



*A charity dedicated to finding
the cause of Multiple Sclerosis*

DIRECT - MS

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Dear Members of Parliament,

I commend you all for conducting such a thoughtful, intelligent and caring debate on the need for CCSVI treatment and research in Canada on the evening of June 14.

I am the president and research director of Canada's second largest multiple sclerosis charity, Direct-MS (www.direct-ms.org). Needless to say, we are much smaller than the Multiple Sclerosis Society of Canada (MSSOC) and we differ from that organization in a few significant ways.

First of all we are very science oriented and the majority of our officers/directors are practicing scientists. I am currently a senior research scientist with the federal government and have been practicing science for 42 years. Furthermore, our officers and directors are all affected by MS (a requirement) and this provides a strong, patient-centred approach to our goals and activities. In short, our board contrasts sharply with that of MSSOC which has very few scientists and few people affected by MS

Direct-MS is entirely volunteer run and we pay no salaries. This allows us to keep our administration costs under 2% of our revenue and avoids a major conflict of interest that comes with charities such as MSSOC that have a very large, salaried staff. The development of an effective MS treatment will have a very major negative impact on MSSOC fund-raising activity and hence on staffing. If you question this, I invite you to check out the staff complement and annual revenue of the Scurvy Society of Canada. This major conflict of interest is rarely discussed but is very real, although the extent of its influence on staff activities and policies is not known. Regardless, it is an important factor which always must be considered when any MSSOC position on a potential effective treatment for MS is offered.

Direct-MS provides reliable, science-based information on various aspects of MS with an emphasis on nutrition and MS, and, over the past year, on CCSVI and MS. This again clearly separates us from MSSOC which offers little, science-based information on nutrition and MS. I might note that Direct-MS was the first MS charity in the world to recommend adequate vitamin D for persons with MS (1999) and we published the first scientific paper (Embry et al, 2000, *Annals of Neurology*) which demonstrated a correlation of vitamin D levels and MS disease activity and the need for 4000 IU/d. Our nutritional recommendations are used by tens of thousands of MS patients throughout the world and have been successfully tested by one small clinical trial.

Regarding CCSVI, Direct-MS was aware of and was providing information on CCSVI long before MSSOC. Our August, 2009 publication (CCSVI, A Major Breakthrough for MS) summarized the 2006-2009 Zamboni research and was used by Dr Zamboni as part of his press release package for the watershed Bologna meeting in September 2009. We have published numerous articles on aspects of CCSVI over the past 10 months including one on CCSVI and Autoimmunity in the recent special

issue of International Angiology on CCSVI (Embry, 2010). Notably, no one connected with MSSOC has ever published a scientific article on CCSVI.

Direct-MS also funds scientific research and funded an important dose-safety trial for vitamin D and MS (\$200K). The scientific paper which describes the results of this trial was recently published in Neurology and was the subject of an editorial which noted the great importance of this work. We began funding CCSVI research in December, 2009 (University of Buffalo) and our most recent CCSVI research grant was made in April, 2010. We are currently in negotiations for helping to fund a treatment trial for CCSVI. This is especially important given MSSOC chose not to fund any treatment trials for CCSVI.

After Direct-MS became aware of CCSVI in July, 2009, we contacted various MS researchers including some on the MSSOC science committee. The scientists showed absolutely no interest in the concept and the available research supporting it. In order to counter this lack of interest, in September, 2009, Direct-MS contacted Avis Favaro of CTV and provided her with background scientific information on CCSVI as well as the contact information for the main scientists involved in CCSVI research (e.g. Paolo Zamboni, Mark Haacke, Michael Dake). To their credit, Ms Favaro and CTV saw the importance of the CCSVI story and produced a riveting documentary which brought CCSVI and its treatment to the attention of the world on November 24, 2009. This greatly increased awareness of CCSVI has had a huge impact on the MS community and has provided the impetus for numerous initiatives, new research and a renewed hope that an effective treatment for MS may be within reach.

Another major difference between Direct-MS and MSSOC is that Direct-MS strongly advocates for the availability of CCSVI testing and treatment throughout Canada within the next 12 months. This advocacy is based on an objective, thorough, and "conflict of interest-free" analysis of all the available scientific information on CCSVI as well as our strong patient-centred culture.

I must emphasize that the available science shows beyond a reasonable doubt that CCSVI is part of the MS disease process. This is often denied by neurologists and MSSOC, but from an objective, scientific view, such a conclusion is inescapable. This interpretation is derived from four established scientific points.

- 1) CCSVI is associated with MS as has been well documented by the Zamboni research and corroborated by the very large (500 subjects), University of Buffalo study. Also of importance is the finding in centres around the world that 80%+ of all persons with MS so far tested (>1000) have CCSVI. Here in Canada, Dr Sandy Macdonald found that 90% of the almost 300 MS patients he has tested in Barrie had CCSVI. Any claim that CCSVI is not associated with MS has no scientific support and cannot be taken seriously.
- 2) CCSVI has been established to be mainly congenital in origin (present at birth) by researchers at Georgetown University and, given the various types of venous malformations which drive CCSVI, this widely accepted interpretation is very hard to dispute. This establishes that the presence of CCSVI definitely precedes the MS disease process although it may well get worse after MS has begun.
- 3) It is also well accepted that biological mechanisms which are a consequence of CCSVI, such as reflux of venous blood back to the brain, the deposition of iron in the brain, hypoperfusion,

and the upregulation of adhesion molecules on the endothelium of the venules, all can be reasonably related to the MS disease process.

- 4) There is abundant empirical evidence that these biological mechanisms are occurring in persons with MS. Furthermore, these biological mechanisms associated with CCSVI help to explain previously unexplained features of MS including the venocentricity of all lesions and the continued progression of the disease despite a total destruction of the immune system.

These four points demonstrate beyond a reasonable doubt that CCSVI is part of the MS disease process. Given this, it is reasonable to expect that relief of an established, key factor in the MS disease process will very likely be of significant benefit for many, especially those in the early phase of the disease.

With the acceptance that CCSVI is a key part of MS, now let us consider the treatment which can resolve CCSVI, venous angioplasty. Notably, the venous angioplasty procedure to relieve CCSVI is very safe by medical standards and compares to a similar, very safe procedure for arterial disease. At least 1000 procedures have been done so far with only two anecdotal, serious adverse effects, both of which involved stents which are not part of the standard, recommended treatment. Notably, both incidences occurred in the same centre soon after treatments started.

No vascular expert has ever questioned the safety of venous angioplasty and suggestions that it may not be safe seem to emanate from neurologists who have no knowledge or expertise in the field. Any claim that venous angioplasty is “experimental” or “dangerous” has to be discounted and questioned as to what motivated such an unsupportable statement.

I would also emphasize that the many reliable and impressive, anecdotal reports of significant improvement of MS-related symptoms following CCSVI relief have been reported in the news and online. The Parliamentary Subcommittee on Neurological Diseases also interviewed a few persons who have enjoyed major relief thanks to CCSVI treatment. These experiential accounts cannot be ignored or simply written off as “placebo effect”. Again, the motivations of any person or organization which does not acknowledge the reality of these important results must be seriously questioned.

Most importantly, in the next 10+ years when CCSVI research is being conducted, many people with MS will suffer major, irreversible, increased disability. Any claim that the required research will be done in less than 10 years is not realistic and most MS drugs have taken far longer from start of testing to final approval. Given all of the above, persons with MS do not have the luxury to wait 10 years before gaining access to a treatment which is very safe, reasonably priced and likely very helpful for many.

Finally, I want to address an awkward and rarely mentioned conflict of interest issue which is clouding the debate. All of the medical opinions and advice provided by the MS Society of Canada, including those to officials of the Government of Canada, are the product of MSSOC scientific and medical committees which are populated exclusively by neurologists.

Notably, almost all of the neurologists on the MSSOC committees have close ties to the pharmaceutical industry and many have received large sums of money from pharmaceutical companies over their careers. Thus, a major conflict of interest exists when it comes to any advice or guidance provided by these neurologists, or an organization which depends on them for advice, on a non-drug treatment such as CCSVI. This conflict exists because an effective, relatively low cost, non-

drug treatment has the potential to replace the current, high cost, very low efficacy drugs which bring in almost \$10 billion worldwide. A large loss in drug revenue will have a very negative impact on the pharmaceutical companies which produce MS drugs and on all individuals and organizations that receive funds from those companies (e.g. neurologists on the MSSOC committees and MSSOC itself).

I hope the exposure of this major conflict of interest helps to put the “no testing/no treatment” position of MSSOC and various vocal neurologists (e.g. Dr Mark Freedman publicly calling CCSVI a hoax) in the proper perspective. I would emphasize I am not proposing a “conspiracy theory” but am simply pointing out that it would be natural and understandable for any individual or organization whose future earnings are potentially jeopardized by a given phenomenon to argue against such a phenomenon. In fact, it would be very odd if they didn't. However, it is important to emphasize that in our democracy, opinions from people or organizations which have a major conflict of interest are given very little, if any, weight. This is a good thing and bad things often result when this common sense convention is not followed.

I encourage the Government of Canada to take objective, science-based, conflict of interest-free actions to help to expedite the availability of CCSVI testing and treatment for all persons with MS in Canada. As one Parliamentarian wisely pointed out in the debate, the federal government must take the lead on this important health issue and bring together health representatives from all 13 provinces and territories. I am confident that the health leaders of Canada can resolve this harmful impasse which is preventing persons with MS from having a safe, low cost and likely effective therapy. All that is needed is an examination of the current science and the treatment results in an objective fashion, free from self-serving opinions, and taking the much needed actions which are supported by that information.

Thank you very much for considering the views of Direct-MS on the current CCSVI Crisis in Canada. We are most hopeful that federal and provincial policy makers will do what is best for those who live with MS rather than what is best for those who live off MS. Unfortunately, in this situation, you can't do both.

Sincerely,

Dr Ashton Embry
President and Research Director, Direct-MS