● Phone 613-829-6667 ● Fax 613-829-8518
● 512-33 Banner Road
●Ottawa, ON K2H 8V7 Canada
●mefminfo@mefmaction.com
● (BN) 89183 3642 RR0001

September 30, 2016

To: Advisory Panel for the Review of Federal Support for Fundamental Science

Unfunded science: A case study

On August 25, 2016, CIHR announced that a review committee had rejected the only application CIHR had received in its funding competition for a Canadian research network focused on ME/CFS (Myalgic Encephalomyelitis / Chronic Fatigue Syndrome).

The review committee, made up of only a few people, assumed a psycho-social model for ME/CFS, criticized the application for focusing on physical pathology and biomarkers, and went as far as to say that the "there is no evidence that CFS is a real disease". This is reminiscent of a 2013 book by a Canadian academic referring to CFS as a quasidelusional disorder.

CIHR has chosen to stand behind the review committee decision. Nobody in the federal government has stated what should be obvious - that the committee's evaluation does not stand up to scientific scrutiny.

According to Statistics Canada's Canadian Community Health Survey, there are over 400,000 Canadians with a diagnosis of ME/CFS and over 500,000 with a diagnosis of Fibromyalgia. The data shows that these Canadians have high degrees of disability, high levels of health care utilization, high levels of unmet health and home care needs, high levels of socioeconomic disadvantage, and high levels of social isolation.

According to the prestigious US Institute of Medicine in February 2015, "ME/CFS is a serious, chronic, complex, systemic disease that often can profoundly affect the lives of patients". The IOM added that "remarkably little research funding has been made available to study the cause of ME/CFS, mechanisms associated with the development and progression of the disease, or effective treatment, especially given the number of people affected" [emphasis mine].

Esteemed researcher Dr Ronald Davis describes ME/CFS as probably one of the last major diseases we know nothing about. It has been speculated that discoveries into ME/CFS will not only benefit the patient population, but would open up our understanding of a number of other unexplained illnesses. In other words, fundamental science into ME/CFS could not only enrich the lives of Canadians with this complex chronic and disabling disease, it could have far wider impact.

CIHR is mandated to develop health research in emerging areas. Patients have been asking CIHR for years for help in building research capacity for both ME/CFS and Fibromyalgia. Currently, there is only one project being funded by CIHR which even mentions ME/CFS for a total of $45k this fiscal year. There are two studies that mention Fibromyalgia for a total of $152k. We have suggested the establishment of a new institute, pointing out that an institute was the strategy used to develop aboriginal research. Failing an institute, we suggested multi-year designated funding to attract researchers. We conservatively suggested that funding should be about $10M/year for ME/CFS and the same for Fibromyalgia, not taking into account retroactive entitlement. Note that $20M/year is typical institute funding.

In early March 2016, CIHR announced a competition for a catalyst grant to build a ME/CFS research network in Canada. Funding was set at $200k per year for three years. There was no commitment to any additional or ongoing funding and there was no support offered in putting together the application.

Despite the paltry offering, a dream team came together – Canadian researchers who have become interested in ME/CFS, public health academics, supportive clinicians, and patients representatives.

The major focus of the application was on the physical pathology of ME/CFS and biomarkers.

The ME/CFS community has suffered from decades of scientific abuse and scientific neglect as biological research was pushed aside in favour of the psycho-social approach favoured by the review committee. With the announcement of the catalyst grant competition, the community found new hope. With the rejection of the application, the community felt abused and abandoned once again.

Ironically, just before this decision was announced, the psycho-social approach was seriously undermined in two separate ways, no surprise to anyone following events. Several days after this decision, a study came out of a US university that found a metabolite signature for ME/CFS and suggested that ME/CFS could represent a hypometabolic state caused by the activation of an evolutionary cell protection mechanism. While the study needs to be debated and replicated, the study provides a very promising way of looking at ME/CFS.

Fundamental research into ME/CFS is already happening and much more is going to happen. Europe recently established a research network and the US NIH is moving in this direction. Canada missed this opportunity to get off the ground in a coordinated fashion, though individual researchers are involved in ME/CFS research.

From Canada's point of view, it cannot be a leader in all areas of science. From the patient perspective, it does not matter if discoveries are made in Australia or Norway or the US. So what is the problem?

The problem is that Canadian public policy is based on false science. For years, public policy has ignored evidence that ME/CFS is real, is having a major impact on Canadians, and is not being properly addressed by the health and social systems. For CIHR to reject an application because there is no evidence that CFS is a real disease sends the message that it is okay to blame patients for their misfortune and that there is no need for clinical care or social policy to change.

Maybe Canada cannot be a leader in all areas of science, but it must be involved in this area of science. Otherwise, patients will continue to suffer from neglect.

What would we like the Science Panel to do? We would like it to look carefully at the measures of success for CIHR. As far as we can see, the current measures of success include avoiding controversy and not getting involved in stigmatized areas. We would like the measures of success to change to include resolving scientific conflicts, exploring new areas, confronting stigma, and focusing on high needs areas. More broadly, a measure of scientific success would be public policy based on a solid foundation.

Yours truly

Margaret Parlor

President

Notes:

Reasons for refusal of the catalyst grant competition can be read here:

http://www.meaction.net/wp-content/uploads/2016/08/Catalyst-Grant-C2SAME_previewAps.pdf

The reasons include the following:

- The review panel chose to rely on the view that ME/CFS was not real ("There is no evidence that CFS is a disease") and that patients were responsible for their condition (the CFS cohort is "a population that is defined by unhelpful vigilance to physical symptoms and somatic attribution"). The US Institute of Medicine found ME/CFS to be real and serious. http://www.nationalacademies.org/hmd/Reports/2015/ME-CFS.aspx

- The review panel continued to support the PACE trial referring to it as "a rigorously-conducted randomized controlled trial". The study has been discredited. See, for example: http://nymag.com/scienceofus/2016/09/a-big-chronic-fatigue-syndrome-study-has-been-discredited.html

- The review panel continued to support Graded Exercise Therapy, citing a Cochrane review that included studies based on the Oxford definition. Meanwhile, the Agency for Healthcare Research and Quality had recommended that the Oxford definition be "retired" because it was too heterogeneous. AHRQ reran its literature review without Oxford definition studies and found no evidence supporting GET. http://www.meaction.net/2016/08/18/ahrq-agrees-get-useless-cbt-ineffective/

- The review panel was very skeptical that this was a science problem ("the strong focus on undiscovered physical pathology...is concerning", and "My concern lies with ... the apparent strong focus on unidentified physical pathology as causative of CFS"). Much is known about the physical pathology of ME/CFS. See for instance the IOM report.

- The review panel questioned the value of seeking biomarkers ("clear focus on biomarkers is likely to provide limited additional value"). A number of biomarkers have been proposed and a metabolic study published a few days later added to the possibilities: http://www.pnas.org/content/113/37/E5472.abstract

- The review panel criticized the proposal for not balancing the biological approach with a psychological and social approach, not recognizing that research has been out of balance.

- The review panel also seemed to expect policies and plans to be in place, not recognizing that there is no research infrastructure for ME/CFS research in Canada and never has been.

This story of the catalyst grant refusal was featured on the CTV National News:
http://www.ctvnews.ca/health/stigmatized-chronic-fatigue-syndrome-sufferers-seek-recognition-1.3067130

The international ME/CFS community has harsh words for the decision.
http://www.meaction.net/2016/08/26/canada-officials-turn-down-grant-app-because-cfs-isnt-real/

“It probably took them several months to review the application because they had to spend a lot of time trying to get it to fit on a 5.25″ floppy disc,” commented one patient. “They were also probably having trouble finding a ribbon for their dot matrix printer. Their knowledge of ME/CFS is really on the cutting edge of 1988.”

http://www.healthrising.org/forums/threads/the-dark-north-canada-denies-me-cfs-grant-because-disease-is-not-real
Unless the Canadian Health Institutes disavow this grant review, though, I can't imagine that anyone else with a biologically based grant application will try Canada in the next one.

In his 2013 book “How Everyone Became Depressed”, Edward Shorter wrote: “After...it has been determined that the patient is not suffering from one of those quasidelusional disorders such as “chronic fatigue syndrome”...

For statistics on ME/CFS and Fibromyalgia see:
http://www.phac-aspc.gc.ca/publicat/hpcdp-pspmc/35-1/ar-02-eng.php and
http://meao.ca/files/Quantitative_Data_Report.pdf

For the social impact of ME/CFS, see:
http://meao.ca/files/Recognition_Inclusion_Equity-full.pdf

The one ME/CFS study being funded in 2016-2017 is a research fellowship in epigenetics
http://webapps.cihr-irsc.gc.ca/funding/detail_e?pResearchId=6207995&p_version=CIHR&p_language=E&p_session_id=2414956

For historical correspondence with CIHR, see for example (2012). This correspondence documents the suggestion of $10M/year for ME/CFS research and the same for Fibromyalgia research.
http://mefmaction.com/index.php?option=com_content&view=article&id=448:network-inquiry-to-cihr&catid=69:networknews&Itemid=287

Dr Ronald Davis was named by Atlantic Magazine as one of Today's Greatest Inventors:
http://www.theatlantic.com/magazine/archive/2013/11/the-inventors/309534