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Ms. Genevieve Currie General Council c/oPatient Ombudsman of Ontario 393 University Ave Suite 1801 Toronto, ON M5G 1E6

Re. Complaint re. Cancer Care Ontario's PET Scan Policy, Case File# 201700672

#### AN EXAMPLE OF:

#### EXCELLENT CARE FOR ALL IN ONTARIO

Dear Ms. Currie

This letter is in response to the phone conversation on November 15th, and the letter stating your legal position and the ruling by Ms. Elliott. In this letter I will ask you to clear up a few of the 'legal points' you have made as well as answer several questions.

#### PART A:

#### **RE:Patient Ombudsman Mandate Section:**

"can receive complaints from patients, former patients or caregivers about actions or inactions of a health sector organization that relate to the care and health care experience of a patient or former patient. Health sector organizations are defined in the act as a publicly funded hospitals, long-term care homes, and local health integration networks."

#### **Point of Clarification:**

Every aspect of both patient's issues that I raised, but in particular with respect to patient, ID 21337, took place entirely within the confines of a publicly funded hospital. This includes all of this patients visits with her oncologists, all her investigations, including the 'CCO standards of compulsory investigation with a CT', and also an MR which lead to the gross mis-staging of this patient who was told that there was a chance of curing her cancer. Based on this advice she underwent a what in reality was the 'contraindicated therapy' of radical radiation therapy to her pelvis. Had the patient been allowed a PET/CT as part of her initial staging it would have demonstrated that she was not 'curable' but in fact had terminal Stage IV cancer and this contraindicated therapy would not have taken place. The result was that she suffered terrible and unnecessary complications directly due to the contraindicated radical radiation therapy to her pelvis. In addition she underwent a marked increase in her stress levels.

Firstly because she was told she had a possible cure only then to be given the correct diagnosis of terminal cervical cancer following her PET/CT. In addition, she was a nurse and as I spent a great deal of time discussing the issues as to how PET was being introduced in Ontario, she came to the realization that how she had managed her patients, having trusted Cancer Care Ontario, may have been based on a similar process. Further, as Cancer Care Ontario physicians and even Ms Wynne her Premiere and Dr Hoskins, our Minister of Health became aware of the details of her case, they refused to answer her question regarding her investigation, or even acknowledge what happened to her as she spent her final months in a hospital bed in constant pain and distress.

The medical literature based on the accepted international norms of using a long-standing and scientifically validated review by her physicians, as was done and discussed with the patient, was clear that she would have benefited from a PET/CT for staging. The patient and her physician were given a copy of these 'peer reviewed' papers.

- Everyone agrees, including the government's 'experts', that
  the decision NOT to allow a PET/CT in her staging was not
  based on a scientifically validated assessment of the
  medical literature, which in the end no one has denied or
  challenged, was based on an 'agenda'.
- Ms Elliott is aware of the statement by an acknowledged world class PET expert, Professor Rodney Hicks from Australia who stated to me in July 2016:

- Ontario has the most egregious and politically motivated agenda against PET (read our patients) in the world.
- One of the 'unanswered questions' the patient addressed to the government 'medical experts' was on what basis was the decision not to allow her a staging PET/CT made. However, as you have pointed out, this would not be addressed by Ms. Elliott.

Again to reiterate, every aspect of this woman's investigations, physician consultations, treatment and follow up *took place entirely within the boundaries of Thunder Bay Health Sciences, a Publicly Funded facility.* In addition, she communicated with her McMaster based physician via the Ontario Telehealth, who was using the facilities in a *publicly funded Ontario hospital* 

- At no point was she assessed, imaged, treated, or followed up outside of a publicly funded hospital setting.
- [This applies equally well to the other patient I presented for review.]

#### **QUESTION 1:**

 I would ask that you explain in detail and in a way that patients, and in particular the family members of patient ID 21337, <u>why these cases</u> <u>would not lie within the section of the mandate</u> you have quoted with respect to why the portion referring to publicly funded hospitals is not considered part of the Patient Ombudsman Mandate.

Given that it would be understandable that the patient, her family and indeed my colleagues would assume that having taken place in a publicly funded hospital that this would be under covered within the 'mandate of the Patient Ombudsman of Ontario. Therefore:

#### **POINT OF CLARIFICATION 1:**

Please describe in detail a case example of a patient **that would** be covered under the section of issues related to:

a. 'actions or inactions of a health sector organization that relate to the care taking place within a health sector organizations are defined in the act as a publicly funded hospital.'

#### Question 2:

Why would the statement from Professor Hicks not be of concern to Ontario's Patient Ombudsman, Ms Elliott, and indeed not even acknowledged in your ruling?

### CONSEQUENCES TO THIS PATIENT'S PHYSICIANS FOR TRYING TO GET A STAGING PET/CT FOR THIS PATIENT:

Ms. Elliott, and you as her legal council are fully aware that I acted as what surely would be defined as a true 'patient advocate'. In addition, I based my advice to this patient and her physicians based on the standards of care expected of Ontario physicians. That is by using 'peer reviewed medical literature'. Yet, for my 'professional efforts' as a physician who took the Hippocratic Oath, to try and prevent this patient from going through the terrible consequences of NOT having a PET/CT before her treatment, I have been threatened with loss of my privileges at this hospital. That by acting as her advocate, a call was placed to the Senior Administration of Thunder Bay Health Sciences by the office of the Senior Executives of Cancer Care Ontario, and subsequently confirmed in person by their Thunder Bay representative, Dr. Mark Henderson, that:

- If I continue to speak to physicians and patients about how the government has handled PET/CT, or even use case examples from their PET/CT without 'identifiers', that I will risk losing my privileges at the hospital.
- It is worth pointing out once more, that no one from CCO or the government, or Dr. Henderson has ever questioned that the statements I am making are not correct, but that I am just not allowed to discuss these "facts" with colleagues or patients.

As I am sure you would agree, most physicians and patients would think that this might be of concern to the Ontario Patient Ombudsman, particularly in light of what happened to this patient. However, Ms. Elliott has chosen not to even comment on these issues which would seem to 'fly in the face' of the idea that Ontario is an 'open, transparent and accountable democracy'. This is in fact stated in documents from Cancer Care Ontario, and in particular from the Provincial Imaging Section.

#### **QUESTION 3:**

Why has Ontario's Patient Ombudsman, Ms. Christine Elliott, chosen not to comment on the threats against my ability to practice medicine when it would be reasonable to conclude that all the medical advice and information I gave to the patients and their physicians was in fact true

and meeting the standards of practice of what is expected of Ontario physicians?

#### FACTS OF THE CASE REGARDING ID 21337:

The patient was grossly mistaged having been told, based on the compulsory 'CCO Standards of investigation' that she was potentially curable and thus consented to undergo radical radiation to her pelvis which would then be following by extensive surgery to her pelvis. As the patient was a nurse she fully understood the implications of this approach and the potential for severe and long standing morbidity as a result of this approach.

Having been refused a PET/CT before her therapy, she was allowed the PET/CT following completion of the radical radiation therapy to her pelvis.

- Her PET/CT correctly demonstrated that she had untreatable and therefore eventually terminal Stage IV cervical cancer from the beginning.
- That she underwent what would be universally accepted as a CONTRAINDICATED radiation therapy to her pelvis that had absolutely NO chance of prolonging her life and could only result in gross and mutilating damage to her pelvic organs as was the case.

This woman would suffer miserably both physically and emotionally, and <u>UNNECESSARILY</u> for the remainder of her life. She died some six months after the PET/CT scan.

I will restate my position as I approached this patient both as a 'Consultant Specialist' in her care, and as 'her advocate'.

- 1. Her physicians were forced to practice 'substandard medicine' based on the 'Standards' set by Cancer Care Ontario and their McMaster Colleagues to stage and then advise her on the most appropriate plan of treatment, using only CT and MR.
  - a. That this was done against our better judgment, and our advice to the patient.
- 2. That the accepted and <u>scientifically validated medical literature</u> had already determined there was role for PET/CT in staging her cancer. Her 'non-McMaster based' physicians and the patient was given copies of relevant medical papers with respect to roles for

PET/CT in management of patients with cervical cancer.

3. That the decision to NOT ALLOW her a Staging PET/CT in Ontario was based on a 'scientifically baseless PROCESS' used by the Ontario government's 'medical experts'.

#### MS ELLIOTT'S RULING:

Ms. Elliott has not made any comments or recommendations based on a complete assessment of the issues that affected this patient. This would therefore imply that:

- 1. This woman's care in a publicly funded hospital is consistent with at least some aspects of "excellent care for all" in Ontario.
- 2. Or, that not a single aspect of the information reviewed is covered under Ms. Elliott's mandate.

#### **POINT OF CLARIFICATION 2:**

If Ms. Elliott has ruled that the 'standard of care that patient ID 21337' received in a publicly funded Ontario hospital' is consistent with "excellent care for all" in Ontario, please explain in full detail which, if any aspects of this patient's care, are consistent with what would be implied by 'excellent care for all."

#### PART B:

# ASSESS ESTABLISHED GOVERNMENT "POLICY" OR ASSESS "PROCESS" TO ESTABLISH THE GOVERNMENT'S POLICIES WITH RESPECT TO PET

I would now like to consider the sections of your letter and in particular the statement:

"The Deputy Ombudsman confirmed that their prior investigation was "focused on concerns relating to process, rather than the merits of whether the province should be adopting this technology" and that "[i]t is not the role of an Ombudsman to investigate matters of broad public policy."

You had full access to the information that allowed Mr. Marin and subsequently, Mr. Dube and Ms. Finlay to come to these conclusions, and you have made clear you are in full agreement with them. Therefore I will assume that you will now be required and fully prepared to back your legal position with

the 'facts contained within the documents' that were provided to you and the Ombudsman's Office.

#### IT IS ACKNOWLEDGED:

That, you Ms. Currie, are aware that repeated attempts to get Mr. Dube, and Ms. FInlay, including by Registered Letter Delivery, to provide supporting documentation, or 'evidence from the documents' to support their conclusions, *have been ignored*.

You have stated you are in agreement with the Ombudsman's Office, that my colleagues and I believed that the role of Ontario's Ombudsman's Office, was determine whether or not official government 'Policies' had merit or not. As you have reinforced the 'actual role' of the Ombudsman's Office is to:

"focused on concerns relating to process"

#### **POINT OF CLARIFICATION 3:**

By claiming all the issues we raised were related to established government **policy**, did you mean the following?

That once the decision had been made by Ontario politicians with their CCO 'experts' in the late 1990's or early 2000's, to allow the use of a scientifically baseless and agenda driven 'methodologies/processes' to assess the "quality of evidence" of "science based medical papers with respect to PET", as well as the basis of deliberately designing 'experiments on human cancer patients', and how the results would be analyzed:

That this was now 'accepted Government Policy' and therefore would no longer be covered by the Patient Ombudsman mandate.

Yes, or No?

Let us assume that your answer is YES. Therefore being 'Official Government Policy' it therefore will be documented appropriately and available for review.

#### REQUEST FOR DOCUMENTATION:

## Would you please send me a copy of the relevant 'policy documents' establishing this as 'Government Policy'.

Everyone could then agree that if this if is 'official government policy' then the Ombudsman's Office would be in no position to assess this decision.

It is understood that it is not the Patient Ombudsman role to determine whether established government policy is justified or not. However, as you might imagine, most physicians and certainly patients would assume that even if this was 'official government policy' that it would be reasonable for them to assume that this would be of significant concern to Ontario's Patient 'Ombudsman/Watchdog'.

#### Question 4:

Why would this issue be of so little concern to Ms. Elliott that it is not even mentioned in her ruling?

Please answer this in sufficient detail so that the 'naive' physicians and patients will now understand why this is of no concern to the individual designated to act independently of the Ontario government and prevent government abuses or other actions, not in the best interest of Ontario's patients.

#### RELEVANT POINTS FOR FURTHER DISCUSSION AND CLARIFICATION:

- 1. In following such 'policy' the actual methodology used to evaluate the "quality of the medical and scientific literature, and designing and evaluating PET experiments on cancer patients would qualify as the <u>'PROCESS'</u> or 'the mechanics' of how the government's 'experts' would access possible roles for PET, to then advise the government.
- 2. That based on the advice their 'medical experts' would have given to the government based on the various 'processes' used to evaluate PET, the Government's role would be then to decide whether or not they were in a position to fund some or all of the indications for PET as determined by their 'experts'. The basis on which politicians would make these decisions is affected by many factors, such as impact on government spending and how this might impact other publicly funded programs. However, their decisions would not be expected to be based on a scientifically validated process:

- a. I would suggest there would be universal agreement that just because the 'experts' had declared there was "quality evidence to support various PET/CT indications" would not mean that the government was obligated to fund them.
- 3. That everyone on both sides of this issue agree that there is no scientific evidence or validation to justify using 'health technology assessment' [HTA] on ANY diagnostic imaging equipment, including PET, CT, or MR.
  - a. This was confirmed by Dr. Julian Dobranowski, Provincial Head of Imaging for CCO, in 2009.
  - b. Repeated attempts by me to have various CCO Committee's or their physicians provide "quality evidence" to justify using the HTA to evaluate PET have been ignored, and not a single 'medical reference has been put forward' to justify the use of the HTA.
- 4. The only response I have received over the past 15 years asking government 'experts' to justify using the HTA to assess the "quality of evidence" regarding PET was from Dr. Andreas Laupacis. Dr. Laupacis the first President and CEO of the Institute for Clinical Evaluative Studies [ICES]. You have a copy of his response wherein he states:
  - I believe there is a role for the use of health technology assessment of diagnostic imaging devices.
- 5. It is also understood, and the basis of my complaints on behalf of these patients that as their physicians:
  - a. We MUST follow the 'Standards of Care as established by the Ontario Government's 'expert advisors' with respect to whether or not we would be allowed to obtain a PET/CT for our patients.
  - b. Therefore I maintain my claim that these patient's physicians, including myself, were forced to practise <u>"incompetent care"</u> for our patients.
  - c. I am assuming that Ontario physicians are still required to make 'clinical decisions and advise our patients' based on our reading of the 'medical literature' established using the accepted norms of a scientifically validated process.

#### Question 5:

Would this 'justification to set 'Standards' for investigation and treatment decisions for patients based solely on one's 'belief/faith' that

the approach was correct, apply to all Ontario physicians, or just the Ontario government designated 'physician experts'?

#### Question 6:

Does accepting that it is 'legitimate government Policy' to exempt Ontario physicians from the longstanding and Internationally accepted norms of using a validated scientific methodology/process to make critical decisions with respect to our patients now mean:

That in a potential malpractice case against a physician in Ontario, that it would be a legitimate defense to say that the physician based their investigation and treatment decisions solely on their 'belief/faith' in the validity of this approach and thus they were applying the 'Standards of Medical Care as appropriate to Ontario?

# THE PET PREDICT TRIAL AND THE DECLARATION OF HELSINKI

I am now specifically referring to the issues with respect to how experiments were, and continue to be conducted on human subjects as an integral and critical part of the **PROCESS** by which government 'medical experts' would assess PET. The government's 'experts' will then advise the Government on what their 'process' of evaluating potential roles for PET/CT has identified as having 'sufficient **quality evidence**' to consider funding in some fashion in Ontario's publicly funded healthcare system.

You may chose to take the position that what is discussed below specifically refers to an experiment on women with breast cancer, and that the patient ID 21337 had cervical cancer. The other patient had urethral cancer. However I would suggest the PET PREDICT Trial demonstrates in a vivid and disturbing manner just what lead to the unprecedented and profoundly serious and disturbing accusations made by Canadian and International PET experts with respect to how Ontario government 'experts' assessed the roles of PET for Ontario patients.

That there were clear contraventions of the accepted international norms of 'Ethical Experimental Design for Human Experimentation', makes clear the "capricious and egregious" PROCESS utilized by the

government 'experts' to assess roles for PET in Ontario.

 You are aware of the statement by the President of the Society of Nuclear Medicine in an Editorial in the Journal of Nuclear Medicine stating that the Ontario experts were "capriciously" using a scientifically baseless process (HTA) to block Ontario patients from access to PET.

The willingness of the government's 'experts' to deliberately contravene the norms of experimental design reflects what these 'experts' were prepared to do to cancer patients and that this 'line of thought' and their subsequent actions, and ultimately policies of the Ontario government <u>would lead directly</u> the unnecessary suffering of patient ID 21337.

To be specific it demonstrates:

- What the Ontario Government's 'expert advisors' were prepared to do to Ontario cancer patients, arguably some of the sickest and most distressed patients to carry out their mandate to assess PET.
- The 'egregious, unethical and immoral' nature of the PROCESS by which they would evaluate PET typifies how the PROCESS to determine that this woman with cervical cancer would NOT be allowed to have a PET/CT scan BEFORE her treatment with Radical Radiation therapy to her pelvis.

In 2009, Dr. Julian Dobranowski gave a presentation on how CCO would continue to evaluate PET in Ontario. Dr. Julian Dobranowski was appointed to be Provincial Head of Imaging for Cancer Care Ontario in 2009. After his presentation, Dr. Al Driedger who had headed the Independent Multidisciplinary Committee assessing possible roles for PET in the late 1990's, and then would become the Senior Member of the CCO PET Steering Committee, went to the public microphone and stated the following to Dr. Dobranowski. There were a large number of number of physicians, scientists, technologists, government officials and lay public at the meeting:

- 1. "I resign from the PET Steering Committee."
- 2. "I regret my having worked on this committee."
- 3. That what those who are evaluating PET (in Ontario) are doing, borders on immoral."

# PET TRIAL DESIGN ON ONTARIO PATIENTS CONTRAVENES DECLARATION OF HELSINKI

#### WHAT MS ELLIOTT AND LEGAL TEAM ARE AWARE OF:

In 2005 the Canadian Association of Nuclear Medicine [CANM] passed several unprecedented and disturbing motions with respect to the 'process' used by the Ontario Government's 'experts from Cancer Care Ontario, and colleagues as McMaster University' to design experiments on patients related to roles for PET, and then how the results would be analyzed. In particular they declared that:

- "The PET Trials in Ontario were unethical" and that they be halted immediately.
- They also demanded an investigation by Canadian experts in Ethics and Health policy to establish how this could have happened in Ontario.
  - It is important to note there was no demand to evaluate the merits of the 'science of the process to evaluate PET, as everyone, including the government's 'experts' agree there is none.
- These unprecedented motions and serious accusations by a respected professional association of Canadian physician experts in cancer imaging were dismissed by the Minister of Health, Mr. George Smitherman, and the CCO Committee Chairs.
- TO DATE THIS REVIEW OF THE 'ETHICS' HAS NOT TAKEN PLACE.
  - I have asked the various CCO committee's assessing PET, and the Senior Executives of CCO to demand that this review take place.
  - Without exception everyone involved with assessing PET/CT for the Ontario government, including Ms. Wynne and the Minister of Health, Dr. Hoskins are very proud of their efforts.
  - Surely this would be the most definitive manner in which to clear these issues up and presumably validate the 'PROCESS' by which they have assessed roles for PET/CT in Ontario
    - Not a single CCO committee chair or otherwise has supported finally carrying out this 2005 motion by the CANM.

■ In addition they have not challenged the motions, or acknowledged these statements in any responses to my questions and concerns.

The PET PREDICT TRIAL violates several serious fundamental aspects of experiments performed on humans as defined by the Declaration of Helsinki. This includes:

- 1. The PET PREDICT TRIAL was knowingly and deliberately designed to fail. This is a direct contravention of the "Ethical Design of Experiments" on human subjects.
  - a. The PET camera <u>was not physically capable of detecting the</u>
    <u>vast majority of the cancers the participants were told the</u>
    <u>'government physician experts' were trying to detect.</u>
- 2. The PET scans would expose those entering the experiment to between 300-400 chest x-rays worth or radiation.
  - The harmful effects of radiation to patients are cumulative over time and thus the more ionizing radiation patients are exposed to over their life, the greater the risk of developing a cancer related to their radiation exposure.
  - For women who would go on to more advanced stages of breast cancer where therapeutic radiation might be indicated, there cumulative exposure to ionizing radiation could limit how effective a treatment dose could be given to the patient.
- 3. Ethical trial design requires that patients considering entering the trial must be given all the relevant information, including points of controversy that would go beyond the explanations patients are informed about before a medical test or treatment. They clearly need this information so they can make an informed decision to enter the trial or not.
  - I am not absolutely certain that the patient's were not told the PET camera was not capable of detecting the cancers they were told the experimenters were looking for. However, it would be hard to imagine someone would enter the trial if they were fully aware of this.
    - 1. One might have imagined this would be something the Ombudsman would want to find out about.
  - They were not told that the trial was designed and the resulting data would be analyzed using a <u>scientifically</u> <u>baseless process</u>.

- They were not told, as Dr. Dobranowski confirmed in 2009, that the actual purpose of the experiment was NOT to assess PET, but to use PET (implying it was ALREADY an acceptable standard) to VALIDATE THE USE OF THE HTA TO EVALUATE PET.
- 4. That these women considering entering this experiment were likely in a state of significant anxiety and stress. There would now be the added stress of waiting for their appointment for the PET scan; then lying inside the PET scanner after their intravenous injection of the radioactive tracer; then waiting to hear from their doctor, the results of the scan.
  - Thus the government's 'experts' involved in the trial design were knowingly and therefore DELIBERATELY and UNNECESSARILY increasing the already high stress levels these women and their families were experiencing.
  - I would suggest that this was an "unconscionable and cruel" act by the government's 'experts' and consistent with the statement of Dr. Al Driedger quoted above, that these actions should be considered, "bordering on", if not defining, 'immoral experimental design' on cancer patients.
- 5. It is also critical to note that <u>all the PET/CT exams performed on the</u> <u>women entering the PET PREDICT TRIAL took place in 'publicly</u> funded Ontario hospitals.'
- 6. In addition ethical experimental design of experiments on humans must follow the principle of Equipoise. That is, if it is clear that the experiment will fail, *it must be halted immediately.* 
  - Given that the experiment was designed to fail, it would have been immediately apparent that the experiment would fail.
  - However, the experiment was not stopped, and over 300 women were put this is "unethical and bordering on immoral" trial.
  - Given that this experiment had to be approved by the McMaster University Ethics Review Committee it begs the questions of:
    - 1. Why did they give approval for this trial in the first place?
    - 2. Why did they not stop the trial when it was obvious it would fail?

#### PREAMBLE TO RELEVANT QUESTIONS FOR YOU TO ADDRESS:

It would be reasonable for Ontario patients, my colleagues, and indeed anyone living in Ontario and subject to the 'Wynne/Hoskins: "Evidence-Based, Patients

First' Health Care Policies, to assume that designing and carrying out unethical experiments on cancer patients for any reason by the government's medical experts would be exactly the kind of issue, that Ms. Elliott, as Ontario's PATIENT Ombudsman would be responsible for.

However, in spite of having full knowledge backed by appropriate documentation, that "unethical experiments were carried out knowingly and deliberately by government 'medical experts' your ruling on this matter does not even contain any mention of what most would consider to be a profoundly disturbing act by these 'experts'. Therefore it would be reasonable to assume one of two possibilities:

- 1. Such actions by Ontario government 'medical experts' is consistent with therefore a good example of "Excellent Care for All".
- 2. Such matters are not within the mandate as covered by this 2010 Act outlining Ms. Elliott's roles and responsibilities.

# SPECIFICALLY WITH RESPECT TO THE PET PREDICT TRIAL DECLARED UNETHICAL BY CANM IN 2005

#### **POINT OF CLARIFICATION 4:**

It is a matter of established fact that the "unethical, and bordering on immoral" actions of the government's 'medical experts' and all investigations and PET/CT exams as part of CCO designed PET experiments on patients took place fully within publicly funded Ontario hospitals.

Please state clearly why there was not any acknowledgement or mention in your ruling of such serious and unprecedented actions by Ontario government 'experts' directly impacting 'Ontario Patients' and leading inevitably to the unnecessary and severe physical and emotional suffering of the patient and a profound and severe impact on Ontario patients in general:

#### Question 7:

Given that all of these 'experimental' PET scans were performed on these patients *in publicly funded hospitals, why this would not be covered under the Patient Ombudsman's mandate?* 

#### PART C:

### ISSUES RELATED TO YOUR AGREEMENT WITH THE PREVIOUS RULINGS OF THE OMBUDSMAN'S OFFICE OF ONTARIO

Let us now assume that it is <u>not your position</u> that the decision to "evaluate the quality of evidence and design experiments on cancer patients and interpret the results" was based on official and fully documented government "policy".

#### RELEVANT FACTS FOR PART C:

- That EVERY issue that my colleagues and I raised with the Mr. Marin, <u>TOOK PLACE BEFORE ANY PUBLIC POLICIES ON PET IN</u>

   ONTARIO WERE IN PLACE WHICH WAS IN 2009.
- Therefore, in fact, the issues we asked Mr. Marin to consider were entirely about the 'methodologies' in which the government's 'experts' would assess PET in Ontario and this very clearly is about the <u>PROCESS</u> by which the Ontario Government's 'experts' would base their advice to the Government on and from which the government would then determine POLICIES RELEVANT TO PET USAGE IN ONTARIO.

Therefore it would be appropriately considered with the mandate of the Ontario Ombudsman's Office:

• "The Deputy Ombudsman confirmed that their prior investigation was "focused on concerns relating to process,"

However, you have ruled that what Mr. Marin, and Mr. Dube were asked to consider on was the 'merits of established government policy', which we have already agreed, would not be covered in the mandate of the Ombudsman's Office.

### YOUR DEFENSE OF THE OMBUDSMAN OF ONTARIO'S CONCLUSIONS ABOUT ASSESSING PET IN ONTARIO:

Therefore as I have previously challenged the Ombudsman's Office:

I would respectfully request that you provide all the necessary

documentation, and in particular:

- Listing the examples of the 'established government policies with respect to PET' that you are claiming my colleagues and I asked the Ombudsman's Office to review.
- Specifically making clear why issues my colleagues and I raised such as: the use of a 'medical poster' to halt the introduction of PET in Ontario; the 'elevation of this medical poster to a Level A quality medical reference; the downgrading of Level A/B papers that favoured PET to unacceptable Level C/D papers; the 'methodological tools such as health technology assessment' in the design of experiments on patients and evaluation of the results; WERE NOT ABOUT THE PROCESS RELATED TO HOW GOVERNMENT EXPERTS DETERMINED POSSIBLE ROLES FOR PET IN ONTARIO.

#### **CONCLUSIONS:**

I would respectfully ask that you answer the above questions and requests for documents and the defense of your legal positions on these matters fully and in a clear and specific manner, at a level that patients can follow, and where appropriate with appropriate legal or otherwise backing documentation.

Given the length of time you have had to carefully consider the 'legal position' of what Ms. Elliott has concluded, it should not require much time to clear up the issues I have raised. As I am sure you can appreciate, patient ID 21337's surviving family members in particular would like to bring this issue to resolution as soon as possible

Respectfully Submitted:

Dr. Dave Webster