

REVIEW OF THE CANCELLATION OF THE CANADIAN HIV VACCINE INITIATIVE'S HIV VACCINE MANUFACTURING FACILITY PROJECT

Report of the Standing Committee on Health

Joy Smith, MP Chair

OCTOBER 2010

40th PARLIAMENT, 3rd SESSION



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THE STANDING COMMITTEE ON HEALTH

has the honour to present its SEVENTH REPORT

Pursuant to its mandate under Standing Order 108(2), the Committee has studied the Cancellation of the HIV Vaccine Manufacturing Facility under Canadian HIV Vaccine Initiative and has agreed to report the following:

INTRODUCTION

On 11 March, 2010, the House of Commons Standing Committee on Health passed a motion to conduct a review of the Government of Canada's decision to cancel the establishment of a Pilot Scale HIV Vaccine Manufacturing Facility in Canada that would be used for the production of HIV vaccines for clinical trials, as part of the Canadian HIV Vaccine Initiative (CHVI). As part of its review, the Committee held three meetings in April 2010, in which it heard from a broad range of witnesses, including: government officials, organizations that submitted applications to create the facility, government partners, and other interested stakeholders. This report summarizes the testimony from these hearings and presents the Committee's findings and recommendations.

BACKGROUND

A. HIV/AIDS and the Need for a Vaccine

Infection by the Human Immunodeficiency Virus (HIV) can lead to serious health effects due to the progressive weakening of the immune system. Once an infected individual has reached the point where the immune system can no longer cope, the condition is known as Acquired Immunodeficiency Syndrome or AIDS. In Canada, there are an estimated 2500 confirmed cases per year and a total of 58,000 Canadians are living with HIV/AIDS. Globally, close to 5 million people are infected each year and an estimated 39 million people are living with HIV/AIDS, of which 90% are in low- and middle-income countries (LMICs). One approach to reducing the impact of the HIV epidemic is the development of a vaccine, which is currently not available due to significant technical challenges in understanding the biology of the virus and the body's immune response to infection, underscoring the need for large-scale, well-coordinated, and adequately funded efforts. ²

B. Canadian HIV Vaccine Initiative (CHVI)

In February 2007, the Government of Canada established the Canadian HIV Vaccine Initiative (CHVI) in partnership with the Bill & Melinda Gates Foundation to accelerate global efforts to develop a safe, effective, affordable and globally accessible HIV vaccine. The CHVI brings together five federal departments and agencies in support of this goal: the Canadian International Development Agency, the Public Health Agency of Canada, Industry Canada, Canadian Institutes of Health Research and Health Canada. The CHVI's specific objectives are based upon the 2005 Scientific Strategic Plan of Global HIV Vaccine Enterprise (GHVE), an alliance of researchers, funders, advocacy groups and stakeholders' organizations committed to developing a vaccine for HIV. GHVE was established in 2004, after 24 leading researchers in the field of HIV vaccines

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Public Health Agency of Canada, *HIV/AIDS Research and Surveillance*, http://www.phac-aspc.gc.ca/aids-sida/research/index-eng.php#1 (accessed 6 April 2010).

Kahn P, AIDS Vaccine Handbook: Global Perspectives (2nd edition), "Where are we in the search for an AIDS vaccine?", http://www.avac.org/ht/d/sp/i/2311/pid/2311 (accessed 7 April 2010).

³ House of Commons Standing Committee on Health, "Evidence" number 008, 3rd Session, 40th Parliament, http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4418568/HESAEV08-E.PDF, p.1

concluded in June 2003 that "current attempts to develop such a vaccine were insufficient in scale and focus and that a renewed HIV vaccine research effort was required." Based upon GHVE's 2005 Scientific Strategic Plan, CHVI's specific objectives include: 5

- Providing support for HIV vaccine research, social research and collaboration between researchers in Canada and LMICs;
- Strengthening production capacity to conduct high-quality clinical trials, particularly in LMICs;
- The establishment of a pilot scale manufacturing facility in Canada to increase the capacity to produce HIV vaccine candidates;
- Providing support to improve the regulatory capacity of LMICs and address policy, legal, ethical and human rights issues that will promote access to a HIV vaccine; and
- Coordination of the activities of the CHVI with other partners to ensure that Canada's contribution to the GHVE is most effective.⁶

The Government of Canada and the Bill & Melinda Gates Foundation made the following financial commitments in support of these objectives:

Table 1: Financial Allocations to the Canadian HIV Initiative

(in millions of dollars)

CHVI Priority Areas	Government of Canada		Gates	Total Funds
	Existing	New	Foundation	available
	Contribution	Contribution		
Discovery Research & Capacity	\$10	\$12		\$22
Clinical Trial Capacity Building		\$16		\$16
& Networks				
Production Capacity	\$5	\$55	\$28	\$88
Policy & Regulatory	\$4			\$4
Community & Social	\$5	\$2		\$7
Dimensions				
Planning Coordination &	\$2			\$2
Evaluation				
TOTAL	\$26	\$85	\$28	\$139

⁴ Global HIV Vaccine Enterprise, "History of the Global HIV Vaccine Enterprise," http://www.hivvaccineenterprise.org/content/history-global-hiv-vaccine-enterprise.

House of Commons Standing Committee on Health, "Evidence" number 008, 3rd Session, 40th Parliament, http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4418568/HESAEV08-E.PDF, p. 1

Canadian HIV Vaccine Initiative, "Invitation to submit applications for funding from the Government of Canada and the Bill & Melinda Gates foundation on behalf of the Canadian HIV Vaccine Initiative for a Pilot Scale HIV Vaccine Manufacturing Facility in Canada for Clinical Trial Lots," 15 April 2008, http://www.chvi-icvv.gc.ca/archive-eng.html (accessed 7 April 2010).

Source: adapted from Memorandum of Understanding between the Government of Canada and the Bill and Melinda Gates Foundation, August 2006," http://www.chvi-icvv.gc.ca/pdf/mou_e.pdf.

C. The CHVI Pilot Scale HIV Manufacturing Facility Project

The CHVI allocated \$88 million to support the establishment of a not-for-profit pilot scale manufacturing facility in Canada to produce HIV vaccine candidates for use in clinical trials primarily in LMICs, where the burden of HIV is highest. The not-for-profit manufacturing facility was to operate in accordance with the following objectives⁸:

- ensure that the principles of global access were at the foundation of decision-making;
- develop relevant partnerships;
- develop a self-sustaining business model;
- attract financial in kind contributions to the initiative;
- conduct outreach to promising HIV vaccine candidates from around the world through an open and transparent application and selection process; and
- negotiate and conclude agreements with selected HIV Vaccine Developers.

In order to find a suitable candidate to establish the Pilot Scale HIV Manufacturing Facility, the CHVI Secretariat posted an Invitation to Submit Applications (ISA) and a Letter of Intent (LOI) Form on its website outlining the criteria for a successful bid on 15 April, 2008. On 15 June, 2008, five LOIs were received from interested applicants, but only four were invited to submit full applications on 10 November, 2008.

From April 2009 to January 2010, a comprehensive review of the applications was completed by both internal and external expert review panels. The external review was completed in June 2009 by an international panel of experts with expertise in HIV vaccine research, facility construction and operations, vaccine manufacturing, governance and financial management. The internal review was then conducted between July 2009 and January 2010 by officials from the Government of Canada and the Gates Foundation.

On 22 January, 2010, the applicants were informed by the Chief Public Health Officer of Canada from the Public Health Agency of Canada that their applications were not approved for funding. The Government of Canada and the Bill and Melinda Gates Foundation then announced on 19 February, 2010, that they had decided not to move forward with the facility project.

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Canadian HIV Vaccine Initiative, "Invitation to submit applications for funding from the Government of Canada and the Bill & Melinda Gates foundation on behalf of the Canadian HIV Vaccine Initiative for a Pilot Scale HIV Vaccine Manufacturing Facility in Canada for Clinical Trial Lots," 15 April 2008, http://www.chvi-icvv.gc.ca/archive-eng.html

⁸ Ibid.

⁹ Unless otherwise noted, the timeline of the application process for the Pilot Scale HIV Manufacturing Facility project is based upon information submitted to the committee by officials from the CHVI Secretariat, entitled. "Canadian HIV Vaccine Initiative-Chronology of Events,"

WHAT THE COMMITTEE HEARD REGARDING THE CANCELLATION OF THE CHVI PILOT SCALE HIV MANUFACTURING FACILITY PROJECT

In their appearances before the Committee, government officials and representatives from the Bill and Melinda Gates Foundation indicated that the reasons behind the decision to cancel the CHVI Pilot Scale HIV Manufacturing Facility project were twofold. First, government officials articulated that none of the four applicants were successful in meeting the criteria outlined in the Invitation to Submit Applications (ISA). Though each applicant had its respective strengths and weaknesses, either the internal or external review panels found that they were unable to meet the criteria in the technical, management and financial aspects of their proposals. Government officials further indicated that the internal and external review did not result in a comparative ranking with one candidate being ranked higher than another, but rather they provided an individual based ranking for how well each applicant met each specific criterion outlined in the ISA. It was based upon this evaluation that none of the applicants were found to be successful. Officials further noted that specific details regarding each application could not be provided to the Committee, in order to protect the confidentiality of the application process.

Second, government officials and representatives from the Bill and Melinda Gates Foundation indicated that the scientific landscape had substantially changed since the Global HIV Enterprise's evaluation in 2005 that indicated that there was a need for increased production capacity for HIV clinical trial lots, in turn affecting the need for the establishment of a pilot scale HIV manufacturing facility in Canada. Representatives from the Bill and Melinda Gates Foundation further explained that when the partnership between the Government of Canada and the Foundation was announced in 2007, a potentially promising HIV candidate was in advanced stages of human testing. As experts believed that the vaccine trail would show partial effectiveness, it was thought that more clinical trials would need to be conducted, which would in turn require increased capacity to produce clinical lots for those same trials. Yet the vaccine trial was unsuccessful, which led to a halt of HIV vaccine clinical trials and researchers to

House of Commons Standing Committee on Health, "Evidence" Number 011, 3rd Session, 40th Parliament, 22 April, 2010, http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4453676/HESAEV11-E.PDF, p.7

¹¹ Ibid.

¹² Ibid, p.18

House of Commons Standing Committee on Health, "Evidence" Number 009, 3rd Session, 40th Parliament, 15 April, 2010, http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4431229/HESAEV09-E.PDF, p.2

¹⁴ Ibid.

call "for a return to basic research to discover new vaccines candidates and better way to identify which vaccines were most promising." 15

In addition, the Committee heard that the Gates Foundation had commissioned an independent analysis of global manufacturing capacity in March of 2009, which was conducted by Oliver Wyman. ¹⁶ The results of the independent analysis, which were made available in July 2009, indicated that there had been significant increases in vaccine manufacturing capacity in North America and Europe since the publication of the Global HIV Enterprise's Scientific Strategy in 2005 and as a result, there was no longer a need for the construction of a new facility. ¹⁷

The Committee heard that the Gates Foundation then shared the results of the Wyman study with officials from the Government of Canada in July 2009. ¹⁸ The findings of the study combined with the failure to find a suitable candidate to construct the pilot manufacturing facility resulted in the Government of Canada and the Bill and Melinda Gates Foundation jointly deciding that the project should be cancelled in February 2010. ¹⁹ They concluded that there was greater "value for money" in investing in other areas of HIV vaccine research, rather than in the creation of a pilot manufacturing facility in Canada. ²⁰

However, other witnesses appearing before the Committee raised concerns regarding the Government of Canada and the Bill and Melinda Gates Foundation's decision to cancel the project. First, organizations that submitted bids for the manufacturing facility indicated that there were problems with the application process. Witnesses articulated that though the criteria for a successful bid were clearly outlined, they found that there were delays and insufficient information provided to them throughout the process. ²¹ As one witness stated:

But to say that things moved smoothly and in a timely way and that all the information that could have been provided was provided would be inaccurate. I think in terms of timelines, there was a fairly frequent shifting of timelines and delays for reasons that were not explained clearly. Certainly in terms of

¹⁶ Ibid.

¹⁵ Ibid.

¹⁷ Ibid.

¹⁸ CHIV Secretariat, "Canadian HIV Vaccine Initiative-Chronology of Events," Brief Submitted to the House of Commons Standing Committee on Health in April 2010.

House of Commons Standing Committee on Health, "Evidence," Number 008, 3rd Session, 40th Parliament, 13 April, 2010, http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4418568/HESAEV08-E.PDF, p.2

²⁰ Ibid.

House of Commons Standing Committee on Health, "Evidence" Number 009, 3rd Session, 40th Parliament, 15 April, 2010, http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4431229/HESAEV09-E.PDF, p.8

the findings of the expert panel and the reviews, we did receive some fairly cursory remarks that were a summation from the experts who had reviewd the process. Normally we would see the full set of comments from the external panel or the reviewers, and those are very helpful to us. Then we see exactly where we've gone wrong, where we need to go, how we would now move on to develop a stronger proposal or to go back in the future. I think that was key.²²

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They further articulated that a normal review process for a large research grant competition, such as the pilot manufacturing facility, would have included a site visit which enables reviewers to clarify any misunderstandings or omissions that have emerged from the initial paper application process. ²³ However, witnesses were surprised that a site visit was not part of the application process. As a result of these weaknesses in the application process, witnesses recommended that in future, large research grant competitions should be run by federal agencies that have greater experience in research funding, such as: the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, or the Canadian Foundation for Innovation. ²⁴

One witness also indicated that he was surprised that applications for the pilot manufacturing facility were not found to have met the financially self-sustaining business model criteria outlined in the ISA. ²⁵ He explained that he had been quite successful in establishing several vaccine pilot manufacturing facilities both in Canada and Korea, which were both run at a substantial profit. He therefore concluded that there was sufficient expertise in Canada to run a financially self-sustaining vaccine pilot manufacturing facility. ²⁶

The Committee also heard from HIV researchers, who argued that despite the findings of the Oliver Wyman study, there was still a need for a pilot scale HIV vaccine manufacturing facility in Canada. First, they articulated that though there was theoretical capacity to produce HIV clinical trial lots among for-profit pharmaceutical companies, HIV researchers faced significant cost barriers in accessing that capacity in

²³ Ibid, p.8

²² Ibid, p.17

²⁴ Ibid.

House of Commons Standing Committee on Health, "Evidence," Number 008, 3rd Session, 40th Parliament, 13 April, 2010, http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4418568/HESAEV08-E.PDF, p.4

House of Commons Standing Committee on Health, "Evidence," Number 008, 3rd Session, 40th Parliament, 13 April, 2010, http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4418568/HESAEV08-E.PDF, pp. 4-5

the private sector. ²⁷ HIV researchers indicated that it costs approximately \$100 million to bring a vaccine forward into human trials. ²⁸ The Committee heard that the creation of a not-for-profit manufacturing facility would eliminate these cost barriers faced by HIV vaccine researchers in accessing vaccine manufacturing capacity and enable them to pursue their research independent of industry interests and needs. ²⁹

Others argued that a pilot scale HIV vaccine manufacturing facility in Canada could also be used to meet other scientific needs, including the development of vaccines for other diseases including pandemic strains of influenza. They further articulated that the creation of such a facility would lead to economic development, as well as contribute to Canada's efforts towards meeting its international obligations in addressing HIV/AIDS worldwide. HIV/AIDS

Finally, some witnesses raised particular concerns with the Oliver Wyman study, articulating that it did not take into account the quality of the existing manufacturing capacity for HIV vaccine lots, which is of significant concern in HIV vaccine production. However, government officials indicated that all vaccine manufacturing facilities operating in Canada, Europe or the United States are regulated to meet the highest levels of quality. However, account the United States are regulated to meet the

IDENTIFYING NEW PRIORITIES FOR CHVI FUNDING

Despite the cancellation of the CHVI Pilot Scale Manufacturing Facility project, the Committee heard that government officials and representatives of the Bill and Melinda Gates Foundation were both committed to maintaining their CHVI partnership.³⁴ Furthermore, they were working together to find different areas in which they could invest the \$88 million previously allocated to the manufacturing facility.

Witnesses appearing before the Committee identified possible areas of HIV research, where these funds could be reallocated in order to make a significant impact. In order to address the high cost that researchers face in gaining access to vaccine manufacturing capacity, researchers recommended that the CHVI establish grants for

²⁸ Ibid.

²⁹ Ibid.

³⁰ Ibid. p.5

31 Ibid.

³² Ibid, p.5

³³ Ibid, p.10

http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4431229/HESAEV09-E.PDF, p.11 and House of Commons Standing Committee on Health, "Evidence," Number 008, 3rd Session, 40th Parliament, 13 April, 2010,

 $\frac{http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4418568/HESAEV08-E.PDF,}{p.9}$

²⁷ Ibid, p. 3

House of Commons Standing Committee on Health, "Evidence" Number 009, 3rd Session, 40th Parliament, 15 April, 2010,

researchers to pre-purchase capacity in existing certified facilities that would allow researchers to get priority service in the production of their clinical trial lots.³⁵

The Committee also heard that there was significant research expertise in the immune system's response to HIV and cases of natural immunity to HIV, knowledge that could be used to determine the building blocks of a possible vaccine. Witnesses suggested that CHVI investments in Canadian immunology research related to HIV could be a way in which Canada could make a significant impact in HIV research. Other witnesses stressed the importance of increased investments to produce cheaper and more effective anti-viral drugs as means of preventing the transmission of HIV. Finally, witnesses articulated that CHVI's current investments in team grants were necessary to enable researchers to conduct work in the heart of the epidemic in LMICs in Africa and Asia.

House of Commons Standing Committee on Health, "Evidence" Number 009, 3rd Session, 40th Parliament, 15 April, 2010, http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4431229/HESAEV09-E.PDF, p.14

³⁶ Ibid, p.3

³⁷ Ibid.

³⁸ Ibid, p.6

³⁹ Ibid, p.14

COMMITTEE OBSERVATIONS AND RECOMMENDATIONS

During its review of the cancellation of CHVI the pilot scale HIV vaccine manufacturing facility project, the Committee heard that from the perspective of organizations submitting bids for the project, there were delays, a lack of communication from the CHVI Secretariat, and minimal feedback on proposals during the course of the application process. These organizations further articulated that a site visit was not conducted as part of the application process, which, according to witnesses, is a step that is normally undertaken in large federal grant competitions. This resulted in witnesses recommending that future competitions of this nature be conducted by federal agencies that have greater experience in research funding, such as: Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, or the Canadian Foundation for Innovation.

Based upon a timeline provided by the CHVI Secretariat, the Committee's review also revealed that a study evaluating the need for the manufacturing facility was only initiated by the Gates Foundation in March 2009, a year after the applicants had invested a significant amount of time, effort and funds in submitting their bids for the project. For some witnesses appearing before the Committee, it remained unclear as to why the Government of Canada did not undertake this due diligence prior to posting its Invitation to Submit Applications in April 2008.

The Committee considers the Government of Canada and the Bill and Melinda Gates Foundation's continued commitment to the Canadian HIV Initiative to be of the utmost importance. During the course of its hearings, witnesses suggested several areas in which the \$88 million originally allocated to the pilot scale HIV manufacturing facility could be reinvested in other areas in order to make a significant impact in the development of an HIV vaccine, including: immunology research, low cost anti-viral drugs, and team grants. The Committee also heard that the funds could be used to mitigate the costs that researchers face in gaining timely access to vaccine production capacity for their HIV candidate vaccines, a need that the original not-for-profit pilot scale HIV vaccine manufacturing facility was meant to address. The Committee therefore recommends:

Recommendations

- 1. Where feasible, that the Government of Canada conduct future Canadian HIV Initiative grant competitions through arms length federal research agencies, such as the Canadian Institutes of Health Research, or the Canadian Foundation for Innovation, which may allow for increased interaction between applicants and the granting agency during the application process.
- 2. That the Government of Canada and the Bill and Melinda Gates Foundation take into consideration the following priorities identified by HIV researchers, as possible areas in which to allocate funding from the Canadian HIV Initiative: immunology related HIV research; team grants for HIV researchers; anti-viral drugs; and the pre-purchasing of vaccine production capacity for HIV vaccine candidates put forth by HIV researchers.
- **3.** Where feasible, that the Government of Canada conduct independent needs assessments in relation to projects funded under the CHVI.

APPENDIX A LIST OF WITNESSES

Organizations and Individuals	Date	Meeting
Canadian Association for HIV Research	2010/04/13	8
Bill Cameron, President		
PnuVax Inc.		
Donald Gerson, President and Chief Executive Officer		
Public Health Agency of Canada		
Rainer Engelhardt, Assistant Deputy Minister, Infectious Disease Prevention and Control Branch		
Steven Sternthal, Head, Canadian HIV Vaccine Initiative Secretariat, Director, Office of HIV Vaccines		
Vaccine and Gene Therapy Institute Florida		
Rafick-Pierre Sekaly, Co-Director and Scientific Director		
Bill & Melinda Gates Foundation	2010/04/15	9
Stefano Bertozzi, Director, Global Health HIV		
Global HIV Vaccine Enterprise		
Alan Bernstein, Executive Director		
International Centre for Infectious Diseases		
Heather Medwick, Acting President and Chief Executive Officer		
International Consortium on Anti-Virals		
Jeremy Carver, President, Chief Executive Officer and Chief Scientific Officer		
Patrick Michaud, Chairman of the Board of Directors		
University of Manitoba		
Keith Fowke, Professor, Departments of Medical Microbiology and Community Health Sciences		
University of Western Ontario		
Ted Hewitt, Vice-President, Research and International Relations		
Public Health Agency of Canada	2010/04/22	11
David Butler-Jones, Chief Public Health Officer		
Frank Plummer, Scientific Director General, National Microbiology Laboratory		

Organizations and Individuals	Date	Meeting
Public Health Agency of Canada	2010/04/22	11
Steven Sternthal, Head, Canadian HIV Vaccine Initiative Secretariat, Director, Office of HIV Vaccines		

REQUEST FOR GOVERNMENT RESPONSE

Pursuant to Standing Order 109, the Committee requests that the government table a comprehensive response to this Report.

A copy of the relevant Minutes of Proceedings (Meetings Nos. 8, 9, 11, 27 and 30) is tabled.

Respectfully submitted,

Joy Smith, MP Chair

Research, a fundamental issue for Quebec

First of all, the Bloc Québécois wishes to thank all the witnesses who appeared before the Standing Committee on Health with regard to the cancellation of the HIV vaccine manufacturing facility. The Bloc Québécois notes that the Committee quickly demonstrated in its report how poorly the Conservative government coordinated the Canadian HIV Vaccine Initiative, which in turn led to the failure of the project and created false expectations among organizations submitting proposals.

Challenge of finding an HIV vaccine

In keeping with the observations made in the report, the Bloc Québécois recognizes the importance of creating an effective HIV vaccine and finding alternatives further to the cancellation of the HIV vaccine manufacturing facility. Since a promising experimental vaccine has not produced the anticipated scientific results and the number of clinical trials has decreased, the Bloc Québécois also agrees that funding must be reallocated from the CHVI to basic research. The head of the Bill and Melinda Gates Foundation, Dr. Stefano Bertozzi, noted that "prominent researchers called for a return to basic research to discover new vaccine candidates, and for better ways to identify which vaccines are truly promising".

However, federal funding for basic research is currently awarded through funding agencies, such as the Canadian Institutes of Health Research (CIHR). The Bloc Québécois cannot support the report's recommendations as they encroach on the jurisdiction of Quebec and the provinces.

A question of jurisdiction

Although more must be invested in research, it must be noted that the federal government, through CIHR, has given itself the power to impose its priorities and beliefs on the health sector, and in turn on university chairs. While the Bloc Québécois is calling on the federal government to substantially increase research budgets, it maintains that this money should be transferred to Quebec and the provinces, which will then be better able to support university research chairs, for instance. In conclusion, whether the issue is basic or clinical research in the health sector, it falls under the jurisdiction of Quebec and the provinces.

The Bloc Québécois therefore recommends that:

Since health and education fall under the jurisdiction of Quebec and the provinces, the federal government must not interfere in research funding through funding agencies. The Bloc Québécois accordingly demands that the federal government transfer to Quebec its share of the \$88 million initially allocated to the HIV vaccine manufacturing facility so that Quebec may use that funding in accordance with its own policies and on its own terms.