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Dr. Andreas Laupacis
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RE:YOUR ROLE IN THE 'EVALUATION/BLOCKING' OF PET IN ONTARIO.

Dear Dr. Laupacis

PREAMBLE:

It would appear that since you left ICES you have moved on to bigger and better things. Possibly this is a reward for the extraordinary work you did with ICES in accessing the roles, if any for PET, for some of Ontario's sickest and most distressed patients. Your resume is very impressive.

Your efforts through ICES to take Ontario patients to the most restricted access to PET, and the most clinically inappropriate indications in the world, at least according to 'non-government medical experts', should be seen as your 'greatest achievement'. Given the unique position Ontario has assumed on PET in the world, this was no small feat.

- **Surely you will be anxious to have your role as President and CEO of ICES seen as the crowning achievement of your career.**

I note that you were even "included in the Medical Post's "Power List" of the 30 most powerful physicians in Canada". Perhaps that explains why the Medical Post would not touch the article I wrote pointing out the unprecedented condemnation of how Cancer Care Ontario carried out's mandate to 'discredit, delay and block' PET in Ontario. That is if I am to believe the conversations Mr. Michael McCarthy had with the Ontario Association of Nuclear Medicine Executive when I was President. He was, as you know the Senior Medical Assistant to the Minister of Health, Mr. Tony Clement. He claims to have been at the meetings where various government

'medical experts' were to told to 'discredit, delay and block PET since the government did not want to pay for it.

- You will no doubt recall your answer to the question I asked you at the medical meeting at White Oaks Resort in Niagara-on-the-Lake way back in 2004.
- You did not say there was no evidence, but could not have been clearer that:
 - ***'As physicians we have all had patients sitting across the desk from us when we know there are tests and treatments that the government just can't afford to pay for.'***
 - *You saved the 'no evidence' remarks till you left the stage to talk to a scientifically illiterate journalist.*

You also will recall the Multidisciplinary Committee Report from 'non-government medical experts' that assessed the literature on the five roles for PET in the late 1990's. They recommended at least 24,000 patients would benefit from a PET even then. At that time the role of PET in lung cancer was essentially considered the accepted world standard for imaging management. You will then recall the first ICES report that decided that '0' patients would benefit from PET because of the abysmal quality of evidence. Remarkably ICES even dismissed any role for PET in CNS diseases such as Dementia:

- ***This in spite of the fact that most of what was understood about integrated human brain function was based on PET, as this was the original role for PET!***
- *Since ICES and the Ontario MOH have still not found any use for PET in CNS diseases, presumably they will make sure to let the world beyond Ontario's borders know that all their research and findings of brain function utilizing PET are useless, and should be discarded.*

Yet this was only the beginning of ICES and other CCO workhorses such as the PET Steering Committee claiming to have figured out the proper way to assess diagnostic imaging devices such as PET. The rest of the world effectively bought 'snake oil'.

- ***Thus when the mantra of no evidence to support the use of PET, other countries such as France, using the same evidence, bulk purchased something like 80 PET scanners. Turkey has just under 100 PET scanners***
- ***FOOLS! RIGHT?***

The CCO position would be very nicely outlined in the publication:

JOURNAL OF CLINICAL ONCOLOGY
ORIGINAL REPORT

Evidence-Based Approach to the Introduction of Positron Emission Tomography in Ontario, Canada

William K. Evans, **Andreas Laupacis**, Karen Y. Gulenchyn, Les Levin, and Mark Levine

Volume 27 – Number 23: November 20, 2009

This in spite of the unprecedented condemnation from Canadian and International PET experts and the motions from the 2005 Canadian Association of Nuclear Medicine meeting declaring that what took place described in this paper was “unethical”, and demanded the Ontario Government PET Trials be halted, and that a panel of experts in Medical Ethics and Health Policy be asked to assess how this could have happened in Ontario!

However, what is seriously troubling is that in spite of repeated comments of how proud everyone involved with assessing PET for the Ontario Government was and claims of having figured out how to assess PET:

- ***Without exception not a single Politician, Ministry of Health Bureaucrat, or ‘medical expert has ever acknowledged or responded in writing to a single question about the process by which the evidence for PET, and the MOH experiments on patients was carried out!***
 - ***This of course INCLUDES YOU, AND YES WE HAVE SOME UNFINISHED BUSINESS.***

This would seem to suggest that those involved with CCO assessment of PET have something very egregious and profoundly disturbing to hide from the public. Most Academics would agree that the questions submitted were proper and indeed very critical questions. I mean after all, surely to go from 24,000 patients to zero just cries out for a detailed defence and response beyond, “***There is no quality evidence to support the use of PET.***”!

- ***Amazing the impact a single 35 mm slide of a ‘mere poster presentation’ claiming no role for PET would have on Ontario patients, as both Dr. Driedger and Dr. Rodney Hicks would point out!***

In a recent email from Professor Hicks he stated:

- ***‘There are still medical jurisdictions trying to block PET, sadly even Australia, but “Ontario has the most egregious and politically motivated agenda against PET (ie it’s patients) in the world.”***

I have vowed to myself, my patients and my colleagues that I will not rest until those that have perpetrated what has been described as a “travesty” and worse against our patients finally stand up and defend their assessment methodology for PET, and the impact this has had on our patients. Indeed when Dr Al Driedger resigned in disgust from the PET Steering Committee in 2009 he stated publicly:

- ***“I believe that what those who are blocking PET are doing, borders on immoral.”***

On the other hand, if the world expert opinion is wrong, I will stop at nothing to congratulate the ‘ahead of their times’ CCO medical experts and offer my apologies for the annoyance I have created over all these years.

THEREFORE DR LAUPACIS:

This will be the first in a series of letters in which I will raise various issues and ask for your responses and appropriate supporting documentation as required. I would respectfully suggest that to continue the pattern of ‘stonewalling’ would not be effective nor acceptable. It should not be necessary to remind you that when you were the President and CEO of the Institute for Clinical Evaluative Studies, ***you were a Public Servant, and thus fully accountable to Ontario citizens who are lead to believe they live an ‘open, transparent and accountable democracy.’***

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 you are 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.

- *Therefore for the moment, it is reasonable to assume that since science wasn't used, it must have been AGENDA DRIVEN as pointed out by Professor Hicks.*

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. As noted above, 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.*** There were no motions to review the 'science' of these PET Trials, since everyone, including you and the CCO, agrees there isn't any science.

QUESTIONS:

1. Therefore I would respectfully request that that you provide the 'powerful and compelling arguments along with appropriate documentation' to defend the use

of Health Technology Assessment to evaluate PET during your tenure as President and CEO of ICES.

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 you now 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 that this will be your 'greatest accomplishment' as a 'public servant' it is hard to understand why you didn't demand this years ago to dismiss presumably groundless accusations against a process you were part of.***
 - b. To not support this motion surely would indicate that Dr. Dr. Driedger was correct when he made the profoundly disturbing accusation that the process "bordered on immoral".
 - ***Therefore if you will not support this motion, then please be very specific and clear in your reasons for your refusal.***

SUMMARY:

Since your tenure as President and CEO at ICES till now you have received endless accolades and awards, and have what I presume is a nice job in Toronto.

In my case, after the better part of 15 years of doing my best to act as an advocate for Ontario's patients I have accomplished nothing, I have been reprimanded by the College of Physicians and Surgeons for demanding that a Chairman of a CCO committee evaluating PET finally answer questions regarding the HTA that everyone had refused to answer; I have been reprimanded by Hospital administrations for putting in my reports comments that everyone agreed were absolutely true, but "you're not allowed to say these things in a report"; I have been reported to a Chief of Staff by the Head of Oncology for my efforts on PET for their patients; and shunned by my colleagues for being 'politically incorrect'. My efforts have also had a significant negative impact on my family and me, and personally cost me a lot of money for my useless efforts.

However, we have one thing in common. As Physicians we both took the Hippocratic Oath, which in part states:

- o ***"first do no harm".***

I am more than willing to stand up publically and defend my efforts. In the end if I am wrong, and an 'elite group of Ontario government medical experts' somehow figured out how to evaluate new imaging technology like PET in spite of the condemnation from PET experts from around the world, I will be equally aggressive at issuing a public apology.

- o ***The question is, Dr. Laupacis, are you prepared to publicly defend the role you have played in assessing PET for the Ontario Ministry of Health?***

At the end of my meeting with Dr. Les Levin, the Senior Medical Advisor to the Ontario MOH in 2004 he stated:

- ***“David, this is not about money, this is about doing what’s best for Ontario’s cancer patients.”***
- *Notwithstanding this is at odds with the statement you made in public at the Meeting in Niagara-on-the-Lake, I would ask that in your answers to these two questions and subsequent questions that you make clear how your efforts in accessing PET:*
 - o ***Where just what was best for Ontario’s cancer patients.***

I would ask that you respond at your earliest convenience, and I once again remind you that to not acknowledge, or provide a detailed response to the two questions will not be acceptable, and completely at odds with the founding principles of the Ontario most of us would like to believe we lived in.

Respectfully Submitted

Dr. Dave Webster

This letter will also be sent by Registered Mail shortly.