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Tuesday, May 11, 2010

Chair

Mrs. Joy Smith

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● (1105)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Order, please.

I call the subcommittee together.

Dr. Bennett, are you sitting on the subcommittee today?

Hon. Carolyn Bennett (St. Paul's, Lib.): I haven't decided yet, Madam.

The Chair: Would you go outside with your conversations then, Madam? Thank you.

Today we have a lot of witnesses, and I think it's going to be an extremely interesting study.

I welcome the witnesses today.

I'm going to have to leave at 11:30, and Dr. Duncan will be taking the chair following that. She's done very good work, as has this whole committee—Dr. Duncan, Monsieur Malo, and Mr. Brown—which has done an exceptional job of trying to get all of this together so we can have our presentations today.

Is there a problem?

Hon. Carolyn Bennett: Madam Chair, I don't know if there's another way of doing this, but I think Dr. Duncan is so knowledgeable on this topic that it would be inappropriate for her to be in the chair.

The Chair: Really.

Mr. Brown, would you like to take the chair?

Mr. Patrick Brown (Barrie, CPC): I'd be happy to.

The Chair: Okay, Mr. Brown will take the chair.

Having said that, we're going to talk to Dr. Samuel Ludwin, from Kingston, Ontario by teleconference.

Mr. Ludwin, can you hear me?

Dr. Samuel Ludwin (Professor of Pathology (Neuropathology), Queen's University, As an Individual): Yes. It's Dr. Ludwin. I'm hearing you loud and clear.

The Chair: Oh, wonderful. Welcome, Mr. Ludwin.

He's a professor of pathology, ladies and gentlemen, from Queen's University.

We have another teleconference, from Montreal, with the Multiple Sclerosis Society of Canada, with Nadine Prévost, director.

Nadine, can you hear me?

Ms. Nadine Prévost (Director, Services and Outreach, Quebec Division, Multiple Sclerosis Society of Canada): Yes, I'm hearing you very well.

The Chair: That's great.

From the University of Calgary, we have Samuel Weiss, professor and director of the Hotchkiss Brain Institute.

Professor, are you there?

Dr. Samuel Weiss (Professor and Director, Hotchkiss Brain Institute, University of Calgary): I'm here, and I can hear you loud and clear.

The Chair: Wonderful.

Well, we're very pleased that you three could join us by teleconference.

As individuals, we have Dr. Sandy McDonald, a medical doctor; Dr. Jock Murray, professor emeritus from Dalhousie; and Janet Salloum. Welcome.

Are you a medical doctor, as well?

Ms. Janet Salloum (As an Individual): I'm here to testify as a witness.

The Chair: Thank you so much.

From MS Liberation, we have Rebecca Cooney.

Rebecca, are you a medical person?

Ms. Rebecca Cooney (Co-founder, MS Liberation): No, I'm not.

The Chair: Okay. You're here, then, as an individual. Thank you.

This subcommittee has been very involved in trying to set up a subcommittee, because we don't have time to look at this issue on the main health committee for this term. Next term we hope we'll be able to do something more. But it's such an important issue that we have formed this subcommittee.

This is the first time I've had to leave. There is a huge school group here. They've flown in all the way from Manitoba, and they want to see me for a few minutes, so Mr. Brown will be taking the chair.

We're going to have five-minute presentations so we can get to the questions and answers. We will start with Dr. Sandy McDonald, medical doctor, as an individual.

Could you please give us your presentation, sir?

Dr. Sandy McDonald (Medical Doctor, As an Individual): Madam Chair, Madam Vice-Chair, honourable members, we are here today to speak on CCSVI, chronic cerebrospinal venous insufficiency, a serious vascular problem. I am a vascular surgeon. Thank you for the opportunity to address this subcommittee on a matter of great importance and, in my opinion, great urgency.

You have the chance to help put an end to an enormously troubling situation in which thousands of innocent victims of multiple sclerosis are condemned to deterioration of every aspect of their lives and are deprived of a simple procedure available to every other Canadian without a second thought—every Canadian, that is, who suffers from a venous anomaly of any organ other than the brain, every single Canadian except those with MS. I am here to ask you to help remove the obstacles that make it impossible for MS sufferers to obtain treatment for CCSVI and make it impossible for doctors to give treatment, even as a matter of compassion.

I am a cardiovascular surgeon. One day not long ago, my lab suddenly experienced a flood of requests for imaging to diagnose CCSVI. We were receiving and continue to receive 1,000 requests a week for this service. I found news about Dr. Zamboni's research with the diagnosis of CCSVI. We did some research. We started to do the same imaging, as requested by the physicians referring the patients. To our astonishment, we found a large number of cases that had verifiable, diagnosable abnormalities seen in the veins draining the brain and the spinal cord.

At first we found these abnormalities in about 75% of the cases. I realized that this was an abnormality I did not understand. I chose to travel to Italy. I spent several days with Dr. Zamboni and his crew. I acquired training that was required to adequately detect these abnormalities and I am now sticking to a very rigid protocol, designed by Dr. Zamboni, to diagnose CCSVI. BVI is now finding abnormalities sufficient to diagnose CCSVI in upwards of 90% of patients with MS referred to us by neurologists.

It is too early to say whether CCSVI is actually causing MS. However, it is not too early to say that the logic of such connections is very plausible and makes scientific sense. Indeed, anecdotal evidence today is very compelling.

We know that patients with MS have a buildup of iron in deep-brain tissue, an area close to draining veins. It is plausible that the compromised venous drainage causes red blood cells laden with iron to leak from the thin-walled veins into brain tissue. As the leaked red blood cells break down, iron is deposited, an immune response follows, neurological damage subsequently develops. The experience of Zamboni and Simka is that virtually all CCSVI sufferers with MS who undergo corrective angioplasty experienced some improvement in their symptoms. I have proceeded to refer six patients to treatment for angioplasty: all six have seen significant improvement, four of them dramatic.

Angioplasty is a well-known, universally practised procedure. It is not experimental. Interventional radiologists do it virtually every day. It is very low-risk. There is nothing special about venous angioplasty. The angioplasty we speak of with Dr. Zamboni is for jugular and azygous veins. It is a simple two-hour to three-hour outpatient visit done under local anesthesia with minimal risk.

I am a cardiovascular surgeon. I fix blood flow. In that sense, I'm a plumber. When I see a serious plumbing problem, I want to fix it. When I see the whole house is suffering, I want to fix the pipes. I can do that without harming the wiring in any way and do not see why we condemn the family to misery while we wait for an electrician to give his permission.

Only this past week, I had to tell a young patient whose young life is being expropriated by MS that I had found a clear obstruction in the blood flow from her brain. I could tell her that technology exists to treat this abnormality quite easily, quite cheaply, and with undue risk. But I had to tell her that this procedure is not available in Canada. She is not the only one. She is one of tens of thousands of MS patients in Canada who simply do not understand how it is possible to justify discriminating against them in this way. They are right not to understand. You should not understand.

Unless we put an end to this Kafkaesque and perfectly discriminatory situation in which we will predictably see MS sufferers seek diagnosis and treatment elsewhere, MS sufferers will litigate and a disproportionately large percentage of MS sufferers will commit suicide.

Yes, more study is needed. The recently requested $10 million for study by the MS Society is a good start, but only that. It will not help any MS sufferer in the meantime. It is fatally flawed if it does not include a treatment arm for CCSVI.

● (1110)

We will only learn the efficiency of treatment with CCSVI if we do the procedure. If this study is done as an excuse to do nothing while we wait for results, then it will harm MS patients. They will simply wait longer for treatment.

We cannot tell MS patients just to wait. We must keep the door open for doctors to deliver on a compassionate basis, if necessary, correction of CCSVI and MS. If universal health care is not accessible for treating patients with CCSVI and MS, then we must, as a minimum, allow these MS patients to purchase their services in Canada from qualified physicians.

Please report to the Standing Committee on Health and advise the minister that there are unconscionable and unacceptably discriminatory obstacles in the way of corrective angioplasty for CCSVI sufferers who also happen to be diagnosed with MS.

Physicians are sworn to help their patients. Please let me help mine.

● (1115)

The Chair: Thank you very much, Dr. McDonald.

Now we'll go to Dr. Murray, please.

Dr. T. Jock Murray (Professor Emeritus, Dalhousie University, As an Individual): Thank you very much.

When I was originally asked to come to this committee, I thought the discussion initially was going to be about the need for neurological research in general, and I was quite prepared to do that, because I still think that's the basis of how we're going to find answers to important questions about diseases that afflict so many Canadians.

There is a very strong research community in neuroscience in Canada. Particularly in the area of neuroscience many of our universities have some of their greatest strength. In MS, we have a group of clinicians and researchers who have been part of most of the advances that have been made in the disease in the last 50 years. There has been a network of clinics across the country, which now can put together a study like the genetics study, which can put 32,000 MS patients into a study to answer questions about the genetics of the disease. So the ability and the power is there, but it has to be understood that most advances that have come in MS as well as other diseases have come from basic science.

The importance, I think, is to make sure that we have adequate funding for all important questions, all peer-reviewed good research involving the neurosciences. In MS, we learn from other research and other fields, and so much of what we're beginning to understand about neuro-protection, about the recovery from damage to the brain, is coming from studies in stroke and is coming from studies in trauma, and all of that will reflect on our ability to manage patients with MS in the future.

We are now within a therapeutic era of MS. I started taking care of MS patients 40 years ago, and initially we had no therapies that altered the outcome of the disease. We now have six therapies that are approved in this country for MS patients that do alter the outcome of the disease, but unfortunately not for all. We have a number that are in the wings waiting to be approved, that have randomized clinical trials that show proof of benefit. We also have some that are now approved in the United States that are soon to come for approval in Canada. It's interesting that there's no media attention at all to these, which have randomized clinical trials to show efficacy.

When a question suddenly arises like CCSVI, it is important that it be treated respectfully and be assessed like all the other hypotheses, of which there are many at the present time. What we have asked for is that there be an accepted, standardized approach to answering the questions, and most of the clinicians involved in this have asked for it to be in two stages. One is to first assess what the importance is of the neck vein problem, because although it has been said to occur in 100% of MS patients, a recent study showed it to be 50%. It was said to be zero in the non-MS patients, and now we find there have been studies over the last five years to show that it is not that uncommon in the normal population. There are questions about what the importance of this is. What we need is a rational approach to answering, first, the basic questions about the importance of this, and then, if it does appear that there is strong evidence, a design of a standardized, randomized clinical trial to show benefit and safety.

One of the things about getting to the age I am is that you tend to become an historian. I have written a book on the history of multiple sclerosis, and there are 100 pages in the book on the history of therapies that have been said to be cures for the disease. Some of these therapies were given to MS patients for as long as 20 years before they disappeared.

All we ask is that there be a reasonable approach to how this question is being answered. If all patients are given the therapy, no one will go in a trial. If that occurs, we will not get the answers. We have had, in recent years, pressure in our clinics, not just for CCSVI, but for dorsal column stimulation. Many patients around the world, because it got into the media, had implanted electrodes on their spinal cords until that turned out to be unsuccessful and it got abandoned. The media never went back to the story of that failure.

● (1120)

We've had snake-venom therapy, bee-venom therapy, Cari Loder diets, hyperbaric oxygen chamber therapy, and our patients were pressuring us to send them and pay for the cost of that in Florida. It's still available. Two years ago the press was raising stories about sending people to China for stem cells. It goes on and on.

Is there any harm in all of this? Yes, there is. Over the years we've had repeated disappointment to the MS community about things that were initially said to be cures. All we ask is that there be a reasonable approach to the assessment of the neck vein problem, and later the therapy itself.

The Chair: Thank you very much, Dr. Murray.

Now we'll go to Janet Salloum.

Ms. Janet Salloum: Good morning.

I wish to thank the committee for allowing me to testify today. I'll try to get through my points as quickly as possible, as I only have five minutes. This feels like the most important five minutes of my life.

I'm here to testify for my sister, Michelle. She is a young woman in her thirties with three small children, ages six, four, and the baby is not yet two. Two and a half months after the birth of her third child, she developed symptoms. She was diagnosed on December 8, 2008. Within seven months, she was confined to a wheelchair. Her disease is both progressive and aggressive.

Studies are currently under way at St. Joesph's and McMaster for CCSVI. As important as these studies are, many with MS, like my sister, don't have time to wait for the results. I'm here to ask the committee to take whatever steps, whatever action necessary, to ensure that those who do not have time to wait for two years for the results of a study get immediate treatment for CCSVI on compassionate grounds.

Like many people with MS, Michelle paid out of pocket to go to Buffalo to have the tests done to determine whether she has CCSVI. The tests showed she has diagnosis in both her jugular veins and needs to have her veins unblocked immediately. Some people with MS have been fortunate enough to pay for and travel to other countries, such as Poland, Kuwait, Italy, to get their veins unblocked and are returning to Canada feeling that they have been cured, liberated.

Even if one had the means to go outside of Canada, there is a waiting list of over one year to get the procedure done. Why isn't it being done right now in Canada?

Canada has an opportunity to be leaders in this breakthrough. Many of you have an opportunity to be heroes. I know for sure that there's at least one right here, right now. I'm asking the committee—no, I'm begging the committee—to take immediate action, whatever necessary, to unblock the veins of those suffering with CCSVI, even if they also happen to have MS, and particularly the ones whose conditions are galloping, like Michelle's.

Why should people with MS be discriminated against? Why should they not have the choice in getting their veins unblocked? Canadians are able to get their veins unblocked for any other organ in the body. Why not their brain? If nothing is done and patients are forced to wait for the results of the study, people like Michelle will die waiting. Knowing this and doing nothing is like watching someone drown while you test flotation devices.

It's manslaughter. It's unethical. It's immoral.

I'm sure this committee has heard the financial comparisons with respect to the cost of CCSVI treatment, which is approximately $1,200 to $1,500, versus $25,000 to $40,000 per year for standard MS drug treatments. From a financial point, then, clearing veins makes sense.

What about the right to choose treatment? Canadians are fortunate, in that they have choices: abortion, circumcision, cosmetic surgery. These can be controversial and rooted in religion, women's rights, or aesthetics. Shouldn't Canadians have the right to unblock their veins?

To improve the quality of their life, take MS out of the equation and treat CCSVI like any other venous insufficiency would be treated in the body. Each day that goes by, Michelle's condition worsens. Neurologists prescribe a host of drugs and drug treatments that carry great risks, such as chemotherapy, and also a drug called Tysabri, which has been known to cause fatal brain disease. Yet some neurologists have been vocal in expressing their concerns about a very low-risk procedure to unblock veins. Clearly, drugs such as these pose a much greater risk than in an angioplasty-type procedure.

One neurologist in particular has expressed fear of losing the research dollars to CCSVI studies and has even suggested that CCSVI and its relationship to MS may be a hoax. It may be like the chicken and the egg: it doesn't really matter at the moment if CCSVI causes MS or if MS causes CCSVI.

The studies under way may provide answers to these questions. What matters and what we do know now is that people have blocked veins and need to get them unblocked. Not doing so is wrong on so many levels, it's immoral.

● (1125)

Michelle is often confined to a bed, since there are times when she can't hold up her head or keep her balance in a wheelchair. She is too weak sometimes to speak and suffers unbearable headaches. Her children look shell-shocked as they watch their mother deteriorate before their eyes. And her husband looks thin, beaten down, frightened, and exhausted.

The only thing keeping her alive is a shred of hope that she may get treatment soon to unblock her veins and that she may one day be able to hold her baby again, change her diaper instead of watching a caregiver do it, and push her children on a swing in the park.

She deserves a chance. Please take whatever steps are necessary to give her this chance.

Thank you.

The Chair: I thank you for your courage in coming to be a witness at committee. I know that many of us have been touched by Parkinson's or MS, and we share your concerns. We really do.

We're now going to the teleconference with Kingston. We have Dr. Samuel Ludwin. I'm sorry to have to give you such a short time, but we want to hear from everybody. You have five minutes, sir.

Dr. Samuel Ludwin: Thank you very much for inviting me to testify.

My name is Samuel Ludwin. I'm a physician, a neuropathologist, which is somebody who studies the brain. I have been studying neuropathology for the last 40 years. During this period, although I look at all brain diseases in my clinical job, my research work has been in the study of multiple sclerosis brains. I'm also an experimental researcher.

My whole academic life has been related to trying to understand the link between what we observe in the experimental situations and what we see in the clinic and what we see in the brains of patients with multiple sclerosis.

I might add that pathology is a unique discipline that gives the physician the privilege of being able to look at a patient from an objective point of view, and we take that responsibility very seriously. I'm also a teacher on both clinical and basic matters.

I have also served as an associate dean of research and the vice-president of research in the Kingston hospitals, and this has given me a unique perspective on research in general. I've served as a patient advocate on both multiple sclerosis and some other myelin-related diseases. Finally, and I will come back to this, I am currently the incoming chairman of the federal panel on research ethics set up by the three funding agencies that provide the guidelines for ethical procedures in human research.

Dr. Murray has mentioned some of the issues, but I think they bear repeating, because a lot of these I will have done. Canada is a unique country in the world of multiple sclerosis, admired throughout the world for the quality of both its clinical work and research. As they say, we punch far above our weight in terms of the number of people treating and publishing and doing research. This has come about, of course, from necessity, because of our large patient load.

But in addition, there have been two very good reasons that our scientists and our clinicians have achieved this very enviable position in the world. The first is an extremely well-organized clinical network, which really looks after most multiple sclerosis patients in the country—this is very different from the situation in most other countries—and also to a very dedicated Multiple Sclerosis Society, which has provided funding for many decades and has funded some of the most important advances in multiple sclerosis.

I can't emphasize too much the relationship between good clinical practice and research. I'll start off by making a general statement from all clinical research: that studies have shown that patients who are undergoing clinical trials generally, whether they're on trial arms or not, have a much more favourable outcome than patients who are not treated this way.

But this is a side effect to providing a rational basis for therapy. Any time one looks at a therapeutic process, one has to have some sort of justification. Sometimes the justification can come from clinical observation and sometimes it can come from experimental observation on animal and tissue culture models. For instance, we all know—and this has some analogies to CCSVI—that coronary angioplasty and coronary stenting is a routine, accepted procedure. But people forget to stop and think about what our knowledge about coronary angiography has derived from. It has derived from a decade and maybe even centuries of observable pathological changes in the actual heart, changes that have shown blockages in the vessels and have led to techniques for diagnosing them, fortunately, before the patients die.

These have been established over many decades before the advent of some of the treatments. With new technology, this observable time can be greatly shortened, so patients will not have to wait for the kinds of decades that they did for coronary angiography.

Research in Canada covers most fields. There are very many important fields—

● (1130)

The Chair: Dr. Ludwin, I have to interrupt you. Could you wrap up now, please?

Dr. Samuel Ludwin: Certainly. What I would like to do is end up with what the importance of the CCSVI is.

The CCSVI is an extraordinarily interesting, novel idea, and in fact the Multiple Sclerosis Society of Canada some time ago took a lead in the world in calling for a research proposal request, for which we were considered to be very great forerunners. It offers many new ideas in terms of pathology, and Dr. McDonald has mentioned some, such as the iron, but this has to be really proven.

There are many flaws in this argument. It may turn out to be right, but it needs good study on both a clinical and an experimental ground.

The Chair: Thank you, Dr. Ludwin.

I know you were asked to come here, but could you please provide documentation and send it to the House of Commons clerk here, so that we can distribute your paper to all the committee members? Could you do that for me, please, Dr. Ludwin?

Dr. Samuel Ludwin: Certainly. It would take a few days, though.

The Chair: Thank you. That would be just fine. And thank you for your presentation.

We'll now go to the Multiple Sclerosis Society of Canada, Nadine Prévost.

You'll have five minutes, Nadine.

[*Translation*]

Ms. Nadine Prévost: Thank you for giving me the opportunity to talk about the concerns of Quebeckers with multiple sclerosis.

The Quebec Division of the Multiple Sclerosis Society of Canada has over 8,000 members. For over a decade, it has been working on raising awareness of the needs of people with multiple sclerosis.

Our office is in Montreal. There are also 25 local chapters across Quebec. There are an estimated 13,000 to 18,000 people with multiple sclerosis in Quebec. Quebeckers are fortunate to have a strong network with 16 multiple sclerosis clinics that ensure medical follow-up. Five of the clinics also conduct research.

The Quebec division offers a number of services. We provide reliable information on multiple sclerosis, treatment options and research. We offer various types of resources, such as publications, a Web site, a quarterly newsletter, information sessions for recently diagnosed people, conferences, an annual congress and a seminar for health professionals. We also provide a range of support services, such as support groups, moral support, referrals to other resources in the community and advocacy. We also have a youth component, which includes a quarterly newsletter, a Web site and a camp for children with a parent with multiple sclerosis. In addition, we offer physical and recreational activities to promote wellness and break the isolation, and we lend equipment.

Today, I would primarily like to talk to you about the continuum of care and the needs of caregivers. Multiple sclerosis most often strikes young adults, and we know that living with this episodic and progressive disease requires frequent adjustments. The residential needs of those living with multiple sclerosis are varied, since the disease itself varies from one person to the next. Some people have to rely on their LCSC for in-home support services on an ad hoc or permanent basis. Others also have to modify their homes to make them accessible.

When people can no longer safely remain at home, they are faced with some difficult choices. At this time, there are very few residential options that include a service component. Nursing homes are the only available option all too often. Therefore, some people have no choice but to move to a nursing home. There are cases of couples that had to separate after a few decades of living together because they did not have any other choice.

There are several possible solutions, among which are increased funding for home care and access to home adaptation programs within a reasonable timeframe. We would like institutionalization to be considered as a last resort and priority to be given to supporting people in their natural environment. The majority of people with multiple sclerosis would prefer to live in an environment that is similar to a traditional home with services and care.

In addition, we would like the development of other home resources to be supported, especially for young adults who can no longer remain in their living environment. That way, we would free up space in nursing homes for people in the final stage of life.

Finally, we would like the living environment approach to be integrated into nursing homes in order to create living conditions that are stimulating and mindful of people's specific needs.

● (1135)

We know of young adults in nursing homes that get lost in a sea of elderly people and so do not receive services appropriate to their age and condition.

[*English*]

The Chair: Ms. Prévost, I'm going to have to stop you now.

We're very tight on time, and so many witnesses were put forward today that we might run out of time for everyone to have equal time to ask questions. I'm going to have to downsize the question-and-answer time to three minutes each, because we have the University of Calgary and Rebecca Cooney yet.

We're going to go to Samuel Weiss.

Is it Dr. Samuel Weiss?

● (1140)

Dr. Samuel Weiss: Yes, it is.

The Chair: You have five minutes, please, and I'll be very tight on the time. Thank you.

Dr. Samuel Weiss: Thank you very much. Thank you for the opportunity to speak today. I'll keep my comments brief.

I am a neuroscientist and a stem cell biologist and director of the Hotchkiss Brain Institute at the University of Calgary. The mission of the institute is to translate discoveries into innovative health care solutions for patients and families with neurological and mental health conditions.

My research in stems cells in particular has been relevant to the development of new novel therapeutics, and over the past five years some of the work that we have done in very fundamental, basic research is now being tested in patients, for stroke in particular, but we also have some work that is being proposed for testing in MS patients sometime in the next 12 to 24 months.

All of this work revolves around using safe compounds to try to activate people's own stem cells to improve neurological function. I should say, however, that it takes somewhere between 12 or 24 to 48 months before some of the very basic, fundamental findings are tested in small numbers of patients to ensure two things: one, that they are safe; and second, that they have a prospect of improving people's lives.

All of the individuals I know, including the patients who come to our clinics, the families of our patients, including individuals throughout our communities, are affected by neurological and mental health disorders, which is why it's absolutely critical that the federal government make important, strategic, carefully thought-through investments in research—both basic, fundamental, and applied research. I applaud this committee and this subcommittee for tackling this very important issue.

I can't speak with great knowledge about CCSVI, and you've already heard from many experts about it. The only thing I can say is that in many cases like this, it is very important that there be careful research before patient populations are subject to new treatments that have not yet been proven to be effective.

From what I understand from both the Multiple Sclerosis Society of Canada and the U.S. MS Society, there has been a call for proposals and there will be announcements of funding for new studies imminently. There will be cooperative studies throughout North America to test the validity of this diagnosis as well as experimental treatments.

I think it's also important to note that one of the leading MS centres in the United States, Stanford University, halted any further CCSVI treatment because of the unfortunate death of one patient as well as the heart attack of one of the other patients. This speaks to the importance of very careful, considered research, both at the basic and clinical level, to ensure the best for all individuals, patients, and families throughout Canada when there are new therapies such as CCSVI.

Thank you, Madam Chair.

The Chair: We'll now go to Rebecca.

Ms. Rebecca Cooney: Canada gave the world insulin, mobile blood transfusion, and the Montreal procedure, a surgical treatment for epilepsy. Back then, the barriers were the frontiers of medicine. Today they're between the specialities of medicine. We are up against myths and self-serving practices.

Fortunately, there's a solution. Venograms and venoplasty are already insured services under the Canada Health Act, so let MS patients have access to them now.

[*Translation*]

My name is Rebecca Cooney, co-founder of MS Liberation, a group of 350 MS patients. Thank you for hearing our concerns and solutions.

[*English*]

All Canadians with vascular problems can be tested and treated in Canada, unless they have MS. Since I've been diagnosed with CCSVI, my family doctor has recommended that I see a vascular specialist, but none will see me without a referral from my neurologist, who in turn won't do it. Why is that?

The treatment of CCSVI is held to the myth of risk-free medicine. What's the reality?

In 2007 the *British Medical Journal* analyzed 2,500 common medical treatments and found that only one-third had proven benefits. The Montreal procedure for epilepsy was implemented without double-blinded trials. Without clinical trials, angioplasty was accepted as the safe and economical way to treat coronary disease. If I had heart disease, I could get angioplasty without a neurology referral. Why is CCSVI held to a different standard?

There is also the myth that the treatment of CCSVI is experimental. In fact, venoplasty is used for thrombosis of the jugular vein and sigmoid sinus.

Another myth is that there are conventional drugs for people with progressive MS. There are no drugs.

Still another myth: Why fix something that is not proven to help MS? The plain answer is that better blood circulation improves health, whether there's MS or no MS, and the goal is to treat the patient, not to research MS.

● (1145)

[*Translation*]

I am not a medical doctor. But I do have an MBA and 15 years of experience in risk assessment. Before deciding whether to wait or act now regarding CCSVI, we need to assess three things: risks, costs and benefits.

[*English*]

The risk of venoplasty is minimal. It has been performed very safely for many years on thousands of people. Conversely, the medical risks of existing drugs for MS are well known.

The costs to test and treat CCSVI are minimal. It's estimated to be $1,500 per person, less than the cost of one month of drugs for a patient with relapsing-remitting MS.

The benefits of venoplasty are the most encouraging yet for MS. Venoplasty actually improves the condition of some patients, which is something that MS drugs rarely do. It stops the progression of the disease in some patients, which is something that no MS drug does. For people with progressive MS, it is the only safe option available. There are no drugs for progressive MS.

Resources must be deployed strategically. The MS Society has asked for $10 million. Since their competition does not cover researching the treatment of CCSVI and only covers the testing, I have serious concerns that I will leave unsaid.

What I will stress is that immediately the Government of Canada can, one, declare CCSVI diagnosis and treatment to be insured services under the Canada Health Act, two, require that all CCSVI data be documented in a nation-wide clinical trial, and, three, ensure that treatment of CCSVI and clinical studies are done in parallel, not in sequence.

[*Translation*]

Four years ago, multiple sclerosis ended my career. Here are some of the things the future holds in store: a wheelchair, incontinence, debilitating headaches, the inability to swallow, dementia. However, the e-mails I receive from all over the world remind me that I am not alone.

[*English*]

For every patient, there are scores of friends, family, and relatives deeply affected. One e-mail from a mother stands out:

> The only thing worse than not having a treatment for your child's MS is knowing that there is a treatment out there, but you are denied access to it by your own government.

Ladies and gentlemen, you can change that. For that, I thank you in advance.

The Acting Chair (Mr. Patrick Brown): Thank you to all of the witnesses who took the time today to share their presentations with us.

I would ask the committee for some direction. We have ten minutes left in our scheduled time, which would only allot three minutes per round. If there is consensus, would we be willing to stay ten or fifteen minutes longer so that we could have a five-minute or seven-minute round?

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): That is not really possible.

[*English*]

The Acting Chair (Mr. Patrick Brown): It's not possible for Mr. Malo.

[*Translation*]

Mrs. Carol Hughes (Algoma—Manitoulin—Kapuskasing, NDP): I would just like to say that we could proceed with three-minute rounds. If there is still some time remaining after that, we can keep going.

[*English*]

The Acting Chair (Mr. Patrick Brown): A three-minute round would be very tight, though. I'll just warn you.

If Mr. Malo went first and we did five-minute rounds it would only take us to 12:10. Is that agreeable?

Is that okay, Ms. Duncan?

We will start off with Ms. Duncan, for five minutes.

Ms. Kirsty Duncan (Etobicoke North, Lib.): Thank you, Chair.

Thank you to all of you for coming.

As a former research scientist, I am concerned about the unidisciplinary thinking we've had around this today. This is being treated strictly as a neurological problem. I believe what Dr. McDonald is asking, what patients are asking, what my colleagues are asking, is that we take MS out of the equation. If you have a vein problem in your liver, in your leg, we image and we treat it.

Since there was discussion about the science, Dr. McDonald, I'm wondering if you can talk to us about the science of CCSVI. Is it a recognized condition? By whom? What are the guidelines for diagnosis and treatment?

● (1150)

Dr. Sandy McDonald: There are 47 countries in the world that recognize CCSVI as a true entity. In terms of the science, Dr. Zamboni did a study. He looked at 65 patients and found that many patients with MS had significant venous anomalies. He treated 65 patients and many of them saw significant improvement in symptoms.

I read his paper. I realize what his paper says. However, I also spent several days with Dr. Zamboni, and he subsequently has done a total of 130 to 135 patients, finding there is significant improvement in the symptom complex in these patients.

The science is also supported by the work of Dr. Simka in Poland, who has done upwards of 300 patients, similarly finding improvement.

If you take the study to Stanford University, Dr. Dake did 40 patients. He was doing a different procedure with those 40 patients. He was stenting the veins in the patients, which is not supported by Dr. Zamboni or his work. He does not stent or believe in stenting. The problems that Dr. Dake encountered were stent problems. That is, the stent migrated and resulted in a cardiotomy. And the other problem was a post-op stroke that the patient's family denies had anything to do with the procedure itself.

Ms. Kirsty Duncan: Thank you, Dr. McDonald.

Why do you think MS patients are being discriminated against—i.e., not receiving a venoplasty for a venous abnormality?

Dr. Sandy McDonald: At present a lot of institutions have adopted a wait-and-see protocol, wait and see what everybody else does. They don't want to go out on a limb and be the first doing a procedure, even though it may be very beneficial for the patient. It is fear of being procrastinated against by the medical society as it exists at present.

Ms. Kirsty Duncan: Do you think it would be fair for every MS patient across this country to be imaged for CCSVI?

Dr. Sandy McDonald: I believe everybody with MS should be imaged. The cost of doing the procedure is small. The problem, however, is the number of people who are adequately trained to do the duplex imaging of patients with CCSVI is small. There are currently three technicians trained in Canada by Zamboni to do the procedure. There is a fourth who lives in Niagara Falls and works in Buffalo. That's it. That's all you have.

Unless they follow the very rigorous protocol set up by Dr. Zamboni they'll get spurious results. What needs to happen is people need to be trained by someone who is very good at it, as is Dr. Zamboni, and then they can do the studies and have reproducible, reliable data. If they just read the book and say this is how to do it, they will do a flawed study, and the research will be useless.

Ms. Kirsty Duncan: Dr. McDonald, who will make the decision whether or not to image for CCSVI in Canada? What criteria have to be met? What timeline are we looking at? What is stopping you from performing this procedure today?

Dr. Sandy McDonald: The difficulty with imaging is that it's not believed by all the people who look after MS that it is useful. Many people do not believe that treating the jugular vein or the azygous vein will improve the symptom complex, and on this basis, different bodies are telling us we can't do it. For instance, in Quebec, the college said they didn't think we should be imaging for CCSVI in patients. Why, I don't know. Why the decision was made, I don't know, but I believe that decision came down roughly a week ago.

Ms. Kirsty Duncan: I think it's outrageous that someone who has a venous abnormality... If it occurred anywhere but in the neck, it would be treated. How do you feel about that?

Dr. Sandy McDonald: I don't understand the resistance of the group treating MS patients and not addressing it as a problem. I understand there must be science, and I understand that science is important, but the cost of doing science can't be the cost of wasted lives at this point. People who have MS with no other treatment must be considered on a compassionate basis for treatment. The data can be captured. A registry can be formulated, and all the people who will be treated will not be lost to science. We can formulate the controlled double-blind study and take as much time as we need to do it, but in the meantime we absolutely have to treat these patients on compassionate grounds; otherwise they're going to die with their disease, with a possible treatment at hand.

● (1155)

The Acting Chair (Mr. Patrick Brown): Thank you, Ms. Duncan.

Mr. Malo.

[*Translation*]

Mr. Luc Malo: After the testimony we have heard, I would just like to add a comment about CCSVI.

Patients, a doctor and specialists have told us that we should focus on treating CCSVI. Others have said that the current state of science is not advanced enough to do that. Both sides are turning to Health Canada. However, no Health Canada representatives could join us today to explain why the treatment is not currently offered.

Even so, I have a question for Ms. Prévost. In her presentation, she listed two points she wanted to add to the discussion, but she only had time to present one of them.

Ms. Prévost, could you please go back to the second point you wanted to present to the committee?

Ms. Nadine Prévost: Very well, thank you very much.

I would also like to say something about caregivers. We know that caregivers make it possible for many people with multiple sclerosis to remain in their homes and their communities.

I would just like to mention that caregivers who stop working to take care of someone close to them are currently being penalized. When they quit their job, they lose their income, and quite possibly some of their future pension benefits.

That is why we would like at least the spouse to be eligible for the Quebec government's caregiver tax credit. This is the last point I wanted to raise.

Thank you.

Mr. Luc Malo: In essence, Ms. Prévost, the demands you make in your presentation would fall under the jurisdiction of the Government of Quebec. Am I wrong?

Ms. Nadine Prévost: No, you are not wrong.

In fact, some of the demands are in line with federal recommendations, but the issues I brought up also come under provincial jurisdiction. You are right.

Mr. Luc Malo: Thank you very much.

I would like to propose something to our witnesses. I know that your presentations were perhaps cut short. If you would like to present to the committee additional or complementary elements, I am prepared to share my time with you so that you can continue or finish your presentations.

[*English*]

The Acting Chair (Mr. Patrick Brown): Thank you, Mr. Malo.

Is there anyone who requires additional time? They finished their testimony, but as Mr. Malo has suggested, they might have been cut off.

Ms. Rebecca Cooney: One of the things I would like to say is that people often say if we start testing and treating MS patients right now, it will take away from doing clinical trials. This is totally false. First of all, trials are usually very small, 100 to 200 people, so what happens to the rest of the 74,000 MS patients? The second thing is trials don't include people usually in the progressive forms of MS very often. Sometimes they do, but usually they don't.

Third, a lot of people with MS who have had MS for more than a certain number of years are excluded, as are people with other chronic conditions. I have Crohn's disease as well, and I would never be even eligible for a clinical trial. So people very often will use that myth, that if we don't do a clinical trial, if we start testing people, we won't have people for clinical trials. That's not true.

That's the only thing I wanted to add.

Ms. Janet Salloum: I would just like to say my sister has had it for about 18 months, so she's gone from an able-bodied functioning person to someone who is barely able to sit up in her wheelchair now. She's going to die without this treatment. She has to get this treatment immediately. So the studies are wonderful, but she needs action now. We have the technology, thanks to Dr. McDonald. He's doing wonderful work. I'm sure that there are facilities available that could take on patients right now and start treating them while the studies continue.

Dr. Samuel Ludwin: If I could just add, to continue, I actually am a great believer in spending money to do the studies as we requested the federal government do and as the National MS Society in the United States has done. I would make a plea, however, that these studies do get carried out before. It may be very counterproductive to what Dr. McDonald would like to do. If they are allowed to go without the studies, we will have a proliferation of many people who, unlike Dr. McDonald, may have not been properly trained and will be doing them willy-nilly. So I would encourage Dr. McDonald to publish his findings, to share his research findings so far and his studies, and all of these colleagues who do it, so that we have more people than just a few reports that have come out from Dr. Zamboni, and from Buffalo as well.

A study that we are proposing would include many, many more centres, which would really strengthen the case and protect patients as well from people who may not be qualified to do it.

● (1200)

The Acting Chair (Mr. Patrick Brown): Okay. Thank you, Mr. Ludwin.

We need to move on to Ms. Hughes now.

Mrs. Carol Hughes: Thank you. This is turning out to be a very controversial treatment, and I don't think it needs to be that.

I have friends who suffer from MS, and a friend whose son passed away very quickly from MS, I think within a year. So we do know how important it is.

Dr. McDonald, I know how passionate you were during your speech, and I think it speaks volumes on what needs to get done right now.

Because of the way the treatment is currently being issued for other reasons—the heart, the liver—with the blockage itself or the narrowing, what is the percentage of complications right now of the procedure itself, for what it is being used for, and what are the risk factors?

Dr. Sandy McDonald: Worldwide, we believe there have been about 750 procedures. The only death encountered was that in Dr. Dake's series in Stanford. He is using stents.

Zamboni says not to use stents. I know that, because I talked to him about two weeks ago.

Mrs. Carol Hughes: I'm actually talking about the other procedures it is being used for. There are thousands of times that this procedure has been used. So what has been the risk factor and the percentages of—

Dr. Sandy McDonald: The risk of an angioplasty is very small. We're talking about two different things, though. Venous angioplasty is different from an arterial angioplasty. Venous angioplasty is done in a structure with very low pressure, compared to the arterial status —save for possibly Budd-Chiari syndrome. A venous angioplasty in a low-pressure system carries with it very little risk of leak, because again, you're dealing with a low-pressure system.

I realize the vein wall is thin. However, we do coronary angioplasty, and I've seen thousands of coronary arteries myself when I was doing my residency and training. The walls of coronary arteries are no thicker, in most instances, than the walls of the veins we're treating with venoplasty. So the risks are very, very small.

Mrs. Carol Hughes: Before I move on to the other questions, does anybody else want to jump in here, those who are on teleconference? No?

The other question or comment I want to make is that I understand the difficulties with MS. I don't particularly live it myself, and I think it's easier for us who are not living it to say that we need more research on this, but obviously with what has transpired here and the urgency, there is a need for us to move forward and do it in conjunction with a research study.

This CCSVI, I believe, would also assist in eliminating some of the stresses on the health care system. In the ones that have currently been done, has the study indicated that there has been less need for medication for those patients?

I'll throw one more question at you as well, just because we've had to deal with this at one of my offices. It happened to be with cancer, where a certain medication for a certain cancer could only be used for that. But someone had a different cancer and there was an opportunity to have that assist, but because it wasn't proven they couldn't have access to it unless we asked for ministerial discretion, which we got. So what is the difference with this?

[*Translation*]

Ms. Rebecca Cooney: Regarding costs, I have conducted a financial analysis to compare the costs of medications for multiple sclerosis with what the costs would be for this procedure.

[*English*]

What we found was that if it basically halts the progression for even 20% of the people with MS, Canada would save millions of dollars, if that were the case. Now, that is a hypothesis, and it has to stop it. But people who have had the procedure—and I've talked to dozens of them—basically say that they have not progressed since they had the procedure. Some of them were from Stanford, and that was six to eight months ago. They haven't progressed at all.

For example, for me, every three weeks I deteriorate. If I could just stop it and still be able to stand in six months, that would be great.

● (1205)

Dr. Sandy McDonald: We've referred six people for treatment.

Dr. Samuel Ludwin: If I may, Mr. Chairman, I will just add that there are a few wrinkles in some of the arguments. First of all, my understanding is that Dr. Zamboni has distinctly said that his procedure does not work for progressive disease; it must be done on relapsing-remitting disease.

The second thing is that many of the patients, in my understanding, and I stand to be corrected, have been continued on their regular medical therapies, many of which are being shown to have an effect on relapsing-remitting that is very similar to that being described for CCSVI. So I think it clouds the picture a little bit, when we....

The Acting Chair (Mr. Patrick Brown): Thank you, Dr. Ludwin.

We need to move on to the next round. I'll take the Conservative round.

Thank you once again, everyone, for being here. It gives me particular pleasure to see Dr. McDonald. I represent the riding of Barrie, Ontario, and we take great pride in Barrie in having such a renowned vascular surgeon in our community.

I want to give you an opportunity to expand a little bit on some of the comments you made. I think it would be helpful if we gave you an opportunity to play devil's advocate. You can reference some of the concerns that have been raised.

I heard last week from a witness that to have an accurate sample size to make sure that this is a safe procedure you would have to have a sample size of 1,500. To have confidence in the safety of this procedure, what do you think would be a fair sample size?

Dr. Sandy McDonald: I'm not an analyst of data, but I am a good physician. I can go back historically and answer your question a little bit.

Several years ago, in the mid-1990s, there was a study done. It was called the NASCET trial. It looked at strokes in patients with blocked arteries in the neck. It was done in conjunction with neurology. The study was aborted, because we found that conservative management, that is, medical management, of carotid artery pathology resulted in strokes, and if we operated, the patient seemed to have significantly fewer strokes. From that perspective, there can be science that can be done that can be aborted in the interest of the patient.

I would like to go back just for a second, if I may, to cost. I'll allude specifically to one patient we treated. His name is Steve. He was virtually unemployable because he had so much fatigue. He had his angioplasty done. Since he's had his angioplasty done, he no longer has a caregiver, no longer lives in supported government housing, has stopped taking his drugs, much against my advice, and is going to send his wheelchair back. He says that he is saving the taxpayer $4,000 a month.

The Acting Chair (Mr. Patrick Brown): What do you think the cost of the procedure would be, just to give us some context?

Dr. Sandy McDonald: The cost to the hospital for the study done, without staffing and without paper costs—we tallied up the costs for the six patients we did—was about $450 per patient. You then have to add the costs of the technicians and radiologists, the paper costs, and the admitting costs and all that nonsense. On that basis, I've been quoted as saying that the cost is $1,500, because I like to leave a margin. I've no idea what the cost of putting a patient through a hospital system is.

There's one caveat, though, where the cost can go up. Dr. Zamboni is saying that in some patients, a cutting catheter needs to be used to facilitate the angioplasty. A cutting catheter costs $1,200. The standard cost for the actual high-pressure angioplasty device is $189.

The Acting Chair (Mr. Patrick Brown): There's been some concern expressed by neurological doctors. What is your response to neurological doctors who may have expressed some concern?

Dr. Sandy McDonald: I've heard a lot of wait-and-see. If everybody takes the wait-and-see venue, we'll never go anywhere. Somehow we have to get, hopefully, this committee to say to the government that this is a real disease and that we really need to treat it, because people are hurting.

Physicians know how to treat it. Patients want to be treated. We're being blocked from treating it, and I have no idea why.

The Acting Chair (Mr. Patrick Brown): You're in a unique position, Dr. McDonald, in the sense that you've actually treated patients with this procedure. And I understand that you've actually done it at your own expense. I understand you've treated six patients. Have there been any complications? And what have you learned from the treatment that you have engaged in so far?

● (1210)

Dr. Sandy McDonald: There have been no complications to treatment.

I'll give you a really nice example. A 23-year-old kid can't feel his left arm or left leg. He gets an angioplasty done and he gets feeling back in his left leg and his left arm. He's living in a house with an elevator because he can't go up and down the stairs. A week later he tells his mom and dad he's moving out of the house and into the apartment with his girlfriend because he doesn't have MS any more.

The procedure works. We have to allow patients to have the procedure.

The Acting Chair (Mr. Patrick Brown): I have one minute left on my time. I know, Dr. Murray, you wanted to say something as well.

Dr. T. Jock Murray: I know that the neurological community is purveyed as being skeptical. Not that they object to the fact that this is an important issue to be addressed, but we recognize that an anecdote is not strong evidence in medicine any longer. There are accepted ways to analyze benefit in any treatment.

One of the reasons neurologists have a concern—and they have a concern—is what Dr. Zamboni published, not what the media has been saying or the stories that we have heard. Dr. Zamboni published results in 65 cases. There were relapsing-remitting patients, secondary progressive patients, and primary progressive patients. His results, after 18 months... He indicated in his paper that the relapsing-remitting patients, if the vein stayed open, got some benefit. But those patients whose veins collapsed did not get a benefit. The secondary progressive patients did not get a benefit; the primary progressive patients did not get a benefit.

The Acting Chair (Mr. Patrick Brown): Unfortunately, Dr. Murray, we are out of time. I have to cut my round off; otherwise, I'll be longer than anyone else. I don't want to do that.

Thank you, everyone, for coming today. This has been very informative. Thank you so much for taking the time to share your experience with us.

Mrs. Carol Hughes: Can we just ask that if they have anything to add, they should send it in?

The Acting Chair (Mr. Patrick Brown): That's a very good point, Ms. Hughes.

If you have any research that you could pass on to the committee as we develop this national strategy on the brain, our study of neurological disorders, it would be much appreciated. And thank you again for your time.

The meeting is adjourned.

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