Dear Colleagues,

Hello and warm wishes.

I am writing to you in response to the Minister of Health’s letter to you of February 17th, 2012, regarding Bill C-280, “An Act to Establish a National Strategy for Chronic Cerebrospinal Venous Insufficiency (CCSVI)”, and ask that you read the following, as 55-75,000 Canadians are depending on your consideration regarding the vote on Bill C-280 on February 29th, 2012.

I have just returned from the “2nd International Society for Neurovascular Disease (ISNVD)” conference (February 18th-22nd, 2012), where I delivered two talks (one for the MS patient day, and the other for the scientific program). ISNVD is devoted to furthering the development of research for neurovascular related diseases, including CCSVI.

I would therefore like to up-date you on the most current information to date. Below in bold, you will see the Minister of Health’s comment, and my response to each statement.

“Working closely with our partners, the Government is taking key action to help the many Canadians affected by MS; for example, we are creating a Canadian monitoring system that will gather and share new knowledge on the use of MS treatments across Canada and their long-term outcomes.”

Dr. Bennett and I asked that the government undertake clinical trials and a registry for CCSVI in May, 2010. Ten and thirteen months later, the government reversed its position and consented to a registry and clinical trials respectively. While the registry was announced in March, 2011, data collection will not actually begin until September, 2012—that is, 33 months after MS patients began travelling overseas for diagnosis and treatment of CCSVI. Since when do scientists fail to collect data? If the science was undertaken earlier as requested, and data collection begun, answers would be available today regarding how MS patients responded at 1 month, 3 months, 6 months, 12 months, and 24 months after treatment for CCSVI.
“In House debates over C-280, you have heard that there is a direct link between CCSVI and MS and that the safety of the Zamboni procedure has already been established scientifically, however neither of these notions has been proven.”

**Positive CCSVI Studies**

**Zamboni et al. JNNP, 2009**

**Zamboni et al. J Neurol Sci, 2009**

**Zamboni et al. J Vasc Surg, 2009**

**Hojnacki et al. Int Angiol, 2010**

Simka et al. *Int Angiolog*, 2010

Ludyga et al. *Phlebology*, 2010

**Zivadinov et al. AJNR, 2011**

Zivadinov et al. *Neurology*, 2011

*Zaharchuck et al. AJNR, 2011*


Bastianello, *BMC Neurol*, 2011

Petrov et al. *J Endovasc Ther*, 2011


Hacke et al. *JVIR*, 2011


*Dolic et al. *Funct Neurol*, 2011*

*Dolic et al. AJNR, 2012*

**Negative CCSVI Studies**

Doepp et al. *Ann Neurol*, 2010

Sundstrom et al. *Ann Neurol*, 2010

Wattjes et al. *JNNP*, 2010

#Baracchini et al. *Ann Neurol*, 2011


Mayer et al. *JNNP*, 2011

**Hojnacki et al. Int Angiol, 2010**

Zivadinov et al. *Neurology*, 2011

Tsvigoulis et al. *Neurology*, 2011

Marder E. *Arch Neurol*, 2011

*Doepp et al. Neurology*, 2011

*Multimodal non-invasive imaging*

**Multimodal non-invasive and invasive imaging**

# Multimodal invasive imaging performed only on CCSVI positive subjects
What should be apparent is that there is a preponderance of positive CCSVI studies. Moreover, those studies that are in bold are those that have used multi-modal imaging (best practices) to determine diagnosis. Dr. Simka, who has undertaken the most procedures worldwide, reports that prevalence of CCSVI in MS patient is very high (>90%).

Regarding safety, there have been three major studies: Ludyga et al. (2010), who studied 331 patients, and found 6% all complications, no major complications, and that CCSVI treatment is a safe procedure; Petrov et al. (2011), who studied 461 patients, and found 6.5% all complications, no major complications, and that CCSVI treatment is a safe procedure; and Mandato et al. (2012), who studied 240 patients, and found a 1.6% risk of major complication, and that CCSVI treatment was a safe procedure.

“Their is that this procedure is being undertaken in 60 countries, and 30,000 procedures have been undertaken worldwide.

I have already addressed the issue of safety above. Now let me address the issue of efficacy. For specific examples, Dr. Petrov reports that 63% of his patients show a functional improvement. Dr. Gupta reports that of his 45 patients, some show gait improvement (4), reduction in stiffness (8), sensory improvement (8), improved vision/speech (2), and improved bladder control (10). Dr. Schulte of Argentina reports that of his 15 patients, all showed improvements on all scales: EDSS (5%); MSIS (24%); Fatigue (21%); and Sleep (39%). Dr. Gilhooly reports that of his 125 patients, they show the following improvements: fatigue (60%); mobility (48%); vision (20%); sensory (60%); brain fuzziness (almost 60%); and bladder (over 40%).
I appreciate the former are small studies, but what is becoming increasingly apparent from multiple countries around the world is that: (1) every patient is different, with different venous anatomy, different course of MS, and different length of illness; and (2) some patients do seem to experience an improvement in symptoms.

ISNVD 2011 reported: Dr. Mehta from Albany Medical Center, New York, studied 150 consecutive MS patients where he identified almost 300 jugular and azygos veins with significant stenosis and performed angioplasty. In the post-operative phase, he monitored important aspects such as chronic fatigue. Chronic fatigue improved significantly in all surgical patients. This was further confirmed by more than 25% increase in the quality of life scores as measured by physiatrists who were unaware of the surgical procedure one year after angioplasty.

Dr. Gianfranco Campalani, a vascular surgeon in Belfast, who has seen marked improvement in his MS symptoms since he received CCSVI treatment in 2007, reported in the fair and balanced “MS Wars: Hope, Science, and the Internet (February, 2012)” documentary that it is “unethical” to deny treatment to those with CCSVI.

Why does the government continue to ignore the evidence from over 30,000 procedures, scientific studies from nine CCSVI conferences, and returning Canadian MS patients--as well as earlier recommendations by, for example, the Ontario Association of Neurologists, the Canadian Society of Radiologists, the Canadian Society of Vascular Surgery, and the American Society of Interventional Radiology? Why does the government continue to ignore leading physicians/researchers (e.g. CCSVI Coalition Scientific Advisory Board Members: Dr. Bill Code, Dr. Mark Godley, Dr. Mark Haacke, Dr. David Hubbard, Dr. Sandy McDonald, Dr. Salvatore Sclafani, Dr. Michael Shannon, and Dr. Gary Siskin) in North America who strongly support bill C-280?

“You may also have heard in debates that the proposed venous angioplasty procedure is a routine procedure. In fact, the only commonly practiced balloon angioplasty done on veins is for patients undergoing regular dialysis treatments. The Alberta Health Services' opinion in this matter is clear: ‘there are no situations where venous angioplasty is an
accepted and satisfactory treatment. [...] Therefore the claims that venous angioplasty is a routinely done procedure are not true.”

This is patently false. For example, venous angioplasty is used to treat Budd-Chiari disease in the liver, and May-Thurner syndrome, which is caused when the left iliac vein is compressed by the right iliac artery.

“The Canadian Institutes of Health Research is currently soliciting proposals for a Phase I/II trial to prove the Zamboni procedure is safe and effective. Supporters of Bill C-280 have called for a Phase III trial that includes a much larger number of patients; international experts are recommending a smaller trial first.”

This statement is meant to mislead. The Bill actually calls for the identification of the most appropriate level of clinical trials for the treatment of CCSVI in Canada, in order to place Canada at the forefront of international research.

The CCSVI Coalition Scientific Advisory Board Members have written: “We strongly believe that an adaptive phase II/III trial will allow for a fast and effective research path to get the answers we all need regarding CCSVI. To do otherwise would waste what little time many Canadians with this disease have left in their search for improved quality of life and be unforgivably wasteful of taxpayer’s money during these difficult economic times. Let us be very clear on this point; the many scientists and clinicians comprising our Scientific Advisory Board, all internationally recognized for their expertise in this area, stand firmly behind your position that the safety of CCSVI angioplasty has been well established and therefore anything less than an adaptive Phase II/III trial would be unconscionable.”

“We cannot and must not turn a blind-eye to international experts’ opinions.”
The government has repeatedly demonstrated wilful blindness (as shown throughout this letter) in ignoring evidence.

Thank you for taking the time and effort to read this letter, and carefully weigh the scientific evidence presented.

Yours very truly,

Kirsty Duncan MP

Etobicoke North