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Chair

Mrs. Joy Smith

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● (0905)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Ladies and gentlemen, I'd ask you to take your seats. I'd like to start the committee now.

Dr. Cameron, I heard that you were held up coming in through security. Is there anything I should know before we start?

Dr. Bill Cameron (President, Canadian Association for HIV Research): It was actually the Pretoria Street Bridge.

The Chair: Well, if it's any comfort, they attempted to hold me up too, until they realized, whoops, I could come in.

Pursuant to Standing Order 108(2), we are studying the cancellation of the HIV vaccine manufacturing facility, under the Canadian HIV vaccine initiative.

I welcome our witnesses here this morning. We're going to give you five minutes for your presentation, and then after that we're going to be going into a seven-minute question and answer period for you as well.

I think I'm going to start with Dr. Rainer Engelhardt. Could you start the presentation, please, Dr. Engelhardt?

Dr. Rainer Engelhardt (Assistant Deputy Minister, Infectious Disease Prevention and Control Branch, Public Health Agency of Canada): Madam Chair, thank you very much.

Members of the committee, thank you for this opportunity to discuss the Canadian HIV vaccine initiative.

As assistant deputy minister of the infectious disease prevention and control branch with the Public Health Agency in Canada, I'm responsible for the development and implementation of national public health strategies to address really a range of infectious diseases, including influenza, pandemic and otherwise, hepatitis, tuberculosis, and HIV/AIDS.

Through partnerships with Canadian and international scientific public health and community organizations, the agency takes a leadership role in mobilizing a comprehensive response to HIV/AIDS. This includes research, surveillance, epidemiology, broad spectrum, including the development of new prevention technologies and specifically a vaccine for HIV/AIDS.

[*Translation*]

In February 2007, the Prime Minister and Mr. Bill Gates announced a collaboration between the Government of Canada and the Bill and Melinda Gates Foundation.

[*English*]

This collaboration's main goal was to help speed up the global development of an HIV vaccine, which is our greatest hope for overcoming the HIV/AIDS epidemic worldwide. Altogether, funding of $111 million was provided by the Government of Canada and $28 million from the Gates Foundation was dedicated in support of this collaboration.

To achieve the important goal of developing a vaccine, in 2007 the Government of Canada established the Canadian HIV vaccine initiative. That brings together five federal departments and agencies: the Canadian International Development Agency, the Public Health Agency, Industry Canada, Canadian Institutes of Health Research, and Health Canada. Each shares a commitment to position Canada at the forefront to develop this HIV/AIDS vaccine.

My agency helps to ensure a coordinated effort among the departments, and currently houses the secretariat for the initiative. I'd like to note that I'm joined here today by Mr. Steven Sternthal, who is the director of the agency's office of HIV vaccines and is responsible for the initiative's secretariat.

[*Translation*]

The initiative is aligned with priorities established by the Global HIV Vaccine Enterprise in 2005.

[*English*]

The Enterprise's global scientific plan followed global consultations, which identified some key obstacles that were facing researchers in vaccine development, and specifically the initiative has focused on four key program areas.

On the first area, discovery and social research, funding is being provided to support HIV discovery and the social research components thereof. We strengthen the research and capacity in Canada, as well as in low- and middle-income countries. Under that, 13 discovery and social research projects are currently in place on HIV vaccines, totalling a commitment of nearly $3 million. A single example, and an interesting one, is that McGill University has received $440,000 to learn about the special characteristics of immune cells in certain people exposed to HIV but who remain uninfected. There are additional research funding opportunities that are funded under that program.

A second key program is the clinical trials capacity building and networks, through which funding is being provided to researchers and to research institutions, particularly, again, in low- and middle-income countries, to strengthen their capacity to conduct high-quality clinical trials on HIV, and HIV vaccines in particular, and other related prevention technologies. A request for applications for clinical trial capacity building is currently under way for Africa, and the results of these trials are supposed to be released by 2010.

The third program area is for the policy and regulatory issues, community and social dimensions, through which funding is provided to strengthen vaccine policy approaches that promote global access to HIV vaccines, regulatory pathways and processes for the vaccines in low- and middle-income countries that can be enhanced through capacity-building initiatives, and, again, community involvement in vaccine research and development, clinical trials, and activities in public awareness and education related to them.

Currently, there are two HIV community initiatives under way and two international initiatives that have been completed, totalling more than half a million dollars, including, for instance, the Canadian AIDS Society, which is receiving $268,000 under this program. Also, just to note, $760,000 has been provided to the Global HIV Vaccine Enterprise's renewal of the global scientific strategic plan, and an additional $2 million is being provided to the World Health Organization to improve the capacity of regulatory authorities in Africa.

I'd like now to turn to the HIV vaccine manufacturing project under the initiative. The primary reason for launching this project was to address a global shortage of pilot-scale manufacturing facilities for an HIV vaccine, as identified by the Global HIV Vaccine Enterprise in 2005. Given the importance of addressing this global gap identified at that time, the establishment of the facility became an initial priority for the Canadian HIV vaccine initiative. Consultations were held in late 2007 by the Government of Canada and the Gates Foundation to seek the input of experts to design the most appropriate process to establish a facility here in Canada. Based on this consultation, a call for letters of intent was launched in April 2008 to seek the interest of not-for-profit organizations and their potential partners. During these consultations, it was also decided that a minimum of two months would be needed to put together a letter of intent and an additional four to five months would be needed to put together a full application. These letters of intent were received in June of 2008 and were subject to a thorough review, and based on that review, it was decided by the Government of Canada and the Bill Gates Foundation that four applicants should be moving forward to develop a full application. That was announced in November of 2008 and those applications were received in March of 2009.

I understand there were several questions from committee members regarding the process that was undertaken to review the applications, as well as how the decision not to move forward with the facility project was made. I'd like therefore to take this opportunity to clarify just a few points.

As Dr. Butler-Jones has previously noted in his appearance before this committee on March 16 and 18, a thorough and comprehensive review process was put in place to assess each of the applications. Key international experts were brought in to assess the scientific merit of the applications. These experts, just as a sidebar comment, were highly qualified in HIV vaccine research, facility construction and operation, governance, and financial management.

● (0910)

Also, officials from the Government of Canada and the Gates Foundation undertook their own due diligence, focusing on two key areas: value for money and applicant risk, meaning the sustainability and feasibility of the proposals. The end result was that the review process found that all four applications had strength in their applications. But overall, it also found that none of the four applications met all of the pre-established criteria, which was a difficult finding on our part. To ensure, then, that full and complete applications would be submitted and considered, the Government of Canada clearly outlined, in the invitation to submit the application, the necessary requirements as stipulated in the terms and conditions.

[*Translation*]

I want to stress that the criteria assessed in the review were shared with all applicants at the outset of the process.

[*English*]

In a separate process, the Gates Foundation commissioned a study that analyzed the current HIV vaccine manufacturing capacity in North America and Europe. That study, by Gates, concluded that at that time, sufficient manufacturing capacity had become available to support the anticipated demand for pilot-scale manufacturing of candidate HIV vaccines. That capacity study was made available to us in late July 2009.

As the overall endeavour of facility construction is certainly costly—potentially valued at $88 million—it was our responsibility to ensure that there was value for money for Canadian taxpayers. It was after careful consideration and much discussion that the Government of Canada and the Gates Foundation decided, as you know, not to proceed with the vaccine manufacturing facility.

I want to reiterate what Dr. Butler-Jones stated, which is that at the end of the day, the decision not to move forward with the facility, which was not an easy decision, was based on purely scientific and technical considerations.

Although the facility project was not moving forward, I'd like to say that there have also been significant benefits arising from collaboration with the Gates Foundation. Through working with the foundation, the Government of Canada has been able to leverage the foundation's scientific excellence as well as its worldwide connections and experience in this field.

[*Translation*]

The collaboration has allowed us to further strengthen our strong Canadian foundation in biomedical science, technology innovation, and vaccine research.

[*English*]

Moving forward, the Government of Canada remains committed to fighting HIV and AIDS. In support of this, the government and the Gates Foundation will continue to work together. They have reiterated their financial commitment to supporting HIV prevention.

In summary, both parties remain committed to accelerating the development of a safe, effective, accessible, and, importantly, affordable HIV vaccine as one of their key priorities.

Thank you very much.

● (0915)

The Chair: Thank you so much.

We'll now go to Dr. Bill Cameron from the Canadian Association for HIV Research.

Dr. Bill Cameron: Thank you, Madam Chairman.

The Chair: Dr. Cameron, do you have a copy of your presentation? I don't have it in front of me. If you could submit it to the clerk, we'll get it translated and distributed to everybody.

Dr. Bill Cameron: I will, and it will be brief.

The Chair: Thank you.

Dr. Bill Cameron: My name is Bill Cameron. I'm a professor of medicine at the University of Ottawa, Ottawa Hospital, and I am speaking as the president of the Canadian Association for HIV Research, which had a large professional and academic interest in the proposal that was nicely described, if not the process of its creation and deconstruction.

Vaccine development nowadays is a complex and highly regulated process. I have a professional history myself in vaccine development in the pre-clinical area, where in animal models of infection I can provide a rabbit very good protection against an infectious disease—so of no interest to rabbits, only to humans. I cannot, as an academic and a clinical investigator, bring this forward into human beings without the good laboratory practice that is required. It is largely a documentary process for regulatory approval to bring a vaccine candidate or a vaccinogen into human clinical trials.

This is not going to happen in our lifetime. There is no economic model that makes sense to do this—it's just the right thing to do. And it's not going to happen because our corporate structures, our industries, and our private sector do not have the business model to make this a solvent exercise. Never mind intellectual property, it's the cost of the process of bringing a vaccinogen forward into human trials. It is unmet by industry. If this is in the public interest, we are going to require public funds to bring this forward. Private funds will not do so.

So if not our country through our government, then who? We can go asking for charity or we can ask our government to bring forward this opportunity. I would say that scientifically and technically we are at the edge of a golden age in infectious diseases and vaccines for prevention, for public health, that we have never had before. We have, in the same time, put forward an enormously complex, highly regulated, and expensive process for doing so, so much so that it will take $100 million to bring forward a vaccine candidate to the point of regulatory approval. If this is not going to come about through industry, then it has to come about through the public sector in some manner.

This explains why, as academic and professional or scientific investigators in vaccine development, we were so unhappy with the decision. We don't question the process. There were criteria—

The Chair: Dr. Cameron, would you address the chair, not Dr. Engelhardt? Thank you.

● (0920)

Dr. Bill Cameron: Of course. I appreciated Dr. Engelhardt's presentation very much. I apologize, Madam Chair.

I appreciate those difficulties, so I polled the heavies at the Canadian Association for HIV Research, and we have a consensus statement to make.

Industrial vaccine production capacity is a useful resource for industrial needs of corporations. On the other hand, if the public interest in vaccine research is to be met, public funding and accessibility of good laboratory production facilities are needed for investigator-driven vaccine research. These needs are not going to be met by corporate and private interests; they must be met by public interests if we are to serve the public's needs.

Twenty years ago, the Medical Research Council of Canada told clinical researchers who were interested in conducting clinical trials to go to industry, that the MRC did not have funds to support clinical trials; these were done by industry. We discovered very quickly that industry does not meet or serve the public interests or the academic interests in clinical research. They make pills to sell.

CIHR, the reincarnation of the Medical Research Council, has since learned to fund randomized controlled trials—clinical trials—publicly. We have established a very productive Canadian HIV clinical trials network to actually execute investigator-driven clinical trials, which are conducted in order to serve the health care needs in management, not just in new drugs, for clinical trials in HIV. This was a necessary and fruitful step. It came from the public sector. It did not come from industry.

The same is true now in vaccine research. If we are going to have the capacity to take investigator-driven discovery and invention that our universities are capable of away from bunny rabbits and into human beings under good regulatory surveillance, we need the public funds to support GLP—good laboratory practice—facilities for production of vaccine candidates suitable for human clinical trials. This is a requirement. It's not going to come from industry.

When this study shows us that the capacity to produce vaccine candidates who might be put forward by industry is met in industry, that same capacity does not address the creativity of discovery that will come from academic and scientific endeavours at our universities. This is a large potential contribution. Its potential in discovery is greater than what can be pursued in industry in the sense that it is more diverse and there is more risk taken.

We do not have the candidate HIV vaccine right now. We need to discover it, and it's going to be discovered in human clinical trials. Right now, we have several under way, but they're huge. They cost hundreds of millions of dollars and they are conducted according to the corporate and industrial agenda. If we want discovery and we want to tap our universities' capacity, we will have to provide a little bit of the industrial capacity to those researchers—not through industry; it doesn't work that way. It has to be provided from the public sector.

Thank you.

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

We'll now go to PnuVax Incorporated, Dr. Donald Gerson, president and chief executive officer.

Dr. Donald Gerson (President and Chief Executive Officer, PnuVax Inc.): Hello. My name is Don Gerson, and I've been involved in manufacturing vaccines for the last 25 or more years. I've produced, under my direction, over 3.5 billion doses of vaccine, some in Canada as head of manufacturing at Connaught Labs and some at other companies around the world.

The thing that I think it is important to understand, in addition to what Dr. Cameron just said, is that right now the HIV epidemic is still growing. It's growing rapidly: nine or 10 people are being infected daily in North America. The demographics are, I'm going to say, universal and ubiquitous. It's not distinguished between one place or another, one person or another. Everyone who gets HIV dies of it. We have not had many epidemics of that nature, possibly except for tuberculosis. This epidemic needs to be stopped or it will basically kill all of us. That's just reality.

I want to talk a little bit about the problem that this facility was intended to address. The important thing, I think, that is hard to understand, unless you've been there and done it—which I have for a very long time—is the exquisite nature of the facilities and the procedures that are required to make a vaccine that's going to be injected into a human being.

You put a small volume of liquid into the person, but you can't get it out again. You have to make it under extreme conditions of care. The facility has to meet not just the government requirements but the industry requirements and the practical requirements, to make sure there is nothing that should not be in it: not a particle that is half a micron in diameter, not some other virus or another living organism, not some chemical that shouldn't be there. This is a massive amount of work, and you can't just do it in a university lab. University labs are meant for discovery.

You can't just do it—I'm going to add one layer—in a GLP facility. That's good, but not good enough. So you have to have a facility where everything is not just clean but proven to be clean, where every chemical is not just a chemical but proven to be the chemical you intend it to be. This is tough stuff, and it's also very hard to expand the work from the laboratory into, first, the larger-scale production of making a few thousand doses for a clinical trial, and second, expanding that into a production of making millions or billions of doses of a vaccine for human consumption.

Particularly with HIV vaccines—I've worked on many, a dozen or so, at various different organizations, and I have seen a number fail because of the failure to follow good manufacturing practices. That was actually the origin of this. I've produced a very large report for the international AIDS vaccine initiative in about 2003, which went to the Gates Foundation, which said that they had been running all over the world looking for facilities of this nature and had had a very hard time finding those that met the requirements. They also said they have had a number of vaccines that have failed because of what somebody else might consider to be minor aspects of contamination or documentation failure but that make the outcome of the clinical trial useless.

The clinical trial comes after $100 million, $200 million, $300 million, or $400 million worth of work. In fact, for the final vaccine—the last vaccine that I produced in the United States was for smallpox after the 9/11 incident—we made a new process for the vaccine: totally new vaccine, 300 million doses, $800 million.

● (0925)

The previous vaccine was for childhood pneumonia. It took 10 years. I took it through the last five years, and it cost almost $1 billion to make the first dose of commercial vaccine. It made money back eventually, but this is tough stuff. You can lose the whole investment by having poor-quality clinical materials. That's what this facility was about.

The other topic I'd like to talk about is the following. One of the various comments made about why this was cancelled was that none of the facilities was economically sustainable. I take serious exception to that. First, while the Oliver Wyman report, which was just shown to you all, says there are lots of facilities, it also says on the first page that they didn't take quality into account, which ignores all of what I just told you.

Second, the concept that a clinical facility operating as a CMO, a contract manufacturing organization, could not make money and be self-sustaining is a conclusion that I think you could only come to if you haven't done it. I've done this many times. I set up the Alberta Research Council's biotechnology pilot plant, which was many millions of dollars in investment and which I ran at a profit in the eighties. I've done other such things time and time again, and so have other people. You can make a very good profit. In the last four years, just before returning to Canada, I set up a contract manufacturing company in Korea. We invested $250 million in a 50,000-litre facility for making monoclonal antibodies. We started cold. We started in a country that had essentially no such industry and we ran it at a profit. The $250 million investment is now a company worth $1.4 billion. It employs 300 or 400 people, and it's a going concern and will continue to be so. So whether it's large or small, this can be done.

The conclusion that this is not profitable either comes from someone who doesn't know how to do this or from someone who does not want it done because it's competition. That's part of the business world too. I think it's important to say, however, that the process by which the evaluation was done, the format that was used or the approach taken, was fine. There were no problems there. It was a little slow to my way of thinking, but maybe I'm not used to government. That's not where the flaw was in this. There's some decision-making process that has deprived Canada of an important facility that could have been a nucleus for economic development, that could have been a source for trial vaccines that could have used Canadian expertise in this field to develop the vaccine for HIV, which is critically important not only to Canada and to the use of huge investment in Canada in infectious diseases, but also to stop an epidemic that could kill every person on earth.

Thank you.

● (0930)

The Chair: Thank you very much for your presentation.

We have one more presenter.

I'm Joy Smith, the chair of this committee, and thank you for making it here.

By video conference, from the Vaccine and Gene Therapy Institute in Florida, we have Dr. Rafick-Pierre Sekaly, co-director and scientific director. Doctor, you have between 5 to 10 minutes. I've been giving people extended time so they can finish their presentations. If you would go ahead and make your presentation to the committee, it would be very much appreciated.

Dr. Rafick-Pierre Sekaly (Co-Director and Scientific Director, Vaccine and Gene Therapy Institute Florida): I just heard what the previous presenter mentioned. I moved to Florida about a year ago. I was initially very much involved as scientific director of the Canadian vaccine network. It was funded by the national centres of excellence to promote the development of the potential collaboration with the Gates Foundation. Some time in October 2003, Dr. Plummer, Dr. Singh, who was at the time the head of the infection immunity institute of CIHR, and I all went to meet the Gates Foundation and entertain the possibility of developing a joint centre between the Gates Foundation and Canada on the development of an HIV vaccine. So that's the way things started.

There was a very good response by the Canadian government at the time. By 2007 there was a signed agreement between the Prime Minister and Bill Gates regarding this mega-collaboration.

I was very much involved in putting together the strategic plan of the Global HIV Vaccine Enterprise. It is a network of independent institutions, including CIHR. All of those institutions are focused on developing a vaccine for HIV. Each one provides their expertise and contributes toward establishing an HIV vaccine. Let's say some place in the U.S. provides some pre-clinical work. In this global HIV enterprise, everybody brings a contribution.

Because there was a very well-identified paucity in vaccine-lot production, we thought of Canada specifically, especially with companies like GSK and Sanofi Pasteur that had vaccine production plants here in Canada. We thought that would be a very significant contribution from Canada. In fact, during those discussions, Sanofi Pasteur was very much involved. At the end they pulled out of the game, but we still managed to put together four very important proposals that were very well reviewed. They highlighted the Canadian expertise in vaccine development, from the basic research to the pre-clinical development, all the way to clinical production. I think the availability of this vaccine-lot pilot plant is going to be a catalyst in fostering Canadian expertise, improving it, and attracting top-notch investigators.

As I mentioned in the press when that decision was made, unfortunately it was a missed opportunity. We went through the whole process, which lasted almost two years, where people really invested a lot of their time and effort and brought highly credible proposals to the table, but in the end everything just fizzled out for reasons I'm still trying to figure out.

It's a missed opportunity, not only because I think Canada has to make a contribution toward HIV vaccine development. You all know that for the past year we've been hit with this swine flu. When we were discussing putting together a vaccine production plant, it was very clear that there was going to be a focus on HIV, but the vaccine plant was also going to be available for any emerging disease epidemic.

● (0935)

When we were talking about this, it was about bio-events. There was all the talk about anthrax and pox, so we all agreed that it was also going to be available in case Canada faced that kind of epidemic. You all know that last year we were grappling with the possibility that you might be hit with a swine flu epidemic. We were all very worried about when the vaccine was going to be ready, and we know there were delays in testing the vaccine to make sure it was safe. Having a facility like this one would certainly help accelerate the implementation of a vaccine for the Canadian population.

At the end of the day, I think the decision is questionable on multiple fronts. First, it fails to put together a cohesive network of scientists, all the way from basic research to clinical development to clinical trials.

Second, I think Canada has to contribute to HIV vaccine development, as Don Gerson mentioned. I think it's a moral obligation that you owe the world community. We have committed to doing this, and I don't understand why we have backtracked.

Third, having this facility would help not only HIV vaccine development; it was meant to be available for any epidemic. That means that Canada was going to be independent from GSK or other companies that might take time to develop a vaccine or might make a decision not to eventually develop a vaccine for a specific disease. That was going to put us in a position of being independent of having other people making decisions for us.

Those three reasons, again, make you question the validity of the decision. I really would like to understand why the decision was made. I would like to contribute to any path that might lead to reversing the decision or convincing the government that the decision has to be modified.

● (0940)

The Chair: Thank you so much, Dr. Sekaly.

As you know, now we're going to seven-minute rounds. I'm going to be very tight on the time, the reason being that I want to get in as many questions and as many answers as we possibly can.

At the end of the meeting, I'm going to go into the business part. We just have to quickly get a budget to cover witness expenses at meetings.

Starting now, we'll have seven minutes for the question and the answer, and we'll start with Dr. Duncan.

Ms. Kirsty Duncan (Etobicoke North, Lib.): Thank you, Madam Chair, and thank you to the witnesses.

I guess I'm struggling. We hear that we need this. We hear that it was a two-year process. We hear your frustration. What happened? I think it's important that we look at the process.

The Chair: Excuse me. The feed is coming in from a different conversation.

We will start again with Dr. Duncan.

● (0945)

Ms. Kirsty Duncan: I guess I'm struggling with what we hear. We hear that this was a two-year process, and yet the decision is questionable on multiple fronts. It was a missed opportunity, and people want to understand what happened. I'm really hoping that we can get past the government talking points, namely that the Gates Foundation study found that there was excess vaccine capacity and that none of the applicants qualified.

With respect, to avoid running out of time, I will be asking yes and no questions, and I'll ask for elaboration if needed. I think I'd like to address these to Dr. Sternthal.

After the technical assessment was complete, was there one applicant that was ranked ahead of the others, yes or no?

Mr. Steven Sternthal (Head, Canadian HIV Vaccine Initiative Secretariat, Director, Office of HIV Vaccines, Public Health Agency of Canada): The exploratory process did have assessments that found strengths and weaknesses for all the applications.

Ms. Kirsty Duncan: With respect, please give a yes or no answer.

Mr. Steven Sternthal: I can't answer that question with a yes or no.

The Chair: Dr. Duncan, let's give him the latitude of adding a few words. He'll be as concise as he can.

Please continue, Dr. Sternthal.

Mr. Steven Sternthal: Sure, but I'm not a medical doctor.

The applications were all assessed, and there were strengths and weaknesses identified for all four applications. Some had different strengths and different weaknesses and some had more strengths and more weaknesses. That information was used as part of the overall assessment and review.

Ms. Kirsty Duncan: Was one bid on top?

Mr. Steven Sternthal: There was no ranking in the external process.

Ms. Kirsty Duncan: We heard from Dr. Butler-Jones that there was a ranking.

Was one applicant recommended by the technical committee?

Mr. Steven Sternthal: No, there was no recommendation from the technical process.

Ms. Kirsty Duncan: Okay.

It's my understanding that a $3 million allocation was discussed, which would be provided to an applicant with potential to move forward to implementation. Yes or no?

Mr. Steven Sternthal: No, I am not aware of anything of that nature.

Ms. Kirsty Duncan: Okay.

Was one of the applicants allowed to resubmit parts of their application as late as October 2009? Yes or no?

Mr. Steven Sternthal: Yes, there was one applicant who did submit additional information in the fall.

Ms. Kirsty Duncan: If this was closed in March, how was this allowed to happen?

Mr. Steven Sternthal: This information was submitted at a time when the review was in its final stages of completion. There was an indication that a partner had changed for one of the applicants. It was not a substantive change to the application.

Ms. Kirsty Duncan: On what date did the government and the Gates Foundation officially decide it was cancelling the project?

The Chair: Dr. Engelhardt.

Dr. Rainer Engelhardt: That decision to cancel the project—in other words, the overall facility—was communicated in February of 2010, this year.

Ms. Kirsty Duncan: Was that on February 19?

Dr. Rainer Engelhardt: That's correct.

Ms. Kirsty Duncan: Thank you.

This project was an $88 million vaccine plant. As you know, it was originally announced by the Prime Minister and Bill Gates in February of 2007 and was cancelled as an administrative error on a Health Canada website. When exactly did this administrative error occur?

Dr. Rainer Engelhardt: It wasn't cancelled, if I may say so, as the result of an administrative error. There was literally a human error made in preparation of material on the website, which inadvertently became public.

Ms. Kirsty Duncan: On what date did that occur?

Dr. Rainer Engelhardt: I don't know right now what that date was, but it was prior to February.

Ms. Kirsty Duncan: Was it in December?

Mr. Steven Sternthal: That was identified around January 20 as being posted on our website. We were not aware of that until that time.

Ms. Kirsty Duncan: If the Gates study was dated July 2009—and this goes back to an earlier question—why was an applicant allowed to make changes in October, which would suggest that the process was ongoing?

Mr. Steven Sternthal: The review process was completed, as Dr. Engelhardt said, only earlier this calendar year. We received the information from the single applicant, identifying that a partner on the application had changed, but the final decision was communicated publicly to the applicants on January 22 and then on our website on February 19.

● (0950)

Ms. Kirsty Duncan: Okay, so the study for the Gates Foundation is dated from July 2009. Why did it take so long for the government to tell applicants that the project was dead?

Dr. Rainer Engelhardt: That study, which was provided, was relatively detailed and was one of the factors that related to the very large project. That required interpretation. It required, first of all, assessment of the technical review that was carried out. The technical review was completed only shortly prior to that and hadn't really been evaluated. Then the whole question of the risk assessment and what it meant to the risk to the federal moneys and Gates' moneys to have a—

Ms. Kirsty Duncan: With respect, Dr. Engelhardt, may I interrupt?

Dr. Rainer Engelhardt: Yes. I can't answer that with a yes or no. I'm sorry, but—

Ms. Kirsty Duncan: Okay. May I interrupt?

Dr. Rainer Engelhardt: Sure.

Ms. Kirsty Duncan: The Gates Foundation came out in July of 2009. It started with a disclaimer. It talked about what evidence it didn't look at. It looked only at capacity rather than quality.

Dr. Gerson was part of the original process, and he gave a critique of that study. It seems that part of the government's decision is based on one study with which there were certainly challenges. If Dr. Gerson was trusted enough to be part of the initial process, why are his comments not being taken into account?

Dr. Rainer Engelhardt: I can't speak for the internal evaluation carried out by the Gates Foundation itself. For us, when we saw the report, it talked about capacity, certainly. Also, by more than inference, in stating that quite a large number of the facilities identified had records of being GMP certified—that's good manufacturing practice—or could easily be GMP certified, it meant that from a regulatory perspective, this assessment of quality carried over into a statement that, yes, there was capacity, and yes, that capacity—these are contract manufacturing organizations in that large industry—had the ability to produce a pilot-scale manufactured vaccine to the standards regulatory authorities would require to move a candidate vaccine through this early stage of production. That early stage of production is an essential component of clinical trialling.

The Chair: Thank you, Dr. Engelhardt.

We'll now go to Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you, Madam Chair.

When the Prime Minister of Canada and Bill Gates are on the same stage to announce the establishment of a centre for clinical trials and a strategy, that has to be something significant, it seems to me. It also has to be a goal set jointly by the Government of Canada and the Bill and Melinda Gates Foundation. I find it curious that, after an announcement like that, the decision is made to end the project.

Why did the project stop being significant when, in 2007, it was significant enough for the Prime Minister and Bill Gates to announce that it was being set up?

[*English*]

The Chair: Go ahead, Dr. Engelhardt.

Dr. Rainer Engelhardt: That's a very appropriate question you ask. It reflects the thinking processes that needed to go on during the evaluation period. If there were no pilot-scale manufacturing capacity, which typically requires production of 10% of the volume of a production batch—that is sort of a regulatory requirement—to GMP standards, there would be a real gap in moving forward a candidate vaccine discovered in Canada, or anywhere, to actually apply to humans. That was assessed, in a separate study, in 2004—I think I have the year right—as not being available in Canada. Steven, am I right that it was 2004?

The scene had changed rapidly, though. I guess when the general background people at the Gates Foundation, in particular, decided as part of their due diligence to re-evaluate whether pilot-scale manufacturing capacity was still unavailable to researchers globally, the finding was that, yes, over the past two or three years, pilot-scale manufacturing capacity had come on stream and had become available. Keep in mind that pilot-scale manufacturing does not involve the same level of effort required in a full-scale, industry type of vaccine manufacturing plant.

The changes that can happen over two and three years can happen relatively quickly. We ended up with a decision that manufacturing capacity for pilot-scale clinical trialling actually had become available, and it no longer made sense to spend $88 million for that priority in HIV vaccine development versus other priorities that were also on the table.

● (0955)

[*Translation*]

Mr. Luc Malo: Despite those comments, these doctors, who seem distinguished to me, tell us that present facilities do not allow us to accomplish what we could have established with the new centre for clinical trials.

How do you respond to them? Your explanations do not seem to have alleviated their concerns.

[*English*]

Dr. Rainer Engelhardt: With due respect to Doctors Cameron, Gerson, and Sekaly, we would like to differentiate the pilot-scale manufacturing capacity from the full-scale vaccine facility. As the report—and not us, per se—said, the pilot-scale manufacturing capacity was available to researchers globally, so it really comes right down to the point of a judgment call on value for money. That's really what the bottom line was: is it better to spend the $88 million for the many other needs in moving candidate vaccines forward, or even discovering effective HIV vaccines, than to spend it on duplicating something in Canada that could have many benefits on the Canadian scene and moving that forward? A value judgment was made, and what we are really here to relay to you is that the value judgment came down on the side of spending the money otherwise.

[*Translation*]

Mr. Luc Malo: Dr. Sekaly, did your leaving Montreal have anything at all to do with the decision not to proceed with this project?

[*English*]

Dr. Rafick-Pierre Sekaly: I don't think so. My decision to move to the U.S. was part of a much larger decision-making process in my mind.

That decision reflects some of the reasons I left. One of the very important reasons I left was that I wanted to do research on human subjects, do as much as I could in clinical trials to accelerate vaccine development. We test a lot of vaccines on mice, and they all work. When you get to humans, nothing works. I thought the pilot plant was going to enable us to make small lots that were going to allow us to do small pilot clinical trials with humans.

Despite the fact that when I left.... It was long before my time that the decision was made. I think it certainly would have given Canada a very strong competitive edge in the current atmosphere of vaccine development. We realize that everything we do in species other than humans doesn't give us the right answers. Having a place where you can make those small pilot-scale vaccine lots certainly would have allowed us to contribute this kind of effort. Having this vaccine plant would have enabled not just me but many other Canadian researchers to contribute in a very significant way to the current realm of vaccine development, which is to do work on humans, and it's unfortunate that it's not going to happen.

● (1000)

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

We'll now go to Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): Thank you, Madam Chairperson, and thanks to all of you for your presentations.

I want to begin by stating to Dr. Engelhardt and Mr. Sternthal that you're telling me today much of what you told me on February 19, after I wrote to the minister asking for an explanation of this decision. I said to you at that time that I didn't believe you then, and I don't believe you now.

In fact, there are so many contradictions in the testimony of you two, Dr. Butler-Jones, and the minister that one can't even keep up with the changing message coming out of your government, which only leads us to believe that you've all been given a talking point and you're getting it mixed up. You can't quite all get it out the same because in fact there is no truth behind it.

Let me point out of few of the contradictions and then ask Bill Cameron, Dr. Gerson, and Dr. Sekaly for their understanding of why this could have happened, because what's been said officially just does not make any sense. I find it hard to believe, both Steven and Rainer, that you don't read the newspaper. In fact, it was reported in December 2009 that there was a web page announcement saying the whole project had been pulled, and you say you don't know—

The Chair: Ms. Wasylycia-Leis, could you get to your question?

Ms. Judy Wasylycia-Leis: Madam Chair, I have seven minutes, and I would appreciate it if you would let me ask my questions. Thank you.

On February 19, when I asked whether a decision had been made, you said it had not in the traditional sense.

Even before March 16, I talked to Dr. Butler-Jones and he did not even understand that the proposal on the bids was for a non-profit facility. He only realized that by the time he testified on March 18.

On March 16, the minister said no decision had been made. The head of the Public Health Agency, Dr. Butler-Jones, contradicted her and said yes, a decision had been made, because in fact he said there was a ranking. A ranking is a decision.

Today you're trying to tell me that there are scientific and technical issues at stake, yet no one has ever raised scientific and technical issues with the applications in the past. In fact, the most recent argument has been about sustainability, which doesn't make sense because in fact that was part of the bid process to begin with. Otherwise, why would the Manitoba bid, the Winnipeg bid, actually go to the trouble of getting a $15 million commitment from the provincial government to be able to sustain the centre and get it on a solid footing? So the questions of sustainability weren't even addressed.

You haven't given us a single solid argument, except for leading us to believe that some political interference happened. You're trying to give us the line and you're failing dismally.

So I want to ask Bill Cameron, first of all, were you ever given any detailed explanations about the rejection of the Winnipeg bid in terms of scientific or technical advice? Tell us also about whether sustainability was part of the original requirements.

Dr. Bill Cameron: To the first question, no.

To the second question, I was not party to the original call for proposals. I understand, through consultation with others at the Canadian Association for HIV Research, that economic sustainability was one of the features of that original call.

If I may add to that point, part of the reason that the explanation for cancellation made no sense to me was that to say we have production capacity for small lots for early clinical discovery and development and that it's merely provided by commercial capacity does not address the issue of discovery and invention, simply because commercial goods manufacturing facilities are out of reach of discovery. The market for commercial production facilities is corporate. We don't get publicly funded grants to contract out vaccine production for a university or investigator. That doesn't happen. It's a corporate level kind of capacity we're talking about. In my opinion, if we want the GLP and GMP capacity to address issues of discovery and invention, it's not going to be done in the industry sector.

So in answer to the second part, it made no sense to me, but you know....

● (1005)

Ms. Judy Wasylycia-Leis: Let me go to Dr. Gerson. The interesting timing of this document, in July, supposedly after the decision was made that none of the applicants met the bill, was only to tell us that in fact the alternatives to this non-profit facility were any number of private manufacturers.

You've pointed out the difficulties with this study, and so has the actual author of this study. Can you tell us where in the world there is a facility now that can do the kind of work that any one of the four bidders might have been able to do had this process been completed?

Dr. Donald Gerson: In looking for exactly that kind of capacity and doing a very detailed assessment of GMP capabilities and quality aspects a few years ago, we came down to a very small number. There was one in Germany where the German government had invested a large sum of money to make a very nice, modern facility. They had implemented GMPs quite well, but needed help from us to make it better. That was basically an economic development project in old East Germany. There was also one in Vienna. In fact, it was only good for the very earliest stage, not even for production of the vaccine per se, but essentially for laboratory work, as they had some exquisite small labs.

We were strapped looking for places, though there was also one in southern California that we used. So there we were, running all over the world trying to solve the problem. We visited many, many places, but very few qualified.

Today, there are maybe a couple more. There's a group of places under one ownership in St. Louis that might be able to do some of this, but in that case there's a capacity, cost, and scheduling question. There's also one in Rockville, Maryland, that I was involved in setting up, funded by the Gates Foundation. However, it's only for bacterial vaccines and it's pretty much dedicated to tuberculosis. After that it gets really thin.

The Chair: Thank you, Dr. Gerson. I gave you a full extra minute to finish your answer.

We'll now go to Dr. Carrie.

Mr. Colin Carrie (Oshawa, CPC): Thank you very much, Madam Chair.

I want to thank all the witnesses for being here today.

I wanted to give Dr. Engelhardt an opportunity to respond. I felt our last questioner was pretty hard on you in questioning your credibility and that of Dr. Butler-Jones, Canada's top doctor. She said some things that I'd like to give you the opportunity to respond to, including that you hadn't given a reason for the cancellation. I believe you said quite clearly today that it was a judgment call. You said there are a lot of priorities as far as HIV research is concerned and that we know it's a worldwide effort. We even heard from one of our witnesses how important it is for public investment.

However, has a decision been made to remove the funds from the table, or are these funds still going to be made available, perhaps for a priority issue, as you mentioned? Are they going to be made available for other priorities?

Dr. Rainer Engelhardt: Mr. Carrie, thank you. You raised several points, but I'll address the last one first, because it brings it all together.

There is an ongoing commitment, a stated commitment, that the $88 million—the $28 million from the Gates Foundation and $60 million from the Government of Canada, amongst its agencies—is still on the table. There is currently an evaluation or assessment going on to determine where such funds should be spent. A multiple number of priorities are under consideration, including recognition of a need in Canada to support the transition from lab bench research to clinical research, and there might very well be a need to set a portion of that money aside to assist our researchers in accessing existing pilot-scale manufacturing facilities, whether in or outside of Canada.

Today, I shouldn't give you any assessment of what those various other priorities are, except that they span the range from research right into implementation of vaccines in needy areas. With the Gates Foundation and the other agencies in Canada, the original partners, or that family, if you like, of Canadian organizations, we are evaluating this almost as we speak. In fact, we have two more meetings on this today.

● (1010)

Mr. Colin Carrie: Thank you very much for that.

What I'm hearing is that Canada is part of a worldwide effort and we're trying to work together as a worldwide team for HIV research.

I did hear a comment by Dr. Gerson, and perhaps you could comment on this. He mentioned that the quality aspect of this was not taken into account. You did allude to it briefly. However, it was a disturbing inference for me, because to me it meant that perhaps some labs out there are not quality labs or are not up to the quality this potential new lab would have been....

Are there international labs out there providing vaccines around the world for people in need that aren't quality labs? My understanding was there are very high standards around the world. Is this something you're aware of among worldwide labs?

Dr. Rainer Engelhardt: If I may, I can't make a personal judgment with respect to the quality of one lab versus another. However, those laboratories, whether they happen to be laboratories where there are pilot-scale manufacturing facilities or not, and whether they operate in Canada or the U.S. or Europe, I believe meet the highest level of quality with respect to the regulatory authorities.

Our own regulatory authorities impose scientifically based quality controls in those facilities. I don't have any reservations in that regard. When somebody talks about a facility being an accredited GMP or a certified CGMP, that means the results coming out of that facility can be trusted in order to be able to proceed along the chain from discovery to ultimately having a registered drug.

Mr. Colin Carrie: That's my understanding. My understanding is that this industry has one of the highest qualities around the world. Even Dr. Cameron mentioned that there seem to be so many regulations there, that for worldwide research now you do need that public money. My understanding is that it is still on the table.

I wanted you to comment on something else as well. There have been accusations that the CHVI has not accomplished very much since it was formed in 2007. Can you tell me what has been done since it was launched in 2007?

Dr. Rainer Engelhardt: I certainly would be happy to. The federal commitment to the CHVI program at that time was up to $111 million, and $51 million of that has either been committed, expended, or will be expended in pre-determined priorities.

If it's all right with the chair, I would like to have Mr. Sternthal give some details.

The Chair: Please, Mr. Sternthal, go ahead.

Mr. Steven Sternthal: Thank you.

I'll just take one example of what is often the side that is not talked much about, and that is the involvement of affected communities, people living with HIV. We have a number of projects that we're currently funding.

One, for example, is with the Canadian AIDS Society. They have been funded to look at some of the lessons learned from existing public health interventions, existing vaccination programs, to see how we can better prepare the HIV community for the eventual availability of not only a HIV vaccine but other vaccines as well. This is just one example in our community, in social dimensions, where we are working collaboratively with the community as well. On the research community, there are currently 13 projects that have been funded through the Canadian Institutes of Health Research, and they range from coast to coast in this country. Certainly, a large initiative that will be launched in the coming weeks by the Canadian Institutes of Health Research as well as CIDA is a collaboration between Canadian and developing country researchers to continue to push forward the discovery of new vaccines and new vaccine concepts, as Dr. Cameron talked about, which is really critical to ensuring we have a robust pipeline in the long term for finding vaccines.

● (1015)

The Chair: Thank you very much, Mr. Sternthal.

We're now going into our five-minute Qs and As. Committee, when I say to you, “Do you have a question?”, I'm giving you a signal that you've used up almost half of your time. It's up to you whether you want to make comments or have questions. I just want you to make sure, because we all lose track of time. I am watching the time very tightly today, so it's not meant as an affront to your questions. I just want you to know the time that you have left.

We're now going into the five-minute round, and I believe Ms. Neville and Dr. Duncan are going to share their time.

Keep in mind that you have five minutes.

Hon. Anita Neville (Winnipeg South Centre, Lib.): I have a very quick question to each of you, and I appreciate your being here today.

My quick question to each of you is this. Are you aware that in the early fall of 2009, representatives of the provincial government of Manitoba had been advised informally that they were the successful bidder on the Canadian HIV vaccine initiative?

The Chair: Who would like to take that question?

Dr. Engelhardt.

Dr. Rainer Engelhardt: We were informed, at least through the media more than anything else, that this had occurred. Literally, we went back internally and scratched our heads, saying, how could that have occurred? We tried to trace it, and there is nothing we can say that would be attributable to the process that we followed.

Hon. Anita Neville: Does anybody else want to comment? No?

Thank you.

Ms. Kirsty Duncan: I guess I am still concerned. By saying that none of the applicants were up to the task, this is announcing to the world that Canadian researchers, universities, and private industry could not meet the criteria.

Can you specify or make clear what criteria these applicants failed on? We've heard different stories.

Mr. Sternthal.

Mr. Steven Sternthal: I'll answer the specific criteria, but first I want to say that the applicants themselves, of course, had many strengths. There was a broad range of organizations and partners that each organization mobilized, and that was recognized throughout the letter of intent stage as well as the application stage.

Ms. Kirsty Duncan: You've mentioned that.

Mr. Steven Sternthal: In terms of specific criteria, we've given, confidentially, each of the four applicants feedback on all of the criteria that were made available to them at the beginning of the process.

Dr. Engelhardt has mentioned that there were criteria in technical areas, in governance, in financial sustainability. All of that specific feedback has been provided to the applicants.

Ms. Kirsty Duncan: Thank you, Mr. Sternthal.

Dr. Gerson, how do you feel about the fact that no one met the selection criteria?

If I can ask also, what has the cancellation of this facility done to Canada's reputation in HIV science, and what will happen in a few years if the lab is not built?

Dr. Donald Gerson: Well, first of all, it's clear that Canada has spent enormous sums of money developing expertise in infectious disease and vaccines since, really, the inception a very long time ago of Connaught Laboratories, and Canada has been a world leader in this. To say without a lot of detailed explanation that no one in Canada is capable of doing such a thing really is self-depreciating in Canada. I think it's really an unfortunate outcome for the government to say that none of the people it has supported are capable of doing this task, which I think clearly is otherwise. Whether it's directly in vaccines or in large-scale production—I mean, Canada has had some of the best researchers in scale-up and production of biopharmaceuticals at Waterloo, Western, and McGill—it's an extremely unfortunate outcome for this whole event.

Ms. Kirsty Duncan: Thank you.

How does this affect Canada's reputation in HIV science internationally?

Dr. Donald Gerson: If the government says everyone's incompetent, then people tend to believe that more than what would be said otherwise. Incompetence is my word, but that's the message I think that was essentially delivered. It's hard then for people to go to outside agencies, or to the Gates Foundation, or to NIH and say, "Oh well, you know, really we are competent."

● (1020)

Ms. Kirsty Duncan: I know this is difficult science—you don't predict the future—but what are the potential ramifications of not building this lab facility?

Dr. Donald Gerson: I can answer that in a positive sort of way. There was a significant investment when, for instance, we put in the facility in Alberta for making similar scale...similar in terms of stage of going from research to manufacturing lots of material for industrial biotech. But the consequence there was that that area now is surrounded by a number of small biotech firms, and it has had a big economic effect.

The Chair: Thank you, Dr. Gerson.

Ms. Duncan, your time is up now, thank you.

Ms. Davidson.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): Thanks very much, Madam Chair.

Thanks very much to our presenters both here and on videoconference. We certainly appreciate the input that you've given us this morning.

Dr. Engelhardt, I'd like to ask you a question, if I may.

It's been fairly obvious this morning that we've got some differences of opinion and differing views around this table about how and when the decisions were made about the CHVI manufacturing facility. I know you've alluded to the process in your opening remarks and in answering some of the questions, but I wondered if you could just walk us through, step by step, how that final decision was made—if you can give us that chronological order, please.

Dr. Rainer Engelhardt: All right. I'd be happy to.

If it's all right with you, if I falter in my memory, I will rely on Steven.

Mrs. Patricia Davidson: Certainly.

Dr. Rainer Engelhardt: I do believe that you have a chronology that was provided, Madam Chair. The applicants, as I said in my introductory remarks—

The Chair: Can I just say this was provided to the clerk by e-mail. I don't believe it has been distributed. It wasn't translated.

We do have it translated now? I didn't know it was here. We can hand it out so people have it.

Dr. Rainer Engelhardt: If it's agreeable with you, I could give just a brief overview of that, because that would give you the chronology.

The Chair: Absolutely. We'll make sure everyone has it.

I'll just give you a moment to hand it out so we don't lose time here. I wasn't aware that the clerk had it with her today.

Dr. Rainer Engelhardt: From the perspective of time, if it's agreeable with you, I already mentioned that in April 2008 the invitation for the LOIs, the letters of intent, had gone out.

There was a response that we received by June 15—the LOIs from applicants. Then in November of that same year, 2008, four of the applicants were informed that their LOIs were successful, adequate to solicit a full application. They were invited to submit their applications, which then were received on March 25 of the following year, 2009.

Coincidentally, in March 2009, the Bill and Melinda Gates Foundation started their due diligence with respect to capacity. This was done really independent of us, of the Government of Canada, at that time, but it's a natural and I think a normal due diligence process.

So the applications were received, and then for really the rest of that year those applications were assessed according to, as we've said, the scientific and technical criteria by the external committee. They were also, subsequent to that, assessed on the basis of some internal reviews that the terms and conditions for the applications had already identified. We identified that there would be an external review by an external committee—a scientific and technical committee—and there would also be an internal review with respect to value for money and feasibility and with respect to risk to government and basically to the Canadian taxpayer.

As we said, that external review was completed by the end of June. In July, it was basically tabled to the Government of Canada to take voluminous assessments to the people's desks and to go through and collate the information. Then, in July, the Gates Foundation tabled its study, the Oliver Wyman study, that said there was capacity available. In fact, that made our assessment of sustainability more difficult in that we now really were dealing with an additional risk—that risk, or value judgment almost, being posed by the fact that there actually were capacities available, and was it valuable enough to repeat that capacity within Canada with respect to other priorities for HIV advancement?

So that internal process took some extensive time—it literally took many months, as I think all of us know here—but the volume of material that had to be assessed and validated and gone through was very large.

The end result was that towards the end of the year, it looked as if we were going to be saying, "Hmm, the facility issue is a serious one." It came down to the crunch, really, of the final stages of evaluating what was going to be the decision that would go public, and informing the applicants on their application alone with respect to all of its criteria, including value for money and sustainability, and then also announcing that they ultimately would have to do that and wanted to do that, but the facility proposal, that component, also no longer made sense in Canada.

● (1025)

The Chair: Thank you, Dr. Engelhardt. Have you just about finished?

Dr. Rainer Engelhardt: That's fine. I think that captures the extension of the process.

Thank you.

The Chair: Thank you so much.

We'll now go to Monsieur Dufour.

[*Translation*]

Mr. Nicolas Dufour (Repentigny, BQ): Thank you, Madam Chair. I would like to thank the witnesses for being here to discuss such an important subject.

My two questions will be mostly financial in nature. Dr. Engelhardt told us at the beginning that the $88 million set aside for this project would be invested, at least for the most part, in the fight against HIV. He also told us that an evaluation process was underway in order to determine where that money would go and how it could be invested.

I wonder as well—this is the first question I would like to ask the witnesses—where should the money go? The second question is: is putting $88 million into the research facility the best use of the money? Could something else be done? The witnesses are in a position to answer that question, I feel.

[*English*]

The Chair: Dr. Engelhardt.

Dr. Rainer Engelhardt: Thank you.

It really is the valid question that we're dealing with at the moment: how do we effectively apply the money that had previously been earmarked for a facility, as we said, to where it can now provide the greatest value?

I have to start by repeating what the process had been. We had come with a value judgment that going forward with a facility would not give us as large a return on moving the HIV advances forward as other needs. As we're looking it at right now, the other needs really range from gaps in scientific information that's necessary to develop a new vaccine to gaps in moving the vaccine forward through the clinical process, not only in clinical trial facilities accessible in Canada but also through clinical processes in countries where we actually need to have an effect, for instance, in western Africa—maybe there'll be a question on why Africa—to the point of providing some assurance that the vaccines can be delivered well in the target areas. Those target areas could be in Canada or outside Canada.

It's a very large project. Many tens of hundreds of millions of dollars are spent globally to move the HIV agenda forward. We, Canada, jointly with the Gates Foundation, need to pick and choose where we can have the greatest effect for our money.

As a final quick point, we were not acting alone on this. We are in a partnership with the Gates Foundation. Even though the Gates Foundation puts in less money than we do, their influence and reach into the global HIV vaccine advancement community is phenomenal.

[*Translation*]

Mr. Nicolas Dufour: Thank you, Mr. Engelhardt.

Could Mr. Cameron and Mr. Gerson also tell us where they feel the money could be invested?

● (1030)

[*English*]

Dr. Donald Gerson: I don't know exactly what is being considered right now in terms of alternate uses for the funds. Having been involved in many HIV projects, a lot of funds are spent on clinical trials. A lot of funds are spent on research, but it's been clear for some years that the gap between R and D and commercialization is large.

This facility would have bridged the first part of that gap, to make clinical trial materials that meet all standards and to make them so that the clinical result is not compromised by the quality of the vaccine used in the clinical trial, as has happened with a number of HIV vaccines. I still feel it's a significant gap within the entire HIV enterprise. There are other gaps, but that's a very significant one. To the best of my understanding, it is still inadequately met.

The Chair: You only have 15 seconds left, and I will watch the clock.

Dr. Cameron.

Dr. Bill Cameron: I would say the money should be spent in Canada. It should be spent on vaccine discovery development. One unmet need is a production facility. It should be spent there. Second, if not there, then it should be used to facilitate academic investigator-driven research on vaccine development in Canada.

The Chair: Thank you, Dr. Cameron.

We will now go to Ms. McLeod.

Mrs. Cathy McLeod (Kamloops—Thompson—Cariboo, CPC): Thank you, Madam Chair.

Thank you to the witnesses today for a very important discussion.

FIrst, I have a short question. We've heard the term “GMP”, but I thought I heard Dr. Gerson say “GLP”.

Dr. Donald Gerson: Let me give you a quick vocabulary lesson. GLP, good laboratory practice, is usually applicable to the very earliest stages of developing a vaccine. GMP, good manufacturing practice, is what you have do when making a product that will go into a person either at the clinical level or the commercial level. The other one we're probably going to hear about is GCP, good clinical practice, to make sure the clinical trial follows all of the regulations.

Mrs. Cathy McLeod: Thank you. I was trying to determine whether they were the same thing or different. I appreciate the clarification.

I think perhaps unlike any other effort, this has truly been a global effort. There are many different areas of need. It's certainly been determined by the Gates Foundation that there might be capacity in this area. There's certainly no lack of places to spend funds in terms of moving the initiative forward.

I'd like to hear a little about how collaborating with the Gates Foundation has helped the CHVI to work towards achieving the main goal to aid in the development of a safe, effective vaccine. I'd like to hear about the relationship not only with Canada but throughout the world. It's a very important piece of what we're doing, Dr. Engelhardt.

Dr. Rainer Engelhardt: Thank you.

We haven't spoken very much about the Gates Foundation, and I'm going to be limited in what I can say because it's, in a way, second-hand. My observation, working with the foundation, has been that they are very scientifically driven and use evidence-based science as the basis for any of their decisions. They are also very strategic in developing their program. Their program is focused on areas of need, in this case for HIV, typically in Africa rather than in Canada. They are also, however, very much impressed by Canada's capabilities or, as esteemed colleagues have said, their record and history of having produced extremely valuable knowledge with respect to HIV vaccine production and the overall definition of the disease altogether.

There is a coupling that has come together between our capacity in Canada and the very fact that we have definite social and medical problems with HIV/AIDS expression in Canada in a whole series of populations. So we think whatever we do jointly with the Gates Foundation is going to be beneficial in Canada to Canadian social and medical structures as well.

There was a comment that the Gates Foundation is in itself strategic, that it is developing a large strategic plan for how the vaccine implementation can benefit the issue of HIV all over the world. It hasn't been mentioned around the table here that the Gates Foundation supported a vaccine trial. It was an early-stage vaccine trial in Thailand, which, for the very first time, had some efficacy. That has given us a tremendous boost in thinking that perhaps there is a solution available. It's the first real indication. That is actually forcing the issue more. We have a promise that there is a vaccine coming, which is being developed through the Gates Foundation. Trials on people have shown a low level of efficacy, not one you would say is ideal yet, but at least the solution seems to be around the corner.

It is that large view of the issue that the foundation has taken. Canada is, frankly, a small player, but for them we are a very important player. The Gates Foundation has said they view Canada as an essential partner in their efforts. Altogether these are good things for us, as the Government of Canada, to move our own very specific agendas or points forward to where we think we can get the greatest value for our expenditures.

● (1035)

Mrs. Cathy McLeod: Do I have more time?

The Chair: Yes.

Mrs. Cathy McLeod: Perhaps I will ask this question to Dr. Cameron. Prior to any of this discussion regarding a facility within Canada, if there had been a really promising vaccine candidate, how would you have processed it to move it to the next steps?

The Chair: Time is up, so just respond very quickly, Dr. Cameron.

Dr. Bill Cameron: Before this discussion, if I had had a good vaccine candidate, I would have taken it to a GLP/GMP facility and asked them to produce a lot suitable for conducting clinical trials. I would then have gone to the CIHR Canadian HIV trials network with a proposal and had them vet the proposal and, with public funding for operational costs of the clinical trial, execute the clinical trial. That's what I would have done.

The Chair: Thank you, Dr. Cameron.

We'll now go to Ms. Murray.

Ms. Joyce Murray (Vancouver Quadra, Lib.): Thanks for all of your testimony on this complex issue.

My first question is for Mr. Engelhardt and Mr. Sternthal. Were there any members of the government involved—in person, on paper, or over the phone—in the discussion in the fall of 2009 concerning whether to proceed with this project, which of the applicants would be in the lead, or whether the project should be cancelled?

Mr. Steven Sternthal: When you say “members of the government”, do you mean officials?

Ms. Joyce Murray: No, I actually mean elected members.

Mr. Steven Sternthal: Of course, throughout the process, we kept our minister informed that this was being undertaken, that we were undertaking a review, and what the review included. Of course, our advice, as we developed that at lower levels of organizations, the government departments, and the Gates Foundation, was shared with our minister, who was informed about the fact that we felt that—

Ms. Joyce Murray: Were other ministers involved?

Mr. Steven Sternthal: This initiative was to be co-funded by the Department of Health and the Department of Industry—so the Minister of Industry—as well as CIDA, which is under the Minister for International Cooperation. So definitely all three ministers would have been briefed and kept informed of how this process was proceeding.

Ms. Joyce Murray: And in being briefed, were there conversations, or was there involvement or decision-making by those ministers or other ministers?

Mr. Steven Sternthal: This was, of course, as Dr. Butler-Jones indicated to the committee in March, advice provided up through officials, and it became the Government of Canada's position—

Ms. Joyce Murray: Last fall, yes.

Mr. Steven Sternthal: In terms of the timeframe, it was towards January when this was communicated to the applicants.

Ms. Joyce Murray: No, my question was about last fall, in the—

Mr. Steven Sternthal: With Dr. Engelhardt, discussions were ongoing, and that advice was being generated during the fall.

Dr. Rainer Engelhardt: Madam Chair, the information flow was really unidirectional: on process and how far we had achieved the process. Obviously we're obliged to inform our minister on an interesting project like this—where we were, were we meeting, the milestones, the process—but there was not a judgment call requested, or a request, if you like, for approval from the minister at all. This was done, in that sense, within the government, within the officials' group—including during last fall.

● (1040)

Ms. Joyce Murray: So there were no conversations involving other ministers last fall in wrestling with this decision. Is that correct?

Dr. Rainer Engelhardt: Not in wrestling with the decision, no; there was no influence that way.

Ms. Joyce Murray: We have heard very contrary views to those of the officials on basically all of the criteria that were suggested as a reason for this cancellation, whether it be dollar sustainability, technical capability, or the need for the facility.

Mr. Engelhardt, you mentioned that eventually the decision was made by someone somewhere that this facility would not provide as much value as spending the money on other priorities. That would assume there was an assessment, a cost-benefit analysis, if you will, of certain other priorities that was then tested against the cost-benefit of spending the $88 million this way. Can you table that cost-benefit analysis? Your testimony has been very vague as to what other priorities were assessed as providing greater value. I would like to see that assessment, if there is one. Could you comment?

Dr. Rainer Engelhardt: I think what I said—and I hope I was clear, but perhaps I wasn't—is that the overall issue of dealing with HIV/AIDS on a global basis has many large components. I don't mean to be vague about it here.

From a strict cost-benefit analysis...? Steven could respond to that. There was no additional study carried out that assessed cost-benefit of the multitudes of other opportunities that were there—

Ms. Joyce Murray: But I wrote your words down directly. You said It was cancelled “because it would not provide as much value as spending it on other priorities”, so I assume that someone has assessed those alternative priorities, if that's the basis for the decision to cancel this program.

So my last question is, how much money collectively had been invested to get this project from 2002 or 2003, when it was first conceived, to this point when one bidder was informally advised that they were successful? How much was sunk into the process? Could you answer that very quickly, Doctor, or Mr. Sternthal?

The Chair: I'm sorry, time is up.

Mr. Steven Sternthal: We can provide that information after the meeting, if you'd like.

The Chair: Thank you.

We will now go to Mr. Uppal.

Mr. Tim Uppal (Edmonton—Sherwood Park, CPC): Thank you, Madam Chair.

Dr. Gerson, you obviously have a great deal of experience in this area of vaccine development, and you mentioned that you have been involved in several vaccine projects with a number of organizations. Have you had any affiliation with any of the applicants in this case?

Dr. Donald Gerson: I had not before any of this occurred. After the first evaluation, the first phase was to look at a pre-proposal from each applicant and decide which ones would then be asked for a full proposal. After that, there was a gap. Then there was a request for people to review a second round of proposals, and I declined to be involved in that. The reason I declined was that I was moving back from Korea to Canada.

After that, I was asked by Western to help with theirs, but that was totally after the first evaluation, and I had nothing to do with the second. And I had nothing to do with the one that led to this conclusion.

Mr. Tim Uppal: And had you worked with any of the companies prior to this project?

Dr. Donald Gerson: No.

Mr. Tim Uppal: Very good.

Dr. Engelhardt, what progress has the Government of Canada made in continuing to engage the Canadian HIV/AIDS stakeholder community in the work of CHVI?

Dr. Rainer Engelhardt: I'm going to, if it's agreeable to you.... I have to admit that some of this predates my being with the federal government, so some of the details I'm not as privy to.

Steven, would you be able to respond to that?

● (1045)

Mr. Steven Sternthal: I think, as I indicated earlier, we're currently providing funding to the Canadian AIDS Society and a number of other stakeholder groups as well in the HIV community. For example, in Montreal a couple of months ago, there was a large meeting called the Canadian HIV/AIDS Skills Building Symposium, in which over 500 people affected, working on the front lines, came together in Montreal to improve their skills and their capacity. We sponsored a workshop focusing on HIV vaccines and other prevention technologies such as microbicides to try to raise awareness and understanding of these complex issues and to try to increase their engagement in working with the scientific community moving forward. Our intention is to try to be collaborative and work with them in moving this forward.

Mr. Tim Uppal: Very good. Thank you.

Madam Chair, I'm done.

The Chair: Thank you very much, Mr. Uppal.

Now we'll go to Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Thank you, Madam Chairperson.

Rainer and Steven, you've done it again: you've contradicted previous testimony. Maybe that's what happens when you become engaged in this tangled web of deceit and obfuscation. You just said, in fact, that—

Mr. Colin Carrie: Madam Chair, I have a point of order.

We've heard this line of questioning from the NDP member, and she's questioning the integrity of our witnesses. She has attacked Dr. Butler-Jones, who is not able to be here to defend himself—

Ms. Judy Wasylycia-Leis: He was requested to be here.

Mr. Colin Carrie: I realize that the witnesses here all have different opinions, as does each of us as parliamentarians around the table, but—

Ms. Judy Wasylycia-Leis: Can I finish my—?

Mr. Colin Carrie: —I think personal attacks are inappropriate.

The Chair: Dr. Carrie, what committee rule has been breached that you know of?

Mr. Colin Carrie: Parliamentary behaviour, personally attacking our witnesses....

The Chair: I need the actual rule. This is a matter of debate, not a point of order.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Can I start again with my five minutes?

The Chair: No, continue from where we stopped when this debate started. You have used up over a minute.

Ms. Judy Wasylycia-Leis: I think it was 30 seconds, when I just made my opening comment.

The Chair: Ms. Wasylycia-Leis, continue.

Ms. Judy Wasylycia-Leis: I have a time keeper right beside me, so I'll be able to....

The Chair: So do I.

Ms. Judy Wasylycia-Leis: You have just said, in fact, that while the expert committee that was brought in from all over the world to evaluate the bids was at work, suddenly the study appeared, sponsored by the Gates Foundation. In fact, on March 16, Butler-Jones was very clear when he said:

> Once it was clear that none of them were successful, we found out that in fact additional capacity has developed in the last few years that made this unnecessary.

Again I say that when you start to give us a line that isn't based on fact, it starts to diverge all over the place.

I want to ask Bill and Don and Dr. Sekaly, what would be the reason for this change of heart? We know it's not based on anything to do with the bidders not meeting the task at hand. We know that Winnipeg actually was told that they were successful. We know that it has nothing to do with capacity, because in fact the very reason for this in the first place is still there today.

So my question is, what's the reason? Do you have any sense of why this government is trying to scuttle this project? Is it petty politics because Terry Duguid was involved in Manitoba? Is it big pharma politics because they don't want to concede the agenda to a non-profit or generic sector? Is it regional politics because if Winnipeg were going to get it, then Quebec would be left out? Is it ideological politics in terms of AIDS and trying to find a vaccine?

What would be the reason for stopping something this significant that would put Canada on the map, that would have been important for Winnipeg, that would have actually made a difference in terms of preventing AIDS and finding a cure?

Bill, Don, Dr. Sekaly, could you please answer that?

Dr. Bill Cameron: I can't speak for what's in the minds of our public service or our political representatives. I don't know what it is, but I think you've given us the perspective that it's political. You offered ten political ideas as to why something might have happened.

I can say that when I got wind of the decision, I got mixed messages. I got two reasons, not one reason: that none of the proposals fit the requirements, and second, that we have new capacity. When I hear that kind of argument, it makes me think there's probably something else as well that's unspoken. I wouldn't call it deceit. I would say that maybe there was a policy change somewhere that has happened in the five years or more of the program and that this proposal is no longer favoured.

You said it was political. That's your opinion. It's okay.

Ms. Judy Wasylycia-Leis: Dr. Gerson.

● (1050)

Dr. Donald Gerson: Well, at the moment I've just been back in Canada for the last year and I don't know enough of the background, but it's still a mystery to me. I think that's the simplest statement I can make.

Ms. Judy Wasylycia-Leis: Dr. Sekaly.

Dr. Rafick-Pierre Sekaly: I would paraphrase what Dr. Gerson said. I mentioned it from the beginning. I think Canada had done a lot, together with the Gates Foundation, to be where we should be. That suddenly everything filters out, to me, remains a big mystery. I don't want to put it on the shoulders of politics or anything like that, because I respect Canada and Canadian politics too much, but I just don't understand it. Maybe, as Bill mentioned, it's a change of priorities, but it's not justified. I think it's not justified, because it's really a missed opportunity. There are many arguments to counteract this.

Ms. Judy Wasylycia-Leis: Thank you.

The Chair: Time is up, I'm sorry, Ms. Wasylycia-Leis.

Mr. Brown, would you go ahead.

Mr. Patrick Brown (Barrie, CPC): I think we've exhausted a lot of the questions about the manufacturing facility, but one thing I would like to hear a little bit more about from the Public Health Agency would be the impact of Canada's contributions to HIV and AIDS. I think we're all aware every year, at budget time, when we see investments through CIDA. We understand it's $640 million in the three years from 2006 to 2009. That's obviously a significant investment from Canadian taxpayers.

Could you share with us some examples of how this has had a very positive impact in fighting this epidemic?

Dr. Rainer Engelhardt: Thank you for the question.

Canada has taken the whole envelope of AIDS-related research and accepted it in the broadest context: supporting research at the discovery level, as Dr. Cameron mentioned; supporting palliative research for people affected by AIDS; supporting the development of antivirals, so that their condition can be ameliorated; and, in conjunction with universities within the country and outside of the country, supporting investigations that try to get at the root cause of HIV infections. A lot of that is resident in Africa. That's its origin. Some of the discussions we've been having about how to properly tailor clinical trials and so forth does require Canada to expend some of its money, hopefully in conjunction with the Gates Foundation and others outside of the country, because that's where the advances for vaccines and the trialling are going to be done.

This is, I guess, somewhat personal—subjective, at least. As a scientist, I know that Canada has a very high reputation globally in the work it has done and the moneys it is expending, both from a research and science perspective, as well as, really, in how it's dealing with AIDS on a more personal or patient level.

Mr. Patrick Brown: Now, I understand we've seen some reductions in the rate of infections in sub-Saharan Africa, and also an increase in access for treatment.

Is there any information that you could share on that front?

Dr. Rainer Engelhardt: I must say only in the general sense right now. The modelling that has been carried out about the advancing rate of HIV infection, in Africa in particular, although we have somewhat similar figures in Canada, is that even the antivirals that are being put in place are not numerically able to cope with the advancing rates of infection, so that antivirals are a palliative stop-gap measure. The only way of bringing AIDS under control is through a fully preventative vaccine approach.

● (1055)

Mr. Patrick Brown: Now, I also understand Canada put $150 million into the WHO's 3 by 5 initiative in 2007.

Is there any information on the success of that contribution?

Dr. Rainer Engelhardt: I don't know.

I would defer, maybe, if it's agreeable, Madam Chair, to Dr. Cameron.

The Chair: Dr. Cameron, would you like to make a quick comment?

Dr. Bill Cameron: Well, 3 by 5 had no impact on the epidemic. Fewer people were treated than were newly infected during the period of time it was achieved, and only half the number of people got on treatment as were hoped to get on treatment in that 3 by 5 initiative.

The Chair: Dr. Engelhardt, just very quickly, time is up. Go ahead.

Dr. Rainer Engelhardt: That type of information, really, is available through our colleagues at CIDA, and if you like, we can bring that to you or to the committee as a whole.

The Chair: If you could bring it to the committee as a whole, I would really appreciate that, Doctor.

Dr. Rainer Engelhardt: Certainly.

The Chair: Now, very quickly—I'm not going to suspend because we don't have time—committee, the proposed operational budget, in the amount of $17,900, for the committee's study on the cancellation of the HIV vaccine manufacturing facility, under the Canadian HIV vaccine initiative, needs to be adopted.

Are you all in agreement?

Some hon. members: Agreed.

The Chair: Thank you so much.

I must tell you that the subcommittee meeting on neurological disorders will be meeting in this building, in room 752, immediately following this committee.

I want to say a special thank you to our guests this morning. I thought all of your answers were very helpful and very insightful. I want you to know that this is the way committees are, where the hard questions are asked, and we appreciate your endurance and your graciousness.

The committee is adjourned.

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