

Letters to Alain Beaudet, Minister Aglukkaq and Deputy Minister Yeates regarding the CIHR/MSSC Report on CCSVI

Ashton Embry

A few months ago I received a short letter from Alain Beaudet, the chair of the MSSC/CIHR Committee which looked at CCSVI and MS. He had been sent the Direct-MS In-Depth Analysis of the Report of the Beaudet Committee on CCSVI and MS. In that analysis we had been very critical of the "Beaudet Report" on both ethical and scientific grounds. In his reply he did not address any of our criticisms but simply repeated the standard lines of the committee had a variety of experts and that the Report stands on its scientific merits.

Now that the Toronto doctors have also pointed out the major lack of required expertise on the Beaudet Committee, I thought I would release the reply I sent to Beaudet as well as a letter to Minister Aglukkaq and her Deputy Minister, Glenda Yeates, asking them to reconsider their acceptance of a highly flawed and basically bogus report. Given that Ms Yeates had attended the Beaudet Committee deliberations as an observer and was well aware of all the ethical and scientific shortcomings of the Committee and its Report, I had no expectation that neither Beaudet/CIHR nor Health Canada would do anything about this great injustice to persons with MS.

It would appear that the Beaudet Committee/ Report was an elaborate charade jointly organized by the MS Society, CIHR and Health Canada with the intent of ensuring nothing of any substance would be done regarding CCSVI for as long as possible. This is the only realistic explanation for all the blatant ethical and scientific problems associated with the Beaudet Committee/Report and its instant acceptance by Health Canada.

So what can be done? Basically nothing. The MS Society, MS researchers, neurologists and the government do not want CCSVI treatment available in Canada, each for their own reasons. When all of those in power want something to happen or not to happen in the MS world, you can be sure they will get their way.

The two letters are below:

October 10, 2010.

Dear Dr Beaudet,

Thank you for your reply to the Direct-MS "In-Depth-Analysis of the Summary Report of the CIHR/MSSC Committee on CCSVI and MS" which was sent to Minister Aglukkaq. Presumably she forwarded it to you and asked you to reply to it. I am somewhat disappointed by your reply because you did not respond to any of the multitude of specific shortcomings which are in your report, including both scientific and ethical issues which are detailed in our In-Depth Analysis.

I think it is best to deal with the ethical issues first. The main task of the CIHR/MSSC committee of "experts" was to produce a recommendation on whether or not clinical trial research on the effectiveness of CCSVI treatment for MS should be funded at this time. This was

a most critical assignment given that many persons with MS suffer unrelenting, progressive decline and, if CCSVI treatment actually is of value, the longer it takes to determine this, the greater will be the suffering by a large number of Canadians. Thus, there was a great deal at stake regarding your committee's final recommendations on this most important health issue.

For any valid report with worthwhile recommendations to be produced, it is necessary to have a committee of experts which includes persons who have had first hand experience with the topic at hand. Certainly, not everyone has to have such experience, but a good number do. For your committee to properly complete its task, it was essential that it included persons who have had first hand experience with CCSVI research and persons who have been involved in the application of venous angioplasty and the use of stents in extra-cranial veins.

Because your committee had no one with any first hand knowledge of CCSVI and MS or anyone with any first hand experience with venous angioplasty, there can be no doubt that that the resultant recommendations lack credibility. There are numerous people with such expertise who would have been appropriate for your committee. Furthermore, it is hard not to wonder if the purposeful exclusion of such required experts for appraising the need for CCSVI treatment was done to bias the committee so as to ensure a negative recommendation. Regardless, such a biased selection process is totally unacceptable because the necessary scientific expertise was not represented, and it may well also be unethical if it was done intentionally.

Of course, for any reliable report with acceptable recommendations to be issued, it is also critical that no one influencing the discussions and recommendations has a conflict of interest. I cannot overemphasize how fundamental this is. In terms of your committee, this means it would have been necessary to exclude any person who has an overt conflict of interest with the potential introduction of a non-drug treatment for MS. Thus anyone who had received monies or gifts from pharmaceutical companies which manufacture and market drugs for MS should not have been included on your committee for obvious ethical reasons.

A clear and present ethical problem was the inclusion of a majority of committee members with an overt conflict of interest. You may see nothing wrong with stacking a committee with a majority of persons with an overt conflict of interest and perhaps that is how things are done at CIHR and MSSC. However, in my scientific realm, such an action is regarded as highly unethical and this alone negates the value of your report. Health Canada's acceptance of such an ethically tainted report is of concern. I am hopeful the Health Canada position on this most important issue will be revisited now that they have been informed of the serious ethical and scientific problems associated with your report.

Your comment that "the report stands on its scientific merits" really says the report should be rejected because of a lack of scientific merit. I refer you to our In-Depth analysis which includes nine pages of discussion of all the scientific errors and unsupported pronouncements which pervade your report. I would note you have not refuted a single point which was made regarding the faulty science in the report. This is not surprising given it would be impossible to do so.

How do you refute criticisms of the fundamental errors in your report such as the one that wrongly described blood flow in the jugular veins? And how do you refute our critiques of the numerous baseless pronouncements such as the one which claimed that we do not know if

CCSVI is associated with MS. The fact that every week over 500 people with MS are having their CCSVI treated leaves no doubt about the high association between MS and CCSVI. Just imagine if a CIHR report claimed that we don't know if heart transplants are possible while at the same time 500 heart transplants are being done every week in other countries. In summary, unless you can properly refute all the documented scientific failings of your report, I think it is safe to say that any recommendations based on such flawed and inadequate scientific analysis have no value and any acceptance of them has to be seriously questioned.

You note that “the Minister has accepted the scientific evaluation and advice provided”. As mentioned above, such acceptance presents a major problem for Health Canada. **The public needs to have confidence that Health Canada makes decisions on important health issues on the basis of solid, comprehensive and objective scientific analysis which is free from ethical problems. There can be no doubt that this is not the case in regards to Health Canada's decision on whether or not to fund CCSVI treatment research. This decision was based on flawed science put together by people with no first hand experience with the subject at hand and with overt conflicts of interest.**

Now that Health Canada has been informed of the unacceptable nature of your report which formed the basis of their decision, we are all waiting to see how they will handle this very problematic situation. I want to emphasize that the Health Canada decision on this issue will affect the lives of tens of thousands of Canadians who are already suffering the consequences of MS. It remains to be seen if Health Canada will add to their suffering by continuing to accept an ethically challenged and scientifically flawed report, or will help to alleviate it by making a proper decision with reliable information in a timely fashion.

I can assure you this issue is not going to go away until a proper and fair resolution is attained. If you would like to discuss this issue further, please feel free to contact me by phone or email. I am also open to a meeting to try to reach an acceptable solution to this most unfortunate and potentially very harmful problem.

Sincerely,

Ashton Embry

October 10, 2010

Dear Minister Aglukkaq and Ms. Yeates,

Please find enclosed my letter to Dr Alain Beaudet which is a reply to his letter on his thoughts on the Direct-MS “In-Depth Analysis of the CIHR/MSSC Report on MS and CCSVI. Given that Dr Beaudet did not refute or even address any of the numerous ethical and scientific problems which our Analysis discussed in detail, one has to assume that our Analysis is correct and that Dr Beaudet's Report is unacceptable from both ethical and scientific perspectives.

Given that Health Canada made a very important decision based on the contents of this unacceptable report, it seems to us that Health Canada might want to revisit this issue so as to

obtain reliable information which will allow a proper decision to be made as soon as possible. We are confident that Health Canada wants to make the best possible decision on this most important health issue.

As I noted at the end of my letter to Dr Beaudet, **this problematic situation of Health Canada basing an important health decision, which will affect the lives of tens of thousands of Canadians, on an ethically challenged and scientifically flawed report, is not going to simply disappear.** Many lives will be affected by the decision of whether or not to fund a proper CCSVI treatment trial in the near term. I can assure you no one is going to feel good that such a critical decision was based on poor, scientific analysis done by inappropriate persons, most of whom had a major conflict of interest.

I am hopeful that, now you both are aware of the serious problems that completely compromise the reliability of the CIHR/MSSC report, you will rectify this unacceptable situation. I realize it is important that everyone save face as much as possible and thus I would suggest that Health Canada, CIHR and MSSC issue a joint statement that new information has made it necessary to revisit the decision and that Health Canada is reexamining the question of whether or not to fund, clinical research into the efficacy of CCSVI treatment for MS in the near term.

I think this is a golden opportunity for Health Canada and the current government to gain support from the MS community. As perhaps you saw, the issue of CCSVI became a political one in the New Brunswick election campaign and the MS community worked hard to help elect candidates from the Conservative party which had promised to help New Brunswickers with MS get CCSVI treatment outside of Canada. I can assure you, when a federal election is held, the CCSVI issue will be very important for the MS community and their families and friends. If the federal government and Health Canada maintain their current position of denying the need for CCSVI treatment research in the near term on the basis of an ethically and scientifically flawed report, they will not be looked upon favourably by the MS community. Of course, if Health Canada reached a decision on the matter in a fair, objective and transparent manner, or even better yet, if the government were to support the immediate need for such research, such actions would be seen in a very favourable light. All persons with MS are asking is that Health Canada and the Government of Canada act in an acceptable fashion in regards to making a decision this key question. Currently this is not the case, and the unacceptable failings of the Beaudet Report are widely known throughout the MS community in Canada.

In summary, Direct-MS is hopeful Health Canada will revisit its decision on whether or not to fund CCSVI treatment research in the near term. **All we are asking is that a decision on this question be based on objective, comprehensive science and data from CCSVI treatment centres which are evaluated by knowledgeable and experienced scientists and practitioners who are free from a conflict of interest concerning a non-drug treatment for MS.** We are certainly open to a meeting where this issue can be openly and confidentially discussed. Thank you very much for considering this important problem and we look forward to hearing from you by end October.

Sincerely,

Ashton Embry