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December 31, 16

Dr. Ur Metser Chairman
PET Steering Committee

RE:PET Steering Committee and PET [PSC] in Ontario

Dear Dr. Metser

I fully realize that you were not involved with the PET Steering Committee at its inception, and during much of the most controversial issues surrounding the assessment of PET in Ontario. However just like being a 'co-authors' on a medical publication you along with other committee members who are more recent members will need to be able to defend the previous actions of the PSC, unless you are willing to officially reject their actions and conclusions. Everyone will of course be accountable and responsible for their own actions and positions taken while they remain on the committee.

Although this letter is addressed to you, Dr Metser, I am addressing you as the Chairman of the PET Steering Committee and would ask that you distribute this letter and subsequent letters and documents to all members of the committee.

BACKGROUND:

My name is Dr. Dave Webster and I am a Nuclear Medicine physician, with full training in PET. I ran the first private PET facility east of Vancouver as well as the first MOBILE PET unit in Canada. I have training in England, several sites in the US and in Sherbrook Quebec with Dr. Francois Bernard and have given numerous lectures on PET to professional and lay groups, at four different medical school campuses, and have been an invited speaker at Provincial level meetings.

I also served as the President of the Ontario Association of Nuclear Medicine [OANM] during the early critical and highly controversial early period of the Ontario Ministry of Health assessment of PET. To say the assessment of PET in Ontario is "controversial" is a gross understatement, and remains so to this day. There are a number of unresolved issues, unanswered questions submitted to various MOH groups tasked with assessing PET and disturbing and unprecedented motions from

the Canadian Association of Nuclear Medicine [CANM] which have not been acted on.

I have spent the better part of the last 15 years trying in vain to get the MOH, and the various Cancer Care Ontario Committees to defend the manner in which PET has been assessed in Ontario. I have made a promise to myself and my patients and colleagues that I will not rest until those assessing PET stand and defend their methodology and various methods, which I charge, have been intentionally used to discredit, delay and ultimately block patients from PET, uniquely in the civilized medical world.

The impact on Ontario's patients has more than once been called a "travesty" both in the Media, and by individuals familiar with the situation. Notwithstanding the claims I have heard over the years, and continue to hear, about how proud everyone is about how they handled PET over all these years, the condemnation from 'non-government' medical experts has been unprecedented. PET experts and others have described the efforts to block PET in Ontario in very disturbing terms.

- ***"unethical", "arbitrary and capricious", "egregious and politically motivated agenda against PET, and even:***
 - ***"BORDERING ON IMMORAL", this by the most senior member of the PET Steering Committee, Dr. Al Driedger when he resigned from the committee in disgust in 2009.***

Contrast this with the words of Dr. Les Levin, who was the Senior Medical Advisor to the Ontario Ministry of Health when I met with him in 2004.

- ***"David, this is not about money, this is about doing what's best for Ontario's cancer patients."***

Most importantly the impact on our patients is profound and in some cases bordering on criminal, yet offered up as 'Standard of Care' according to CCO. It is worth noting that in Australia, criminal charges were brought against Ministry of Health Officials for the methods they used to block PET. The facts speak for themselves:

- ***Ontario patients have not just the most restricted access to PET in the civilized medical world, BUT, the most blatantly wrong indications.***
- ***In the case of lung cancer the indications are the exact opposite of the entire world expert body of opinion.***
 - ***The results for the patients are gross overexposure to unnecessary and unhelpful radiation; exposure to unnecessary high-risk biopsies, gross delays in starting appropriate treatment. AND:***
 - ***MAXIMIZING THE STRESS TO PATIENTS AND THEIR LOVED ONES.***
 - ***The PSC will have an opportunity to defend it's stance directly to patients that I will now be representing, and who have I would***

argue been made victims of a failed attempt to reduce Health Care costs.

- *Patients are entitled to full informed consent, and I will no longer do the dirty work for Cancer Care Ontario.*
- ***The time has come for those that have made the rules, to give the full informed consent and backing documentation for the opinions of the various committees'.***

In 2006 the Canadian Cancer Advocacy Coalition was reported to have said:

- ***If you do NOT want access to modern imaging investigation (PET) or treatment for your cancers, move to Ontario.***

For many of some of our sickest and most distressed patients, they simply have a undergoing unnecessary high morbidity and mortality procedures, virtually a guarantee of 'massive over doses of radiation exposure from CT', and a greater chance of dying because they have the misfortune of living in Ontario, and not Quebec, or for that matter Argentina or Turkey.

The PSC members may strongly disagree with these statements, so the PSC will now have the opportunity to dispute them publically, and finally make public their arguments for the defence of how PET was handled in Ontario. I say "publically" since the ONLY defence offered for the handling of PET to date is to repeat the mantra:

- *The "quality of evidence of PET" is poor and remains unproven technology.*
- *When officially asked to justify the methods used to assess this quality of evidence, without exception:*
 - ***Letters and requests for documents and defence of the methodology were ignored, or when responded to, NOT A SINGLE QUESTION OF RELEVANCE IS ADDRESSED.***

This will no longer be tolerated, and it should not be necessary to remind the PET Steering Committee members that they are serving on government committees in a supposedly open, transparent and accountable democracy and ultimately responsible for their opinions and actions to the citizens of Ontario.

This will be the first in a series of letters in which I will raise various issues and ask for an official response from the PET Steering Committee along with appropriate supporting documentation as required. I would respectfully suggest that to continue the pattern of 'stonewalling' would not be effective or acceptable. I will use and any and all legal means available to me to persist, until the patients and this physicians

have access to all the information they need to decide for themselves whether Dr. Levin was right in saying this last 15 years has been all about doing:

- ***“Just what is best for our cancer patients.”, or not.***

LETTER ONE:
ROLE OF HEALTH TECHNOLOGY ASSESSMENT [HTA] AND THE CANM MOTIONS
FROM 2005

1. Justification for the use of HTA for evaluating PET in Ontario.

Although in keeping with the ‘stonewalling’ of questions regarding the use of PET it is clear that pretty much everyone involved with PET around the world acknowledges:

- ***There is no scientific validity or justification to use HTA to evaluate PET or any other diagnostic imaging technology.***

Dr. Les Levin confirmed this when I met with him in 2004.

- ***In fact he ridiculed it, saying it was something that would be found in the back pages of the less reputable medical journals!***

Then in conversation in 2009 with Dr. Julian Dobranowski, who as you know was Provincial Health of Imaging for Cancer Care Ontario, confirmed the following:

- 1. There is no evidence to support or validate the use of HTA to assess PET or any other diagnostic imaging device, but that CCO would continue to use HTA to do just that.***
- 2. That the Ethics Review Boards assessing PSC PET Trials and the patients entering the trials were not told there was no evidence to support HTA evaluation of the results of the experiments.***
- 3. That CCO was not evaluating PET, but in reality using PET to try and validate HTA, and that no one was told this either.***

You may also be aware of the Editorial in the Journal of Nuclear Medicine by Dr. Sandy McEwen that commented on:

- ***The arbitrary and capricious use of a scientifically baseless process (HTA) to block access to PET in Ontario.***

So unless the PET Steering Committee is prepared to refute their statements and positions, with all the supporting documentation we will all assume that there simply is no scientific basis to justify the use of HTA to evaluate PET.

However, if the process of assessing PET was not based on science it is reasonable to assume that it was **agenda based**. Dr. Rodney Hicks an Australian PET expert who published an article in the Journal of Nuclear Medicine outlining how the evidence related to PET in lung cancer was ‘manipulated’ including elevating a mere ‘poster presentation’ claiming PET was not useful was to a Level A paper. Indeed as Dr. Driedger has pointed out:

- ***A 35 mm slide of this poster presentation was THE reason used to justify stopping PET in Ontario and as an excuse to perform their own PET trials.***
- ***Trials which were deliberately underfunded:***
 - ***Needed some 1,500-1,700 patients to complete at five hospitals.***
 - ***Hospitals only funded to do 32 patients per year!***
 - ***Very effective at delaying PET.***

In a recent email, Professor Hicks wrote:

- ***“David, medical jurisdictions are still trying to block PET, sadly even Australia. However Ontario has the most egregious and politically motivated agenda against PET (ie our patients) in the world.”***

No doubt the PET Steering Committee will want to make a strong objection to these statements, and this will be the opportunity to do so.

- ***I will be happy to send your rebuttals to Dr. Driedger, Dr. Hicks, and the other physicians who have published editorials or otherwise made statements condemning CCO committees, so they can respond to the PET Steering Committee’s defence of its actions.***

PREAMBLE FOR QUESTIONS:

1. Given the unprecedented accusations and condemnation of Cancer Care Ontario’s process of evaluating PET, including ICES, any explanations to justify this position must be very powerful, convincing and well documented to be able to stand up to the withering criticisms.
2. In 2005 the Canadian Association of Nuclear Medicine [CANM] passed motions declaring the PSC PET Trials as “unethical” ***and demanded an independent panel of Canadian experts in Medical Ethics and Health Policy investigate the ‘ethics’ of the Liberal Government’s approach to cancer patients.***

QUESTIONS:

1. Therefore I would respectfully request that the PET Steering Committee provide the ‘powerful and compelling arguments along with appropriate documentation’

to defend the use of Health Technology Assessment to evaluate PET and use as a basis for designing experiments on cancer patients and evaluating the results, particularly in light of Dr. Dobranowski's statements.

2. The ultimate 'litmus test' of the role of ICES in evaluating PET would be to assess the 'ethics' of its methodology since it is this aspect that has led to the most disturbing accusations.
 - a. ***Therefore, will the PET Steering Committee vote to support demands to finally carry out the CANM motion to have a full independent and unfettered review of the 'ethics' of how PET was assessed by the Ontario Ministry of Health?***

Given the grievous accusations made against the PET Steering Committee over the years it is hard to understand why it didn't demand this motion be carried out when it was passed in 2005. After all it would have presumably dismissed the accusations as groundless and Cancer Care Ontario would then be able to make a valid claim that it truly did not get sucked in by the PET hype and:

- ***Thus all the actions of CCO physicians has been truly:***
 - ***JUST WHAT WAS BEST FOR ONTARIO'S CANCER PATIENTS.***

If the PET Steering Committee does not want its work to be given this ultimate scrutiny this would surely suggest that they have something rather disturbing to be hidden from the public, and give credence to Dr. Driedger's statement about actions ***"bordering on immoral."***

- Therefore if the PET Steering Committee will not support this motion for the ethical review of its work ***please send a detailed response outlining the reasons for this position so the public and physicians can judge for themselves whether this position is reasonable or not.***

I would ask that the PET Steering Committee respond as soon as possible, which should not be onerous since these are two very straightforward questions. To not acknowledge, or provide a detailed response to the two questions submitted will not be acceptable, and completely at odds with the founding principles of the Ontario most of us would like to believe we live in.

Respectfully Submitted

Dr. Dave Webster

This letter will also be sent by Registered Mail shortly.