

Despite Canadian government woes, neuroscience should win out

MONTREAL — When Canada's Conservative government presented its 2011 budget in late March, the fiscal plan didn't contain too many surprises for science funding. Like previous budgets, the proposal offered modest increases to the country's national research agencies and replenished the coffers of Genome Canada, its genomics and proteomics outfit. But the budget also contained a flashy and unprecedented new move: a multimillion-dollar earmark for neuroscience research.

Under the Conservatives' proposed scheme, the government would contribute up to C\$100 million (\$105 million) over several years to the Canada Brain Research Fund, a public-private partnership led by the Brain Canada Foundation in collaboration with the Canadian Association for Neuroscience and Neurological Health Charities Canada (NHCC). The government money would then be matched by funds raised from private sources by Brain Canada to support large, multidisciplinary neuroscience grants, postdoctoral fellowships and training programs.

The organization would not speculate on how much it might raise or what its annual research budget might be, but the funding would still probably be far less than the roughly

C\$165 million spent annually by the Canadian Institutes for Health Research (CIHR) on neuroscience and mental health research.

For now, however, the budget proposal remains in limbo. Opposition parties found the ruling Conservatives in contempt of Parliament a few days after the budget announcement, triggering an election slated for 2 May. As *Nature Medicine* went to press, the Conservatives, who have vowed to honor the original C\$100 million commitment to brain research if reelected, remained ahead in the polls, followed by the Liberals, who similarly outlined a C\$100 million, two-year 'brain health strategy' on 8 April. Thus, regardless of who forms the next government, neuroscientists and disease advocates are confident that brain research will receive a big boost in the country.

"This is a nonpartisan issue. We hope that after the election this will be supported in whatever its form," says Brain Canada president Inez Jabalpurwala from the foundation's headquarters in downtown Montreal. "We're crossing our fingers."

Jabalpurwala argues that Brain Canada's team-based grants—previously funded to the tune of C\$500,000 per team per year for three

years, for a total of C\$8 million, plus additional funds for networking—help fill an important, unmet niche in the country. "We asked scientists if there was something the Canadian Institutes of Health Research wasn't able to do that could advance the science of brain disorders," she explains.

The response: interdisciplinary big neuroscience. "In the Canadian system right now, there are not a lot of opportunities for teams to be funded to work on common projects," says Louis-Eric Trudeau, a neuropharmacologist and former grant recipient from NeuroScience Canada, an earlier version of Brain Canada.

But the proposed shot in the arm for Brain Canada is not without its critics, even among the neuroscience community. "My concern is about giving the money to fund a foundation, rather than increasing support to the research councils," says Robert Dunn, associate director of scientific affairs at the Montreal Neurological Institute and Hospital. "I think it is a mistake."

According to a Liberal spokesperson, if elected, party leaders plan to consult with CIHR, NHCC and Brain Canada officials about how best to allocate funds for its proposed brain health strategy.

Hannah Hoag

NIH faces marching orders on orphan drug shortage

Ever since a virus contaminated Genzyme's production plant in Allston, Massachusetts close to two years ago, people with Fabry's disease have faced severe shortages of the medicine they need, Fabrazyme (see editorial on page 515). In August 2010, three people with Fabry's petitioned the US National Institutes of Health (NIH) to step in and demand that Genzyme allow other companies to make the enzyme replacement therapy on the basis of the government's so-called 'march-in' rights. The provision of the Bayh-Dole Act allows funding agencies to override exclusivity rights to intellectual property arising from government-funded research when people's lives are at risk.

The NIH denied the request late last year. But, given Genzyme's continuous production delays—the company now says it won't be manufacturing Fabrazyme again until closer to the end of the year—on 5 April the petitioners appealed the original decision.

Such requests have historically failed. But this time could be different. "There's no guarantee that they'll march in, but if not now, when?" asks Dan Vorhaus, a New York-based attorney with the law firm Robinson, Bradshaw & Hinson. "This is almost as bad as you can imagine," he adds. "If it's not Chernobyl, it's Japan."

Only three other march-in requests have been made to the NIH since 1997. We review them here.

Stemmed try: In 1997, a small Washington State device manufacturer named CellPro called on the NIH to intervene after a federal court judge ruled that the company's device for sifting stem cells from blood or bone marrow infringed on intellectual property held by Baltimore's Johns Hopkins University and licensed to Baxter Healthcare of Deerfield, Illinois. The NIH, unconvinced that the device offered much clinical benefit over other technologies, declined the request.

No-go on Norvir: In 2004, the Washington, DC-based advocacy group Essential Inventions asked the NIH to rein in the cost of a widely used HIV medicine called Norvir (ritonavir). The drug's manufacturer—Abbott Laboratories of Chicago, which had developed the protease inhibitor with support from a five-year, \$3.5 million NIH grant—had increased US retail prices of the medication by up to 400%. The NIH rejected the claim that the price hike made the drug unavailable to the public.

Blocked vision: In another 2004 petition, Essential Inventions also pleaded with the NIH to exercise march-in rights on Pfizer's Xalatan (latanoprost) glaucoma treatment, which was discovered at Columbia University in New York with a grant from the National Eye Institute. Essential Inventions claimed that Xalatan cost up to five times more in the US than abroad, but the NIH held that the use of "march-in was not an appropriate means for controlling prices."

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