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

Ms. Barbara Finlay Deputy Ombudsman of Ontario

Cc:Mr. Gareth Jones Director of the Special Ombudsman Response Team

RE:Letter dated August 31,2016 dismissing the concerns I have raised about PET in Ontario, the 'government process' that lead to the travesty of the situation, and the actions of Mr. Andre Marin, and now indeed your actions.

"Other countries in the world continue to try and block PET, sadly, even in Australia. However Ontario has the most egregious and politically motivated agenda in the world".

2016 statement from Professor Rodney Hicks recognized world PET expert from Australia.

Dr. Hoskins knows, because he published a medical paper in 2011 demonstrating exactly the "process" by which the Ontario MOHLTC came up with a policy on PET that is the exact opposite of the entire expert world community opinion.

Dear Ms. Finlay and Mr. Dubé

I wish I could say that regurgitating what Mr. Marin said and did was a surprise to anyone, or the fact that you also chose to insult my intelligence and professionalism

by claiming I was confused about the role of Ontario's 'Watchdog', but it wasn't. It simply makes clear the precariousness and indefensibility of your position. Now I must challenge whether you, Ms. Finlay, and Mr. Dube are following in the footsteps of Mr. Marin and are acting as Ms. Kathleen Wynn's 'Lapdog'.

In response to your letter dated August 31 2016, I will now submit my request for three 'points of clarification', and a summary of what you fully support when it comes to how the Ontario Liberal Government continues to investigate PET to 'decide what it's policy on PET will be, moving forward'.

Mr. Marin hid behind "privacy of information" and refused to respond to my requests for clarification on his ruling. However, since *I INSTITUTED THIS CUURENT INVESTIGATION I SHOULD BE ENTITLED TO FULL AND COMPLETE ANSWERS TO MY REQUEST FOR CLARIFICATION ON YOUR ASSESSMENT*.

Given the length of time you and Mr. Dubé had to review the material before making your 'ruling' there should be no problem in promptly answering this letter.

POINT NUMBER 1:

You've concluded that my colleagues and I thought the role of the Ombudsman was to "investigate matters of broad public policy". Do really imagine that those of us who have evaluated the 'processes' by which the government assessed PET, and have challenged without success, the appropriate people to defend these "processes" did not understand that your role was to:

- Evaluate the "processes" by which the Ontario Liberal Government CAME UP WITH THEIR 'BROAD PUBLIC POLICIES' on PET AND NOT THE POLICIES THEMSELVES?
- Do you really imagine we might imagine that your role would be to evaluate the final "broad policies" the government came up with when we would be well aware that you would have no training or expertise to evaluate whether the policies themselves were sound or not?

Let me first start by using a standard definition of 'process'.

proc∙ess¹ prä₁ses,¹prō₁ses/noun noun: **process**; plural noun: **processes**

- **1**. A series of actions or steps taken in order to achieve a particular end.
 - In the case in question, the series of steps the Liberal Government used to evaluate PET and THEN determine it's 'Broad Public Policy' on PET.

The key question of course is whether this was the manner in which the Public Policy was developed, or the alternative:

- Did the Liberal Government DEVELOP THEIR POLICY ON PET FIRST, and then instruct Cancer Care Ontario [CCO] to come up with the answers they needed to implement the 'Policies'?
- We also know that CCO was told to do whatever was necessary to discredit PET because of concerns about cost, not about the evidence supporting the use of PET.
- In fact we know this to be the case based on:
 - The information from Mr. Michael McCarthy who was the person directly under the Minister of Health when these discussions took place and present when government physicians were told to discredit and block PET because of cost concerns.
 - O Dr. Andreas Lepaucis, Head of the Institute for Clinical Evaluative Studies [ICES] inadvertently answered a question correctly from the audience when he spoke at a Nuclear Medicine meeting. He was very clear the issues were not the lack of evidence, but because the government "just can't afford to pay for every investigation and treatment that is available."
 - To his 'credit', he recovered quickly though, refused to answer the rebuttal question, and then met with News Reporters, and said "There is no evidence to support the use of PET" keeping perfectly in line with the official government position on PET.

POINT OF CLARIFICATION NUMBER 1:

I want you to be **VERY CLEAR** and **VERY SPECIFIC**, and using quotations from my letter and the documents I sent, to show exactly why you concluded that I thought your role was to "investigate matters of broad public policy" rather than me challenging the "process" and the manner by which the Liberal Government evaluated PET to determine it's policy and what would be included under OHIP funding.

• And don't even dare try to use my including facts about the impact the Liberal Policy on PET has had on patients. Ms. Finlay, you and Mr. Dubé are well aware that the absolute main focus of my letters and why I have challenged our "Government Watchdogs", and the international condemnation of what this government has done to cancer patients, is about the 'manner' in which the evidence on PET was handled, and the experiments performed on cancer patients, to come up with the subsequent policies on PET which have, and continue to make victims of our patients.

However, perhaps my colleagues and I are confused about what kind of "process" our "Government Watchdogs" would evaluate. So let me outline very carefully what I mean by the 'process by which the Liberal Government' evaluated the utility of PET and whether or not they should publically fund PET for patients under OHIP.

- Being a Medical Diagnostic Imaging Device this would naturally fall under the jurisdiction of the Ministry of Health and Long-Term Care.
- They then assigned this to Cancer Care Ontario [CCO] and it's various Advisory Groups and committees such as the PET Steering Committee [PSC], the Institute for Clinical Evaluative Studies [ICES], and the Ontario Clinical Oncology Group [OCOG] to name but a few.
- They then employed such 'processes' as reviewing the current medical literature on PET and designing and performing their own experiments on cancer patients in order to 'advance the understanding and knowledge base of PET using their own 'high quality' investigative tools.
- The main "high quality process" tool used was Health Technology Assessment [HTA] to determine the 'quality of evidence for or against PET scanning in cancer.'
 - o In fact EVERYONE AGREES. There is absolutely no scientific validity or justification to use the HTA to evaluate PET or any other diagnostic imaging device such as CT or MR.
 - Dr. Julian Dobranowski, Head of Imaging at CCO agrees completely with this statement!
 - Indeed he agreed that the Ethics Review Committees and Patients entering the PET Experiments designed by the CCO groups WHERE NOT TOLD THERE WAS NO BASIS TO JUSTIFY USING THE HTA TO EVALUATE THE RESULTS OF THE EXPERIMENTS THEY PERFORMED ON PATIENTS.
 - Further he did not object to, and therefore by default, agrees that the purpose of CCO PET trials was not to evaluate PET, but to try and 'validate the HTA'! This, of course a gross breach of ethical experimentation and full and proper disclosure to the Ethics Review Committee's and patients participating in these "unethical" experiments as declared in motions by the Canadian Association of Nuclear Medicine.

It would be an understatement' to say that the PET experiments designed by CCO affiliated groups and performed on cancer patients were 'not just controversial but truly "bordering on immoral".

- The first version of the PET PREDICT TRIAL on early stage breast cancer
 patients was pulled without explanation after the strongest possible
 objections from the 'non-Liberal government physician experts on PET.'
- However after almost two years it was introduced utterly ignoring the objections of PET experts.

As you know this lead to the highly disturbing and unprecedented motions declaring the experiments the Liberal Government sanctioned on cancer patients (ie: as part of the "process" to evaluate PET"), as "unethical". Eventually the most senior member of the PSC resigned saying these 'processes' carried out by the government to 'evaluate PET' "bordered on immoral".

My colleagues and I have always assumed that it was government based and sanctioned "processes" to come up with a 'broad Public Policy on PET'. After all, the information I gave you and raised as concerns about the way PET was being 'accessed':

• All took place before presumably there were any policies in place!

However, based on the conclusions of Mr. Marin now fully endorsed by you, Ms. Finlay and Mr. Dube, none of this *qualifies as 'government process'* and what it was prepared to do to some of its sickest and most distressed patients to come up with their 'broad Public Policy' on PET.

POINTS OF CLARIFICATION NUMBER 2:

Please make very clear why what my letter to you contained, and what I have described in brief above, is **NOT GOVERNMENT PROCESS** that would be considered by the Ombudsman as to how the Liberal Government developed it's 'policies on PET' and **DEFINE VERY CLEARLY WHAT YOU WOULD** "**LABEL**" what they have done to evaluate PET to come up with their 'policies on PET.

In doing so it is critical that you make clear that whatever you want to label how CCO evaluated PET for the government to 'decide it's policies on PET', would **NOT BE** something that would be under the jurisdiction of Ontario's Watchdog against possible abuse by the Liberal government and its experts against cancer patients in Ontario.

POINT NUMBER 3:

You also have dismissed my concerns about the fact that the Ombudsman *buried BOTH his investigations on PET from the public*, yet went on to congratulate the Liberal Government on what a great job they were doing in 'whatever you want to call how they would set policy and fund PET under OHIP.

You have stated:

"The Ombudsman takes many factors into account in deciding whether or not to issue a public report...."

He did of course discuss the 'outcomes' in the 2009-2010 Annual report.

However, that was **NOT THE ISSUE I RAISED**.

My issue was:

• Why did Mr. Marin then 'bury the actual full investigation and its details' from Public Access?

To have released the full details of Mr. Marin's investigation would be absolutely in keeping with Cancer Care Ontario's Mission Statements about "openness and accountability". Then everyone who had concerns about the way PET was being handled could decide for himself or herself whether Mr. Marin's published report, and now yours, was a reasonable interpretation of the information considered. One might have thought that given the level of condemnation leveled at the government and the CCO groups involved in accessing PET, that THEY WOULD DEMAND the full investigation details be made very public so they could then rightfully claim the accusations were unfounded and they were right about PET and the rest of the world expert community was wrong!

- To briefly recap Mr. Marin's second investigation on PET he stated that this was one of the most complex investigations he had undertaken.
- According to the person I dealt with from the Ombudsman's Office, the government was 'stonewalling' the requests from Mr. Marin to get information.
 - How ironic since in his first investigation that I initiated, the issues of concern was all about Mr. Smitherman and other's from the MOH, 'STONEWALLING' everyone who tried to get them to justify their approach to PET.
 - Mr. Marin, as you recall, DISMISSED the concerns of my colleagues me regarding this matter!
 - You presumably would concur with Mr. Marin's conclusions and dismissal of the concerns I raised.
- Regarding the second and more complex investigation into the Liberal Government's handling of PET, I was told by the woman I dealt with at the Ombudsman's Office that a 30 plus page document with questions and points of clarification was delivered to the MOH in December 2008 and that Mr. Marin had given till the end of February 2009 to respond.
- They didn't meet this deadline and I would be willing to bet that the government never in fact addressed the issues raised in this document.

However, for Mr. Marin to have decided that he had to bury the actual investigation from the public, and most importantly of course from those who could actually evaluate his 'work and judgment', would seem to scream out:

- There is something profoundly important to hide from the public and actual medical experts WHO DID NOT WORK FOR THE GOVERNMENT!
- It would seem the obvious solution would be to release the full investigation in all it's details, and then we could all rest easier.

However, you Ms. Finlay, and you Mr. Dubé are *NOW FULLY AWARE* of the issues, and the very serious and profound accusations made about surely one of the most important government ministries and those who head it! It is also a fair statement that most people, especially in an aging population consider concerns about their health a major priority.

POINT OF CLARIFICATION NUMBER 3:

Ms. Finlay, and Mr. Dubé, given that you two <u>are now fully informed about the</u> <u>profoundly serious and contentious issues and the 'unique position of some of our sickest and most distressed patients:</u>

• I would ask you, Ms. Finlay, and Mr. Dube, to make it very clear as to why you do not believe that the two full investigations that lead to Mr. Marin's report on how PET was introduced in Ontario, as well of course YOUR OWN full investigations, should NOT BE RELEASED IMMEDIATELY so that the public and actual experts in PET can determine for themselves whether the conclusions from the Ontario Ombudsman's Office are fair and reasonable.

As you are formulating your responses to my request for clarification in this issue please make it clear why you think that this 'complex' investigation and the 30 plus page series of questions and concerns from Mr. Marin *could all simply be solved by the Liberal Government announcing that it would fund an extremely small number of PET scans under OHIP! Then of course the actual investigation is BURIED FROM THE PUBLIC!*

You also quoted the total number of PET scans performed in Ontario under various programs is 56,626, *OVER A COURSE OF ALMOST 15 YEARS! BRAVO!!!*! Of course in Quebec, with half our population, they scan as many as 3,000 patients/camera/year (the usual work load in a civilized medical jurisdiction). When Ontario was only allowing less than 500 PET scans/camera/year, Quebec was funding 2,500!! But then of course only Ontario knew *from the "process", or however you choose to label how they evaluated PET, THAT THERE WAS ALMOST NO EVIDENCE TO SUPPORT THE USE OF PET IN CANCER PATIENTS!*

You also bring up the PET Access Program! They of course use the same methods to **block PET**, which you will recall is what CCO was told to do many years before. I will be sharing with the appropriate people the interesting case of a woman with breast

cancer they dealt with. Based on a recent letter I sent to Ms. Wynn, and her dismissal of my concerns, what we now know is that the first woman Premier of Ontario, fully supports the PET PREDICT Trial on breast cancer patients and is happy with the 'special attention' that CCO has taken to block breast cancer patients from PET.

- This woman would have clearly qualified for PET in any civilized medical jurisdiction offering PET on the planet.
- Instead, PET Access turned down the request for a PET and suggested a CT with contrast. It would have VIRTUALLY ZERO ability to determine the activity of any lesions identified as to whether active cancer or not.
- She had a serious reaction to the CT contrast and was hospitalized.
- A couple of months later, a **SECOND REQUEST** was sent for a PET scan.
- THIS TOO WAS REJECTED AND THEY RECOMMENDED ANOTHER CT SCAN!!!
- The only reason the woman got the PET scan eventually was because **SHE WENT THE NEWS MEDIA!**

And all this with the 'blessing of Ms. Wynn, and Dr. Eric Hoskins.'

SUMMARY:

In closing I will summarize some of the issues, my colleagues, patients and world PET experts agree are very disturbing and have indeed made 'victims' out of our patients.

 A simple fact is that many patients will suffer unnecessary investigations, complications, have distressing and unnecessary delays in getting the proper diagnosis and have a higher likelihood of dying from their cancers simply because they live in Ontario, and not Quebec. (Remember the Canada Health Act about equal access to health care?)

You are also now aware of the issues he has dismissed and based on your letter to me I can only conclude that now that you have done *your due diligence* you have *absolutely no problem* with the 'actions' of the Liberal Government and its various 'expert advisory bodies' and how they determined their policies on PET for Ontario's cancer patients.

So Ontario's patients can assume that Ontario's Watchdogs investigation was full and complete and you two have dismissed any concerns against abuse of the public by the government or it's agents.

Therefore it is reasonable to assume that you, Ms. Findlay, and Mr. Dubé fully agree with and would give your seal approval for all the issues listed below that also have the full backing of Ms. Wynn, Dr. Eric Hoskins, and Cancer Care Ontario.

- 1. It does not concern you in the least that Canadian and world PET experts have openly named and condemned the Ontario Liberal Government and its and its bureaucracies and accused them of performing "unethical" experiments "bordering on immoral" on cancer patients.
- 2. Being fully aware of whatever you have decided the 'methods' by which the Liberal Government and CCO assessed PET, you have no problem with the fact that this has lead to Ontario patients having the most restricted access to the world standard of imaging management of cancer, on the planet.
- 3. You are perfectly comfortable with and would congratulate the government and it physicians "capriciously" using a scientifically baseless process [HTA] to determine the "quality of evidence" for or against PET.
- 4. You have no trouble with the fact, and would congratulate the government and its physicians for designing an experiment on women with breast cancer when the camera was *not physically capable* of detecting the vast majority of the cancers they told the women they were looking for.
 - a. You of course would also agree that it was perfectly reasonable that in their efforts to determine the uses of PET for breast cancer patients, THEY EXCLUDED FROM THE TRIAL THE VERY PATIENTS THE ENTIRE WORLD KNEW MIGHT HAVE BENEFITED FROM A PET!
 - b. To this day, this "unethical and bordering on immoral" trial is used to justify NOT performing PET scans routinely on breast cancer patients that would be acknowledged anywhere else in the world.
- 5. You two support the practice of CCO groups in manipulating medical evidence, downgrading papers favouring PET, and impossibly, elevating a 'poster presentation' to a 'high quality paper' that didn't favour PET as pointed out in a medical journal article by Professor Hicks in 20011.
- 6. You see absolutely no reason to believe that the province funding only funding approximately 700 PET scans/camera/year has, in any way violated the Canada Health Act that guarantee's equal access to medical treatment in Canada, when in Quebec with half the population they scan 3,000 patients/year.
- 7. That you are completely satisfied with how the PET Registry works handled how a woman with breast cancer described above was dealt with and continues to base its decisions on the scientifically baseless HTA.
- 8. Since you are in complete agreement with however the MOH evaluated PET to establish it's policy on PET, that at a time when CCO analysis continued to say there was almost no evidence to support PET:
 - a. France bulk purchased some 75 PET scanners, and Turkey was accumulating up to almost 100 PET scanners!
 - b. However our cancer patients can rest assured that our "Watchdogs" have absolute confidence and trust in how the Liberal Government experts 'evaluated the evidence on PET', and we can all be proud of the fact that CCO was right and the *entire world expert community was wrong about PET*.

- 9. You fully support the manner in which CCO evaluated PET that has lead to patients having OHIP funded PET scans that:
 - a. Could be considered incompetence outside Ontario.
 - b. Leads to unnecessary high-risk biopsies, and unnecessary exposure to radiation exposure.
 - c. A gross delay in their diagnosis and management when they do have cancer.
- 10. You are in support of public servants such as the Ministers of Health, breaking Provincial Laws, and refusing to acknowledge or have someone on their staff respond to letters from professional medical associations, or individual PET experts.
- 11. You support the refusal of the various chairs of Cancer Care Ontario to acknowledge and respond to questions submitted to them by professional medical associations and individual PET experts. This in a province that claims to be 'open, transparent and fully accountable to the public of Ontario'.
- 12. You are 100% behind the methods and conclusions of your predecessor, Mr. Andre Marin, including his decision to bury the actual investigation in all its details from Public Access.
- 13. You, Ms. Findlay and Mr. Dubé believe that it was perfectly reasonable for Mr. Marin to dismiss his 30 plus pages of questions and points of clarification by the MOH simply announcing they would fund a few PET scans for lung cancer patients.
- 14. That you would presumably be more than delighted to offer up the now three assessments by the Ombudsman's Office on the Liberal Government's handling of PET as an exemplary model of what a great job the Ombudsman of Ontario do and above all demonstrating it is absolutely *immune to any pressure or influence from the government as you carry out your 'sacred duties'*.

I look forward to a quick and full and detailed response to my request for points of clarification and questions regarding your letter to me dated August 31 2016.

Regards

Dr. Dave Webster