

Dr. Dave Webster  
Department of Diagnostic Imaging  
Health Sciences North  
41 Ramsey Lake Road  
Sudbury ON  
P3e 5J1

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Mr. Paul Dubé  
Ombudsman of Ontario  
Bell Trinity Square  
483 Bay Street, 10th Floor, South Tower  
Toronto, ON  
M5G 2C9

RE:COMPLAINT AGAINST PREVIOUS OMBUDSMAN, ANDRE MARIN

Dear Mr. Dubé

I am sure you will find this an odd complaint, but once I have made my case, I would hope that you find this appropriate and indeed essential. The office of the Ombudsman is described as the 'Watchdog' of Ontario against inappropriate government process in dealing with citizens.

- The question I will pose to you is whether Mr. Marin acted as a 'watchdog', or a 'lapdog' for the government for the government of Ontario?

This relates to a key medical diagnostic test called PET, which has lead to extraordinary and unprecedented condemnation by the world medical community. This is related to how Ontario has treated its cancer strictly out of economic concerns. The economic concerns are very real, but how the government has handled the issue is unconscionable.

### **INTRODUCTION:**

The issues relate to the process that the Ontario Government has used to block access of cancer and other patients to PET through the efforts of various 'expert advisory groups' for the Ministry of Health [MOH].

Positron Emission Tomography or PET is the Imaging Cornerstone in the Era of Personalized Molecular Medicine, and the world standard of imaging management of most cancers for almost 15 years. This is because of it's unique ability to 'image' the patient's 'own cancer cell metabolism' and response to therapy. There are other

critical uses as well. PET combined with a low dose CT as PET/CT, safely produces images of cellular metabolism using trace amounts of radioactive molecules.

Ontario has the most limited access and blatantly wrong indications for PET in the civilized medical world. The MOH has accomplished this disturbing and deliberate assault on patients through its use of scientifically baseless Health Technology/Evidence Based Medicine [HTA/EBM] tools. These tools are designed to get the answers the government needed to implement policy they had already decided on. It is the exact opposite of how the process is purported to work. In theory, Cancer Care Ontario [CCO], for example, is supposed to have its experts assess the evidence on various diagnostic tests and treatments.

The government cannot afford to pay for every possibility in a publically funded system. Based on the best evidence provided by CCO, the government will make 'informed decisions' regarding what it will or will not fund. In reality, the Ministry of Health tells its 'expert advisory physicians' the answers it needs to implement policy they've decided on. Then CCO and the other 'experts' produce the supporting evidence the MOH needs. Sound like a conspiracy theory? If only it were. The power of EBM to come up with the answers the government needed is best demonstrated best by the following example:

- As much as 90% of OHIP funded PET scans are to assist in the determination of whether lung nodules are cancerous.
  - The indication is the exact opposite of the entire world expert opinion and could result in charges of incompetence in most medical jurisdictions. Professor Rodney Hicks, a recognized world expert in PET from Australia published a paper showing how the MOH 'experts' manipulated the research data to suit the MOH demands, as I will describe in more detail below.
    - This paper won't be in the information package I sent to Mr. Marin since it was published in 2011. I will include a copy. However it is critical since it completely validates the accusations that Dr. Driedger made in a letter to the Minister of Health, Mr. George Smitherman in 2004. Mr. Smitherman refused to acknowledge the receipt of this letter, hardly in keeping with 'appropriate government process.' This will be dismissed not once but twice by Mr. Marin.
  - The OHIP funded indication leads to massive overexposure of patients to radiation and potential unnecessary exposure to high-risk biopsy procedures and clearly unnecessary stress and anxiety to patients including delays in resolving their questions.
  - For those who do have lung cancer it leads to:
    - A 6 TO 8 WEEK DELAY IN THEIR MANAGEMENT!

In 2007, three motions by the Canadian Association of Nuclear Medicine [CANM] declared the Ontario Government PET Trial experiments on cancer patients “unethical”; demanded they be halted; and that an independent Ethics Commission be set up to determine how this could have happened in Ontario. Mr. Smitherman, and the PET Steering Committee [PSC] Chaired by Dr. Bill Evans, and the other MOH advisory groups as well as the Senior Medical Advisor to the MOH, Dr. Les Levin, ignored these profoundly disturbing motions.

In 2009, following a presentation at a medical conference by Dr. Dobranowski from CCO, the most senior member of the PSC, Dr. Al Driedger resigned publically. Dr. Dobranowski had outlined how CCO would continue to use HTA/EBM to determine the utility of PET for all patients, cancer, and the other uses of PET such as CNS, and Cardiac Imaging. Dr. Driedger had been working with the government since the mid 1990’s on trying to introduce PET into Ontario. Dr. Driedger finally had had enough. He went to microphone and said:

- “I resign from the PSC.”
- “I regret having ever worked with this group.”

And then he made a statement, which shocked everyone in the audience, many of whom knew Dr. Driedger and his many years of distinguished work in Nuclear Medicine in Canada. He stated:

**“What those who are blocking PET in Ontario are doing borders on immoral.”**

These are extraordinary claims and statements I’m sure you would agree and in particular is entirely related to the ‘process’ by which the government and the MOH assessed PET. How could this possibly have come about? More to the point how could Mr. Marin, the ‘watchdog’ of Ontario, dismiss all these profoundly disturbing statements and indeed congratulate the government and it’s physicians on their efforts on PET?

It was the PET PREDICT trial on women with breast cancer that galvanized the Canadian and even the international medical community. Consider this:

- MOH ‘experts’ designed a PET experiment, with an average radiation exposure equivalent to approximately 300 Chest X-rays, for women with early stage breast cancer. (Acceptable if medically indicated.)
  - **The PET scanner was NOT PHYSICALLY CAPABLE of detecting the vast majority of cancers they told the women they were looking for.**

- In addition, the ethical human research principle of equipoise demands an experiment must be halted immediately if it becomes apparent that it is not the correct approach and now there were only risks to the subjects with no possibility of benefit.
  - Given the 'experiment' was designed to show PET was not indicated for this group of cancer patients, this was immediately apparent and the experiment should have been halted.
  - Instead, they exposed more than 300 victims, distressed with their diagnosis, to unnecessary radiation as an excuse to block PET.

**Ontario remains the only medical jurisdiction on the planet refusing to accept the recognized indications for PET in breast cancer and therefore they are not funded by OHIP.**

The position of the various MOH bodies blocking PET is that there is insufficient evidence to support more than the limited indications they currently fund for PET. Yet based on the same evidence, years ago France bought 75 PET scanners. There are almost 100 PET scanners in Turkey, and it has been the standard of care in places such as Chile and Argentina since the late 1990's. We currently sit behind Paraguay, which worked at getting the infrastructure in place to offer PET for their citizens almost three years ago.

They are also continuing to use 'sophistry' to further claim they will only pay for tests which "improve patient outcome/survival". An utterly inappropriate, question to be asked of an imaging technology whose role is to help the physician and their patient best determine how to navigate through the various stages of diagnosis, staging, treatment monitoring and restaging of their cancers. Only treatments ultimately can improve patient survival.

A large Canadian study by Worsley et al. (2010) evaluated the impact of PET on treatment changes and decision-making in 3,779 consecutive patients at the British Columbia Cancer Agency in Vancouver, British Columbia. Based on a standard physician's questionnaire, it was found that the information derived from PET imaging resulted in a change in an individual patient's treatment plan in 50% of cases and physicians reported an improved decision-making ability in 83% of cases.

Yet in spite of the fact there are is no evidence to show that CT would prolong survival, (equally inappropriate question), pay for as many as six to eight CT scans to follow a patient, when a CT has essentially no ability to differentiate scar tissue from cancer in a mass. Yet this is the key strength of PET that looks at the metabolic activity of the mass. In many cases a single PET can most appropriately direct the next step in patient

management. The blatant hypocrisy is “egregious and politically motivated” to quote a recent communication I had with Professor Rodney Hicks.

With the exception of some of the most recent statistics and the article by Hicks and Worsley, Mr. Marin was fully aware of all of this and much more. However after two investigations, he completely cleared the government of any abuse of process or wrong doing, buried the reports from public access, and then was quoted in Hansard as congratulating the government on the great job it was doing on handling the issue of PET.

I worked with the Ombudsman’s Office on both of these files. I was outraged with his final response. When I wrote him expressing my concerns, the individual writing on Mr. Marin’s behalf insulted me. He implied that I had somehow mistaken the Ombudsman’s role as being to determine what were the best indications for PET. I was informed that the Ombudsman’s role was to assess the process by which the government had evaluated PET. How pathetic, but very much in keeping with his previous actions on the first enquiry into the process by which the government was handling PET.

I was the President of the Ontario Association of Nuclear Medicine [OANM] during most of the more controversial issues surrounding PET. In addition the OANM had hired a lobbyist, Mr. Michael McCarthy. Mr. McCarthy was the Senior Aid to Mr. Tony Clement when he was Minister of Health. Mr. Clement gave the marching orders to the MOH expert physicians to block PET because of cost concerns. This was a result of his review of a multidisciplinary group of experts that looked at how PET, which was rapidly becoming the world standard, would impact health and thus health care expenses in Ontario. Since Mr. McCarthy was present at all these initial planning meetings, we were fully aware of what took place.

I will assume that you have access to all the documents related to the two investigations I will outline briefly below. However if you need any of these or other documents I will be happy to send them to you.

### **KEY PLAYERS:**

1. Dr. Les Levin, Senior Medical Advisor to MOH and currently Chief Scientific Officer of MaRS, which uses EBM to evaluate technology. (This is presumably a promotion for how successful he was in blocking PET in Ontario. In a private meeting with Dr. Levin in 2004 Dr. Levin ridicules HTA and EBM, yet this is exactly what he would endorse to block PET, and now leads this group which continues to use this scientifically baseless process.)
2. The PET Steering Committee, chaired by Dr. Bill Evans through the most controversial issues of the experiments to block PET. He was also involved in designing the PET Trial experiments and an author on the published papers.

- a. Dr. Evans has stated to the Media and also in a published article with Dr. Lapaucis, that the reason experts from the provincial to the international level have been so vocal in trying to get answers on PET is because we will benefit financially by reporting them! This must justify to him the extraordinary and egregious methods to make sure we didn't get paid to read PET.
3. Of interest out of frustration I sent a letter directly to Dr. Bill Evans as Chair of the PSC. It was an angry letter to be sure, but I insisted he answer key questions that everyone had been stonewalling on. Instead of answering the questions, he reported me to the College of Physicians and Surgeons[CPSO]. Curiously I was reprimanded, but the COPS did find any problem with the PSC members were doing to patients in light of official motions by an expert group declaring the PSC trials unethical.
4. The Institute for Clinical Evaluative Studies [ICES] chaired by Dr. Andres Lapaucis during most egregious attempts to block PET.
  - a. It would be this group in particular that Professor Hicks will detail how they deliberately manipulated data to get the results the MOH needed for what it was prepared to fund through OHIP for lung nodules described above.
5. The Ontario Clinical Oncology Group [OCOG] chaired by Dr. Mark Levine.
6. Cancer Care Ontario. Currently, Dr. Julian Dobranowski heads the assessment of PET for all medical indications.
  - a. As Dr. Dobranowski walked off the stage following Dr. Driedger's charges of immoral assault on patients, I went up to him and addressed several questions to him. Without exception my colleagues and I had not received a single answer to the clearly important issues we raised with various physicians and MOH officials. Yet the websites and mission statements from groups such as CCO proclaim: Timely Access to Quality Imaging all with "transparency" and "evidence based" approaches.

In short he confirmed there was no evidence to support the use of HTA to evaluate any diagnostic imaging device but that CCO would continue to use it to assess PET. Indeed he agreed that they were not evaluating PET, but using PET to try and validate the HTA! True to those blocking PET, when I wrote him asking him to put in writing what we spoke of, he refused and instead accused me of not being collegial. More importantly, he did not challenge the content of our conversation, thus confirming his statements.

7. Dr. Karen Gulenchyn. Nuclear Medicine Physician and member of the PSC. She was involved in designing the PET trials and an author on the papers.

Of note, none of these people are PET experts, even Dr. Gulenchyn to the best of my knowledge. One of the key characteristics of HTA/EBM is that they avoid dealing with actual experts as much as possible.

### **MOH PET INVESTIGATION NUMBER 1:**

I instigated the first investigation into the process by which the MOH experts were blocking PET based on my intimate knowledge of the details. They were not sure how to handle my complaint since normally they received complaints from individuals who felt wronged by the government. I was presenting concerns on behalf of those who were suffering and ultimately having substandard management of their cancers, or took part in unethical experiments because of government process.

- One of the major complaints from the OANM and myself was the complete lack of transparency related to PET. There were numerous meetings either by myself, or with the OANM executive with various MOH officials. Mr. McCarthy was present during a number of these. There were also many other letters addressing such issues as the government deliberately underfunding the PET trials so that they couldn't be completed.
  - They ultimately needed some 1,500 patients for the initial trials.
  - The government introduced Bill 8 making it illegal for hospitals to run a deficit.
  - Yet they only funded hospitals providing PET with enough funds to perform approximately 30-scans/camera/ year. There was something like 8 scanners at the time. The experiment could not be completed at this funding rate within the time required to be valid studies.
  - A report from Ombudsman in 2007-2008 stated:
    - **“Seven years since the process started, only two of the five clinical studies have closed.”**
- In most cases there was never even an acknowledgement that they had received our letters. When we did get a response, **without exception, to this day, not a single question of relevance was addressed.**
- This includes a letter I sent to the current Minister of Health, Dr. Eric Hoskins in May 2016. This letter was sent after he requested that I write him with concerns. In January 2016 France Gelin as the NDP Health Critic handed it to him personally. Still no response. Dr. Hoskins has fit in well with the 'time honoured' Liberal Government tradition on PET.
- A key document was written in 2004 when Dr. Al Driedger bypassed Dr. Evans, Chair of the PSC. He wrote to Mr. Smitherman regarding his grave concerns about the process of the PSC.

- Dr. Driedger accused the MOH of blocking PET because of cost concerns.
- That members of the PSC were deliberately denying data that favoured PET.
  - World expert Professor Rodney Hicks of Australia subsequently confirmed this in a Journal of Nuclear Medicine publication.
    - The PSC and ICES ect, deliberately downgraded level A,B papers favouring PET to unacceptable level C,D publications.
  - This article in particular demonstrated what Dr. Driedger had said to me in conversation.
  - PET was stopped in Ontario by a 35 mm slide of a poster presentation from a medical meeting in Australia that stated that PET was not useful in lung cancer.
    - **This poster was elevated to a level A paper.**
    - **This is as close to academic fraud as you can get.**
  - NOTE: The indication for PET in lung nodules that is the opposite of world expert opinion was the final result of this PET trial.
- That the technology was already changing to PET/CT and Ontario was already a decade behind the rest of the world.
- **Mr. Smitherman also refused to acknowledge or respond to this letter from the most senior member of the PSC and thus set in motion the stonewalling that has been maintained to this day.**
- It remains my understanding that the Minister of Health is required by Provincial law to have someone on staff acknowledge and respond to such communications.
- I was instructed to write letters again asking for responses. The key letter I wrote was to Mr. Smitherman. In this letter one of my main inquiries was why he did not acknowledge or respond to Dr. Driedger's letter. I then again submitted the same statements and questions that he had ignored.
- I did get a response from Mr. Smitherman's office.
- However, true to form, not a single question or issue I had raised of any relevance was answered.
- Mr. Marin then stated that:
  - **I believe that the MOH officials have addressed the questions and concerns I had raised on behalf of the OANM.**
  - **He dismissed our concerns and closed the file.**
- I responded by sending a copy of the letter I'd sent to Mr. Smitherman along with a copy of the response, pointing out the obvious that there was no correspondence or answers to key questions put forward. However, I said that since you are convinced our questions have been addressed then "you must have the answers, so would you mind sharing them with us?"

- **Mr. Marin responded by stating that such responses were protected because of privacy issues and he could not share them with us.**
- I responded by stating: “It is comforting to know that the Ombudsman of Ontario is the equivalent of Jean Chretien’s Ethics Commissioner.” Not politically correct, but to imagine I should treat this man with respect was unthinkable.
  - Of interest, a short while later, someone from the Ombudsman’s Office called me and said that things would work out eventually and my concerns would be addressed.
  - They weren’t and in fact there was a second investigation.

### **PET INVESTIGATION NUMBER 2:**

It is my understanding that a woman from Ottawa with breast cancer among others precipitated this investigation; an investigation that eventually Mr. Marin would publically declare was the most complex he’d undertaken. After considerable deliberation I decided to give him another chance. I needn’t have bothered. I contacted his office and was assigned to a caseworker. I sent all the documents and information I had. I also included a detailed summary airing all the ‘dirty laundry’ such as the attempts by Radiology to claim PET from Nuclear Medicine. I put Mr. Marin in contact with key people, including Dr. Sandy McEwen from Edmonton. Dr. McEwen at one point was the President of the Society of Nuclear Medicine, the major US Nuclear Medicine Professional Association. In this capacity, he wrote an editorial pointing out the complete lack of scientific validity to the use of Health Technology Assessment [HTA] to assess roles for PET for funding by the Ontario MOH.

- **He described the “capricious use” of this scientifically baseless *process* to block Ontario cancer patients from access to PET.**

It was my understanding from the woman handling the information that the government was also ‘stonewalling’ the Ombudsman’s request for information. Each summer the Ombudsman would give a summary of issues, and I recall that Mr. Marin stated publically that this was the most complex case he’d handled. My recollection was that he also commented the government was not forthcoming with the information he was requesting.

Eventually in December 2008 the representative called me and said that a thirty something page document had been prepared with issues to be addressed by the MOH. They were to respond by February 2009. There was no response. Then in his June address he again declared that the MOH was not getting back to him on the issues. A few weeks later in July, the MOH announced that they would provide very limited OHIP funding for PET. They also announced that the three private PET facilities would be able to apply to be allowed to bill under OHIP and must do so before October. Also, no more private PET scanners would be allowed.

- Mr. Marin immediately declared that all his concerns had been addressed. He closed the file, and then **declared it was to be removed from Public Access.**
- Summary Statement from Ombudsmans office 2009-2010:
  - “In light of the Ministry’s response to his findings, the Ombudsman determined that the matter could be resolved without a published report. At the time this report was written, the Ministry was developing an accountability agreement with Cancer Care Ontario (CCO) to look at uninsured PET services.”
- The Ombudsman site added this statement at the end of this summary:
 

“Your team is to be congratulated for their dogged and thorough approach to moving this important PET scan issue forward. Your continued monitoring gives people some confidence that the program will be rolled out as described. God bless all of you.  
Darwin Brunne, comment posted at Ombudsman.on.ca

I was simply dumbfounded. I wrote him with my profound disappointment at what he had done and received his childish and pathetic attempt at justifying what of course he could not possibly defend.

### **MR MARIN AND MR SAM BRUNO OF SUDBURY:**

Mr. Sam Bruno was a remarkable man who ultimately would die of his colon cancer. In the midst of this terrible stress on Sam and his close knit Italian family he tried to stand up against the government and the Ombudsman. His goals were to get a PET for Sudbury and similar access to PET in Quebec and rapidly evolving around the world even in countries we would consider Third World such as Argentina. Sam was aware of all of the issues since I informed him of the details and supplied him with the information to support my statements.

Sam got the attention of the government and sadly Mr. Marin. How often does a Minister of Health take the time to call one cancer patient in the province? Ms. Deb Matthews did just that. She called to see how Sam was doing. Then when he died she wrote a ‘nice’ letter about him in the Sudbury Star newspaper. And then she insulted him when he could not defend himself against her lies. She said:

- “But Sam got a few things wrong.” Sam got nothing wrong. I wrote a short rebuttal to the Letters to the Editor that the Sudbury Star to the best of my knowledge refused to publish.

Sam was also asking Mr. Marin to release his report on PET in Ontario. An article published on the Ombudsman Website includes story by the same Sudbury Star that allowed Ms. Matthews to insult Sam. The reporter, Ms. Carol Mulligan was well aware that Sam had gotten nothing wrong.

The Ombudsman sent a representative to talk to Sam in Sudbury. What they duped Sam into doing was to ignore his request to have the Ombudsman's Reports on PET released, by instead letting him know that the MOH would finally fund PET. Of course the Sudbury Star let them get away with their cruel deception to a dying man.

After Sam's death in 2010, the Sam Bruno Fund was started to fund a PET scanner for Sudbury.

**The tragic, almost obscene irony, is that even if we had a PET scanner, and Sam was alive:**

**He almost certainly would still not be allowed to have a PET scan on the scanner that will be named in his honour! Simply because, like thousands of other cancer patients, he would have the misfortune of living in Ontario. However, it is clear that this is perfectly fine with Mr. Andre Marin.**

So the obvious question is why did Sam get 'special attention' from the Minister of Health, Ms Deb Matthews, and the Ombudsman, Mr. Andre Marin?

- One of the main reasons Quebec was forced initially to start covering PET was because they were sued by; you guessed it, a colon cancer patient named Mr. Barry Stein.
- **They did not want Sam to be the 'Barry Stein' of Ontario.**
- So they shut him down! How dare they do this to such a remarkable and inspiring individual. It speaks volumes about the kind of people he was mistakenly hoping would help in his quest.
- As I have said to Sam's wife Cheryl; Sam was a noble man, but sadly those he dealt with, were anything but.
- And they continue to get away with it to this day. Many of the individuals charged with blocking PET at all costs, continue to do so today. And I can tell you that Dr. Les Levin is very proud of what they've accomplished. When I was leaving Dr. Levin's office after our meeting, he stopped me and said:
  - **"Dave, we're just trying to do what is best for Ontario's cancer patients."**
  - I shall never forget that this man could say such a thing. Sadly there many other 'Dr. Levins' who have been not just able but willing do

whatever was asked of them unless you accept what Mr. Andre Marin has concluded.

Our patients deserve better, and the question is whether you will be prepared to be part of helping right this terrible and "immoral" wrong.

**SUMMARY:**

If Mr. Marin had of been acting as the 'watchdog' he claimed, do you believe that Ontario would to this day have the most restricted and blatantly wrong indications for PET in the world?

As you might expect, I have no faith in the Ombudsman's Office, and I believe the facts I have outlined here are adequate to support this position. What also is clear is that other Ontario Government agencies that are also supposedly acting at 'arms length' from the government have committed what surely are crimes against some of our sickest and most distressed patients. Indeed, Professor Hicks, was able to get out information leading to successful criminal charges against MOH officials in Australia.

**Therefore, Mr. Dubé, my question to you, is are you prepared to act as the 'watchdog' which the Ombudsman's Office is founded on and begin a full investigation into the actions of Mr. Marin when he acted as Ombudsman, or not?**

What also surely should be clear, is that Sam's demands that the two reports of Mr. Marin on the *process* by which the Ontario Government investigated and funded PET MUST BE RELEASED AS SOON AS POSSIBLE.

Surely given the facts above, to suggest that it would not serve the 'Public Interest' to release this document, is to simply compound the abuse that has occurred to Ontario cancer patients.

If you were not prepared to proceed with an immediate investigation into the actions of Mr. Andre Marin in his capacity as Ontario's Ombudsman, then I would request a very detailed explanation to justify your decision.

Regards

Dr. Dave Webster

1-705-675-4714 private office  
immoralpetontario@gmail.com

