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Dear Senior Executives of CCO, Chairman of the CCO Board, and CCO Committee Chairs:

ISSUES RAISED TO CCO COMMITTEES AND OTHER GOVERNMENT GROUPS RELATED TO HOW THEY EVALUATE PET/CT FOR THE ONTARIO GOVERNMENT:

NOTE:

As outlined in the introductory letter to this series of letters:

- *I will be using Dr. Hoskins' demands for evidence to justify imaging tests performed on patients, and with a particular emphasis on the total radiation exposure to patients from their diagnostic imaging tests, where appropriate.*
- *Unless someone is able to finally provide evidence with sufficient power and widespread international based agreement to support the use of Health Technology Assessment [HTA] in keeping with the 'extreme position' the Ontario Liberal Government has taken on PET:*
    - *No HTA evidence will be allowed to justify the positions of the various Cancer Care Ontario [CCO] committees or their colleagues at the McMaster School of Evidence Based Medicine, with respect to the use of PET scans for Ontario patients.*

I sent a letter to Dr. Andreas Laupacis, the first President and CEO of the Institute for Clinical Evaluative Studies [ICES] asking that since everyone agreed that there was no scientific evidence to justify the use of HTA to assess PET or any diagnostic imaging device, how did he justify using HTA to assess PET? In his response he does not offer any evidence to support HTA. He proudly states that his justification to use HTA is based on his "faith" that there is a role for HTA to evaluate imaging devices for patients. It is clear that in a court of law such claims as a defense of how physicians investigate or treat their patients would not be allowed. These documents will be sent as an accompanying document.

PREAMBLE OF GENERAL ISSUES:

The PET PREDICT TRIAL was developed by the PET Steering Committee [PSC] and sponsored by the Institute for Clinical Evaluative Studies. [ICES]

What has been established to date is as follows but please feel to challenge and offer appropriate documentation and literature challenging anything felt to be inaccurate so that adjustments can be made if necessary. These positions and medical literature will then be sent to the appropriate physicians and medical associations who have made claims at odds with the Ontario government's 'medical and scientific experts' evaluating PET.

A: Based on a conversation with Dr. Julian Dobranowski and various letters the following is true:

1. CCO is aware that there is no scientific basis or justification sufficient to assess PET or any other diagnostic imaging device with HTA.
2. However, CCO will continue to use HTA to assess PET for use in Ontario.
3. That patients entering trials were not informed that there was no basis to use HTA to design the PET trials in Ontario, nor to evaluate the results of these experiments in contravention of being fully informed for human experimental trials.
4. That the actual purpose of the PET Trials was NOT to evaluate PET, but *to use PET to try and validate HTA.*

In the CCO document:

> Cancer Imaging Program,
> Cancer Care Ontario
> Strategic Directions
>
> Timely Access to
> Quality Imaging
> January 2012

This 'Mission Statement', among other things makes clear that they intend to be "transparent" and with "Active Engagement" which I will take to mean, active engagement with the non-government medical practitioners and in this case, specifically with Specialists in Radiology and Nuclear Medicine.

I was President of the Ontario Association of Nuclear Medicine [OANM] starting in around 2004 when the most active engagement with the Ontario Ministry of Health took place with respect to our concerns about PET was to be assessed by CCO and it's McMaster colleagues. We had hired Mr. Michael McCarthy as our lobbyist. Mr. McCarthy had been the Senior Assistant the Minister of Health, Mr. Tony Clement, when the initial decisions were being made about not to fund PET because of cost concerns and how CCO was to achieve this goal. CCO would partner with colleagues at McMaster University to discredit, delay and block PET.

Mr. McCarthy had been in attendance at these meetings and thus was fully informed of the issues of concern for my colleagues and me. He would accompany us to all the meetings we had at Queen's Park with various Ministry of Health Officials. The last one my executive, Mr.

McCarthy, and I took part in was with Mr. Ali Samiian who was the Senior Assistant to the Minister of Health, Mr. George Smitherman and took place in September of 2004.

Our approach up to this point was to be professional and respectful in these meetings and that this was all done without pubic notices or discussion. A follow up letter to the meetings would then be sent with specific questions to be answered.

- In most cases there was not even an acknowledgement that we had met, and whenever there was a response to our letter of inquiry, without exception, not a single question of importance or relevance was addressed.
- At this meeting I advised Mr. Samiian that given their lack of respect and professionalism to our concerns that we would now have to make our concerns known to the public.

NOTICE:

The response of the government and CCO to my advocacy efforts for Ontario's patients has been to threaten me with loss of my hospital privileges. In addition, CCO has registered a complaint to the College of Physicians and Surgeons of Ontario [CPSO] and I am being formally investigated.

- I was previously reprimanded by the CPSO based on a letter I sent to Dr. Bill Evans who was the Chair of the PSC. It was a 'strong and emotional letter' because of my passion for my patient advocacy efforts and my extreme frustration with the complete stonewalling of my colleagues and me. However there were no threats made to Dr. Evans or anyone else from CCO.
- It is worth noting, by this time, Dr. Al Driedger, the Senior Member of the PSC had bypassed the Chair, Dr. Evans, and written directly to Mr. Smitherman. Among other issues raised in this letter was Dr. Driedger's accusations that the CCO 'medical experts' were deliberately denying evidence that favoured PET.
    - *Dr. Driedger's accusations were confirmed and elaborated upon in a 2011 Journal of Nuclear Medicine Article by Dr. Ware and Hicks.*
    - ***I**n 2009, Dr. Driedger publicly resigned from the PSC and declared what those blocking PET were doing "bordered on immoral".*
- Although required by provincial law to have someone from his office acknowledge and make some response to this letter from Dr. Driedger, Mr. Smitherman would refuse on more than one occasion to do so.
    - *Mr. Smitherman set the precedent for refusing to acknowledge or answer questions submitted regarding PET to Ministry Officials and CCO and their colleagues at McMaster University.*
- On one occasion I had been unprofessional in my response to Dr. Evans in front of a newspaper journalist, but I had unconditionally apologized for that error in judgement.
- In the letter that lead to my reprimand by the CPSO, I had said to Dr. Evans that since you are the Chair of the PSC then you should be answering the questions everyone is

refusing to acknowledge or answer. Specifically I asked him about the scientific validity and justification for using HTA to evaluate PET.
- Instead of answering my questions reported me to the CPSO as “threatening and harassing him”. They agreed, and I was reprimanded.
- In response, *I made available to the CPSO all the documents, including the 2005 CANM motions declaring the actions of the PSC as “unethical”, and making clear what CCO was doing on behalf of the Liberal Government.*
- *The conclusion of the Registrar of the CPSO, <u>was they saw no problems with how CCO was evaluating PET.</u>*

Thus in spite of having all the necessary documents including more recent ones related to the “unethical and bordering on immoral actions” of the CCO Committees, the Registrar has chosen to threaten me again.

As a result of the CPSO investigation I have retained a lawyer from the Canadian Association of Medical Protection [CMPA].

- I have a legal opinion from my CMPA lawyer that those serving on CCO committees are considered acting as ‘public servants’ and as such ***<u>are expected to be open transparent and accountable, IN THE PUBLIC SPHERE for their actions.</u>***

Therefore it is my expectation and that of Ontario’s physicians and patients that the government’s medical experts assessing PET in Ontario will answer the questions submitted in this document.

- *It is also acknowledged as fact that with the single exception of the response from Dr. Laupacis, my repeated letters to the various CCO committee members have refused to address the critical issues I have put to them for consideration.*
- *That members of PET ACCESS have refused to acknowledge or to respond to questions submitted to them by cancer patients. Questions they have the right to expect to be answered, particularly since they were addressed to the physicians that would determine whether or not they would be allowed a PET/CT scan.*

As I made clear to the CPSO, every aspect of my investigation and possible disciplinary action will be made public, even though as a private practice physician I am not obligated to do so. My position is that if I’m the kind of doctor that Ontario patients should be protected from, then I deserve my punishment, and will do so publicly.

<u>THEREFORE:</u>

- *This and all subsequent documents related to the issues at hand, and any response, or lack of responses to these issues will be made widely available to the public.*

QUESTIONS PART A:

1. *Please explain in detail why the various CCO committees knowingly used the HTA to evaluate PET given it's lack of established evidence to support its use, particularly in light of the end result for Ontario's patients and the unprecedented condemnation of these trials by Canadian and International PET experts.*

With respect to the mission statement of the CCO Imaging Group:

2. *Why have CCO Committee's and physicians, with but one exception, refused to defend the use of HTA to evaluate PET?*
3. *Do the Committee members agree with the statement of Dr Laupacis the original President and CEO of ICES, that all that was required to justify the use of HTA was his FAITH in the process?*

B: **STATEMENT:**

The PSC [PSC] took the public position that the PET Trials and their design would be open and transparent and that experts were invited to participate.

REALITY:

The handling of PET in Ontario has generated the most serious and unprecedented concerns and official motions by the Nuclear Medicine community against those assessing PET for the Ontario government in modern medical times. The trials were written in secret and repeated attempts by the Ontario Association of Nuclear Medicine [OANM] and others who were PET experts to be part of the trial designs were rejected by the PSC. In the 2009 JCO paper by Evans et al, and statements made in the press this process is presented as one of the best examples of cooperation amongst physicians in Ontario to introduce PET.

> *"First, oncologists and nuclear medicine physicians, who, in Canada, have rarely collaborated on research have worked together to design and execute clinical trials."*
>
> *'..standardizing how PET scans were performed and reported, and gaining acceptance by health professionals for the evaluative program.'*

The only way that the OANM physicians were able to see what was happening in the trial design was that someone from the PSC, leaked copies to the executive.

- The one true PET expert on the PSC was Dr. Kevin Tracey who was removed from the PSC in part because of his insistence the evaluation of PET be carried out using the accepted norm of scientific peer reviewed literature. It is noted that in a malpractice suit

against a physician, this would be demanded, and not treatment and investigations based on the physician's personal *"beliefs"* in what the lawsuit from a patient entailed.

- Repeated attempts by the OANM to have Dr. Tracey's position on the committee replaced by a qualified PET Nuclear Physician were rejected by the PSC.
- At the time of writing the trials it had been established that to be considered an adequately trained and qualified PET physician, that they:
    - *Be a certified Nuclear Medicine physician and should have at least three months training at a recognized PET center of excellence.*
    - *That this training MUST take place outside Ontario, since no PET centre in Ontario did sufficient PET work to allow a Nuclear Medicine Physician to get adequate training.*
- To the best of my knowledge, no one involved in designing the PET trials, and in particular the PET PREDICT Trial had the minimal recommended qualifications.
- In articles written about the use of HTA, the point has been made that HTA uses try if at all possible to avoid the involvement of actual experts in the particular field that HTA is being applied to:
    - *This because they would be biased and thus best to have those using HTA to have little or no expertise in the studies, in this case involving PET.*
    - *Although there is some truth in this assumption, the nature of peer reviewed literature is that this will eventually be exposed and resolved.*

QUESTIONS PART B:

1. *Why were the PSC Trials written in secret and the repeated effort of the OANM to have fully qualified PET experts involved rejected?*
2. *Why have those from CCO claimed that there was such excellent co-operation between the CCO experts and the Canadian Nuclear Medicine community when in reality there has never been a more divisive issue amongst Canadian Nuclear Medicine community?*

C:POSTER PRESENTATION STOPS THE INTRODUCTION OF PET IN ONTARIO:

In the late 1990's a Multidisciplinary Team of experts in Diagnostic Imaging and Oncology looked at the literature on PET for five possible indications for PET. Amongst their recommendations was that anywhere from 24 to 40,000 patients would benefit from PET scans as part of their imaging management of their diseases. They went to their final meeting expecting to that PET would finally be available to Ontario patients much like it already was in places like Chile.

- *A Ministry of Health representative presented a 35mm slide of a 'poster presentation' on a couple of pieces of bristol board at an Australian Medical meeting claiming that PET did not change lung cancer management.*
    - *At this time the use of PET in such situations was essentially already established as the accepted standard of investigation.*

        - *Dr. Al Driedger presented an email to the PSC from an expert from the NIH in Bethesda making clear that what was being proposed as an experiment regarding the role of PET in lung nodules and cancer was already the accepted standard of investigation.*
        - *In addition, at least in the earlier stages of the PET trial on lung nodule patients, those subjects being asked to participate were not informed that this discrepancy in the position of the CCO committees and the world PET expert community existed.*
- *On the strength of this single 'poster' the government announced that given the controversy surrounding PET the MOH would have to do it's own PET studies to determine what if any roles there would be for PET.*
- *The first report from ICES concluded that ZERO patients would benefit from PET because of the 'poor quality of papers'. Dr. Laupacis made clear how proud he is of this report.*
    - *We have already established that this assessment was made using a tool that had no scientific basis to assess the quality of the papers that were rejected due to lack of evidence.*
    - *In 2004, Dr. Driedger bypassed the Chairman of the PSC and wrote to the Minister of Health, Mr. George Smitherman. Dr. Driedger made the accusation that the government members of the PSC were downplaying evidence that favoured PET. Mr. Smitherman refused to respond to this letter on more than one occasion.*
    - *A 2011 paper by Drs. Ware and Hicks in the Journal of Nuclear Medicine confirmed the role of this medical poster in blocking PET; that even though the published paper from this poster was ultimately rejected by the PET community due to significant population bias issues, it was considered a "quality evidence" paper by CCO;, that level A/B papers favouring PET were 'demoted' to the "poor quality medicine" category.*

<u>QUESTIONS PART C:</u>

1. *Do committee members support the use of the 'poster presentation' to overturn the conclusions of the Multidisciplinary Committee?*
2. *Do committee members support that this poster was sufficient to justify the need for Ontario to perform its own PET Trials through various Cancer Care Ontario committees which would be set up to do so?*
3. *Do committee members reject the findings of the 2011 paper by Ware and Hicks?*

If anyone chooses to disagree with Dr. Driedger or challenge the paper written by Drs Ware and Hicks, I would be happy to send your rebuttals to them.

2016 STATEMENT BY PROFESSOR RODNEY HICKS TO ME IN AN EMAIL REGARDING PET ISSUES:

"Ontario has the most egregious and politically motivated agenda against PET in the world."

D: THE PET PREDICT TRIAL VERSION ONE:

One of the mandates of the PSC amongst others, was to set up experiments to determine what would be the most appropriate roles if any for particular cancers.

When it came to the issue of possible roles for breast cancer, I think everyone will at least agree on the fact that *the Ontario Ministry of Health and Cancer Care Ontario Committees made 'very special efforts' to in the end, and still present to this day, block women with locally advanced breast cancer from access to PET/CT exams on a routine basis.*

TIMELINE:

- The OANM executive were aware they were finalizing the PET Breast Trial.
- A copy was leaked to us. We were shocked when we read it. Instead of proposing an experiment that would determine a role for PET in women with breast cancer:
    - *They deliberately designed the experiment to fail!*
    - *This is blatantly "unethical" and against an document on guidelines for experimenting on humans.*
    - *They chose women with early stage breast cancer where they would be expected to have small lesions and by definition most likely that they either did not have axillary metastasis, or that if they did they would only allow one such metastasis to be greater than 2 mm in size. The goal of the experiment however was to determine if there was a role for PET in detecting axillary metastasis.*
        - ***There was not then or now a macroscopic diagnostic imaging device that can detect disease of the size these patients were carefully chosen and assumed to have, and then entered in to the trial.***
    - *It was well established at this time, that based on the imaging characteristics of the standard PET camera's of the time that they were often missing breast cancers, within the breast as much as two centimeters in size.*
        - *The resolution would be expected to be worse in the axilla and clearly no PET scanner or any imaging device would be able to pick up microscopic metastasis.*
- **IN SHORT:**
    - ***The PET camera was incapable of seeing the very cancers they would tell women considering entering the trial, they would be looking for.***

The OANM Executive declared this an “unconscionable’ action, and considering that the radiation dose to these patients would be equivalent to approximately 300-400 plain chest x-rays, that this was an assault on these women!

- *A more egregious and potentially harmful aspect of the trial was the experimenters would be fully aware and therefore would deliberately cause an unnecessary increase the already high level of stress levels these women were likely to be experiencing. This would at least include the waiting for their appointment; lying in the scanner; and then waiting to go to their physicians for the report.*
- Without explanation the trial was pulled. It would be almost two years before a new version would be put forward. I had numerous email exchanges with Dr. Bill Evans, the Chairman of the PSC.
- Dr. Evans assured me that they were all working very hard on getting the new version out.
    - The delay fit nicely into the ‘tools’ used to ‘delay’ the introduction of PET.
- The new version was again leaked to the OANM Executive.
- After reading it over the conference call, there was stunned silence!
    - *The ‘new and improved version’ was IDENTICAL to the first version with such a trivial addition to it that it was laughable, something that could be given to a FIrst Year Nuclear Medicine Resident as a project.*
    - ***In short the “unethical” design concerns of PET experts and Canadian Nuclear Medicine Community were untouched.***
    - This lead to a press conference at Queen’s Park with the new President of the OANM speaking, Dr. Christopher O’Brien and taking questions.
- There was no outcry from politicians or the media.
- Behind the scenes there was much discussion I was involved with since I had just finished my full PET training requirements to be considered an expert in PET at UCLA. It was in preparation for the 2005 meeting of the Canadian Association of Nuclear Medicine to be held in Vancouver, that these discussions took place with respect to *this egregious issue blatantly using these women terrified with their new diagnosis of breast cancer as mere pawns in their game to block PET.*
- Several motions were passed by the CANM at the 2005 meeting. In short:
    - 1. The CCO PET trials in Ontario were declared “unethical”.
    - 2. The Trials must be stopped immediately.
    - 3.***That a panel of acknowledged Canadian experts in Medical Ethics and Health Policy be put in place to determine how this could have happened in Ontario.***
- The motions were rejected and ignored by the Minister of Health Mr. George Smitherman, the PSC and the various CCO groups.

SECTION E:
PET PREDICT VERSION 2:

The PET PREDICT TRIAL was carried out and finally completed and published demonstrating what it set out to do:

- ***That PET scanning was not indicated in early stage breast cancer.***

QUESTIONS REGARDING SECTION E:

PET PREDICT TRIAL DESIGN:

QUESTION 1:

> *Why did the PSC design the PET PREDICT TRIAL to fail in light of the fact that PET cameras were NOT physically capable of identifying the axillary metastasis the patients were told the researchers were trying to detect?*

INFORMED CONSENT TO ENTER PET PREDICT TRIAL:

The principles of ethical human experimentation demands that subjects being asked to enter an experiment are expected to be given a far more detailed discussion of not just all the aspects and intentions of the trial, but *controversies* related to the experiment, and detailed discussion of risks. The following is from a course on ethical human research that I completed at the National Institute of Health in Bethesda Maryland under the section on INFORMED CONSENT it was stated: (emphasis added)

> "Informed consent in research means more than simply obtaining the signature of the potential research participant. It is a process that involves *conveying accurate and relevant information about the study and its purpose*; disclosing known risks, *benefits, alternatives*, and procedures; answering questions; and *enabling the potential participant to make an informed decision about whether to participate."*

Under ELEMENTS OF CONSENT: (again emphasis added)

> "***The research team must DISCLOSE all relevant information to the potential participant***. The information must be sufficient to allow the potential participant to decide whether to participate. It is generally accepted that the potential participant must be given the following information: the purpose of the study; nature of the procedure; reasonable alternatives to the proposed intervention; and risks, benefits, and uncertainties of each possible intervention."

QUESTION 2:

In light of the CANM motions, and the clear expectations of ethical research for the subjects to be adequately informed why were potential entrants NOT INFORMED:

- *2a. That there was NO validation to support the use of HTA in the design and/or evaluation of this trial?*
- *2b. That the PET cameras were not physically capable of detecting the cancers the women were suspected to have that entered the trial?*
- *2c.That at the time of the trial the science based medical literature had already confidently shown that PET was not of any use in Stage I or II breast cancer because of the small size of the metastasis of which the PET cameras were not capable of detecting?*
- *2d. Given that patients are supposed to be informed of any issues of potential contentiousness relevant to the proposed experiment, why were these women not told of the unprecedented and serious concerns raised by Canadian and International PET experts with respect to the trial design including the fact that the PET PREDICT TRIAL in both versions had been declared "unethical"?*
- *2e. Were the trial subjects told that the significant radiation dose they would receive from the PET experiment was not medically indicated, and the subsequent lifetime risks from this radiation exposure in light of the fact that risks from radiation are cumulative?*

In a 2009 discussion with Dr. Julian Dobranowski, Provincial Head of Cancer Imaging, Cancer Care Ontario agreed that there was no scientific basis or validation to use HTA to assess any piece of diagnostic imaging equipment, PET, CT or otherwise. I asked him the following question to which he shrugged his shoulders which I took to indicate agreement, and did not challenge this statement in a subsequent letter I sent to him in 2010.

- *That the purpose of the "PET TRIALS" was not about evaluating PET, but using PET to try and validate health technology assessment."*
- *Those considering entering the trial were not told this critical information. This also becomes very relevant to ongoing experiments on patients through the McMaster School of Evidence Based Medicine.*

QUESTION 3:

Why were the women being asked to participate in the PET Trials not told the true purpose/aim of the PET Trials use PET to try and validate the health technology assessment tool, and not to determine appropriate roles for PET?

THE PRINCIPLE OF EQUIPOISE:

Besides approving trials and experiments on humans, research ethics committees must follow the progress of the trial to ensure that it remains compliant to all the principles of ethics.

Principles of Ethical Experimental design are clear:

A: If it becomes clear during the trial that the principle in question is clear the correct answer then the trial must be stopped and everyone gets the drug.

B: Equally true *is that if it clear the experiment will fail THEN IT MUST BE STOPPED IMMEDIATELY.*

Given the trial was by its very design meant to fail, the PET PREDICT TRIAL should have been stopped almost immediately after it began and certainly after less than 20 patients had completed the trial.

- *Instead more than 300 women were knowingly and deliberately exposed to non-medically indicated and therefore harmful radiation from the PET scans as a result of taking part in the PET PREDICT TRIAL*.

QUESTION 4:

> *Why did the PSC and those involved with the PET PREDICT TRIAL NOT halt the trial when it became obvious that the trial would fail in keeping with the principle of equipoise?*

WOMEN EXCLUDED FROM THE PET PREDICT TRIAL:

Using the accepted methods of science and medical based literature it was established that women with locally advanced and more advanced forms of breast cancer could obtain significant benefit from a PET scan.

QUESTION 5:

> *Why did the PSC in trial design of the PET PREDICT TRIAL exclude the patients that the accepted standards of science based and peer reviewed literature had established to an acceptable degree of certainty had the potential for significant benefit from a PET/CT scan?*

UNNECESSARY ADDED STRESS TO PATIENTS AND THEIR SUPPORT GROUPS:

Given that it would be reasonable to expect that many of the patients considering entering this trial would have been under enormous personal stress with their new diagnosis of breast cancer; and given that it is acknowledged that waiting for various investigations of their cancer, and undergoing various investigations and waiting for an appointment to find out the results of investigations is very stressful to patients and their support groups; *and that these patients would be desperately looking for reassurances and would trust those asking them to take part in the PET PREDICT TRIAL:*

QUESTION 6:

> *Why did the PSC deliberately put these women through what was clearly unnecessary EXTRA STRESS knowing already the results of the trial and that the trial would fail?*

PRIDE EXPRESSED BY THE VARIOUS GOVERNMENT EXPERTS IN THEIR EFFORTS TO EVALUATE PET FOR THE ONTARIO GOVERNMENT:

Without exception, and including letters of support from our recent Minister of Health, Dr. Eric Hoskins speaking on behalf of himself and Ms. Wynne, that everyone is very proud of their efforts to assess PET in Ontario. In the 2009 paper in the JCO by Evans et al. the methodology used to evaluate PET by the various government medical experts is offered up to the world medical community as an excellent example of how to investigate new imaging technologies. Dr. Laupacis made clear how proud he was of the two first two reports he was involved with from ICES.

Presumably you would all support the statement made to me in 2004 by the Senior Medical Advisor to the Ontario Ministry of Health, Dr. Les Levin, when I met with him regarding questions the OANM had about how PET was being evaluated.

- *“Dave, it is not about the money, it is about doing what is best for Ontario’s cancer patients”.*

In light of the enthusiasm and pride expressed with the PET Trials in Ontario and in keeping with the responsibilities of individuals working in the capacity of a “public servant”, and in particular involved in the process of coming with health care policies of the government, one of the biggest issues of concern for voters in Ontario:

3. *Is the PSC and the various CCO groups, and your colleagues from the McMaster School of Evidence Based medicine prepared to release a statement to the women who took part in the PET PREDICT Trial and the breast cancer patients living in Ontario today justifying your pride in your efforts and in keeping with the statement from Dr. Les Levin?*

If those involved with these PET trials are not prepared to reassure the participants in the PET PREDICT TRIAL and women living today in Ontario with breast cancer about your efforts, and the direct and profoundly important impact it is having on patients, then *it is expected and indeed demanded that you make clear why you are not prepared to meet the requirements of our supposed open, transparent and accountable democracy.*

SECTION F:

THE USE OF THREATS AND INTIMIDATION BY THE ONTARIO GOVERNMENT AND CCO:

Over the years I have repeatedly made the statements to colleagues, patients, and during lectures that:

- ***The Ontario Liberal Ministry of Health and Cancer Care Ontario works by threats and intimidation.***

In January of this year I was consulted by some oncologists of the appropriate imaging management of their patients in light of my expertise and knowledge regarding PET. It was my recommendation based on the current accepted, and legally demanded, process by which as a physician I make decisions, that a patient with cervical cancer should have a PET/CT to appropriately stage her and thus make informed decisions about her management and prognosis. This was refused. We were forced to use the CCO 'standards of investigation' appropriate to the mid to late 1990's'. As a result it was determined she would benefit from radical radiation therapy to her pelvis followed by surgery.

She was only allowed a PET/CT after her therapy which demonstrated correctly that she was Stage IV from the beginning, the *radical radiation therapy she underwent would have been contraindicated.* In addition, a McMaster surgeon had been consulted on the patients case. The patient who was a nurse and thus understood the medical aspects asked the surgeon an entirely appropriate question. "Will I now be followed by PET/CT instead of just CT scans?" The response of the surgeon was to insult the integrity and professionalism of this women. The response was:

- *"You will only be allowed a PET/CT if your CT is not definitive."*
- *The patient fully understood that it was because her CT and MR exams were not definitive that she was now having to face a terminal disease but now suffering from unnecessary and severe complications from the radical radiation therapy to her pelvis.*
- *In addition she understood fully that the CT and MR exams were inherently incapable of being definitive. The PET/CT appropriately demonstrated that she had metastatic disease:*
    - *<u>In normal sized lymph nodes by CT and MR criteria!</u>*

In addition, given that patients in Ontario are fully entitled to have their questions and concerns about proposed investigations and therapies, she submitted her questions to PET ACCESS. Given that this was the group that would determine whether or not and when she was allowed a PET/CT exam, this would be entirely appropriate. The response of PET ACCESS initially was to inform me I was not allowed to order PET/CT exams on this patient, even though initially they had no problem with allowing me to do this.

- *PET ACCESS repeatedly refused to provide the documentation stating that I would not be allowed to order a PET/CT for this patient.*

When this approach didn't intimidate me, someone from Cancer Care Ontario spoke with the administration of the hospital where this consult had taken place. It was made clear that the hospital administration was to shut down my efforts on PET. I was told that I could no longer be involved with advocating for patients with respect to PET, and that I would not be allowed to use any case examples to demonstrate my points, even when no patient identifiers were included.

This was eventually made in person from a physician in the hospital associated with CCO. But I was also told:

- *"But CCO still wants you to continue to advocate for PET for patients in Ontario."*

It was clear from conversations with the referring oncologists and their patients, that these physicians *were also told to cease and desist from using science based literature to advise their patients with respect to PET. They must use the CCO determined 'standards of investigation'.*

As it currently stands:

> *If I continue to speak to physicians and/or patients about how PET is being assessed in Ontario, or supply them with the supporting documentation, or use PET case examples publicly to demonstrate my points, and even without patient identifiers, they will block my hospital privileges.*

In addition, CCO registered a complaint to the CPSO, and in September I was notified by the Registrar of the CPSO that an investigation into my advocacy efforts was being initiated.

<u>QUESTION 1 SECTION F:</u>

> *Does the PSC and the various CCO committees involved with assessing PET for the Ontario government support the use of threats and intimidation to my ability to work as a physician if I give physicians and patients access to the documents from Canadian and International experts, physicians and professional associations with respect to how CCO*

and their McMaster colleagues evaluate PET/CT which will ultimately be used by the Ontario government to write health care policies affecting Ontario patients?

Respectfully submitted

Dr. Dave Webster.