palliative billing codes. As per OHIP:

K023 is a palliative support care code billed for providing palliative care for half an hour or the major part of half an hour which is considered to be 1 billable unit.

[1173]G512 is a weekly palliative case management code.

[1174]Dr. Tozer explained that K023 is a palliative care code, which is used when treating a patient with palliative intent, and to provide pain and symptom management. If one is treating an end-stage patient with chemotherapy, there would be an understanding that the patient will die of their cancer so the goal must be palliative to "hopefully prolong their life and hopefully relieve some symptoms." He stated that since patients often have palliative care teams and family physicians doing a great share of this work, he himself tends not to bill this code very often.

[1175]As previously discussed, the information provided to Dr. Khan's patients through his communications such as his website, Dr. Matsumura's website and his SAFE chemotherapy consent form did not describe SAFE chemotherapy as a palliative treatment. Rather, they asserted that SAFE chemotherapy is superior to conventional chemotherapy in efficacy and rate of cancer remission, with fewer side effects. In fact, Dr. Khan's SAFE chemotherapy consent form stated:

I understand that instead of SAFE Chemo ®, I have a choice to receive no treatment for my cancer, and that I have the option of receiving only comfort care (palliative care).

[1176] Thus, according to Dr. Khan's own documentation, when patients consented to SAFE chemotherapy, they were actively declining palliative care.

[1177] We considered only those patients for whom we could review OHIP billing records. Of the 10 SAFE chemotherapy patients at issue, we were provided with Dr. Khan's OHIP billing records for six. In each of these cases, we found no documentation in Dr. Khan's patient chart that he provided palliative care. There was nothing in the records to show that Dr. Khan conducted discussions about palliative care goals or plans around the provision of palliative or end of life care with any of these patients, either before he began to treat them with SAFE chemotherapy or after. The six patients in question are:

*Ms. C*

[1178] When Ms. C became Dr. Khan's patient in October 2012, she had metastatic pancreatic cancer with no curative options. On October 3, 2013 she signed a Medicor SAFE chemotherapy consent form in which she declined palliative care.

[1179] Dr. Khan's billing for Ms. C included the following OHIP billing Codes:

- October 1, 2012 visit: K023 x 2
- November 11, 2013 visit: K023 x 2

[1180] The records also show that:

- for seven visits between July 22, 2013 and June 12, 2014, Dr. Khan billed 15 K023A units; and
- from January 3, 2013 to July 3, 2014, Dr. Khan billed 79 G512A codes.

[1181] Dr. Khan denied that he offered Ms. C aggressive treatment with SAFE chemotherapy. However, even in 2014, when her disease had progressed further, Dr. Khan would not acknowledge that C was a palliative patient, as evidenced by his July 3, 2014 letter to her physician, Dr. Sandhu, in which he said that Dr. Sandhu should not be "writing her off as a palliative case."

[1182]Ms. C's records do not contain any documentation showing that Dr. Khan discussed palliative care goals or plans around the provision of palliative or end of life care with her.

[1183]We find that Dr. Khan submitted palliative care billing codes K023A and G512A for Ms. C even though he had not been providing her with palliative care as defined by the OHIP Schedule of Benefits.

[1184]By billing OHIP for care that he had not provided to C, Dr. Khan engaged in conduct that was disgraceful, dishonourable or unprofessional.

*Ms. D*

[1185]Ms. D was a woman with incurable metastatic colon cancer. As noted earlier in these reasons, we found that Dr. Khan either directly told Ms. D (and her family) that SAFE chemotherapy could cure her, or by way of omission of key information or encouragement, led them to believe that it could. We also noted that Dr. Khan was not providing Ms. D with palliative care, but rather was treating her with curative intent as evidenced by her communications to her oncologist, her daughter's communications with Dr. Khan and Dr. Khan's communications with Dr. Matsumura.

[1186]Dr. Khan's clinical records for Ms. D do not contain documentation of any discussion with her about palliative care goals or plans around the provision of palliative or end of life care. Furthermore, Ms. D signed a Medicor SAFE chemotherapy consent form in which she declined palliative care.

[1187]However, Dr. Khan's OHIP billing records show that:

- for the 12 visits that occurred between November 7, 2013 and May 26, 2014, Dr. Khan billed 19 K023A units for Ms. D; and
- from October 7, 2013 to June 2, 2014, Dr. Khan billed 34 G512A codes for Ms. D.

[1188]Dr. Khan's representation to OHIP through billing these codes that he was providing palliative care to Ms. D is not consistent with the information he provided to Ms. D and her family, nor with Dr. Khan's own communications to Dr.

Matsumura, all of which demonstrate that Dr. Khan was attempting to provide Ms. D with active and aggressive cancer treatment.

[1189]We find that Dr. Khan submitted palliative care billing codes K023A and G512A for Ms. D although he had not provided her with palliative care as defined by the OHIP Schedule of Benefits.

[1190]By billing OHIP for care which he had not provided to D, Dr. Khan engaged in conduct that was disgraceful, dishonourable or unprofessional.

*Ms. G*

[1191]Ms. G was diagnosed with NSCLC which was metastatic to her brain, liver and lymph nodes. After a good initial response to conventional chemotherapy, her metastatic disease recurred. After the disease continued to progress despite an additional six rounds of conventional chemotherapy, Dr. Khan started her on SAFE chemotherapy. Ms. G signed a Medicor SAFE chemotherapy consent form declining palliative care.

[1192]Dr. Khan's clinical records for Ms. G do not contain documentation showing that he discussed palliative care goals or plans around the provision of palliative or end of life care with her. Furthermore, the records do not show that Ms. G wanted palliative care or that Dr. Khan was providing it. To the contrary, Dr. Khan provided SAFE chemotherapy to Ms. G as the alternative to the palliative care she turned down and on the premise that his treatment satisfied her request for the "more aggressive treatment" she was seeking because her cancer had progressed despite conventional chemotherapy.

[1193]Dr. Khan's OHIP billing records show that:

- over the six visits that occurred between April 4, 2013 and September 3, 2013, Dr. Khan billed 12 K023A units for Ms. G; and
- from April 4, 2013 to January 9, 2014, Dr. Khan billed 45 G512A codes for Ms. G.

[1194] We find that Dr. Khan submitted palliative care billing codes K023A and G512A for Ms. G although he had not provided her with palliative care as defined by the OHIP Schedule of Benefits.

[1195] By billing OHIP for care that he had not provided to Ms. G, Dr. Khan engaged in conduct that was disgraceful, dishonourable or unprofessional.

*Mr. K*

[1196] Mr. K had SCLC, which was treated with conventional chemotherapy after which he had NED and in the words of Dr. Khan, a 20% chance of cure. Throughout his three years of care from Dr. Khan, Mr. K continued to show NED and he did not display any symptoms of cancer.

[1197] Dr. Khan's clinical records for Mr. K contain no documentation of any discussion with Mr. K about palliative care goals or plans around the provision of palliative or end of life care. Mr. K signed a Medicor SAFE chemotherapy consent form in which he declined palliative care.

[1198] Further, given that conventional treatment dictated that Mr. K did not need further treatment (due to NED), by providing Mr. K with chemotherapy, Dr. Khan was providing aggressive, non-palliative therapy to Mr. K.

[1199] OHIP billing records show that:

- over the seven visits that occurred between January 8, 2013 and November 6, 2014, Dr. Khan billed 10 K023A units for Mr. K; and
- from January 4, 2013 to June 19, 2015, Dr. Khan billed 129 G512A codes for Mr. K.

[1200] We find that Dr. Khan submitted palliative care billing codes K023A and G512A for Mr. K although he had not provided Mr. K with palliative care as defined by the OHIP Schedule of Benefits.

[1201] Mr. K was not in a terminal phase of his illness and was not in need of palliative care throughout the period during which he was Dr. Khan's patient. For this reason, as well as the other reasons discussed, Dr. Khan should not have been submitting palliative billing codes for Mr. K's care.

[1202] By billing OHIP for care that he had not provided to Mr. K, Dr. Khan engaged in conduct that was disgraceful, dishonourable or unprofessional.

*Ms. J*

[1203] Ms. J began seeing Dr. Khan when she was in her early 20s. She had been initially diagnosed with melanoma in 2008 when she was a teenager. She received numerous conventional therapies and surgery, but developed metastases to her brain, ovaries and arm. Dr. Khan explained that she had no symptoms from her cancer, so he monitored Ms. J with scans of her brain and liver, and via CTC.

[1204] Dr. Khan's clinical records for Ms. J do not contain documentation showing any discussion with Ms. J about palliative care goals or plans around the provision of palliative or end of life care, nor do they show that he provided her with palliative care-related services as defined by OHIP. Ms. J signed a Medicor SAFE chemotherapy consent form declining palliative care.

[1205] OHIP billing records show that:

- for the 63 visits that occurred between January 10, 2013 and July 16, 2015, Dr. Khan billed 110 K023A units for Ms. J; and
- from January 7, 2013 to July 28, 2015, Dr. Khan billed 13 G512A codes for Ms. J.

[1206] We find that Dr. Khan submitted palliative care billing codes K023A and G512A for Ms. J although he had not provided Ms. J with palliative care as defined by the OHIP Schedule of Benefits.

[1207] By billing OHIP for care that he had not provided to Ms. J, Dr. Khan engaged in conduct that was disgraceful, dishonourable or unprofessional.

*Ms. F*

[1208] When Ms. F presented to Dr. Khan in 2013, she had incurable triple negative breast cancer. Documents show that Dr. Khan treated her with DCA and 24 cycles of SAFE chemotherapy. However, Dr. Khan's clinical records for Ms. F do not contain documentation of discussion about palliative care goals or plans around

the provision of palliative or end of life care. Nor do they show that he provided her with palliative care. Ms. F signed a Medicor SAFE chemotherapy consent form declining palliative care.

[1209]OHIP billing records show that:

- over the 22 visits that occurred between January 14, 2013 and July 16, 2015, Dr. Khan billed 34 K023A units for Ms. F; and
- from January 14, 2013, to July 21, 2015, Dr. Khan billed 94 G512A codes for Ms. F.

[1210]We find that Dr. Khan submitted palliative care billing codes K023A and G512A for Ms. F although he had not provided her with palliative care as defined by the OHIP Schedule of Benefits.

[1211]By billing OHIP for care that he did not provide, Dr. Khan engaged in conduct that was disgraceful, dishonourable or unprofessional.

### Summary

[1212]Some of these six patients were in the last year of their life (which is one of the elements of the definition of palliative care in the OHIP Schedule of Benefits) while Dr. Khan was treating them with SAFE chemotherapy. Yet even if a patient's clinical scenario is consistent with a terminal prognosis requiring palliative care, this is not sufficient to submit palliative care codes to OHIP if the physician is not actually providing palliative care. One cannot conclude that a physician is providing palliative care to a patient based only on the fact that the patient's prognosis and disease stage indicate that palliative care is required. A physician's patient chart is key to demonstrating the care the physician actually provided to the patient. Dr. Khan's records for these six patients do not demonstrate that he was providing palliative care.

[1213]Further, with reference to the OHIP Schedule of Benefits definition of palliative care, there was no documentation in Dr. Khan's records for any of the six patients that a "decision has been made that there will be no aggressive treatment of the underlying disease and care is to be directed to maintaining the comfort of the patient until death occurs." To the contrary, all six patients signed the Medicor

SAFE chemotherapy consent form, in which they declined to have only comfort care or palliative care in favour of a treatment that “it is hoped...will cause shrinking of cancer, or remission of cancer... early data indicate the likelihood [of these benefits] is substantially greater [with SAFE chemotherapy] than conventional chemotherapy...”

[1214]In his communications, Dr. Khan made extraordinary claims, which painted a picture of SAFE chemotherapy’s increased efficacy of high remission rates, and also referred to SAFE chemotherapy as “life-saving”. These descriptions are notably different from palliative care as defined by OHIP.

### Conclusion

[1215]With respect to the six patients discussed in this section, Dr. Khan billed OHIP for palliative care that he did not provide. In doing so, Dr. Khan engaged in conduct that would reasonably be considered by members as disgraceful, dishonourable or unprofessional.

## **2. Failure to Cooperate in Providing Patient Charts**

### The Allegation

[1216]The College alleges that Dr. Khan failed to cooperate in providing the College with the chart of A, and the charts of 19 other pediatric patients, for the purposes of a registrar’s investigation under s. 75 of the Code. The College says this failure constitutes conduct or an act or omission relevant to the practice of medicine that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional.

#### *a) Delayed Provision of A’s Chart During a Section 75 investigation*

[1217]On September 14, 2017, investigators, including Ms. Lisa Mueller, were appointed by the Registrar pursuant to section 75 of the Code to investigate whether Dr. Khan, in his complementary medicine practice, including his cancer and palliative care practice, had engaged in professional misconduct or was incompetent.

[1218]On the same day, Ms. Mueller sent a letter to Dr. Khan’s then-counsel requesting the complete patient records and audit trails for three pediatric patients: A, and two other patients whose care was not the subject of this hearing.

[1219] There was no response from Dr. Khan or his counsel, and on October 20, 2017 Ms. Mueller sent a second letter to his counsel requesting the charts.

[1220] Dr. Khan produced the charts of the two other patients to the College on November 7, 2017. Dr. Khan's counsel advised the College that A's parents objected to the College's seizure and review of their son's chart and therefore Dr. Khan would not produce it.

[1221] Between November 13 and December 15, 2017, there were numerous exchanges between the College and Dr. Khan's counsel. The College clearly communicated its position that the objection of A's parents was not a valid reason to withhold the chart, referencing the pertinent sections of the legislation. Dr. Khan was put on notice that failure to provide the chart could lead to the Inquiries, Complaints and Reports Committee (ICRC) taking action for Dr. Khan's failure to cooperate, including referring allegations of professional misconduct to the Discipline Committee.

[1222] On December 15, 2017, Dr. Khan's counsel advised the College that Dr. Khan would not obstruct the College from physically retrieving A's chart from his office. A College representative collected the chart on December 19, over three months after the College's initial request.

*b) Failure to Provide the Charts of 19 Further Patients*

[1223] On December 7, 2017, Ms. Mueller sent a letter to Dr. Khan's counsel requesting that Dr. Khan produce the charts for 19 other pediatric patients. College counsel wrote follow-up letters to Dr. Khan's counsel on January 10 and February 1, 2018, the latter of which included a warning that failure to provide the charts would be reported back to the ICRC to consider Dr. Khan's failure to cooperate.

[1224] Counsel responded to the December 7 letter on December 21, 2017. In her letter, she stated that for Dr. Khan to be called upon at that juncture of the investigation to provide more charts was inappropriate. Citing *Sazant v. College of Physicians and Surgeons of Ontario*, 2012 ONCA 727, she took the position that the scope of the College's investigation went beyond the reasonable and probable grounds that underlay the appointment of investigators, which were limited to A.

[1225] Counsel for the College responded in a January 10, 2018 letter. She described the materials that were before the Registrar or his delegate when he formed reasonable and probable grounds, which she said gave a clear indication of the nature of the alleged acts of professional misconduct and therefore the scope of the investigation. Based on this, she stated that the scope of the investigations encompassed Dr. Khan's care and treatment of pediatric patients. She noted, "Dr. Khan is required to co-operate with this investigation," and she requested that the outstanding charts be delivered without further delay.

[1226] In letters to Ms. Mueller dated July 24 and October 19, 2018, Dr. Khan's counsel<sup>58</sup> reiterated Dr. Khan's position. Dr. Khan objected to producing the charts for the 19 other pediatric patients on the grounds that the complaint that gave rise to the appointment of investigators had nothing to do with these patients, the request for additional patient charts was inappropriate given that the reasonable and probable grounds of the investigation were limited to A, there was a complete absence of evidence to substantiate the request and the complaint was baseless and vexatious. Counsel submitted that "maintaining this reasonable legal position does not constitute any failure to cooperate."

[1227] Dr. Khan never provided the 19 requested charts to the College.

### Parties' Positions

[1228] The College's position is that Dr. Khan's failure to provide A's chart despite repeated requests, forcing an investigator to attend at his office to obtain it, was a failure to cooperate with the investigation, as was his failure to provide the additional 19 charts. The College called this a "significant departure from acceptable professional standards." The College submitted that patient confidentiality does not provide a basis for a physician under investigation to refuse to release medical records.

[1229] Dr. Khan denied that he failed to cooperate. He testified that he found himself in a conflict between his professional obligations to the College and what he saw as

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<sup>58</sup> By this time, Dr. Khan had appointed new counsel. None of the counsel who were involved in the correspondence referred to in this section were counsel at this hearing.

his duty to A's parents, who objected to the release of their child's chart. In his view he could not ignore the parents' assertion of their child's privacy interest and he had to allow that assertion to be resolved legally. His counsel set out what Dr. Khan described as a "reasonable compromise": that he would not provide the chart but would not obstruct a College representative physically retrieving it from his office. He submitted that his good faith attempt at a compromise between his duties is not a basis to find that he failed to cooperate.

[1230] With respect to the request for the 19 pediatric patient charts, Dr. Khan submitted that he did not fail to cooperate. He took a principled legal position through his counsel that he did not have to produce them, he did not destroy the records or take any steps to prevent the College from seizing them and the College could have, but chose not to, seize the records, as it had done with A's records.

[1231] The College argues that because Dr. Khan did not provide any of the 19 pediatric patient charts that it sought, it has been unable to evaluate Dr. Khan's quality of care of these children. Nor, says the College, has Dr. Khan provided acceptable or legal reasons for withholding the charts. The College submits that the fact an investigator did not attend Dr. Khan's office to seek the additional charts he had already refused to provide is not an excuse for Dr. Khan's refusal to cooperate with the investigation.

### Finding

[1232] We find that Dr. Khan's failure to cooperate in providing A's chart and the 19 other pediatric charts, constitutes a significant departure from the acceptable standard of the medical profession and as such is behaviour that would reasonably be regarded by members as disgraceful, dishonourable or unprofessional.

### Analysis

[1233] We start our analysis with a review of the College's broad powers of investigation relevant to the issue before us. They include:

- the Registrar's s. 75(1)(a) power to appoint investigators if she believes, on reasonable and probable grounds, that the member has committed an act of professional misconduct or is incompetent, and the ICRC approves the appointment;

- where appointed an investigator may: inquire into and examine a member's practice and s. 33 of the *Public Inquiries Act, 2009* applies to that inquiry and examination (s.76(1)); make reasonable inquiries of any person including the member, on matters relevant to the investigation (s. 76(1.1)); enter a member's practice and examine anything relevant to an investigation (s. 76(2)); and copy any document the investigator is entitled to examine or remove any document if a copy is not sufficient (s. 78(1),(2));
- a prohibition on obstructing an investigator or withholding, concealing or destroying anything relevant to the investigation (s. 76(3));
- the obligation on a member to cooperate fully with an investigator (s. 76(3.1)); and
- this section applies despite any provision in any Act relating to confidentiality of health records (s. 76(4)).

[1234]As the Court of Appeal concluded in *Sazant* at paras. 99-101, these powers are a necessary component of the College's public interest mandate. The courts have interpreted professional discipline statutes "with a view to ensuring that such statutes protect the public interest in the proper regulation of the professions." Section 76(1) of the Code "should be given a broad and purposive interpretation to enable an investigator to carry out his or her duty to investigate".

[1235]In *College of Physicians and Surgeons of Ontario v. SJO*, 2020 ONSC 1047 at para. 41, Justice Morgan noted the significance of the College's public interest mandate:

As regulator of the medical profession, the College and its investigative staff play an important role in "monitoring competence and supervising the conduct of professionals [which] stems from the extent to which the public places trust in them": *Pharmascience Inc. v Binet*, [2006] 2 SCR 51, para. 36. Under s. 3(1)(2) of the Code, it has a duty to serve and protect the public interest and, in general, it is authorized to "inquire into and examine the practice of the member to be investigated": *Gore v College of Physicians and Surgeons of Ontario*, 2009 ONCA 546, para. 11.

[1236]In *Reid v. College of Chiropractors of Ontario*, 2016 ONSC 1041, the Divisional Court considered the content of the obligation to cooperate in a request for

production of materials, and whether delay in production will amount to professional misconduct. It stated at para. 81:

The few cases on professionals not cooperating with disciplinary investigations suggest that it is not enough for there to be delayed or sparse responses, but rather there must be a clear refusal to cooperate with the investigation.

[1237] However, in the recent case of *Law Society of Ontario v. Diamond*, 2021 ONCA 255, the Court of Appeal stated at para. 64 that “clear refusal to cooperate with the investigation,” in the sense of an outright refusal of a member to cooperate, “would set the standard too high, rendering it susceptible to a purely subjective test. Any such approach would stand in opposition to the laudable goals underlying the self-regulated...profession.”

[1238] The test that the Court of Appeal in *Diamond* accepted (at para. 50) for when a regulated professional fails to cooperate focuses on the determination of the member’s good faith efforts to cooperate. The Court stated that: (a) all of the circumstances must be taken into account in determining whether a member has acted responsibly and in good faith to respond promptly and completely to the regulator’s inquiries; (b) good faith requires the member to be honest, open, and helpful to the regulator; (c) good faith is more than an absence of bad faith; and (d) a member’s uninformed ignorance of his or her record-keeping obligations cannot constitute a “good faith explanation” of the basis for the delay.

[1239] The Court of Appeal further stated (at para. 61) that failure to cooperate with the regulator once found constitutes a “significant departure from acceptable professional standards.” Citing a Law Society Tribunal decision, it held that:

[F]ailing to cooperate is “properly stigmatized as professional misconduct if the [member] failed to act responsibly and in good faith to promptly provide the necessary information.” In other words, the label of professional misconduct is only given to a failure to cooperate – the failure to act responsibly and in good faith in responding to [regulator] requests – because this type of conduct constitutes a significant departure from the acceptable standards of the profession.

[1240] In *SJO*, the Superior Court granted the College’s application to obtain patient records from a physician who refused to produce them on the basis of privilege and confidentiality. Justice Morgan noted that s. 76(4) of the Code expressly

provides that the investigation provisions apply “despite any provision in any Act relating to the confidentiality of health records.” He went on to observe, relying on the Court of Appeal’s decision in *Gore v. College of Physicians and Surgeons of Ontario*, 2009 ONCA 546, at paras. 44-46,

[44] (...) the College’s statutory powers of investigation contemplate the prospect of an intrusion into the confidentiality of the relationship between a physician and patient. The Court noted at para. 23 that “An investigation under s. 76 will have to take into account the patients’ interests and the section does not purport to override those interests, *except with respect to health records as articulated in subsection (4).*” [emphasis in original]

[45] Accordingly, the Court of Appeal reasoned that the principle of patient confidentiality does not provide grounds for a physician under investigation to refuse to release medical records:

Further, both the *Act* and the Code contain explicit provisions to prevent public disclosure of confidential patient information. For example, College employees and agents are required, with limited specific exceptions, to keep confidential all information that comes to their knowledge in the course of their duties. I also find compelling the observations of McLachlin J.A. in *College of Physicians and Surgeons of British Columbia v. Bishop*, 1989 CanLII 2674 (BC SC), [1989] B.C.J. No. 48, 56 D.L.R. (4th) 164 (S.C.), at p. 171 D.L.R., that ‘while the public has an expectation that medical records will be kept confidential, that expectation is subject to the higher need to maintain appropriate standards in the profession’.

*Gore*, para 24

[46] This authority to override concerns about patient confidentiality has itself been read broadly, in keeping with the College’s duty to the public at large. Thus, where the College is engaged in an investigation prompted by a patient complaint, it is entitled to continue that investigation even if the patient subsequently wishes to withdraw the complaint. (*Volochay v College of Massage Therapists of Ontario*, 2012 ONCA 541, para 46) [...]

[1241] These statements by Justice Morgan leave no ambiguity as to the law on patient confidentiality and on a physician’s duty within the context of a College investigation, even when the patient objects to disclosure to the College by the physician. Section 76(4) of the Code is particularly important under the circumstances, as it expressly provides that the investigation provisions apply “despite any provision in any Act relating to the confidentiality of health records.”

[1242]The Divisional Court in *Reid* held that delay in providing requested materials alone may not constitute professional misconduct as, depending on the circumstances, it could be viewed as an error in judgment. In that case, the Divisional Court set aside the Discipline Committee's finding of professional misconduct because the appellant only initially refused to meet with an investigator, based on incorrect legal advice, and he complied with the investigation once he was informed of his obligation.

[1243]In this case, however, Dr. Khan not only initially refused, but he also continued to refuse to cooperate with the investigation. He sent numerous communications to the College, through his legal counsel, which repeatedly and deliberately stated that he would not hand over A's chart, nor those of the 19 other pediatric patients. He did so despite the fact that College counsel provided him with careful and complete explanations of the law and his professional obligations including relevant case law and warned him of the potential consequences if he did not comply. Unlike in the *Reid* case, it cannot be said that he was unaware of his obligations. We do not see how his conduct could be viewed as a simple error in judgment, nor has the defence characterized it as such. With each communication, Dr. Khan was making a choice and voicing his deliberate refusal to cooperate with the College.

[1244]We also reject the suggestion that repeatedly communicating his reasons for refusal was sufficient to relieve Dr. Khan of his obligation to cooperate and provide the charts requested. Just saying no can never be a defence to such a fundamental aspect of the College's investigation powers, particularly where the reason given for refusal is clearly legally unsound.

[1245]Pointing out that Dr. Khan did not destroy the records has no bearing in mitigating the delay or failure in the delivery of requested records. Retention of records is an expectation of the profession, and willful destruction of records in an effort to obstruct an investigation would clearly constitute a breach of s. 76(3) of the Code.

[1246]In our view, the fact that the parents objected to the release of A's chart did not override the legal duty and professional obligation on the part of Dr. Khan. We do not accept that refusing to produce the chart, while not obstructing an investigator from seizing it on the day he came to collect it, was a demonstration of

cooperation with the College investigation or a “reasonable compromise.” The College seized the charts since Dr. Khan gave it no other option. By the time the seizure occurred, Dr. Khan had already obstructed the College in its duty to investigate by withholding the chart in the first place. The physical removal of charts is a backup measure that the College should not be forced to use each time a physician prefers not to provide records and fails to do so. Rather, we see Dr. Khan’s repeated and unjustified refusals to provide the chart within a reasonable time, necessitating its seizure, as a clear and absolute failure to cooperate with the College investigation.

[1247] Dr. Khan had a clear legal and professional obligation to respond promptly and completely to the College’s inquiries and to produce A’s chart to the College, and he failed to do so. We viewed Dr. Khan’s behaviour as an obstruction to the College’s mandate to serve the public interest and a “significant departure from acceptable professional standards” that rose to the level of professional misconduct.

[1248] With respect to the 19 pediatric patient charts requested by the College, we are unable to accept that Dr. Khan’s attacks on the investigation process support a refusal to cooperate with it. The College has a duty to investigate allegations of physician misconduct and incompetence in the public interest. If the College receives information that causes it to have to dig deeper, that is within its mandate and responsibility to investigate in the public interest. The fact the physician feels there was no factual basis for the complaint that gave rise to the investigation, or questions the motives of the complainants, or disagrees that there were reasonable and probable grounds for the investigation, does not entitle them to refuse to cooperate, as both the College investigator and counsel told Dr. Khan’s counsel.

[1249] In this case, as set out above, the mandate of the College investigators was broad. College counsel provided a careful explanation to counsel for Dr. Khan as to how the request for the additional charts was within the scope of the original investigation. Dr. Khan had no reasonable basis on which to refuse to comply.

[1250] With regard to the 19 charts, the mere fact a physician is acting on legal advice does not render his decision reasonable, particularly in a case such as this one in

which there was no legal basis for him to withhold his cooperation. This is not a case like *Reid*, in which the chiropractor originally acted on legal advice but then, when he realized the advice was mistaken, reversed his position.

[1251]The Code places an obligation on a physician to cooperate with an investigation. That obligation includes producing requested patient records promptly. Dr. Khan failed to meet that obligation. That the College had other means to obtain records does not relieve Dr. Khan of his obligation to cooperate.

### Summary

[1252]To perform its duty to protect the public, the College must be able to investigate physicians to ensure that their care meets the standard of practice of the profession. This requires that it be provided with access to patient records.

[1253]The Code articulates the legal framework for the release of patient records to the College. Furthermore, the courts have provided detailed guidance on this matter. Dr. Khan's behaviour actively obstructed the College's mandate to serve the public interest. We find that Dr. Khan's failure to provide the records was conduct that would reasonably be regarded by members as disgraceful, dishonourable or unprofessional.

### **Summary of Findings**

#### Allegation 1 - Disgraceful, Dishonourable or Unprofessional Conduct

[1254]The College's allegation in the Notice of Hearing is proven. We find that Dr. Khan engaged in conduct or an act or omission relevant to the practice of medicine that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional, (a) by billing OHIP for palliative care for six patients that he did not provide, and (b) by failing to cooperate with the College's investigation.

#### Allegation 2 - Failure to Maintain the Standard of Practice of the Profession

[1255]The College's allegation in the Notice of Hearing is proven. We find that in his professional care and treatment of the 12 patients who were the subjects of this hearing, Dr. Khan failed to maintain the standard of practice of the profession.

### Allegation 3 - Incompetence

[1256]The College's allegation in the Notice of Hearing is proven. We find that in his professional care of the 12 patients who were the subjects of this hearing, Dr. Khan displayed a lack of knowledge, skill and judgment of a nature and to an extent that demonstrates that he is unfit to continue to practise or that his practice should be restricted, and therefore that he is incompetent.

### Dr. Khan's Request for a Publication Ban

[1257]We deny Dr. Khan's request for the continuation of the order made on October 9, 2020 pursuant to ss. 45(2) and (3) of the Code, that the public be excluded from the portion of the hearing in which there were questions about Exhibit 149 and that Exhibit 149 be prohibited from public access. We order that Exhibit 149 and the *in camera* testimony about it should be made available to the public.

[1258]We request that the Tribunal Office schedule a penalty hearing.

**ONTARIO PHYSICIANS AND SURGEONS DISCIPLINE TRIBUNAL**

**Citation:** *College of Physicians and Surgeons of Ontario v. Khan*, 2022 ONPSDT 26

**Date:** July 15, 2022

**Tribunal File No.:** 17-002-I

**BETWEEN:**

College of Physicians and Surgeons of Ontario

- and -

Dr. Akbar Nauman Khan

**PENALTY REASONS**

**Heard:** May 6, 2022, by videoconference

**Panel:**

Mr. Peter Pielsticker (chair)

Mr. Mehdi Kanji

Dr. Susanna Yanivker

**Appearances:**

Ms. Morgana Kellythorne and Ms. Jessica Amey, for the College

Mr. Brandon Chung, for Dr. Khan

Ms. Zohar Levy, Independent Legal Counsel

**RESTRICTION ON PUBLICATION**

The Tribunal ordered, under ss. 45-47 of the Health Professions Procedural Code, that no one may publish or broadcast the names and any information that could disclose the identity of any patients or the complaint referred to during the Tribunal hearing or in any documents filed with the Tribunal. There may be significant fines for breaching this order.

## Introduction

- [1] On February 7, 2022, we found that Dr. Khan is incompetent and failed to maintain the standard of practice of the profession in his care and treatment of 12 cancer patients. Further, we found that Dr. Khan engaged in disgraceful, dishonourable or unprofessional conduct by billing the Ontario Health Insurance Plan (OHIP) for care that he did not provide and by failing to cooperate with the College's investigation. See *College of Physicians and Surgeons of Ontario v. Khan*, 2022 ONPSDT 5.
- [2] The misconduct and incompetence we found are extremely serious. Among other things, Dr. Khan used therapies on vulnerable patients that were not sufficiently supported by evidence and science. He did not give them the information they needed to provide informed consent. He misled colleagues. He took thousands of dollars of public health care dollars to which he was not entitled, billing OHIP for palliative care when he was not providing it and when patients had declined palliative care. He failed to fulfil his professional duty to cooperate with a College investigation. His misconduct is multifaceted, pervasive and impacted many patients and their families. It threatens public safety, the profession's reputation and undermines the public's trust in the profession and in its effective regulation. In these circumstances, the appropriate penalty is revocation.
- [3] Dr. Khan argues that the penalty should be a suspension and terms, conditions and limitations on his certification of registration that would restrict him from providing cancer treatment. This would not fulfil the objectives of penalty. It would not sufficiently recognize the seriousness of his multiple types of misconduct, his lack of integrity and the risks and harms he caused many patients. It would not fulfil the objectives of specific and general deterrence. And it would not protect the public. Dr. Khan's actions showed profound ethical failings as a physician that are not specific to treating cancer. We have no evidence that Dr. Khan has taken steps to change his approach to practising medicine.
- [4] Dr. Khan asks to pay costs at a rate that is less than the tariff in the Tribunal's rules. We find that he should pay costs of the hearing at the same rate as other physicians who have been found by this Tribunal to have committed misconduct.

## **Evidence and Submissions on Penalty and Costs**

- [5] The only evidence specific to penalty consisted of letters of support for Dr. Khan. Both parties made submissions and submitted caselaw in support of their positions at the penalty hearing.

## **Positions of the Parties**

- [6] The parties' submissions focused largely on whether Dr. Khan's certificate of registration should be revoked or he should be permitted to continue to practise subject to terms, conditions and limitations following a suspension.
- [7] The College submitted that Dr. Khan's certificate of registration should be revoked and he should be reprimanded. The College also sought costs of \$197,030.
- [8] The College acknowledged the need to satisfy the penalty principles with the overarching goal of public protection. It cited the seriousness of Dr. Khan's repeated failures to meet the standard of practice as evidenced by his widespread deficiencies, impaired knowledge, skill and judgment and incompetence which it submits pertain to his overall practice of medicine and are of such a serious nature that he poses an ongoing risk to public safety if he continues to practise.
- [9] Counsel for the College submitted that "[p]hysicians are granted a position of high public trust by society at large and the individual patients whom they treat," and that "[t]he general public lacks expert medical knowledge. Patients are vulnerable, and physicians are authorized to perform potentially dangerous acts, such as prescribing medication. There is a high level of societal and individual dependence on the advice of competent physicians. This charges the regulator with great responsibility to protect the public and to maintain public trust in the profession." The College also emphasized that integrity and risk to the profession's reputation are overarching concerns. It emphasized Dr. Khan's failure to cooperate with the College and that his "disgraceful, dishonourable and unprofessional billing of OHIP *abused the honour system* on which public health funding depends." [italics in original factum] The College argued that these issues could only be addressed with revocation.

[10] While the College agreed rehabilitation was a relevant factor, it took the position that Dr. Khan lacks the necessary insight into his misconduct to make rehabilitation a meaningful option.

[11] Dr. Khan's counsel acknowledged the need to satisfy all of the penalty principles, and that protection of the public is the paramount consideration. He asked that any penalty be fair and just and noted that rehabilitation warrants a special mention. While our findings were serious, what is most important, in his submission, is that our findings did not form a concrete basis for concern about Dr. Khan's medical practice outside of cancer treatment. He argued Dr. Khan's letters of support confirm this.

[12] Dr. Khan submitted revocation is too harsh a penalty. Therefore, he proposed that he be permitted to continue his non-cancer medical and wellness practice. He also proposed that our findings concerning Dr. Khan's failure to adequately document consent discussions and to obtain informed consent be addressed through the completion of a medical record-keeping course.

### **Decision on Penalty and Costs**

[13] For the reasons that follow, we order and direct:

- the Registrar to revoke Dr. Khan's certificate of registration, effective immediately;
- Dr. Khan to pay the College costs of \$197,030 no later than October 17, 2022;
- Dr. Khan to appear before the panel to be reprimanded;
- Dr. Khan's practice to be closed in accordance with the CPSO policy on "Closing a Medical Practice."

### **Purposes of Penalty Orders**

[14] The Tribunal has the power to impose a penalty under s. 51(2) (misconduct) and/or s. 52(2) (incompetence) of the Health Professions Procedural Code, Schedule 2 to the *Regulated Health Professions Act, 1991*, SO 1991, c. 18 (Code).

[15] In *College of Physicians and Surgeons of Ontario v. Fagbemigun*, 2022 ONPSDT 22 at paras. 7-8, the Tribunal expressed the purposes of penalty as follows:

Several purposes or values should be considered throughout the analysis and underlie the analysis of individual factors. The most important goal of a penalty order is the protection of the public. The public must have confidence in the member, the profession and in the College's ability to govern the profession in the public interest. Patients place their physical and mental health, their bodies and lives in the hands of physicians. The public expects that every member of the medical profession will protect that trust by acting in the interests of their patients and the public, upholding the high standards of the profession.

Other penalty purposes support the goal of protecting the public. These include discouraging the member and other physicians from committing misconduct (specific and general deterrence), rehabilitating the physician, ensuring a safe return to practice where appropriate and expressing the Tribunal and the profession's disapproval of the misconduct.

[16] Dr. Khan submits that his misconduct is not the most serious and thus revocation is not required. However, we do not need to find his conduct is among the "most serious misconduct by the most serious offender" for revocation to be an appropriate penalty. Nor are we obliged to impose the least restrictive penalty. *College of Physicians and Surgeons of Ontario v. McIntyre*, 2017 ONSC 116 (Div. Ct.) at paras. 47-53.

[17] In *Fagbemigun* at paras. 12-19 the Tribunal set out a non-exhaustive list of the key considerations on penalty:

- the seriousness of the misconduct;
- any discipline history;
- the physician's actions since the misconduct; and
- personal circumstances of the physician.

[18] We are tasked with satisfying all of the penalty principles which includes exercising our discretion to arrive at a penalty that is "fair and just," as the court stated in *College of Physicians and Surgeons of Ontario v. Peirovy*, 2018 ONCA 420, at para. 64.

[19] We now apply these principles to the facts before us.

### **Seriousness of the Misconduct (Aggravating Factors)**

[20] Dr. Khan's misconduct is extremely serious. His lack of knowledge, skill and judgment is to such a degree as to render him incompetent. He repeatedly breached the professional obligations that define the core of this profession and demonstrated a broad and disturbing pattern of clinical failings and misconduct. Further, he displayed a disregard for his patients' welfare.

[21] The principal aspects of Dr. Khan's misconduct that place it at the serious end of the spectrum are:

- The extent of the misconduct:
  - Our findings relate to 12 patients. Dr. Khan's misconduct and deficiencies in knowledge, skill and judgment were ubiquitous throughout his care of the patients addressed at this hearing.
- The degree of his departure from standards of evidence-based medicine:
  - Dr. Khan treated his patients with therapy that could not be reasonably expected to remedy their ailments and was not supported by evidence and science.
  - Dr. Khan's approach to treatment of all these patients was based on the unpublished word of one person, and what appeared to be his personal beliefs and own biased personal observations. In his use of carboplatin and mesna, he essentially treated patients with a combination that had no evidence that it was anything other than conventional chemotherapy rebranded. Evidence-based practice is at the core of what it means to be a competent and ethical physician.
- As discussed in detail in the liability reasons, he undermined patients' autonomy by failing to obtain informed consent, another core tenet of physician ethics.
- Dr. Khan's conduct lacked integrity.

- He provided misleading or inaccurate information to patients, their families, other health care professionals and other agencies.
  - His communications often differed or were contrary depending on the audience.
  - By billing OHIP for care he did not provide, Dr. Khan took tens of thousands of dollars to which he was not entitled from the taxpayers of Ontario and the health care system. The system by which physicians are remunerated is based on trust that physicians will ensure that their billings reflect the care they provided. Dr. Khan did not do so.
- Dr. Khan continued his approach to treatment even when its problems were brought to his attention. He could have stopped but chose not to. For example, when the level of evidence and science for SAFE chemotherapy was brought into question by several other physicians, the College and Dr. Khan's own understanding that the evidence for his therapy was lacking (as demonstrated by his repeated requests to Dr. Matsumura to send him scientific support of SAFE), he continued to use it to treat his patients.
  - Dr. Khan's patients were particularly vulnerable.
    - Many of his patients had terminal cancer or were worried about life-threatening cancer diagnoses. This heightened the power differential in the doctor-patient relationship. Dr. Khan failed his patients when they most needed high-quality care from a trusted physician.
  - Dr. Khan's care led to both the risk of and actual harm or injury to his patients.
    - Harms included medical morbidity, economic loss, personal suffering (as evidenced by Patient B's testimony) and false hope.
  - His failure to cooperate actively obstructed the College's mandate to serve the public interest. Dr. Khan continues to obstruct a College investigation by withholding the charts of 19 pediatric patients, members of a particularly vulnerable population.

- Dr. Khan's behaviour and poor care were not an isolated incident or single lapse in judgment: they were repetitive and occurred over a span of years.

[22] Dr. Khan's misconduct and incompetence are multifaceted, pervasive and impacted many patients and their families. They threaten public safety, the profession's reputation and undermine the public's trust in the profession and in its effective regulation. They pertain to vital areas forming the foundation of physician skills and understanding of scientific principles informing much of physician decision-making, and which may reasonably be considered elemental and expected of every physician. Dr. Khan demonstrated critical failures along the diagnostic, treatment and monitoring pathways of his clinical care and consequently repeatedly breached the standards of this profession. Many of these actions on their own would point towards revocation. Taken together, revocation must be the penalty.

[23] Through his misconduct, Dr. Khan impugned not only himself, but the integrity and trustworthiness of the entire medical profession. In addition to his standards failures and incompetence, he billed OHIP for care he had not provided, and he knowingly failed to comply with a College investigation. The College's ability to regulate the profession in the public interest is harmed when physicians do not cooperate with investigations.

### **Mitigating Factors**

[24] Mitigating factors may impact a physician's culpability for misconduct and may serve to lessen the severity of a penalty. Dr. Khan relies on the following mitigating factors: he has no discipline history, he is well regarded as demonstrated by letters of support and he has complied with the Inquiries, Complaints and Reports Committee (ICRC) interim order from September 2017 which placed restrictions on Dr. Khan's practice.

[25] The absence of discipline history is of limited weight as the Tribunal expects physicians to practise without the need for disciplinary intervention as outlined in *College of Physicians and Surgeons of Ontario v. Attallah*, 2020 ONCPSD 38 at p. 23, aff'd *Attallah v. College of Physicians and Surgeons of Ontario*, 2021 ONSC 3722:

Dr. Attallah has no prior discipline history. The Committee puts limited weight on this as a mitigating factor as it is expected of physicians that they not be involved in discipline matters, and because his misconduct was calculated and went on for several years.

[26] A similar line of reasoning applies based on expectations of physician behaviour which is free from misconduct, and the fact that Dr. Khan's misconduct went on for years. With respect to Dr. Khan's compliance with the September 2017 ICRC restriction, it is of limited weight for similar reasons: Dr. Khan was obligated to comply with it.

[27] We also paid close attention to the letters of support written by Dr. Khan's patients for the penalty hearing. All of these patients stated that they were aware of the liability findings against Dr. Khan. The letters are detailed, open and heartfelt. The patients spoke highly of Dr. Khan and his positive impact on their medical conditions, their lives and the need for his services in the community.

[28] However, we place limited weight on the letters of support. In *College of Physicians and Surgeons of Ontario v. Wai-Ping*, 2004 ONCPSD 11 the panel stated at p. 46 that letters or support from patients are of:

...limited value as they are not in a position to know from a medical perspective the serious risks to patients demonstrated in the findings of incompetence.

[29] Counsel for the College emphasized that given the nature of Dr. Khan's deficiencies, there is a strong possibility that these would not be readily apparent to a patient. We agree. Indeed, while three patients who were the subject of this hearing gave letters of support or positive comments, they gave their praise prior to our findings on liability. However, when the hearing subjected Dr. Khan's care and conduct relating to these patients to scrutiny, we found that they did not meet the standard of the profession and that he disregarded his patients' welfare. This illustrates the point that patients do not always know when the care they receive is poor or provided by an incompetent physician.

[30] Even when letters of support are from medical colleagues or as was the case in some of Dr. Khan's letters of support, from patients who themselves work in health care, we agree with the panel in *Wai-Ping*, also at p. 46, that:

While testimonials from colleagues carry weight, in the matter of penalty to be decided, they also were of limited value.

- [31] We also considered the important point regarding the need for physicians in the community but find that this cannot be given significant weight. For any practising physician with access to the community, public safety must supersede all other considerations. This was noted in *Wai-Ping* at p. 46:

...there is a significant community need for physicians, this was not considered by the Committee to be a determining factor in deciding penalty. An incompetent physician is dangerous to the public and is worse than a shortage of physicians in a community.

- [32] In Dr. Khan's case, public safety cannot be achieved if he is in a position to provide medical care to the community.

- [33] We also note that the seriousness of Dr. Khan's misconduct towards some patients is not lessened by positive comments from others who may not have experienced the failures in care.

- [34] Other potentially mitigating factors can include admissions of misconduct, demonstration of insight and remorse and taking other steps to address the misconduct (*Fagbemigun* at para. 16). Lack of these steps is not aggravating but may be pertinent to potential for rehabilitation. Dr. Khan is entitled to defend himself against the allegations against him, maintain his position that there was no wrongdoing on his part and require the College to prove its case in a contested hearing. His having done so is not an aggravating factor.

- [35] Mitigating factors include those pertaining to the physician's personal circumstances such as: physical and/or mental health issues; relevant experiences as an Indigenous or racialized person or member of another marginalized group; experiences of trauma; other personal circumstances, such as family or workplace stress (*Fagbemigun* at para. 18). Dr. Khan presented no evidence of such factors.

### **Possibilities for Rehabilitation in a Restricted Practice**

- [36] We now address Dr. Khan's argument that since his care outside of cancer treatment has never been impugned, he should be permitted to continue practising medicine following a suspension. Dr. Khan suggested that we could make an order

that cancer care be “excised” from his practice but that “...it would be appropriate to restrict Dr. Khan from providing treatment for cancer...” His submission is that “...once Dr. Khan cannot treat cancer, the patient-related concerns underlying the Tribunal’s decision disappear.” We do not believe this would be appropriate.

[37] First, as we have concluded above, Dr. Khan’s misconduct is so serious it merits revocation whatever the prospects for rehabilitation. We also find that the public would not be adequately protected if Dr. Khan returned to practice.

[38] The underlying deficits that led to our findings, including the finding of incompetence, reflect Dr. Khan’s broad deficiencies in knowledge, skill, judgment, communication, critical thinking and the understanding and application of evidence-based medicine. Dr. Khan’s disgraceful, dishonourable or unprofessional conduct also has implications well outside the area of cancer treatment, and a direct impact on public trust, the profession and public safety. Given the many different and serious aspects of his misconduct and the lack of any evidence that he has addressed them, the public would be at risk if Dr. Khan returned to the practice of medicine.

[39] Defence counsel asked that we consider “Dr. Khan’s prospects for rehabilitation and the real value he brings to the profession and to patients” and that rehabilitation “...is forward-looking: it is about the member’s own prospects for addressing the causes of the misconduct and doing whatever is necessary to prevent repetition...rehabilitation is important because the member will continue to be a member of the profession. The order imposed by the panel should assist the member’s efforts in this regard, both for the member’s own benefit and in the interests of the public.”

[40] Even if this were an appropriate case to consider a restricted practice, it would be necessary for there to be a realistic prospect of rehabilitation. As noted in *Kamermans, R.J. (Re)*, 2014 CanLII 99715 (ON CPSD) at p. 57, aff’d *Kamermans v. College of Physicians and Surgeons of Ontario*, 2018 ONSC 529 (Div. Ct.):

When considering the potential for remediation, the first consideration is the physician’s amenability to the process. If the physician does not engage with his or her own remediation, it is for naught.

- [41] The foundational starting point for rehabilitation is insight and an openness to self-evaluation and to evaluation from others, including the regulator, when necessary. These traits allow all physicians, not only those before a tribunal, to hone their craft and improve their knowledge, skills and judgment throughout their careers. This is especially important if deficiencies are ultimately identified, as actively working on rehabilitation will facilitate the timely addressing of these problems to ensure that the public is not only safe, but is able to receive the best care possible.
- [42] Dr. Khan did not provide a plan for remediation or rehabilitation specifically addressing his incompetence, failures in standards nor his disgraceful, dishonourable or unprofessional conduct in obstructing a College investigation and billing of OHIP for services that he did not provide. These are not aggravating factors, but they would need to be the foundation for any order that would return Dr. Khan to practice.
- [43] We note that the proposal does not include much effort by Dr. Khan in rehabilitating himself. Apart from indicating his willingness to submit to education on charting, Dr. Khan did not provide any type of plan for rehabilitation to address the grave deficiencies that led to our findings. As opposed to pertinent efforts such as education, monitoring and reassessment by a qualified expert, which may impact the clinical issues underlying our findings, a record-keeping course completely fails to address the true deficiencies that led to our findings.
- [44] Neither would the proposal address the ethical violations stemming from his billing practices and failure to cooperate with the investigation, or even begin to address the true depth and pervasiveness of the deficiencies in patient care that we found.
- [45] We cannot rely on the “member’s own prospects” for rehabilitation when the proposal does not address any such prospects. We cannot see “the real value he brings to the profession and to patients” if his deficiencies remain unaddressed and public safety cannot be assured. We find that contrary to demonstrating insight into when and why he erred, and “doing whatever is necessary to prevent repetition,” Dr. Khan does not show insight and has demonstrated little or no action to suggest that he will be able to prevent repeating the types of scenarios that were before us during the hearing.

[46] As such, we do not see a possibility of remediation and rehabilitation, which would have to be the foundation for any restricted practice.

[47] In considering the proposition of restricted practice for Dr. Khan, we were assisted by *Kamermans* at p. 61:

Where there is a finding of incompetence and where lack of knowledge, skill and judgment are found, the Committee must consider the implication of these findings on Dr. Kamermans' practice of medicine in its entirety. To fail to do so would not achieve protection of the public, and could knowingly expose the public to harm.

[48] Dr. Khan's misconduct in this case raises the following concerns about how he may practise medicine with non-cancer patients:

- Dr. Khan accepted the flimsiest of evidence when he wished to treat patients with his therapies, but he rejected even high-quality evidence if it conflicted with his predetermined decisions and viewpoints on efficacy and patient outcomes. His decision-making was essentially evidence-free and based solely on his personal beliefs and choices. Whether for cancer or other medical conditions, there are constantly new claims about diagnostic tests and treatments. A physician must not - however tempting and tantalizing the claims - parrot them to patients, unedited and unverified, as Dr. Khan did. Whether due to his deficiencies in understanding the requisite level of evidence and science, or due to his choices, it appears that Dr. Khan is unduly open to untested and poorly evaluated therapies. Whether it be cancer or not, we are concerned he would use unverified treatments to treat or "prevent" the onset of these diseases. This is pertinent to Dr. Khan's practice of medicine in general, including a practice that excludes the treatment of cancer.
- Dr. Khan did not comply with the CPSO Policy on Complementary and Alternative Medicine (CAM).
- Dr. Khan left his patients to understand the implications of "limited evidence" without giving them the proper medical guidance and information to make an informed choice. Our findings lead us to the concern that if he continues to practise medicine, Dr. Khan may not provide his patients with sufficient

information to make an informed decision. Assisting patients with giving informed consent is a key responsibility of a physician in any area of practice.

- All patients facing death may be desperate and vulnerable, regardless of whether the underlying cause is cancer or some other illness. Medical conditions, even those that have not caused terminal states, can still cause great morbidity and suffering. Patients may be desperate for help such that they are vulnerable to claims that treatments are special and can help them. These risks are not limited to cancer patients.
- Restricting Dr. Khan from treating cancer would not prevent him from treating patients who have not yet been diagnosed with cancer or any other illness but fear that they might be. While preventative care is the best way to “treat” illness, preventative care that is not based on evidence and science leaves the public vulnerable to clinical scenarios such as Patient B, who came to Dr. Khan out of such fears. Dr. Khan cannot be relied upon to resist the use of unverified diagnostic tools that suggest a patient may have or be prone to a disease.
- One of the many characteristics about Dr. Khan’s conduct that greatly concerns us is how seamlessly Dr. Khan switched his narratives depending on his audience and the circumstances. For example, he switched from telling Patient B that he was actively treating her presumed diagnosis of acute leukemia, to telling her that it was her low-grade chronic leukemia that needed treatment to keep it “under control” (para. 528). There is nothing specific about this conduct to the treatment of cancer.
- The palliative state is not particular to cancer. Yet Dr. Khan either failed to recognize this state in his patients or chose to ignore it, and there is no plan to address this if he returns to practice.
- Physicians must understand when and how to use investigations to diagnose and monitor disease. Dr. Khan used the wrong modalities to monitor and diagnose disease. He did so even when he had the benefit of guidance such as internationally recognized RECIST criteria; manufacturer-provided limitations of the diagnostic test, as was the case with ONCOblot (para. 478); a radiologist who suggested what modality is used best to answer the clinical concern, as

was the case with Patient L (para. 1091) and input from various oncologists. Dr. Khan used unverified diagnostic tools while dismissing results of standard and verified testing methods. All illnesses, cancer or not, require effective diagnosis and monitoring.

- Any treatment must only be initiated if the patient gives informed consent. On a number of occasions, Dr. Khan gave patients and their families inaccurate, inadequate or misleading and overly optimistic information about his treatments. Dr. Khan's failures to obtain informed consent are pertinent to his practice of medicine in general.
- On several occasions, Dr. Khan gave patients and their families inaccurate, inadequate or misleading information about test results. Many illnesses other than cancer are diagnosed and monitored through various tests including serum or radiological modalities. Whether it be in reference to cancer or any illness, it is imperative that physicians give patients accurate test results. In all circumstances, they must be free of any physician reinterpretation or bias, including when diagnosing and monitoring illnesses. Dr. Khan demonstrated that he cannot be relied upon to do so.
- It can be confusing and stressful for patients given conflicting information by different physicians regarding their test results or the implications of their test results. For Ms. B, Dr. Khan told her that contrary to her negative test results and confirmation by her oncologist that she did not have cancer, Dr. Khan told Ms. B that she did. Dr. Khan saddled Ms. B with all the mental anguish and life and death considerations that come with a cancer diagnosis, except that in her case, it was a false diagnosis.
- The practice of medicine is not an island, and no single practitioner has all the answers and expertise necessary to provide all the care a patient will need. Patient care may depend on collaboration between multiple physicians. Such collaboration is grounded in effective communication. On numerous occasions, we saw that Dr. Khan did not openly and effectively communicate with other physicians.

- Medical care in general relies on a physician to have an understanding of their relative expertise or lack thereof in a particular field as compared to other physicians with whom they are caring for patients. This is the basis for referring patients to specialist physicians. To ensure that patients receive the care they need, a non-specialist physician must recognize and factor in the greater expertise of the specialist to whom they referred their patient. Dr. Khan referred Ms. B to an oncologist, who specialized in blood cancers, yet despite his comparative lack of expertise and based on an unestablished method (ONCOblot) and in a manner which was outside the limitations described by the manufacturer, he overrode the expert's diagnosis that Ms. B did not have cancer without engaging with the expert or seeking to clarify the discrepancy. He also dismissed Dr. Trinkaus's concerns about SAFE chemotherapy causing myelosuppression in Ms. D. We also saw repeatedly that Dr. Khan reinterpreted radiological study results and a gastroscopy inaccurately or differently from the specialists' conclusions.
- We are concerned that the personal definitions Dr. Khan used for terms such as response, resistance, cure and palliative were so broad and overlap to such an extent as to render them almost meaningless, misleading and confusing to patients. He used these terms without clarifying to his audience, unless under scrutiny, what he actually meant. These terms apply to many illnesses outside of cancer, and patients must be given information in clear and unambiguous language to understand their clinical condition and make decisions.
- Dr. Khan repeatedly billed OHIP using palliative codes for care he had not provided that his patients had actively declined in writing. First, as discussed above, a palliative state can be caused by numerous diseases. Further, in billing for care that he did not provide, Dr. Khan did not ensure he was complying with the trust-based billing system under which physicians are compensated in this province. When a physician fails to ensure they are respecting the rules, there are significant implications for the public interest and trust in the integrity of the profession.
- All physicians are legally required to comply with their regulator's investigations. This goes to public safety and to the core of governance by the College in the public interest.

[49] The underlying deficits that led to our findings, including the finding of incompetence, reflect Dr. Khan's broad deficiencies in knowledge, skill, judgment, communication, critical thinking and the understanding and application of evidence-based medicine. As discussed, Dr. Khan's disgraceful, dishonourable or unprofessional conduct has implications well outside the area of cancer treatment, and a direct impact on public trust, the profession and public safety. Given the many different and serious aspects of the practice of medicine in which Dr. Khan misconducted himself, and the lack of any evidence that he has addressed them, the public would be at risk if Dr. Khan practises medicine in any way.

#### Conclusion on Aggravating and Mitigating Factors

[50] As noted in *Fagbemigun* at para. 19:

The existence of factors that increase or decrease the penalty does not mean that the penalty cannot be at the high end or the low end of the scale. For example, the physician may have taken many positive steps since the misconduct or have compelling personal circumstances, but the appropriate penalty will still be revocation.

[51] The aggravating factors in Dr. Khan's case significantly outweigh the mitigating factors. Many of Dr. Khan's aggravating actions had, and will continue to have significant repercussions for the public's safety and the profession's reputation for integrity and quality of care. Even if Dr. Khan had sufficiently rehabilitated himself so that we could be confident that the public was not at risk, the goals of specific and general deterrence and maintaining the confidence of the public would require revocation. What is more, Dr. Khan poses an ongoing risk to the public.

#### **Prior Caselaw**

[52] Although previous Tribunal decisions are not binding as precedent, the Tribunal has accepted as a principle of fairness that generally, like cases should be treated alike and that prior cases may be of assistance and useful as a guide with respect to the range of penalties imposed for similar misconduct.

#### Prior Cases Presented by the College in which the Tribunal Ordered Revocation

[53] *College of Physicians and Surgeons of Ontario v. Bacon*, 2001 ONCPSD 22. Dr. Bacon was a general practitioner who had restricted his practice to patients with

ADD/ADHD, epilepsy, hyperactivity, learning problems and sleep disorders. Like Dr. Khan, after a contested hearing, he was found to have failed to maintain the standard of practice of the profession and to be incompetent. The panel found that he did not meet the basic criteria for good care. Based on our findings, we believe that Dr. Khan also does not meet the basic criteria for good care.

- [54] The panel considered that Dr. Bacon treated a vulnerable population, and that many areas of his practice fell well below the standard of practice of an average physician. This is also the case with Dr. Khan.
- [55] The panel also found that Dr. Bacon lacked knowledge, skill and judgment and showed a disregard for patient welfare, like we found for Dr. Khan. Of significance, the panel found that Dr. Bacon did not understand the depths of his deficiencies. It found that continued practice would put patients' health at risk. With respect to Dr. Khan, we are concerned about the same issues if he were permitted to continue practising.
- [56] Dr. Bacon's counsel put forward that no harm came to any of his patients. However, the panel emphasized that substandard practice which fortuitously does not result in harm is nonetheless substandard practice, which still has a real potential of harm. We agree with this and add that while some of Dr. Khan's patients experienced actual harm as a result of his care, Dr. Khan exposed all of the patients at issue in this case to the risk of harm or injury.
- [57] The panel in *Bacon* also commented that his practice involved psychiatry, neurology and psychology and that the complexity of his chosen type of practice by a general practitioner without specialty training in any of the main fields demanded much more vigilance in taking care to prevent further harm to this vulnerable group of patients. This analysis is also pertinent to Dr. Khan, who provided cancer care to vulnerable patients, for many different types of advanced cancers despite having no specialized training in oncology.
- [58] However, unlike Dr. Bacon, Dr. Khan has the added findings of disgraceful, dishonourable or unprofessional conduct due to his failure to comply with a College investigation, and for billing OHIP for care he had not provided. These issues have significant impact on the public trust of the profession and subsequently, public safety. Our penalty must address these issues as well.

- [59] As in Dr. Bacon's case, in which the Tribunal ordered revocation, and for many of the same reasons, plus the added reasons on disgraceful, dishonourable or unprofessional conduct, we find that revocation is the only appropriate penalty for Dr. Khan.
- [60] *College of Physicians and Surgeons of Ontario v. Devgan*, 2003 CanLII 74550 (ON CPSD), aff'd *Davgan v. College of Physicians and Surgeons of Ontario*, 2005 CanLII 2325 (ON SCDC). Like Dr. Khan, Dr. Devgan was a physician who provided complementary medicine. He was found to have engaged in disgraceful, dishonourable or unprofessional conduct, had a conflict of interest, charged excessive fees and made misrepresentations regarding treatments in his complementary medicine practice. He also had a prior disciplinary finding.
- [61] Dr. Khan's counsel argued that in *Davgan*, the panel found that the physician "preyed on" vulnerable patients, which we understand to mean that there was an intention to deceive them. He suggested that this showed that such findings are necessary for the penalty to be revocation. We disagree. While we did not make this type of finding regarding Dr. Khan, there are other findings and aggravating factors in Dr. Khan's case that were not made in *Davgan*. Moreover, in our view intention to deceive is not required in order for misconduct to reach the level of seriousness that would justify revocation.
- [62] Like Dr. Devgan, Dr. Khan treated his patients with therapies that could not provide the outcomes he claimed were possible, resulting in false hope. We agree with the statement in *Davgan* that "[g]iving a patient hope is laudable, but promising to prolong life and in some cases to cure patients close to death, when there is no real possibility of that, is truly reprehensible." (p. 3)
- [63] Defence counsel stated that unlike Dr. Khan, Dr. Devgan had developed a predatory pricing scheme designed to exploit vulnerable and terminally ill patients. Given his mistreatment of vulnerable patients, we find that on balance, Dr. Khan's conduct is more similar to Dr. Devgan's than not.
- [64] Revocation was ordered for Dr. Devgan, with the panel observing that it was necessary in order to uphold the values of the profession and to protect the public. The penalty was appealed, but upheld by the Divisional Court which stated at para 100:

There is nothing unreasonable about revoking the right to practise of a physician whose conduct constitutes an egregious departure from appropriate practise and whose conduct undermines public confidence in his profession.

- [65] We strongly agree with the *Devgan* panel at p. 4 that “[c]omplementary medicine is not the issue here. A doctor may offer this type of care without compromising core values of the profession and without offering false hope.” We would add that Dr. Khan’s inadequate care and behaviour undermines not only the good care provided by the members of this profession, including those who practise CAM, but the care of non-physician practitioners providing complementary treatments as well.
- [66] Dr. Devgan had a prior discipline history, whereas Dr. Khan does not. However, that does not mean the case is not of assistance as a precedent.
- [67] Counsel for Dr. Khan also pointed out the excessive fees charged by Dr. Devgan. Here, there is inappropriate billing of OHIP, which is analogous. Defence counsel also submitted that “...these circumstances plainly demonstrate there's something more that's required for revocation.” We disagree that this case demonstrates that “more” is required. It may have been for Dr. Devgan; however, revocation is not reserved for physicians with “something more” to their conduct.
- [68] First, while the panel in *Devgan* did not have to factor in clinical standards issues, we must for Dr. Khan, and as discussed, simply excising the cancer portion of his care for Dr. Khan is not possible due to the broad implications of his clinical failings. The defence proposed that there are important differences between the cases of Dr. Devgan and Dr. Khan, which we appreciate and considered. However, that does not change our evaluation of the seriousness of and risks of the case before us, and on balance we find that these are outweighed by the similarities of these two cases. Furthermore, unlike Dr. Devgan, Dr. Khan has the additional findings pertaining to his standards, incompetence, OHIP billing and obstruction of College investigations.
- [69] *College of Physicians and Surgeons of Ontario v. Liberman*, 2012 ONCPSD 12; aff’d *Bruce Liberman v. College of Physicians*, 2013 ONSC 4066 (Div. Ct.). Dr. Liberman was an anesthesiologist, who also had no prior discipline history. Like Dr. Khan, he fell below the standard, and showed lack of knowledge, skill and judgment. He too was found to be incompetent, but in Dr. Liberman’s case, this was

for the care of a single patient who died while in his care. The panel also found that Dr. Liberman engaged in disgraceful, dishonourable or unprofessional conduct by replacing portions of the patient's anesthesia record with what forensic evidence showed were fraudulent versions. Dr. Khan too committed various other types of very serious misconduct in addition to the failure to meet the standards of practice.

[70] Furthermore, the panel in *Liberman* found that he lacked the necessary insight to remediate, and that his inability to be self-reflective would present continued risk to the public. Dr. Khan is similar in this regard to Dr. Liberman who "...did not present a detailed plan for how his remediation would be implemented," and whose "... plan did not identify his deficiencies nor address how they would be remedied." (p. 21)

[71] Counsel for Dr. Khan submitted that we took issue with Dr. Khan's record-keeping but that he did not read our "...reasons as finding a similar kind of dishonesty that's designed to, in a sort of self-serving way, cover up medical failures." We do not believe that he failed to document his discussions; for the reasons laid out in our findings reasons, we found that Dr. Khan did not have the discussions he claimed to have had with his patients when obtaining consent for his treatments.

[72] In *Liberman*, the Tribunal ordered revocation of his certificate of registration, citing various reasons including those above, and concerns about public safety if Dr. Liberman were permitted to continue practising. For many of the same reasons discussed by that panel, we find revocation to be appropriate for Dr. Khan. Dr. Liberman appealed the panel's penalty order, however the penalty was upheld by the Divisional Court.

[73] *Kamermans*, above. Dr. Kamermans was an emergency room physician who was found, in his care of patients, to have failed to maintain the standard of the profession, demonstrated a lack of knowledge, skill and judgment and was incompetent. Unlike Dr. Khan, he also had the aggravating factor of a prior disciplinary finding in 2013.

[74] The panel in *Kamermans* considered the findings and their implications for the entirety of Dr. Kamermans' practice, including family medicine. It noted the significant overlap between his two practices and the need to protect the public.

- [75] Counsel for Dr. Khan submitted the distinction that in *Kamermans*, the panel had evidence that the physician's deficiencies of care extended from his emergency room practice into his family care practice, whereas we do not have evidence impugning Dr. Khan's non-cancer care. We do not find this consideration to be of much weight. We evaluated the implication of Dr. Khan's deficiencies to patient care overall. We need not have specific evidence that non-cancer patient care failures or harm have occurred due to Dr. Khan. We need only to consider and conclude on the matter of whether the deficiencies in Dr. Khan's medical skill set continue to expose the public to the risk of harm in any of his practices. As laid out above, we have done so, and conclude that the public needs ongoing protection from Dr. Khan.
- [76] *College of Physicians and Surgeons of Ontario v. Wales*, 2017 ONCPSD 37. Dr. Wales was a general practitioner whose practice focused on refractive eye care. His findings included failure to maintain the standard of practice of the profession and incompetence. Like Dr. Khan, he did not have a discipline history. Unlike Dr. Khan, Dr. Wales did not have findings stemming from disgraceful, dishonourable or unprofessional conduct.
- [77] Nevertheless, the Tribunal revoked Dr. Wales's certificate of registration, citing his lack of insight or evidence that he had taken steps to address concerns regarding his rigidity of thought and the grandiose claims made in the evidence. The panel noted that there was no testimony from Dr. Wales in which he demonstrated insight or any willingness to improve. Similarly, we have heard no insight from Dr. Khan who also displayed rigidity of thought which he demonstrated in the form of confirmation bias and rationalizations. We also agree with counsel for the College in their penalty submission that it is fair to describe many of Dr. Khan's claims as grandiose.
- [78] Here again, counsel for Dr. Khan emphasized that the highly narrow practice scope for Dr. Wales left him with no practice options such that revocation was reasonable, whereas for Dr. Khan, who practises outside of cancer care, allows for the possibility that his "offending area" of practice, can be "hived" off. Regardless of the differences between the scope of practice for these physicians, and for the reasons already discussed, we disagree that cancer care can be "hived" off for Dr. Khan.

[79] *College of Physicians and Surgeons of Ontario v. Hill*, 2017 ONCPSD 21, aff'd *Hill v. College of Physicians and Surgeons of Ontario*, 2018 ONSC 5833 (Div. Ct.). Like Dr. Khan, Dr. Hill, who also had no prior discipline history, failed to maintain the standard of practice, was incompetent and engaged in disgraceful, dishonourable or unprofessional conduct. Unlike Dr. Khan, Dr. Hill was shown to have falsified his charts, but both physicians were found to have communication issues, and were noted by their respective panels to engage in rationalizations and justifications regarding their care.

[80] Defence counsel pointed out that Dr. Hill did not attend his hearing and that nobody attended on his behalf. He also noted that the panel had found that Dr. Hill's "...advanced age and in the years leading up to his retirement, his practice had seriously deteriorated, and he had significant knowledge gaps for common medical conditions..." Counsel explained that this, combined with the fact that he was already retired at the time of his hearing, and had no submissions regarding the need for his care (unlike Dr. Khan who did have such submissions), suggested that there were no elements of his practice worth preserving in the public interest, unlike Dr. Khan.

[81] We disagree. What we see, is that Dr. Hill (as well as other physicians whose cases were relied upon at this hearing) may not have had the skill set to continue practising, or the demand for their care (*Hill*); however, this does not lessen the implications of Dr. Khan's deficiencies in his remaining non-cancer skill set and their potential consequences to the public. Further, as discussed above in *Wai-Ping*, an incompetent physician, even when in demand as defence counsel suggests is the case with Dr. Khan "...is dangerous to the public and is worse than a shortage of physicians..." (p. 46)

Prior Cases Relied Upon by Dr. Khan in which Suspension and Restricted Practice were Ordered

[82] Dr. Khan relied upon three prior cases in which revocation was deemed unnecessary by the Tribunal. In these cases, physician breaches of the standard of care were met with suspension, followed by continued but restricted medical practice as the appropriate penalty.

[83] *College of Physicians and Surgeons of Ontario v. Yazdanfar*, 2011 ONCPSD 14, *College of Physicians and Surgeons of Ontario v. Yazdanfar*, 2011 ONCPSD 45; aff'd *College of Physicians and Surgeons of Ontario v. Yazdanfar*, 2013 ONSC 6420 (Div. Ct.). Dr. Yazdanfar was a family physician who had a cosmetics practice in which she performed liposuction and breast augmentation. After a long, contested hearing, which was her first time before the Tribunal, the panel found that she did not understand the limits of her training. Like Dr. Khan, the panel made findings that Dr. Yazdanfar failed to maintain the standards of the profession, lacked knowledge, skill and judgment, was incompetent and engaged in disgraceful, dishonourable or unprofessional conduct. This last finding was specifically due to misleading advertising. The findings against her, like Dr. Khan's, pertained to numerous patients. One of Dr. Yazdanfar's patients died in her care after she ignored the patient's post-operative critical clinical picture. Like Dr. Khan, Dr. Yazdanfar was also found to have failed to obtain informed consent from her patients.

[84] We find that this is an important comparison case. On the surface, the findings on the conduct of these physicians, although not the same, are similar. However, there are critical departure points which guide our decision that Dr. Khan's certificate of registration should be revoked, even if Dr. Yazdanfar's was not.

[85] The panel in *Yazdanfar* considered seriously the prospect of revocation and relied in part on:

- the comments of the Divisional Court in *College of Physicians and Surgeons of Ontario v. Boodoosingh* (H.C.J.), 1990 CanLII 6686, in the words of Justice Montgomery that:

...the penalty of revocation should be reserved for repeat offenders and the most serious cases.

- and the description by Steinecke in *A Complete Guide to the Regulated Health Professions Act*, October 2010, at pp. 6-120, that:

While no exhaustive list of cases warranting revocation can be drawn up, the order will usually only be made in cases involving premeditation, exploitation of a vulnerable person, dishonesty or

lack of integrity or where the member is otherwise not suitable to remain a member of the profession.

[86] While the panel in *Yazdanfar* referred to *Boodoosingh* of 1990, and Steinecke's book in 2010, we note that penalties can change and evolve. *Adams v. Law Society of Alberta*, 2000 ABCA 240 at para. 27, directs that there need not be the "most serious misconduct by the most serious offender" for revocation to be an appropriate penalty. Dr. Khan's standards-related misconduct, and incompetence, coupled with his lack of insight, and disgraceful, dishonourable or unprofessional conduct are sufficiently serious to necessitate revocation of his certificate.

[87] Of significance, although like Dr. Khan, Dr. Yazdanfar showed a lack of insight regarding her deficiencies, the panel felt that in her case, rehabilitation was possible, noting in their penalty reasons at p. 17 that:

- "...Dr. Yazdanfar is at a relatively early stage in her career, and though she has made truly serious errors, there is a reasonable potential of rehabilitation;"
- "There was no evidence to suggest that she was not technically proficient in performing some surgical procedures. The Committee accepted that she has acquired limited technical skill;"
- Dr. Yazdanfar had committed time and resources to furthering her education, which the Committee found spoke to an interest and commitment to learning.
- She had applied to the College to expand her scope of practice for breast augmentation, which the Committee took to suggest that she had a degree of compliance with College policy.

[88] The panel ordered a two-year suspension, followed by a return to a practice that was restricted to surgical assisting in a hospital setting only. It found that in this setting Dr. Yazdanfar would have appropriate oversight and an opportunity to re-establish the core values of her profession.

[89] Where the Tribunal had ongoing concerns about public safety, it acted to eliminate this risk by permitting Dr. Yazdanfar highly limited access to the public, under direct supervision in the operating room, and in a hospital setting only. She would not have patients of her own.

[90] Of importance, we note that in the *Yazdanfar* penalty reasons at p. 9, the panel spoke of her lack of specialized training and her lack of ability to recognize the limitations of her training and how it should have influenced the care she provided;

She ventured down another pathway, believing either that she would not run into serious complications or that she was capable of handling them. Her lack of knowledge and/or ability and her faulty judgment ended in tragic consequences with the death of [the patient]. In failing to observe appropriate limits, she violated her professional responsibility by treating not just one but many patients in an unsafe manner.

[91] As discussed above, Dr. Khan also did not recognize the implications of his lack of training in the treatment of cancer. Like Dr. Yazdanfar, Dr. Khan exposed his patients to the risk of harm.

[92] The panel in *Yazdanfar* also spoke of the importance of public trust in the profession and "...the fundamental need of patients to trust the doctor they consult to inform them of the options and to treat them appropriately." (p. 20) We agree with these concepts, and while the panel believed that taking into account her circumstances, a highly restricted scope was possible for Dr. Yazdanfar, we do not believe that we can maintain the trust of the public, or the integrity and reputation of the profession if Dr. Khan has access to the public at large even if his access is restricted.

[93] Like the panel did when considering the penalty principles in light of Dr. Yazdanfar's specific limitations and abilities, we too must impose a penalty that protects the public and the profession's reputation and integrity, and which suits Dr. Khan's particular set of circumstances.

[94] *College of Physicians and Surgeons of Ontario v. Frank*, 2018 ONCPSD 20. Dr. Frank was an obstetrician and gynecologist who had failed to maintain the standard of practice and demonstrated a lack of knowledge amounting to incompetence. The findings against her pertained to numerous patients, and appeared to primarily involve inadequate investigations of patients before deciding on surgery, the performance of unnecessary surgery, poor pre- and post-operative monitoring and care, including patients who were exhibiting symptoms of complications, and like Dr. Khan, failure to obtain informed consent. The panel accepted a joint submission on penalty which after a two-year suspension would allow her to have an office-

based practice limited to the areas of reproductive endocrinology and infertility, office-based gynecology and early obstetrical care, among other things.

- [95] The panel also took note that Dr. Frank had admitted her professional misconduct and incompetence and expressed responsibility. Further, she had already engaged in the rehabilitation process and was receiving consistently favourable reviews regarding her skill and behaviour from her clinical supervisor. Thus, when the Tribunal considered the proposed joint submission on penalty it was:

...satisfied that the proposed penalty in this case was appropriate. The public is protected by the two-year suspension of Dr. Frank's certificate of registration and by the imposition of significant terms, conditions and limitations on Dr. Frank's certificate of registration on her return to practice. She will be practising only in areas in which she has been evaluated to be competent. She will be closely monitored in a group setting by a supervisor approved by the College and will be supervised and reassessed. (p. 28)

- [96] This is distinctly different in Dr. Khan's case where we do not have similar mitigating factors like acknowledgement of deficiencies, engagement in rehabilitation, nor insight. Permitting Dr. Khan to continue practising, even without treating cancer, would inadequately protect the public. Additionally, although counsel for Dr. Khan submits that it is possible, as discussed, we do not believe that his deficiencies can be isolated to a specific area of practice, as was the case with Dr. Frank.

- [97] Furthermore, unlike Dr. Khan, Dr. Frank was not found to have engaged in disgraceful, dishonourable or unprofessional conduct by withholding her charts, and obstructing her regulator from reviewing her care. It would seem that she was open to being evaluated by her regulator and proposed a plan for remediation which included close monitoring in a group setting, and reassessment by a College approved supervisor. Dr. Frank had also not improperly billed OHIP, as did Dr. Khan.

- [98] Dr. Frank's case is sufficiently different from that of Dr. Khan that it does not serve to satisfy us that suspension with return to restricted practice is an appropriate penalty here.

[99] *College of Physicians and Surgeons of Ontario v. Fenton*, 2017 ONCPSD 16. Dr. Fenton was prescribing controlled substances at excessive quantities and to vulnerable patients. He prescribed narcotics dangerously and inappropriately, engaged in unprofessional behavior with patients and failed to maintain confidentiality. He admitted to the allegations of failure to maintain the standard of practice, incompetence and disgraceful, dishonourable or unprofessional conduct. The panel concluded that Dr. Fenton fell short in his record-keeping, failed to adhere to what it described as evidence-based medicine and noted that he “demonstrated contempt for the College, colleagues and others in his delay in producing records.”

[100] In a joint submission, Dr. Fenton committed to engage in a primary care course and voluntarily agreed to cease the prescription of narcotics and other controlled substances. The panel found these first steps to be “encouraging.” It accepted a joint submission of six months’ suspension, education courses, 12 months’ clinical supervision and reassessment after six months, stating at p. 20:

The terms of the order tailored to address Dr. Fenton’s deficiencies must achieve protection of the public and the Committee is comforted that this will be achieved by ordering the program of supervision, education and a comprehensive practice assessment.

The Committee recognizes that this penalty constitutes a sizable commitment on Dr. Fenton’s behalf. However, anything less would leave the public at risk.

[101] We also see that despite his “contempt for the College” Dr. Fenton, through his commitment to his rehabilitation, was willing to work with the College. Again, this is not the case with Dr. Khan. We note also that Dr. Fenton had not improperly billed OHIP as had Dr. Khan.

[102] It is also important that Drs. Frank and Fenton provided joint submissions on penalty which were accepted in each case, and as a result, the decisions do not fully articulate the Tribunal’s analysis of the suitability of other penalties. They are based on the finding that the jointly proposed penalty would not bring the administration of justice into disrepute or otherwise be contrary to the public interest (*R. v. Anthony-Cook*, 2016 SCC 43).

### Summary of Prior Caselaw

[103] In the cases the College submitted in which the physicians' certificates of registration were revoked, the conduct of the physicians had significant overlap with Dr. Khan's. Although not present in each case, we saw the following dominant similarities emerge between many of these physicians and Dr. Khan: treatment of vulnerable populations; serious failures in maintaining the standards of the profession; lack of knowledge, skill and judgment; incompetence; failure to meet the basic criteria for good care; conduct that was pertinent to areas of practice other than the specific area which was the focus of the disciplinary hearing; lack of, or poor insight into the depths of their deficiencies such that remediation and rehabilitation would be unlikely resulting in ongoing risk to the public if they were to continue practising; disgraceful, dishonourable or unprofessional conduct; implications for the integrity and reputation of the profession; first time before the Tribunal in some cases and the submission of letters of support for the physician.

[104] In the cases Dr. Khan submitted, there was also significant overlap between those findings and ours. However, there were overt distinguishing factors we had to consider which made these cases different from Dr. Khan's, which moved us along the spectrum of penalties towards revocation.

### **Conclusion on Suspension/Revocation**

[105] Due to his multiple failures to maintain the standard of practice of the profession and his incompetence, Dr. Khan not only repeatedly exposed his patients to the risk of harm, but also caused harm. Further, his disgraceful, dishonourable or unprofessional conduct pertains not only to integrity, governability and the profession's reputation, but these in turn have significant implications for the public's trust of the profession, and public safety. Nothing short of revocation would be enough to deter Dr. Khan and other physicians from this type of serious misconduct, maintain public confidence in the medical profession or adequately express the Tribunal's and the profession's disapproval of Dr. Khan's misconduct.

[106] Only revocation can satisfy the most important penalty principle: protection of the public. With serious deficiencies at play that jeopardize public safety, and no clear path for their elimination, we cannot assure the public that they would be safe if Dr. Khan were to continue practising.

[107]More generally, maintaining Dr. Khan's certificate of registration in light of his actions would harm the public's confidence in the medical profession. As the English Court of Appeal said in *Bolton v. Law Society*, [1994] 1 WLR 512 at para. 15, in comments that apply equally to the medical profession:

[The public] is ordinarily entitled to expect that the solicitor will be a person whose trustworthiness is not, and never has been, seriously in question. Otherwise, the whole profession, and the public as a whole, is injured. A profession's most valuable asset is its collective reputation and the confidence which that inspires.

[108]Dr. Khan's misconduct included clinical failures, incompetence, billing OHIP for fees to which he was not entitled, failing to cooperate with the College and misleading communications with patients. It affected multiple aspects of the trust patients and the public place in physicians, in care and the information provided about it, in claims for public dollars under the OHIP system and in acceptance of regulation in the public interest by the College. These varying types of failings have significant and overlapping implications, and it would bring into question the profession's collective reputation if he continued to practise.

[109]We recognize that revocation is a serious penalty with significant consequences to Dr. Khan. As the court said in *Bolton* at para. 16:

[A regulated professional] can often show that for him and his family the consequences of striking off or suspension would be little short of tragic...The reputation of the profession is more important than the fortunes of any individual member...Membership of a profession brings many benefits, but that is a part of the price.

[110]Given Dr. Khan's actions and the lack of evidence that he would conduct himself differently if allowed to practise medicine in any area, we order revocation.

## **Costs**

[111]The College submitted that the appropriate costs under s. 53.1 of the Code are \$197,030, based on the daily tariff rate in the Rules of Procedure of \$10,370. The College emphasized, that under Rule 14.03, it is not required to provide evidence of the cost or expense of a day of hearing if it is seeking the tariff rate only.

[112]Dr. Khan's counsel asked that we think about a wide array of factors in our costs order, including prior caselaw on costs: *College of Physicians and Surgeons v. Iscove*, 2018 ONCPSD 53, from which we should derive that payment amounts must be fair and reasonable. Counsel for Dr. Khan asserted that a payment of \$197,030 would be inappropriate, unfair and punitive. He also relied upon *College of Physicians and Surgeons v. Botros*, 2018 ONCPSD 51, from which he argued we should derive that members should not be liable for the whole cost of defending themselves, particularly when their right to practise is at stake. Defence counsel reminded us that much of Dr. Khan's practice has been restricted by the ICRC since 2017 and that he has complied without incident.

[113]We agree that costs should be fair and reasonable. The tariff rate has been set to take this into account. We have no evidence before us that shows financial hardship on Dr. Khan's part.

[114]Moreover, the tariff rate is not full reimbursement of the College's costs, as set out in *Yazdanfar* at p. 23:

In assessing quantum, the Committee is aware that the per diem tariff does not cover the actual costs of the College of a hearing day before the Discipline Committee. Furthermore, the costs requested did not include investigative costs, the costs of experts or the cost of legal preparation and attendance, all of which may be included in a costs order.

[115]We do not need to decide here whether costs must be split between the College and the member who committed misconduct as Dr. Khan argues, although we note that s. 53.1 of the Code specifically permits the Tribunal to order the member to pay "all or part" of the College's costs. The costs set out in the tariff only reimburse a part of the College's costs. The costs are high because these proceedings were lengthy, complex and pertained to Dr. Khan's misconduct and repeated breaches in standard regarding numerous patients.

[116]Dr. Khan argued that he was prosecuted with real vigour in that the College hired outside counsel, presented multiple expert witnesses and litigated every facet of each complaint. He submits that if the proposed \$197,030 in costs is ordered, Dr. Khan would essentially be punished for defending himself. We disagree. Both sides presented their cases with vigour and there is no reason the profession should disproportionately bear the costs of this hearing.

[117] Having considered the various factors in Dr. Khan's case specifically, and the relevant prior cases, we find that Dr. Khan should pay costs of \$197,030 based on the full tariff rate this Tribunal normally applies as set out in the Rules.

[118] Given the factors that impacted the complexity and length of this case and the fact that the College proved all of its allegations, the tariff amount is reasonable, fair and non-punitive.

[119] We recognize that the tariff cost is a large sum and even though it is not the goal, we are aware that these costs may feel punitive to Dr. Khan. However, it is our view that this amount is sensible and fair, and it is consistent with the Tribunal Rules.

[120] On the point of repayment to OHIP, it should be noted as set out in *Fagbemigun* at para. 28, "this Tribunal has no power to order Dr. [Khan] to repay the monies he took [from the taxpayers of Ontario]. That is a matter for the courts, if OHIP decides to pursue it."

## **Conclusion**

[121] Dr. Khan broke the tenets of good medical care and professional conduct required of all physicians when he repeatedly demonstrated an extremely serious and disturbing pattern of failures and misconduct which impacted the lives and deaths of numerous patients and their families. He exposed his patients to the risk of harm and false hope, and at times, he caused both.

[122] Dr. Khan also broke the trust of the profession and failed to repeatedly ensure he followed the OHIP system when he billed the people of Ontario tens of thousands of dollars for care he did not provide. Dr. Khan also continues in his failure to comply with a College investigation by obstructing its ability to verify the quality of his care as it pertains to 19 children, whose charts he has withheld for years.

[123] Dr. Khan's clinical failures and misconduct are pertinent to the practice of medicine in general. His failures are not confined to treating cancer, which is but a single group of diseases.

[124] The underlying deficits that led to our findings reflected Dr. Khan's choices in conduct, and his incompetence which is rooted in deficiencies in his knowledge, skill and judgment, communication, errors in critical thinking and his understanding

and application of evidence-based medicine, as well as scientific and medical principles, all of which are reasonably expected of all physicians regardless of their area of practice. To a large degree, these abilities define the practice of quality medicine and professional conduct, which inspires the public to trust the profession.

[125]Dr. Khan's deficiencies cannot be repaired with a record-keeping course or by restricting him from treating cancer. These will not address Dr. Khan's fundamental gaps in knowledge and application of scientific and medical principles, nor would these remedy the manner in which Dr. Khan conducts himself, all of which led to his failures and misconduct and brought him before us to begin with.

[126]Rectifying these deficiencies such that we could justify to the public that they are safe, and to the profession that its member is no longer damaging its collective reputation, would require insight on Dr. Khan's part as well as significant effort and commitment to rehabilitation with the caveat that it would foreseeably result in major changes in the way he practises medicine and conducts himself.

[127]We do not have evidence that Dr. Khan has such insight. Further, we do not have evidence that Dr. Khan is interested or willing to engage in meaningful rehabilitation and remediation efforts. There is, therefore, no basis upon which to believe that rehabilitation is likely in Dr. Khan's case and subsequently no reason to believe that he will not engage in similar conduct in the future.

[128]Dr. Khan failed this profession and undermined the hard work and quality care provided by physicians. Moreover, he failed his vulnerable patients and broke their trust at time of great need: when they were sick and dying or feared that they may be, and required sound care from a trustworthy, competent physician. All patients deserve such care, and Dr. Khan's patients should not have received anything less.

[129]We conclude that revocation of Dr. Khan's certificate of registration is proportionate and necessary. This will maintain the integrity of the profession, and the overarching principle of protection of the public.

## **Order**

[130]Therefore, we order and direct:

- the Registrar to revoke Dr. Khan's certificate of registration, effective immediately;
- Dr. Khan to pay the College costs of \$197,030 no later than October 17, 2022;
- Dr. Khan to appear before the panel to be reprimanded;
- Dr. Khan's practice to be closed in accordance with the CPSO policy on "Closing a Medical Practice."

**ONTARIO PHYSICIANS AND SURGEONS DISCIPLINE TRIBUNAL**

**Tribunal File Nos.: 17-002-I and 20-003**

**BETWEEN:**

College of Physicians and Surgeons of Ontario

- and -

Dr. Akbar Nauman Khan

**The Tribunal delivered the following Reprimand**  
in writing on Monday, May 29, 2023.

Dr. Khan,

The College of Physicians and Surgeons of Ontario, your regulatory body, uses its policies to inform the standard of practice and expectations of professionalism for its members. All physicians are expected to practise within the limits of their knowledge, skills and judgment. To treat patients outside of one's scope of clinical competence exhibits a lack of judgement that can be harmful. The practice of medicine in Ontario is regulated to ensure the public is protected from such harm.

This reprimand is being delivered in writing as you have refused to participate in this portion of the OPSDT regulatory process. It addresses the findings and penalties in two proceedings: Tribunal File Nos. 17-002-I and 20-003. In both, all allegations of professional misconduct and incompetence against you were proven and resulted in your certificate of registration being revoked. It is also noted that you chose not to participate in your most recent penalty hearing held January 17, 2023.

You displayed a lack of knowledge, skill and judgment in your care and treatment of patients, including children, who were at their most vulnerable, facing diagnoses of serious illness such as cancer. You profited personally from improper billings, displayed a disregard for evidence-based medicine and have even diagnosed and treated patients inappropriately for cancer they did not have. You falsely claimed these medications were safe, and side-effect free. You gained financially by providing false hope for people at the end of their lives and often in the most tragic of circumstances.

One should remember that a physician must always prioritize a patient's interests. You failed to do so and have, therefore, breached the trust that society expects from the medical profession. We consider your lack of medical knowledge and disdain for even the most basic requirements of obtaining informed consent, good record-keeping and the expectation of honesty in billing OHIP, as well as your contempt for the regulatory process itself, to be dangerous.

We also find your lack of insight to be disturbing, with little hope of remediation. In our view, you are unfit to continue to practise medicine.