Dr. Dave Webster
Diagnostic Imaging
Health Sciences North
41 Ramsey Lake Road
Sudbury ON
P3E 5J1

January 22, 17

Dr. Eric Hoskins MPP
Ministry of Health and Long-Term Care
10th Floor, Hepburn Block
80 Grosvenor Street
Toronto, Ontario
M7A 2C4

Dear Dr. Hoskins

RE:INFORMED CONSENT AND JUSTIFICATION OF DECISIONS ON PET TO PATIENT

Dear Dr. Hoskins:

As promised here is the first letter on behalf of an actual cancer patient. It is PATIENT and his sister SISTER's expectation that you will have someone from your 'expert medical team' you are so proud of, answer their very relevant questions about PATIENT's care in your PATIENTS FIRST Health Care system.

PATIENT and SISTER are well informed about the issues, and have access to all the documentation, including my letters to you and your 'delayed' response. However, it was an extremely useful response since you made clear your expectations for appropriateness and funding for diagnostic imaging tests that we can all agree on and support. In your response you 'chastised me' for seemingly not being concerned about radiation exposure from what CCO still feels is 'unproven technology'. Therefore any response to PATIENT and subsequent patients who have, for example have had 23 and counting CT exams to follow-up their cancers, will pay particular heed to your justified concerns about excess radiation exposure from diagnostic imaging radiation exposure. It goes without saying your 'bed rock principles' wouldn't just apply to PET, ***but to ALL diagnostic-imaging tests.***

In your letter you made clear how proud you and Ms. Wynne are with respect to the work of Cancer Care Ontario in assessing PET. Indeed an article in the Journal of Clinical Oncology by a previous Chair of the PET Steering Committee presents Ontario's approach as a model for the rest of the world to assess imaging technology. Yet for some reason the ***'trademark defense'*** of the PET Steering

Committee, Ontario Liberal Government, the Ministry of Health and Cancer Care Ontario has been to not acknowledge questions from non-government PET experts, or when answering, ***never answer a key question defending CCO's evaluation methodology.*** You yourself have used the same 'defense'.

Although you responded after 18 months, you did not answer a single critical question submitted then, nor in my follow-up letter with two very specific questions. To remind you, the first question asked you to justify using the ***'scientifically baseless process' of Health Technology Assessment*** to determine appropriateness of PET for Ontario patients. The second more important question was whether you supported the ***'ultimate litmus test'*** of the approach the Liberal government is so proud of and carry out the 2005 motion by the Canadian Association of Nuclear Medicine to have an independent review of the 'ethics' of how PET has been assessed and introduced to Ontario patients.

- ***The time has come to see whether the same will apply to actual patients in Ontario who of course are not just living in a supposed open, transparent and accountable democracy, where patients come first, BUT, are ABSOLUTELY entitled to full disclosure and relevant information about proposed diagnostic tests and treatments so they can sign an "informed consent."***

Which ever of your 'medical experts' is designated to answer their questions it clearly **MUST** meet the criteria laid out in your letter of August 2016. It also must pay ***special attention*** to PATIENT and SISTER's questions related ***to radiation exposure*** to tests and treatments according to Cancer Care Ontario's, 'stamp of approval' standards.

> "In Ontario, PET diagnostic services must be:
>
> - Effective (sensitive, specific, accurate)
> - Have the potential to impact patient management
> - Have benefits over other tests/imaging"
>
> "You, as a clinician, would understand that the benefits of exposure to radiation from a diagnostic intervention such as PET scans must be considered along with risks and limitations of the result of the scan. It is essential that the ministry also strives to achieve the correct balance."
>
> Dr. Eric Hoskins August 2016

FIRST PATIENT:

PATIENT: **PATIENT**

PATIENT has given me consent for full access to his information.

> Hello Dr. Dave Webster
>
> Thank you for meeting with us.
> We would very much appreciate if you would look at PATIENT medical file and determine if a PET scan would be beneficial for him. If a PET scan would help in determining how he is responding to treatment...count us in! And/or if it will help narrow the field for more accurate radiation treatments.
> Got a lot of fishing to do and lakes to explore doc...
> Thank you for taking an interest in our case.
>
> Sincerely,
> PATIENT and PARTNER
> 12/31/16

I have discussed I detail with PATIENT and PARTNER all aspects about PET including the ***'unique and scientifically unfounded'*** position your Government and Cancer Care Ontario has taken regarding roles for PET in cancer. I also discussed the current medical literature about the use of FDG PET for his cancer.

I discussed his case and supporting literature with his Oncologist, ONCOLOGIST 1. We have all agreed that PATIENT would have benefited from a PET/CT from the beginning of his investigation, rather than the 'unique' standards set by Cancer Care Ontario with a diagnostic CT.

- I am of course also aware that PET would not be the most appropriate test to image the primary in the urethra and bladder due to the interference from radioactivity in the bladder and potentially the urethra. He did have an MR which outlined this as we would expect given the nature of MR.
- As you will be aware of from my letter to Premiere, Ms. Kathleen Wynne in July 2016, it is my position that OHIP should only be paying for diagnostic imaging tests that have a reasonable chance of assisting in making the most appropriate management and treatment decisions for patients.

PET/CT would be the most appropriate imaging test to determine his response to therapy and in the subsequent decision making process as he works through his cancer. He is aware of the paper by Worsley et al and the role PET played in improving patient management decisions as opposed to Cancer Care Ontario's 'standard' of serial CT scans.

- I would ask that the response to their questions and the supporting

documentation be sent PATIENT through ONCOLOGIST 1of Thunder Bay Health Sciences. ONCOLOGIST 1and I will then discuss the responses to his questions and the issues so that he understands all the information and can then make informed decisions about any course of actions he might decide to take.

WHAT PATIENT UNDERSTANDS:

1. That there is ***no scientific validation to justify the 'evidence-based medicine'*** tools that Cancer Care Ontario has used to determine the 'quality of evidence' for or against PET.
2. He is aware that the world PET expert, Professor Rodney Hicks, who has published about how PET was assessed in Ontario, stated that***: "Ontario has the most egregious and politically motivated agenda against PET in the world."***
3. He understands the principle of Anatomic and Functional imaging in this sense:
    a. A "Functional Bone Scan" can detect osteoblastic metastasis to bone as much as 18 months before the 'Anatomical test' radiographs become positive.
    b. Therefore to order a 'Skeletal Survey' of dozens of x-rays to determine whether or not a patient needed a bone scan would at minimum indicate ***gross ignorance of imaging investigation of cancers by the ordering physician.***
4. He is also aware of the 'standards' that you have set for whether or not a diagnostic imaging test should be covered by OHIP, and ***ESPECIALLY about concerns around excess radiation exposure to patients.***
    a. And of course Cancer Care Ontario wouldn't allow a Skeletal Survey to qualify for a PET. ***PATIENT MUST have a CT scan with much higher radiation dose and the possibility of contrast reaction.*** But this of course will be part of what you'll explain to PATIENT and SISTER.
5. He is fully aware that CT scans have very limited ability to determine whether a mass or ' concerning' lymph node is cancer or other pathology.
6. He is also aware that an FDG PET scan is performed with a low resolution/radiation dose CT without risk of contrast injections. Also that the radiation exposure of the PET/CT is similar to a diagnostic CT scan. He is fully aware that the world beyond Ontario's borders considers CT 'the view from 10,000 feet' in the 'era of molecular imaging' of which PET is the cornerstone. It has been the accepted world standard of imaging management of cancers and other disease is some cases for almost 20 years because not only can it see the masses, but add the critical extra detail about the sugar metabolism of cells in the mass.
7. He is also aware that just because a mass takes up sugar doesn't mean it is cancer, and that PET like any imaging test has strengths and limitations, and must be used only when there is a reasonable chance it can help in

determining the next steps in his progress.

HISTORY:

This unfortunate gentleman has been diagnosed with ureteral cancer after a long delay in sorting out why he was having dysuria and hematuria. At the time of presentation he already had muscle invasion identified on the CT and MR. They did report external iliac and para aortic lymph nodes on the CT scan although the largest was only 6 mm. A 2.6x2.4 cm left inguinal node was also identified which ***"appeared pathological"*** (That wonderful and ubiquitous vague description in CT reports given it's acknowledged limitations at further characterizing cause of the enlarged node…. ***And would it surprise you if the report would conclude by saying: "suggest repeat CT in 2-3 months? Important they follow CCO 'standards' "***) ***.*** An MR was performed and the findings were in keeping with multifocal bladder cancer. The lesion in the right inferolateral aspect of the bladder is extending through the wall of the bladder into the surrounding fat and adjacent vascular bundle.

A bone scan had been ordered and this was how I met Mr. PATIENT. It did not show any evidence of osteoblastic bone metastasis. However, as I went through his imaging I noticed that ***there was a larger node on the right side but below the level of the inguinal canal that was not reported on either the CT or MR.*** I discussed the findings with ONCOLOGIST 1. He noted that it would be unusual that the right-sided finding, being out of the normal drainage territory for his cancer, would be a metastasis, ***BUT OF COURSE***, based on the CT and MR he could not be certain! He then ordered an US guided biopsy. Mr. PATIENT is a large framed man and he felt that most likely the radiologist would not perform the biopsy, ***but that if the right-sided lymph node were cancer, this would change Mr. PATIENT' management and prognosis. The plan is for radical therapy at this point, and has started because of the urgency***.

QUESTIONS PATIENT RESPECTFULLY REQUESTS THAT ONE OF YOUR MEDICAL EXPERTS ANSWERS IN FULL WITH SUPPORTING DOCUMENTATION AS REQUIRED.

1. Why does the Liberal government enthusiastically support the use of a scientifically baseless process to evaluate whether or not I will be allowed to have a PET scan or not?
2. Since the decision making process is not based on science, and keeping mind the statements of Professor Hoskins, how will decisions be made as to whether I will have access to a PET, and more importantly why was ***I not investigated by a PET/CT as part of my initial investigation***?
3. I understand the analogy of "Anatomical Skeletal Survey' to decide whether

or not a patient should have 'Functional Bone Scan': Therefore why was it compulsory that I, ***HAD TO HAVE a high radiation does CT scan with the risk of contrast reaction in order to determine whether I would qualify for the 'cornerstone of functional imaging..at least outside Ontario.., a PET scan***?

a. [This is where the answers to PATIENT ***must include the relevant literature to both support Cancer Care Ontario's standard of his investigation with CT, AND meets your three criteria outlined above***.]
b. ***[****And most critically, given your concern about the risks of radiation exposure, the response must be very clear to PATIENT and SISTER about the 'benefits' of the Ontario approach with respect to his exposure to radiation from his CT scans. In addition, response must explain in detail to PATIENT and SISTER, why the 'Ontario standard of care' to determine his response to treatment will be by CT. Imaging experts would agree that the CT has almost no ability to determine if any residual masses represent scar tissue and thus successful treatment, or persistent cancer activity and treatment failure. Beyond Ontario's border the world uses the PET/CT as the 'standard of imaging management' since it would identify the mass, but critically, assess the sugar metabolism of the cells in the mass. This provides the 'missing information' from CT alone to best assist PATIENT and his physician, ONCOLOGIST 1to determine what is the next step in the management of his cancer.]*

4. Although ONCOLOGIST could use PET ACCESS, I would like to know why PET was not part of my routine investigation and follow-up so that ONCOLOGIST 1 and I could have the best chance of making decisions about the management of my cancer? ***Are the Canadian and International Imaging experts wrong, and CT has a better chance of determining the nature of the findings on my images and thus directing my management with less radiation exposure?*** I would ask that you provide the documentation meeting your criteria along with a clear summary by the individual responding including supporting documentation covering all the above points outlined by Dr. Webster.

    a. [It should be noted that PATIENT and SISTER understand that it is not ideal to have a PET at this point because we don't have a baseline scan. However because ONCOLOGIST 1did not want to delay starting therapy he won't have a baseline scan. However someone will have explained to him ***why he would not have qualified for a baseline PET/CT scan in the first place!*** He also understands that using a PET scan to determine his treatment response post radiation treatment can be delayed because of post treatment inflammatory effects, but that findings outside the area of radiation field can be appropriately assessed.

b. PATIENT also understands that PET is routinely used in determining the extent of radiation fields with IMRT therapy because it can dramatically reduce overall radiation exposure by limiting it to the parts of masses with active glucose metabolism.
c. Please explain meeting Dr. Hoskins criteria and radiation risk concerns, to PATIENT why it is not routine to determine IMRT fields with PET/CT versus a CT since all the mass must be radiated since the CT has no ability to determine which parts of the mass are dead or scar tissue.]

Respectfully Submitted

PATIENT

CONCLUSIONS:

Cancer Care Ontario experts have had more than 15 years of experience assessing PET and of course will have access to how Cancer Care Ontario's Standards of CT as the primary and ***COMPULSORY*** investigation and follow-up of his cancer, meet your stated criteria. Therefore there should be no delay in responding to what I am sure we would all agree are reasonable questions that PATIENT and SISTER are absolutely entitled to. After all they are living in an:

- ***Open, transparent and accountable democracy.***
- ***A province that Ms. Wynne and you have made clear is a PATIENTS FIRST Health Care System.***
- ***Surely this will be an opportunity to demonstrate these principles to PATIENT and SISTER two citizens of a LIBERAL RULED province.***

Therefore please answer all their questions and supply appropriate supporting documentation via ONCOLOGIST 1as soon as possible given the urgency of Mr. PATIENT' condition.

As you might expect, like most Ontario cancer patients, PATIENT has the unnecessary and ***added enormous stresses*** of delays in decision making, increased risks to radiation exposure and potentially unnecessary high risk biopsies and interventions based on the 'standards of care' set by Cancer Care Ontario. To then find themselves faced with the massive discrepancies of how he would have been routinely managed in 'Third World countries', and the absolute refusal of the Liberal Government, the Ministry of Health and Cancer Care Ontario 'medical experts' to answer the disturbing questions and accusations from Canadian and International PET experts, ***IS MORE THAN TROUBLING FOR THEM!***

Will Ontario's Minister of Health, a physician who has taken the Hippocratic Oath, dare to refuse to acknowledge PATIENT and SISTER's questions and answer them fully with supporting documentation?

Surely this will be seen as the perfect opportunity to demonstrate to PATIENT and SISTER how fortunate they are to be living in a Liberal, PATIENTS FIRST, Ontario, and not Quebec, where for some reason they are scanning 3.07 patients/1,000 population with 'unproven PET technology' compared to 'the more appropriate CCO position' of 0.24/1,000 patients.

Respectfully submitted on behalf of Mr. PATIENT and ONCOLOGIST 1by:

Dr. Dave Webster

Cc: PATIENT PATIENT