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Hon. Carolyn Bennett MD
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Dear Dr. Bennett

RE:PET SCANNING ISSUES IN ONTARIO

Thank you for a most inspiring talk at the CANM meeting in Montreal. Everyone I spoke to had nothing but praise for your passion, your vision and your determination. Personally I have all but lost faith in politicians and the political process, mostly based on my PET experience. However you have given me a sense of hope that change may be possible through an enlightened political process.

However I have had hopes before and been disappointed at every effort I have made. I think it is fair to say that no one in Canada has spent more time or money in an effort to get PET for Ontario patients. In spite of sustained efforts by my colleagues and I, we have utterly failed our patients. Up until recently I had resigned from the CANM since I felt there was so much more they could have done to capitalize on the extraordinary and unprecedented events in Ontario ultimately described as "immoral". There has been too much 'political correctness' and our patients have been the victims of this approach.

I would also like to preface this letter by stating that PET is not perfect, nor effective for all cancers or for all of the six common uses in cancer management for each cancer. Like any test it has it's limitations and above all my position is that:

- No Diagnostic Imaging test should be ordered unless it has a reasonable chance of changing a patient's management.

The fact is that Ontario has the most restricted access to PET scans in the civilized medical world.

- We may have 10 scanners, but the restriction refers to the number of OHIP funded indications.
- Three years ago in Ontario with our 12,000,000 population we were only allowed some 350 patients / camera /year.
- At the same time in Quebec with 7,000,000, they were averaging 3,000 patients/camera/year. They have 12 PET scanners and are adding more.
- Turkey has in excess of 90 PET scanners.
- Last year Paraguay made a significant effort to get it's its PET infrastructure in place for it's patients.

No government on the planet has been more successful in their attempts to prevent their citizens from having access to what has been the world standard of care for the management of cancer patients starting over ten years ago. When the Ontario government started blocking PET there were realistic concerns about how to pay for this test in a publically funded system. This concern has only become more acute given Ontario's financial situation. My colleagues and I made it clear we understood this and that PET needed to be regulated. But clearly CT and MR along with all diagnostic tests needed to be regulated as well.

The Australian government also tried to deny the evidence favouring PET but was exposed by Dr. Rodney Hicks. The result was that there were successful criminal charges against members of the government. I will include the article by Dr. Hicks who outlines in detail what Ontario's medical experts did to block PET.

Ontario's unique position in the world has been accomplished by a small but dedicated group of government medical experts.

- Dr. Bill Evans (Former Chairman of the PET Steering Committee)
- Dr. Les Levin (Senior Medical Advisor to MOH)
- Dr. Mark Levin (Head of Ontario Clinical Oncology Group [OCOG])
- Dr. Karen Gulenchyn (Nuclear Medicine Physician McMaster Health Sciences)
- Dr. Andreas Lapaucis (Past President of the Institute for Clinical Evaluative Studies [ICES])
- Dr. Julian Dobranowski (Latecomer and now in charge of PET through CCO)

I know from personal conversations and exchanges with Dr. Les Levin, that they were quite proud of their accomplishment and from their perspective why not? Cleary they have gotten away with what other groups may have tried but failed to accomplish. This mostly because of a PRESS responding in classic Chomskian Fashion, have done a perfect job at creating the illusions the government needed and protecting these 'physicians'.

- When I met with Dr. Les Levin in his office in 2004, after ridiculing Evidence Based Medicine [EBM], in spite of the fact that this is how they blocked PET he said to me, as I was about to leave his office.
- **"David, we're just trying to do what is best for Ontario's cancer patients."**

One very successful critical tactic to block PET was that without exception no one would answer a single question of relevance put to them by various experts or by professional associations such as the CANM and the Ontario Association of Nuclear Medicine [OANM]. This included none other than Mr. Smitherman and his refusal to acknowledge or respond to a letter from the most senior member of his PET Steering Committee.

You may be surprised to know that it was Mr. Tony Clement who assigned them the task of blocking PET when he was Ontario's Minister of Health. We know exactly how this started since the OANM hired Mr. Michael McCarthy who was Mr. Clements right hand man and he attended all the planning meetings on blocking PET.

I will cover most issues in point form, outlining the most important issues and events that I hope will give you an idea of how organized, concerted and wrong their effort was and remains. I do hope you will find what I have to say interesting and concerning enough to allow me to meet with you and expand on the issues and try and answer any questions you may have. I would also be happy to give a short talk on PET to you and your staff or anyone who might be interested.

Some of the dates may not be exact since unfortunately most of my files are on a hard drive I'm having difficulty accessing!

<u>AVOID EXPERTS AT ALL COST:</u>

Towards the end of your talk you spoke of the critical need to talk to experts in the various fields. The Evidence Based Medicine [EBM] approach run by McMaster University goes to great lengths to avoid any contact with experts in PET. None of the government medical experts involved in designing the PET trials had adequate training to supervise or interpret PET.

<u>MY BACKGROUND:</u>

Like you I started my career as a GP 37 years ago in a farming community in southern Ontario called Glencoe. It was officially one of the most underserviced areas in Ontario. I worked in a 45-bed hospital surrounded on three sides by corn with no blood in the hospital and only the most basic of tests available. I did

deliveries some 25 miles away in Strathroy with no OB or Pediatric backup with two GP anesthetists, and three general surgeons. I have always said that I learned how to apply my medical training from interacting with my patients. I have tried to dedicate my career to being an advocate for my patients.

I returned to UWO to get my Nuclear Medicine Fellowship as well as a fellowship in Nuclear Magnetic Resonance Spectroscopy. I came to Sudbury in 1988. Later I did three months training in PET including London England, Dana Farber in Boston, UCLA, the University of Washington in Seattle and in Sherbrooke Quebec. I have read over 5,000 cases. I have given numerous lectures to both professionals and the public including twice at Queen's University, University of Ottawa, and U of T. I also was asked to develop and teach a full day course on PET.

I also have had up to four adjunct professorships at Laurentian University including supervising Physics Masters Students, and developing a course on the biological basis of consciousness, which I taught to fourth year Neuroscience students.

I also was one of Susan Martinuk's advisors and helped extensively with the wording of her final report.

I have also received several local and provincial awards for my efforts on smoking bylaws.

<u>FEDERAL ISSUES</u>:

I will summarize the Federal Regulatory blockades first since you are a Federal Minister.

- Positron Emitting Radiotracers or PER's are regulated by three different Federal Ministries.
    - Health Canada
    - Canadian Nuclear Safety Commission. [CNSC]
    - Biologics and Genetics.
- The major tracer is F-18 Fluorodeoxyglucose [FDG]. It is used in truly tracer quantities at less than a billionth of a gram and has no physiological activity.
- The legislation that governs PERs is based on regulations written at the time of the Irish Potato Famine designed for pharmacologically active medications, not inactive tracers.
    - **There has been in excess of 20,000,000 doses of FDG injected without a single side effect.**
    - **Yet Health Canada is not sure it's safe for Canadians!**
- I have been involved in selecting a cyclotron for Thunder Bay and I can tell you that the most important aspect of the process is making sure that all the safeguards and quality controls are in place to be run by highly trained experts.

- I documented for two previous Federal Ministers of Health and Mr. Tony Clement when he was head of Fed Nor that more than $3,000,000 of money people thought they were donating for cancer research was spent to pay civil servants to fill out forms so we could inject less than a billionth of a gram of FDG into cancer patients.
- As Ms. Susan Martinuk showed, almost 50% of the cost of a dose of FDG is to pay for government regulation. We are grossly overpaying for the drug. When I ran the private PET lab in Mississauga, we got the FDG for a fraction of the cost from Buffalo.
- The world's best bone scanning agent, F-18, is what drips out of a cyclotron and is then combined in automated chemistry kits to produce FDG.
- Yet we are not allowed to inject the F-18 until millions more dollars are spent to determine if this safe for patients.
    - **Surely this defines "unconscionable".**

<u>PET SCANNING THE WORLD STANDARD FOR DIRECTING PATIENT MANAGEMENT:</u>

- PET has been the world standard of care for directing the management of cancer patients for more than a decade.
- It is the imaging cornerstone of Personalized Molecular Medicine.
- It has at least six different uses in directing the management of cancer patients including, as you noted, the ability to allow a patient to make informed choices about how their therapies are working and whether to stop or change if appropriate. This is the essence of Personalized Medicine.
- It is the only way one can monitor the Biologic Therapies since the CT changes are very delayed.
- Places such as Chile and Argentina have had access to PET for almost 15 years.
- PET has a significant role in other diseases including Cardiac disease and can be pivotal in the early diagnosis of the various kinds of dementia.
- CT, is a great 'anatomical imaging' device but has been described by Radiology experts as: "The view from 10,000 feet in the era of molecular imaging. [PET]".

The standard of investigation and management of cancer patients in Ontario is:

- As many as 6-8 serial CT scans when in most cases as little as a single PET/CT would more appropriately direct patient management.
- This is equivalent to over 3,000 Chest x-rays worth of radiation exposure.
- Imagine the enormous stress on patients waiting for their tests, undergoing these tests and waiting for doctor's report only to learn the answer is not clear and they will need another CT in three to six months.
- And what about the delay in appropriate patient management with the potential for fatal consequences, which I have repeatedly seen.

- Imagine the loss of income to radiologists! Apparently one radiologist in the Sault is earning almost $3,000,000 and salaries in excess of a million are not uncommon.
- The Ontario Association of Radiologists [OAR] is the most powerful medical lobby group in the country and they have established a reputation of working by intimidation and threats. When the Bob Rae government ended, they had eight lawsuits pending against the government and individuals.

ONTARIO'S UNIQUE STAND ON PET

- In April 2004, the most senior member of the PET Steering Committee, Dr. Al Driedger, bypassed Dr. Bill Evans and wrote to Mr. Smitherman stating.
    - Mr. Smitherman was blocking PET because of cost concerns.
    - Members of the government were deliberately blocking evidence favouring PET. [confirmed in detail by Dr. Hicks]
    - That Ontario was already a decade behind the rest of the world.

EVIDENCE BASED MEDICINE MCMASTER STYLE:

- Evidence Based has:

    - Absolutely no scientific validity. [All involved in blocking PET are well aware, and confirmed verbally to me by Dr. Julian Dobranowski after his talk in Toronto, but he refused to put in writing.] Absolutely no one would respond to questions about EBM. In particular you will recall that Dr. Les Levin originally ridiculed EBM, but he now heads the government efforts on EBM.
    - It is not peer reviewed.
    - It is internally self-contradictory so that no matter how many patients studied you can't actually prove the diagnostic test is useful.
    - It is designed specifically to get the answers the funding body, in this case the Government of Ontario, needed to implement what they had already decided upon.
    - The article by Dr. Rodney Hicks showed how the Ontario government experts:
        - Downgraded clearly Level A and B papers favouring PET to level C or D. (confirming Dr. Driedger's accusations]
        - **They took a 35 mm slide of an Abstract at an Australian meeting that did not favour PET in lung cancer and elevated it to a level A paper.**
        - As Dr. Driedger told me, this single slide stopped the introduction of PET in Ontario. The government declared that clearly they needed to do their own trials.

        - The Trials themselves were deliberately underfunded so that it was not possible to compete the various trials within even five years.

- **World experts have been specifically naming and condemning Ontario for what they were doing to their cancer patients in journal publications.**
- **In 2007 the CANM meeting passed three motions condemning the Ontario PET trials on cancer patients as "unethical" and demanded they be halted and inquiry take place. (Ignored by government)**
- **2009 Editorial in the Journal of Nuclear Medicine [JNM] by Dr. Sandy McEwan spoke of Ontario's "capricious" use of a scientifically invalid process [EBM] to block patients from PET.**
- At a national meeting on PET in Oncology in Toronto in late 2009, Dr. Julian Dobranowski gave a talk outlining Cancer Care Ontario's approach. Following the talk, Dr. Al Driedger got up and said to the amazement of all attending:

    - **I resign from the PET Steering Committee**
    - **I regret ever having worked with the Government on this.**
    - **I believe what those blocking PET are doing "borders on IMMORAL!"**

<u>POLITICAL ACTION ON PET</u>

- I was President of the OANM during these critical early phases to block PET.
- Suffice it to say that although Mr. McCarthy arranged for us to meet all the key people short of Mr. Smitherman, without exception we did not receive an answer to a single key question, and in many cases they did not even acknowledge the letters.
- When I challenged Dr. Bill Evans as Chairman of the PET Steering to answer the questions everyone had refused to, he reported me to the CPSO stating I was threatening and harassing him. They agreed! Yet when I reported what the PET Steering Committee was doing to patients supported by the motions and world expert comments on what was happening in Ontario, the CPSO did not think there was a problem.
- I would add that I have had numerous conversations and given all the information to both Ms. Shelley Martel the Past NDP Health Critic and Ms. France Gelinas, the current Ontario NDP Health Critic. They have absolutely refused to ask the government a single question that would expose this process. Ms. Gelinas has proposed a motion to get PET scanner for Sudbury, to score political points, but absolutely refuses to challenge or publically discuss Ontario's appalling, unethical and even immoral stand on PET.

WHY SUCH UNPRECEDENTED MOTIONS AND ACCUSSATIONS OF IMMORAL BEHAVIOUR?

Early Issues:

PET LUNG CANCER TRIAL:

- Dr. Driedger submitted a letter to the PET Steering Committee from experts at NIH in Bethesda stating that FDG PET was standard of care for lung cancer and the proposed trial therefore was not indicated.
- In spite of this they deliberately assigned patients to a No PET control wing, thus denying these patients what was accepted as standard of care. They did not tell patients of the discrepancy between the PET Steering Committee's position and the world expert opinion as required by informed consent for human trials.
- The data was manipulated as described above using non-valid EBM methods.
- The result of that trial is that the major OHIP funded PET procedure in Ontario is for dealing with Single Pulmonary Nodules [SPN]. The directive is the exact opposite of the entire world expert community:
    - **It would potentially result in claims of incompetence for using it in this manner in many medical jurisdictions!**
        - In the rest of the world you do the PET before you decide if and where to biopsy. Often PET identifies biopsy sites more accessible and safer than lung biopsies. Patients can be staged without even the need for a single diagnostic CT!
        - PET can direct the biopsy to the most active part of the mass to get the best possible sample for pathology.
        - **In Ontario, you must stick the needle in the chest first before you can get a PET!**
    - For patients who do have lung cancer it typically leads to a six week delay in management.
    - This demonstrates the 'power' of EBM as used by the government's medical 'Experts' to get the answers the government needed to implement policy they had already decided on.

PET TRIAL ON ONTARIO BREAST CANCER PATIENTS.

This directly lead to the three unprecedented motions passed by the CANM although I am having trouble recalling when due to trouble with my backup disk but would be able to get a copy.

The motions passed and:

- Declared the Ontario Government PET Trials unethical.
- It demanded the PET Trials be halted.
- That a formal investigation involving Ethicists and Health Specialists be set up to review how this could have happened in Ontario. They did not recommend science experts, since there was no science here with it clear that EBM had not scientifically validity
    - **The government ignored the motion and proceeded with the Breast PET Trial**

BACKGROUND:

- Select members of the PET Steering Committee developed all the PET Trials in secret.
- Although there were PET experts on the committee they were not consulted in spite of repeated offers to do so by them and the PET expert Nuclear Medicine Community. They were not allowed to see trial proposals.
- The OANM however was able to get a copy of the first proposed PET Trial on Breast Cancer. I had just finished my PET training and reviewed it. It was clear this trial should not take place, other colleagues agreed and we declared to the PET Steering Committee it was unconscionable to perform this trial. Why:

    - **The Breast PET Trial was designed to look for spread of disease to sentinel nodes in early stage breast cancer. This is unlikely, and if present is most likely to be microscopic in nature.**
    - **The PET scanner with a resolution of 6mm was <u>not physically capable of detecting these lesions.</u> Indeed with standard PET cameras, breast cancers as large as 1.5 cm could be missed in the breast itself.**
    - **They deliberately excluded the very breast cancer patients the rest of the world new would benefit from a PET scan.**
    - **It was clear the Trial was designed to fail which is against the Helsinki Declaration on Ethical Human Research.**
    - **The Ethical Principle of Equipoise was also grossly violated. It would have been clear after less than 20 patients that PET would fail, since the experiment was designed to do so and it should have been stopped. Yet they put over 300 women through this doomed experiment and exposed them to some 300 Chest x-rays worth of radiation exposure knowing the trial had to fail!**
    - **Later Dr. Dobranowski would confirm to me verbally but refused to put in writing that:**

        - **Neither the patients nor the Ethics Board were told the camera could not detect the lesions by design.**
        - **They were not told that the data would be analyzed using the non-validated method of EBM.**
        - **I said to Dr. Dobranowski that they were using the trials to try and validate the EBM tool and not the validity of PET, and again no one was informed of this.**
            - **From the 'shrug of his shoulders' I took this as a yes.**
        - I don't believe Dr. Dobranowski was involved in the original trial design. He was eventually appointed to the Cancer Care Ontario's section on assessing ALL indications for PET, not just oncological indications. This conversation took place following his talk at the Toronto conference leading to Dr. Driedger's resigning from PET Steering Committee and declaring the process "bordering on immoral".

- Without explanation the trial was pulled and I believe it took almost two years before the second trial was ready and again we obtained a copy before the trial started.
    - It was identical to the first trial with an addition so trivial as to be only useful for a first year resident in Nuclear Medicine.
- We were outraged and declared what they were doing was unethical.
- This lead to a press conference at Queen's Park by Dr. Chris O'Brien.
- It did lead to the motions at the CANM meeting.
- Dr. Karen Gulenchyn of McMaster was involved with this trial and also on the OANM Executive. Because of her involvement we voted unanimously to not allow Dr. Gulenchyn to be involved in any discussion by the OANM about PET.
    - When the trial was ongoing, Dr. Gulenchyn gave a short talk to the OANM on how the trial was proceeding: She stated:
        - "There seems to a lot of histologically positive metastasis but PET negative studies."
        - I was outraged since she made it sound as if this surprised her and perhaps this made sense since she did not have what would be considered adequate training in PET to direct or interpret PET studies.
        - Dr. O'Brien cut the discussion short, as he did not want to see the meeting deteriorate.

- The indications for PET in breast are limited to those with advanced disease at presentation, and in restaging.
- **Although these women can get a PET scan in Quebec, or for that matter in Paraguay, to this day, breast cancer patients in Ontario cannot get a PET scan unless they pay for it themselves.**

ONE FINAL POINT:

ONTARIO OMBUDSMAN AND PET. (Watchdog, or Lap Dog?)

Investigation 1:

- Andre Marin ran two investigations into the government process on PET.
- I instigated the first one and it included addressing a letter to Mr. Smitherman. This letter included the communication to him from Dr. Driedger and asked among other things why he did not respond to this as the law required.
- In response, Mr. Smitherman's office did not address a single issue of relevance.
- Mr. Marin closed the case stating:
    - "I believe the Ministry has addressed all of the concerns raised by you and your colleagues."
- I was simply 'dumbfounded. I again sent a copy of the letter I had sent to Mr. Smitherman and his response showing the obvious, that not a single issue of importance had been addressed. I then said:
    - "But you must have the answers since you're so sure the issues have been addressed. Therefore could you send me a copy of the answers" The response of his office:
        - "Because of privacy issues, I cannot share this information with you."
- I had nowhere to turn and as you might expect that throughout this process and over the years the PRESS refused to touch the issues. Most of the news stories in the National Press came through me. In some circumstances they even reversed statements I have made, or would not include key statements that would have implicated the government and their experts in this "unethical process".

Investigation #2:

- Initiated by a breast cancer patient.
- I contacted the Ombudsman again and had numerous exchanges through the individual assigned to the case. I gave a large amount of information including the 'behind the scenes' issues of radiologists concerned about lost income if PET came on line ect. I put them in contact with experts including Dr. Sandy McEwan and they were fully informed about the "unethical motions" from CANM.
- At one point Mr. Marin stated publically this was the most complex investigation he had undertaken and that the government was not getting back to him. I was told that the government refused to even respond to requests for information for a year.

- I was called by my contact in December 2009 as I recall, and I was informed a 37 page document outlining questions and concerns had been delivered to government and told they were to respond by end of February.
- There was no response and in June 2010 Mr. Marin mentioned this in a public address.
- Some six weeks later the MOH announced limited funding of PET.
- Mr. Marin immediately declared "that all his concerns had been met". He closed the investigation and then buried it from public access.
    - It is almost certain that the 37 page letter was never responded to.
- I was dumbfounded and outraged. My contact sympathized with my concerns but said Mr. Marin had the authority to bury a report if he didn't think releasing it would have any public benefit!
- I wrote him a letter and received an insulting reply implying that somehow I imagined Mr. Marin's duty was to access whether PET was useful. They explained to me that his job was to assess government process. The only issues I brought to their attention were of course concerning government process!
- I do know from Hansard that as little as 1-2 years ago, Mr. Marin was publically congratulating the government on their handling of PET.

AND WHAT OF THE SAM BRUNO PET FUND IN SUDBURY:

- Mr. Bruno was a colon cancer patient and named Man of the Year in Sudbury because of his efforts to get a PET scanner for Sudbury. He unfortunately died of his disease. There now is a fund in his name to do so.
- Mr. Bruno understood every detail of how PET was blocked, but true to form, all the local press buried this story and deliberately altered statements I had made when articles appeared.
- However some interesting things happened indicating how 'nervous' he was making the government.
    1. Ms. Deb Matthews, the Minister of Health took time out of her busy schedule to call Sam personally to see how he was doing. When Sam died she wrote a letter to the local paper saying how sorry she was, but mentioned Sam "got some things wrong." He of course didn't, and when I wrote a short Letter to the Editor making clear he had gotten things right, the paper chose not to publish it. Why would she call one patient?
        a. Quebec was forced to start covering PET because a colon cancer patient, Mr. Barry Stein, successfully sued them because he had to go to the US to get his PET scans!
    2. Sam was stating publically he wanted Mr. Marin to release his report to the public. The Ombudsman's Office sent someone to share a glass of zambuka with Sam over his kitchen table to explain why they couldn't release the report!

3. It is important to know that a key Liberal in Ontario was Mr. Rick Bartolucci of Sudbury. He only met with me once and said clearly this was amazing. It was the last time he spoke to or was allowed to meet with me.

To this day, 50% of colon cancer patients with metastasis cannot get an OHIP funded PET scan because they do not have an elevated CEA.

SUMMARY:

Governments have never had any difficulty finding experts, including physicians, who are willing to do or say whatever is necessary to support any agenda. Similarly, no educated person would be surprised at the steadfast 'selective blindness' of the PRESS to issues until such times as it meets the agenda of some media owner to reveal what they know. Nevertheless I have been simply overwhelmed and saddened by what the Ontario Government and a handful of doctors have methodically and for more than a decade, done to make sure Ontario patients have the most restricted access to PET in the civilized medical world. And yes there are realistic concerns about money, but clearly proper and inspired political leadership would have found a way forward for our patients. My wife and children have been witness to the enormous stress my failed efforts have had on me. I have personally witnessed far too many tragic stories of patients who might well have survived or had a better quality of life if only they not lived in Ontario.

What perhaps is the most distressing point is that their greatest and most sustained efforts have been to block access to PET for cancers that primarily affect women. Yet perhaps this is not so surprising given the patriarchal nature of our societies and the struggles women still have for equality.

Notwithstanding Dr. Levin's reassurance of just "trying to do what is best for Ontario's cancer patients", the efforts of this small group of physicians and their refusal to publicly defend their actions is contemptible. They have done this to some our sickest and most distressed patients and their families. They have set an unprecedented low point in the history of Publicly Funded Medicine in Canada. The rest of world seems to understand this. The question is why has it been so difficult to get the attention of key people in Canada?

How can I look my children, or my students, or my patients in the eyes and say that you need to have 'faith' in our system of a supposed open transparent and accountable democracy when it has been anything but? To me there is no mystery as to why people are less engaged in the politics in Canada, best reflected in declining numbers of people bothering to vote.

However you have given me a reason to renew my efforts on behalf of Ontario's patients. I do hope to have the opportunity to meet with you and discuss these

critical issues about access to health care not just in Ontario but also in the rest of Canada. The reality is, that with the exception of Quebec, the rest of the provinces have tended to hide behind Ontario's approach rather than face the tough questions of how to pay for PET in our publicly funded system, where poorly informed physicians can order almost any test whether appropriate for patient management or not.

Sincerely

Dave Webster MD FRCP