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RE: SUMMARY OF ISSUES AROUND THE LACK OF ACCESS OF ONTARIO CANCER PATIENTS TO PET SCANNING IN ONTARIO.

Dear Ms. Pierre

I would like to thank for you kindly taking the time to discuss these important issues relevant to the status of Ontario cancer patients and their lack of access to modern diagnostic tools for investigating disease.

I am past president of the Ontario Association of Nuclear Medicine [OANM] and in that capacity along with OANM executive members had numerous meetings with Ministry of Health [MOH] officials regarding PET. I am also one of the most highly trained and experienced PET experts in the province. I have spent over four years of almost endless efforts to get explanations for patients like XXXXXX as to why as an Ontario cancer patient she does not have access to PET scanning which has become the world standard of cancer patient investigation and management. My colleagues and I have repeatedly tried to get the MOH and/or someone from the small group of government physicians who continue to deny the value of PET to answer critical questions about the MOH PET trials. Without exception the MOH officials and the key government spokesperson on PET, Dr. Bill Evans, have refused to answer a single direct probing question explaining their position on PET.

My colleagues and I have failed in our efforts to get accountability from the MOH and the handful of doctors who set up and continue to defend the controversial MOH PET Trials on Ontario cancer patients.

To quote Dr. Christopher O'Brien in a press release in 2005:

- Right now, although PET is proven diagnostic technology, the only way Ontarians can get access to PET is as part of a clinical trial. Despite decades of accumulated evidence of the value of PET, Ontario continues to **hold on to the fiction** (emphasis added) that PET is "experimental and unproven."

- As a clinician, I find this medically unethical. For six years, physicians and patients have waited for PET to be made available. Instead, the clinical trials are ongoing, despite the fact that they are unlikely to generate evidence that would add to the overwhelming proof that PET is useful for patients today.

Maybe now a real 'casualty' of the travesty of PET in Ontario, someone with the drive and courage of Ms. XXXXXXX will finally through her efforts be able to demand accountability from the MOH and those individuals responsible for the third world status of cancer patients when it comes to access to PET.

SUMMARY:

- The official position of the Ontario Ministry of Health [MOH] is that PET scanning is still experimental. It is my position as well as that of other respected PET and scientific experts, as I shall make clear, that the position of the MOH is not based on sound science, but because of concerns over the cost of implementation. Although different medical jurisdictions around the world are quite right in fine tuning where PET fits in their particular health care system, it is simply beyond dispute that PET is of major importance in cancer investigation and management as well as other applications in medicine and research.

- The MOH is also asking the wrong question of PET, I believe deliberately in order to delay PET. They have been asking whether having a PET scan improves a patient's survival. This is an entirely inappropriate question. This has been repeatedly pointed out to the MOH and their experts, but has fallen on deaf ears. World experts speaking in Ontario on PET have pointed this out to members of the PET Steering Committee who have chosen to ignore their expert advice.

The performance of diagnostic tests such as PET or a CT do not treat or improve a patient's survival. This is solely dependent on whether or not treatment is even indicated, and whether or not effective treatments are available. The role of a diagnostic testis to determine how best to manage the patient's investigation and treatment. One role of PET scanning is in staging how far cancer has spread. Typically PET upstages approximately 80% of patients demonstrating that a patient has more extensive disease than was thought.

If the ministry experts are willing to see if they can credit patients living longer by having a PET scan, then presumably they are going to ***blame a PET scan*** for shortening

a patients life when it finds they have worse disease than was thought! ***This is patently absurd!*** Are these same doctors asking whether having a chest x-ray improves a patient's survival? The fact is that on average a PET; scan changes the management of 30% of cancer patients. In other words, conventional investigations such as MR and CT are wrong 30% of the time! For a practical example, 30% of patients in this province thought to have operable lung cancer should not be operated on because a PET scan would demonstrate that an operation would be absolutely useless. However currently these patients are put through one of the most painful incisions they can have, a thoracotomy (open their chest), with absolutely no chance of it having any benefit. Indeed this high risk surgery ***could shorten the patient's life*** given the morbidity and mortality of the procedure itself. Does this significantly change a patient's management? The rest of the world has decided strongly that it has.

- **To NOT put a patient through completely useless aggressive and risky medical and surgical procedures based on their PET scan *DOES NOT IMPROVE SURVIVAL…BUT <u>THIS IS THE MOST APPROPRIATE AND HUMANE WAY OF DEALING WITH THE PATIENT!</u>***

For your information, PET is playing an ever increasing role in monitoring a patient's response to cancer therapies. Traditionally this has been done by repeating a CT to see if a mass is getting smaller. This has been shown to have little relation to whether or not the patient is responding. Typically with chemotherapy patients undergo six cycles and then are reexamined most often with a repeat CT:

- A CT is a high dose radiation procedure. Having a complete CT examination of the abdomen is the equivalent to the radiation dose from some **200 Chest X-rays!**
- The only way we get a hint of whether or not they have responded is to keep repeating CT to measure possible increase or decrease in tumour size.
- Repeatedly I have seen cases of stable tumour size on CT, felt to indicate no disease…***and the PET scan show clearly active cancer as well as new sites of cancer spread not even detected on CT!***
- A PET scan has a significant radiation dose associated with it as well, but it can be made done in a way to make the dose less than conventional CT ***and no risk (death can occur) from use of contrast agents typically used with CT exam. The PET also gives inherently more useful metabolic information…CT, MR ect are wrong 30% of the time!.***

. Since PET scanning monitors the metabolic activity of the cancer, PET has been shown to be able to determine within as little as one or two cycles whether or not the

cancer is responding, and whether one should continue or consider switching therapy. Given the often devastating side effects and increased risk of even death with these toxic therapies, to deny access to a PET scan is unconscionable.

In my opinion it is utterly irresponsible of the MOH and the handful of government physicians defending these trials, trials which as I will show have also been declared unethical for other reasons, to ask the wrong question of a diagnostic test. This has played a significant role of placing Ontario cancer patients into virtually a third world status when it comes to access to PET scanning.

- Of the ODEC countries, Canada is in last place when it comes to the number of PET scanners/ capita. It was recently pointed in a MacLean's Article summarizing access to modern health care that Ontario was the most restrictive for access to PET.

- A 2007 Canadian Cancer Advocacy Report summarized by saying that if you did ***not want access to modern diagnostic procedures (PET) or modern cancer treatments, you should move to Ontario.***

The MOH set up the PET Steering Committee [PSC] in the late 90's to investigate whether there was any role for clinical PET scanning. Dr. Bill Evans is the current chair, a past chair of the PSC, and past Chair of Cancer Care Ontario [CCO]. He has also been the key government spokesperson and defender of the MOH position on PET.

- **I would suggest that you speak to the current chair of CCO, Dr. Terry Sullivan. I have had a very interesting recent conversation with him and I believe it is fair to say that he strongly disagrees with the course Dr. Evans has chosen and continues to defend.**

Based on previous e-mail and letter conversations I have had with Dr. Evans, as well as other sources his defense of the PET trials has in part been that PSC is made of made up of a team of experts who are supportive and in agreement with the directions the PSC have taken.

I would suggest to you that as far as there being a unified position, nothing could be further from the truth.

OF NOTE: It is Nuclear Medicine physicians who are the actual PET experts and typically supervise and interpret these studies.

I would like to present to you background material which I believe makes it clear that there is a small group within the PSC that has been responsible for the lack of access of Ontario cancer patients to PET scanning

- **The PET Breast Cancer Trial exemplifies best the deliberate course of action of the MOH to delay the implementation of clinical PET scanning for Ontario cancer patients.**

I will give a detailed history of the current Breast PET Trial, but it can be best summarized by stating that the MOH through the PSC has deliberately structured the research protocols to present PET in a negative light by having PET fail. Further they have denied evidence favouring PET using a research tool, the Health Technology Assessment [HTA], which itself has never been validated to evaluate a diagnostic piece of equipment such as PET. Please see eloquent article addressing this point by Dr. Sandy McEwen, one of Canada's PET experts with international status.

KEY QUESTIONS FOR CHAIR PET STEERING COMMITTEE:

1. **Has the HTA tool ever been rigorously validated to evaluate diagnostic imaging equipment such as PET?**
2. **If so then why are there such widely discrepant results using the same tool evaluating the same diagnostic piece of equipment?**
3. **If it has not been rigorously validated, then why are you applying it to the role of PET in Ontario cancer patients?**

It is also key to understand there is significant dissent amongst the members of the PSC, and there are some key reasons why their protests about the direction of the PSC are not widely known.

THE MOH PET TRIALS HAVE BEEN DECLARED UNETHICAL BY A BODY OF EXPERTS:

It is worth noting that in an unprecedented series of three motions, in May 2005, the Canadian Association of Nuclear Medicine unanimously declared the Ontario MOH PET trials on cancer patients as unethical. They demanded the trials be suspended and a team of experts in medical ethics and health policy be brought in to evaluate these trials. The MOH has refused.

Further, in a teleconference following the release of the revised Breast PET trial the Ontario Association of Nuclear Medicine [OANM] executive and every Nuclear Medicine member of the PSC, present and past, with the exception of the one who wrote

the trials, unanimously declared the PET trials as "unethical and unconscionable'. This teleconference included the most senior member of the PSC, Dr. Al Driedger.

These facts alone should make it clear that the controversy surrounding PET in Ontario is not, as a journalist recently suggested to me, simply a matter of 'healthy differences of opinion' between experts, but something quite different. Ontario cancer patients through access to the web and other sources of information are well aware that PET is routinely used around the world. Surely there are significant alarm bells that the MOH position and approach to PET is indefensible. The cancer patients of Ontario deserve a full investigation and accounting of why they do not have routine access to PET scanning. This should at a minimum be an independent review of the PET trials and process by external experts in ethics, health policy, PET and oncology as recommended in the CANM motions.

I intend to make clear to the Ombudsman's Office as well as Ms. XXXXXXX that there is significant dissent amongst the members of the PSC, and there is a key reason why those PSC members who strongly oppose the approach and methods of the PSC have not made their position more widely known.

- **The OANM executive and the Nuclear members of the PSC [with the exception of Dr. XX XXXXXXX] have repeatedly raised the issue of whether or not they should they resign in protest.**
    - **Dr. XXXXXXX, a Nuclear Medicine Physician, has not been allowed to be part of these discussions since the OANM moved to have her excluded from discussions based on X having written the trials which the CANM declared unethical for reasons I shall make clear.**

WHY HAVE NOT THE NUCLEAR MEMBERS OF PSC RESIGNED IN PROTEST?

- The key issue to understanding this is the inexcusable rivalry between the two medical specialties of Radiology and Nuclear Medicine.
- PET scanning has been a Nuclear Medicine procedure since its introduction to clinical medicine as early as 25 years ago. PET scanning is the archetypal Nuclear Medicine technique. To obtain specialty certification in Nuclear Medicine in Canada you must have PET training. (Ontario Nuclear Medicine Residents must leave the province to obtain competency in PET) In the recent past, for technical reasons a CT scanner has been attached to the PET scanner. (CT is a procedure interpreted typically by a radiologist)
- At that moment in time the radiologists staked the claim that PET was obviously now 'theirs'.

- **The official position of the Canadian Association of Radiology is that Nuclear Medicine should not exist as a specialty. That with the exception of administering radioactive therapies, all traditional nuclear medicine, including PET procedures should be done by radiologists.**
- **Almost without exception a Radiology Resident has only three months of exposure to entire field of nuclear medicine and only through a Nuclear Medicine Department. This would almost never involve access to PET scanning training, and even our residents have to leave typically the country in order to get experience!**

I AM SADDENED AND EMBARASSED TO SAY THAT THE REASON WHY THE NUCLEAR MEMBERS OF PSC (EXCEPT DR. XXXXXXX) HAVE NOT RESIGNED IS BECAUSE WE ALL UNDERSTAND THAT THEY WOULD BE IMMEDIATELY REPLACED BY RADIOLOGISTS AND THIS WOULD RESULT IN THE COMPLETION OF THE TAKE OVER OF PET BY RADIOLOGISTS.

Although this is a clear example of a 'turf war' I would suggest to you the CAR's position on their qualifications to be Canada's PET experts is indefensible academically and professionally.

SOME IMPORTANT SUMMARY POINTS LEADING TO WHERE WE ARE TODAY:.

- **My colleagues and I have repeatedly raised questions and serious concerns about the PET trials to senior members of the MOH. Numerous meetings were held with MOH officials as well as letters sent to key individuals. Without exception the MOH officials and the key individuals responsible for the PET trials have refused to respond except to reiterate a summary of the government's ongoing PET trials.**

- **In May 2004 I had a meeting with Dr. Les Levin, the governments Senior Medical Advisor. When I asked him about the HTA, he dismissed it saying it was something you saw in the back of journals. Following the meeting I sent him a letter and challenged this as well as numerous other issues surrounding the MOH PET trials. In his reply, Dr. Levin refused to address a single issue I raised except to dismiss me with his response: "If there is any evidence in favour of PET, please bring it forward." The OANM executive was so disgusted with his response that we did not even respond to his insult. My original letter to Dr. Levin however was included as part of an information package to every MOH official we met. Again without exception they would not respond to the questions and concerns my colleagues and I raised about the trials. (copy included)**

- **It is also worth reiterating that in an unprecedented series of three motions, in May 2005, the Canadian Association of Nuclear Medicine unanimously declared the Ontario MOH PET trials on cancer patients as unethical.**
- **In the minutes of the meeting, it was specifically pointed out whether or not Dr. XXXXXXX abstained, yet further proof of the rejection of Dr. XXXXXXX's position on PET by X colleagues.**

- **Regarding the use of the HTA: In the December 2006 issue of the Journal of Nuclear Medicine [JNM], a journal with world wide distribution, Dr. Sandy McEwan wrote an editorial specifically pointing out Ontario's flawed use of the HTA.**

SERIOUS DISSENT AMONGST MEMBERS OF PET STEERING COMMITTEE:

- In April 2004 Dr. Al Driedger had become so disillusioned by the direction of the PSC that he bypassed the Chair, and wrote directly to Mr. Smitherman the Minister of Health.
- In that letter he charges that:

    - **The government is deliberately using the HTA to block PET because of cost concerns.**
    - **That certain members of the team are deliberately denying evidence favouring PET**
    - **That as a result Ontario was now a decade behind the rest of the world.**

- **MR. SMITHERMAN REFUSED TO RESPOND TO DR. DRIEDGER AS HE OR SOMEONE UNDER HIM IS OBLIGATED TO DO.**

- I subsequently formally challenged Mr. Smitherman with these same accussations, and although a response was sent to me the response did not respond to these serious accussations, nor any other numerous questions I posed. The respondent simply regurgitated the standard government mantra that PET is experimental and the government was running these trials…..***TRIALS I POINTED OUT IN THE LETTER HAD BEEN SUBSEQUENTLY DECLARED UNETHICAL BY THE CANADIAN ASSOCIATION OF NUCLEAR MEDICINE….a point which he also refused to acknowledge or address.***

- Similar questions including their position on the letter from Dr. Driedger to Mr. Smitherman were also put to the key government doctors supporting these PET trials:
    - Dr. Bill Evans (Chief government spokesperson and Chair of PET Steering Committee. Head of McMaster Cancer Center)
    - Dr. Les Levin (Senior Medical Advisor to the MOH)
    - Dr. XXXXXXX (McMaster University oncologist)
    - Dr. XX XXXXXXX
    - Dr. Andreas Laupacis. (President of the Institute for Clinical Evaluative Studies..ICES, government office)

- Dr. Levin and Dr. XXXXXXX responded to my letter, but refused to address a single issue of importance that I raised.

RE: DR DRIEDGER'S CLAIM THAT COST CONTROL WAS THE ISSUE:

- Dr. Laupacis gave a presentation on the HTA at a Nuclear Medicine meeting held in Niagara-on-the-Lake. During question period I described to Dr. Laupacis two cases where PET had changed the patient's management 180 degrees. I then challenged Dr. Laupacis by saying, not withstanding your position there is no evidence PET is of use in cancer patients, the world position was clearly different. Therefore ***I asked Dr. Laupacis what I should be telling my cancer patients.***

- **His response was first to tell me not to take the high road since he saw patients too. BUT THEN:**

    - **He said:**
        - **"Dave, we're all faced with patients across the desk where we know there diagnostic procedures and therapies that the *GOVERNMENT JUST CAN'T AFFORD TO PROVIDE."***
        - **I responded by saying:**
        - **"Andreas, you're absolutely right. The issue is about money, you know it, we all know it, so why do you continue to insult the professionalism and integrity of physicians by telling us we do not know how to evaluate the world literature.**

AT NO POINT IN THE EXCHANGE DID HE STATE THAT THERE WAS NO EVIDENCE THAT PET WAS USEFUL FOR PATIENT MANAGEMENT.

- **I would also suggest that you speak to Mr. Michael McCarthy. I can get you his contact information. Mr. McCarthy was Mr. Clement's 'right hand man' and part of critical meetings, when the Conservative government was dealing with what to do about PET, and set up the PSC. The OANM hired Mr. McCarthy as our lobbyist. He arranged numerous meetings with high level MOH officials and was in attendance at those meetings.**

- **During a meeting with a Ms. Karli Farrow, who was Mr. Smitherman's assistant at the time she expressed some shock at how the trials were funded as we made our point that the trials were deliberately under funded. Mr. McCarthy made it clear that he was part of the original meetings of the Conservative MOH caucus where the strategy of how to deal with PET was formulated. It is my recollection that Mr. McCarthy made it clear that the Conservative MOH caucus did not want to pay for PET and so one way of dealing with it would be by under funding the trials to delay their completion.**
- **I'm sure Mr. McCarthy would be happy to speak to you about his experience and knowledge about the PET situation in Ontario.**
- **Of note, I tracked down and met with Ms. Elizabeth Witmer in her Queen's Park Office. Ms. Witmer is the Conservative Health Critic and previous Conservative Minister of Health. As part of my presentation to her I showed a tragic case of a 45 year old female with advanced breast cancer who was having horrible severe symptoms from the cancer somehow pinching the nerves that moved the muscles and controlled pain in her face. Every investigation including CT,MR, bone scan and so on could not find the cancer. Sunny Brook Hospital where she was a patient has a state of the art PET scanner but they were not allowed to scan her just like Ms. XXXXXXX. She arranged to have a PET scan at Care Imaging. I was able to detect the site of cancer trapping the nerves and spoke with her radiation oncologist. I hope they were able to give her some palliative radiation to abnormal areas and let her die more comfortably and with some dignity.**
- **Ms Witmer was most attentive. However her official brief letter to me congratulated me on my efforts, asked me to keep her informed, and "*if there is any I can do to help, please just let me know."* A CLASSIC DON'T BOTHER ME AGAIN LOOSER LETTER.**

Maybe it's time, people like Mr. McCarthy, Tony Clement, Elizabeth Witmer and others that were part of the original process to implement the 'made in Ontario' strategy on PET should be formally questioned about what exactly went on and the logic and motivation for their decisions, such as under funding the trials. Was this based on sound science and concerns about cancer patients, or about playing politics with their lives?

THE MOH BREAST PET TRIAL:
(Why the CANM declared the MOH PET trials on Cancer Patients Unethical)

- The first version of the Breast PET trial was written without the general input of the PSC committee, with Dr. XXXXXXX being the only Nuclear Physician author.
- The trial asked whether or not FDG (the radioactive tracer imaged by a PET scanner following injection into the patient) could detect spread of cancer to the 'sentinel nodes'.
    - Sentinel nodes are the first nodes that a potential spread of the breast cancer might come up against and be trapped in.
    - **Whether or not spread there has been spread/metastasis, of the cancer to sentinel nodes is critical in determining the prognosis and subsequent management.**

EVEN MICROSCOPIC METASTASIS IS CURRENTLY FELT TO BE IMPORTANT IN DETERMINING WHETHER MORE AGGRESSIVE MANAGEMENT IS INDICATED OR NOT.

IT IS IMPOSSIBLE FOR PET SCANNERS TO PICK UP MICROSCOPIC DISEASE!

- Indeed PET scanners can miss tumours in the breast as large as 1.5 to 2.0 cm.
- ***At the time of writing this first version of the trial the published medical literature and even textbooks by experts in PET stated it was not appropriate to use FDG PET to screen for sentinel nodes. If the node was positive on PET, it most likely contained cancer (the commonest false positive is inflammatory tissue), BUT A NEGATIVE PET ABSOLUTELY DID NOT EXCLUDE METASTASIS.*** **Therefore further investigation is required.**

    - **IT VIOLATES A FUNDAMENTAL RESEARCH ETHIC TO DESIGN AN EXPERIMENT FOR WHICH THE INSTRUMENT IS INCAPABLE OF PERFORMING.**

- My colleagues and I rejected this trial because of this reason and **STATED REPEATEDLY TO MOH OFFICIALS, that this trial could only have been designed to fail and therefore present PET in a negative light and further delay the introduction of clinical PET. It would further would be used as a deliberate misrepresentation by the MOH to justify they were right to take their 'made in Ontario approach' "see PET failed"!**

    - **THE REST OF THE WORLD KNOWS THAT THE MAJOR USE FOR FDG PET IS IN RESTAGING BREAST CANCER PATIENTS (determining whether or not the breast cancer has recurred) AS WELL AS A ROLE IN TREATMENT MONITORING OF THOSE WITH KNOWN METASTATIC BREAST CANCER.**

- ***THIS IS EXACTLY WHY MRS XXXXXXX'S ONCOLOGIST WANTED HER TO HAVE A PET SCAN. A SCAN WHICH WAS ABLE TO DETERMINE THE CT FINDINGS IN HER LIVER WERE IN FACT CANCER, SOMETHING ANATOMICAL TESTS LIKE CT AND MR HAVE LIMITED OR NO ABILITY TO DO.***

- Without explanation the MOH withdrew the Breast PET trial and spent almost two years rewriting it.
- When the new 'improved' version was released, ***IT WAS IDENTICAL TO THE FIRST WITH A MINOR ADDITION!***
- This new addition would have been something a first year resident in Nuclear Medicine might have done for a project.

- **IT WAS FOLLOWING THE RELEASE OF THIS TRIAL THAT MY COLLEAGUES AND I HELD THE TELECONFERENCE AND DECLARED THE TRIALS *BOTH UNETHICAL AND UNCONSCIONALBLE.***

- **THE MOH IS THEREFORE PUTTING 330 WOMEN THROUGH AN ALL BUT USELESS MEDICAL EXPERIMENT WHICH WILL FAIL. Was this complete ignorance about the capabilities of a PET scanner, or deliberate designed to fail and delay implementation of PET. Either way it is indefensible. Thus leading the unprecedented motions by the CANM about these trials. .**

- ***WORSE YET:***

    - ***THEY ARE DELIBERATELY EXCLUDING THE VERY PATIENTS LIKE MRS. XXXXXXX WHO WOULD ACTUALLY BENEFIT FROM A PET SCAN.***

When Dr. XX XXXXXXX gave an update on the PET Breast trial 1 ½ years ago at OMA meetings in Toronto, XXX seemed somewhat surprised and disappointed in telling us: "We are seeing a lot of pathology positive lymph nodes for cancer, but negative PET studies."

- **Was Dr. XXXXXXX, who reads these studies, unaware that PET could not identify small volume, but critical disease?**

No one from the MOH or the government doctors supporting the PET trials has responded to questions about the design of this trial.

KEY QUESTION REGARDING BREAST PET TRIAL

It has been the position of the MOH that they are doing due diligence and conducting research to determine what if anything would be the use of PET scanning in the Ontario medical system. My colleagues and I couldn't agree more. This is stuff of 'motherhood and apple pie'!

Yet, if the purpose was determine the most appropriate role for PET:

1. **Why did they design and implement a trial on breast cancer patients that demonstrates *WHERE PET SHOULD NOT BE USED?***

If their response is, well we didn't know it would not be able to adequately detect sentinel nodes, then the obvious retort:

2. **So, you weren't aware that a PET scanner was not capable of detecting small volume and microscopic cancer spread to the nodes?**

I would strongly suggest that these questions about the HTA and Breast PET trial be addressed to the Chair of the PET Steering Committee and the other key members including Dr. XX XXXXXXX who wrote this trial. And don't be distracted by the minor addition to the trial on the second release. …if a node is positive on FDG, how often does it turn out to be malignant.

The point is the major portion of the Breast study is designed to determine whether FDG PET can replace sentinel biopsy, and it won't be able to.

Their position is that they will not recommend clinical PET for anything they haven't proven it useful for. Therefore to determine a possible use for

PET in breast cancer they will have to run a whole new trial. Given that the first trial is not even completed it could easily be five to seven years before another trial would be completed.

Therefore patients such as Ms. XXXXXXX will continue to be denied access to technology available in many third world countries.

This is outrageous and unconscionable. This is not based on proper science.

THE MOH LUNG CANCER PET TRIAL:

- The Lung Cancer PET Trial is another example of the blatant unethical nature of these trials.

- The use of FDG PET in lung cancer is the 'poster child' for PET. At the time of writing the Lung Cancer PET trials, it was already effectively accepted in the world literature that the use of FDG PET scanning in lung cancer was effectively the most compelling case there was supporting a role for PET in cancer patients.

- As pointed out above, PET on average significantly changes the management of 30% of lung cancer patients, with the most common result that the patient is spared a useless, very painful and high risk, not to mention costly medical procedure.
- Since the position of the MOH as implied by Dr. Driedger, is to deny evidence favouring PET **THEY DESIGNED A LUNG CANCER PET TRIAL THAT SETS UP A CONTROL GROUP AND DELIBERATELY DENIES THE CONTROL PATIENTS ACCESS TO A PET SCAN.**

- ***WE HAVE REPEATEDLY POINTED OUT TO THE MOH AND I HAVE CHALLENGED THE DOCTORS DEFENDING THESE TRIALS, THAT TO DELIBERATELY DENY A LUNG CANCER PATIENT ACCESS TO PET SCAN WOULD BE BLATANT MALPRACTICE IN MANY MEDICAL JURISDICTIONS!***

- When Dr. Driedger approached the National Institute of Health [NIH] in the US to get some funding for this PET trial he was refused and told this was standard of care. Dr. Evans was copied this response.

- ***As a further point of unethical research design they did not inform patients entering the trial that the use of FDG PET in lung cancer had effectively become the world standard of care. Ethical trial design demands that patients be given sufficient information to***

make an informed decision as to whether or not they want to be part of a trial.

KEY QUESTIONS REGARDING THE PSC LUNG CANCER TRIALS.

1. **Does the individual in question believe that in light of the world position on the use of PET in lung cancer is it ethical to put a lung cancer patient in a control wing and deny access of to an FDG PET scan?**

At the time of writing the lung cancer trials FDG PET was rapidly becoming the strongest case in supporting the role of FDG PET in lung cancer, and certainly has become so over the course of their running the trial.

2. **Did they fully inform patients entering the lung cancer trial that in most other major medical jurisdictions FDG PET was considered part of the standard work up of most lung cancer patients especially if initial work-up suggested they may be an operable candidate?**

It would appear that they were initially not telling this information to patients by using a non-disclosure clause in research ethics, but after complaints by my colleagues they may now be informing patients who can then make the informed choice they are entitled to as to whether or not they wish to participate, and in particular be denied a PET scan.

There have been patients who have entered the trial and been put in the control wing and then paid privately to have a PET scan done elsewhere.

FURTHER POINTS OF RELEVANCE:

ISSUE OF THE MOH PAYING FOR 'UNPROVEN TECHNOLOGY'.

- Over a number of years the MOH had spent several hundred thousand paying as much as $5,000 US plus travel expenses for patients to have PET scans in the US.
- An offer was made to the MOH that Care Imaging, a private PET scanning service in Mississauga would do the patients for something like $1,100.
- The MOH responded by stating that they could not pay for something using a diagnostic agent, FDG, which had not been approved for human use by Health Canada. [HC]
    - **FALSE: Dr. Driedger pointed out to Mr. Smitherman is his letter referred to above that the MOH had tests routinely covered by OHIP that have yet to have HC approval.**

- Secondly they stated they cannot pay for a diagnostic procedure which has that they do not believe has been shown to be of proven value.

    - **THE WONDERFUL 'CATCH-22' WAS THAT IN ORDER FOR THE MOH TO PAY AMERICAN COMPANIES TO PERFORM THE PET SCAN…THEY HAD TO DECLARE THAT HAVING A PET SCAN WAS MEDICALLY USEFUL FOR THE PATIENT!!!**

- Quebec now routinely covers PET scanning and to the best of my knowledge the MOH is now paying for patients to have a PET scan in Quebec. It appears this may be the case for Mrs. XXXXXXX.

THE MOH UNDERFUNDED THE PET TRIALS AND CONTINUES TO UNDERFUND THE PET REGISTRY TRIALS.

- In Ontario we have Bill 8 which makes it illegal for a hospital to run a deficit.

- The MOH allotted some $4.5 million for the PET trials. It was repeatedly pointed out that hospitals could only perform 35 patients per year based on funding. Five centers are part of MOH PET trials. A total of approximately 1500 patients are required to complete trials. The very design and funding of the trial was to ensure it either couldn't be completed, or at the very least took as much time as possible to complete.

- Those involved with the trials have refused to respond to repeated inquiries about under funding the trials.

- The MOH is now running 'Registry PET patients' for a couple of other indications besides the concurrently running PET trials on Breast, Lung and Head and Neck cancer.

- The money they will pay for the hospital to perform the PET scan is grossly under the actual cost of performing the PET scan.

- Therefore either do the test at a loss and suffer the potential consequences, or better yet, don't do the test.

CONCLUSIONS:

In this rather lengthy letter I have gathered together some of the points and documentation relevant to address the issue of the lack of access of Ontario cancer patients to PET scanning. I have other documents and correspondences which may be of use to you, and which I would be happy to make available. It is my hope and sincere belief that this material will be vital in helping you, and Ms. XXXXXXX, to understand why Ontario cancer patients have been put into what in the media and others have called a "travesty" when it comes to access to PET scanning.

It is no secret that the population at large has little or no respect for politicians, the bureaucratic process and institutions of government. If there is not enough evidence to suggest that what has happened regarding PET in Ontario should not at the very least be investigated by independent experts, then the world just doesn't make any sense. Although I may be too close to the issues to be unbiased, I believe it is fair to say that we could hardly offer this example up to the up and coming physicians, scientists and technologists of Ontario as to the way science and the introduction of new therapies and technologies should take place. Something we could all be proud of, something that separates Ontario from other manipulative and dishonest political regimes elsewhere in the world. In my opinion this is just yet another example of why people have every right to be completely cynical about our government and public institutions.

It is worth noting that currently in Australia it has been shown through the freedom of access to information, that the Australian government deliberately delayed PET because of cost concerns. A recent comment from Dr. Rodney Hicks, the Australian PET expert who brought forward the allegations, was that there may well be jail terms for those involved at the government level.

I have personally tried my best to get answers from the MOH and the critical government physicians supporting these trials, and I have failed, as have my colleagues repeated attempts. Given the unique world position of Ontario and the repeated media comments on the situation in Ontario, Ontario cancer patients deserve to know whether their lack of

access to PET is based on solid and world class scientific efforts, or not. And if not, then it is time that the MOH and their handful of doctors supporting and perpetuating these trials are held fully accountable.

I look forward to discussing this with you further at your convenience.

Sincerely

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